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

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of August 2021

Commission File Number 001-38810

STEALTH BIOTHERAPEUTICS CORP

(Translation of registrant's name into English)

**Stealth BioTherapeutics Corp
c/o Intertrust Corporate Services (Cayman) Limited
One Nexus Way, Camana Bay
Grand Cayman
KY1-9005 Cayman Islands
(Address of principal executive office)**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

FORM 20-F FORM 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

INCORPORATION BY REFERENCE

This report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form S-8 (Registration Numbers 333-253601, 333-237541 and 333-230452) and Form F-3 (Registration Number 333-237542) of Stealth BioTherapeutics Corp (the "Company") (including any prospectuses forming a part of such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Other Information

Included herewith as Exhibit 99.1 and incorporated by reference herein, are selected consolidated financial data, management's discussion and analysis of financial condition and results of operations, from the audited consolidated financial statements as of December 31, 2020 and the unaudited condensed consolidated financial statements as of June 30, 2021 and the unaudited condensed consolidated financial statements for the six months ended June 30, 2020 and 2021 of Stealth BioTherapeutics Corp (the "Company").

EXHIBIT INDEX

Exhibit Number	Description
99.1	Selected consolidated financial data, management's discussion and analysis of financial condition and results of operations, and unaudited interim financial statements

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

STEALTH BIOTHERAPEUTICS CORP

By: /s/ Irene P. McCarthy
Irene P. McCarthy
Chief Executive Officer

Date: August 5, 2021

Forward-Looking Statements

Statements in this Report about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute “forward-looking statements” within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to the Company’s development funding agreement and the timing of payments thereunder. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements as a result of known and unknown risks, uncertainties and other important factors, including: the Company’s ability to obtain additional funding and to continue as a going concern; the impact of the COVID-19 pandemic; the ability to successfully demonstrate the efficacy and safety of the Company’s product candidates and future product candidates; the preclinical and clinical results for the Company’s product candidates, which may not support further development and marketing approval; the potential advantages of the Company’s product candidates; the content and timing of decisions made by the U.S. FDA, the EMA or other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies, which may affect the initiation, timing and progress of preclinical studies and clinical trials of the Company’s product candidates; Company’s ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials; unplanned cash requirements and expenditures; competitive factors; the Company’s ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates it is developing; and general economic and market conditions. These and other risks are described in greater detail under the caption “Risk Factors” included in the Company’s most recent Annual Report on Form 20-F filed with the Securities and Exchange Commission (“SEC”), as well as in any future filings with the SEC. Any forward-looking statements contained in this Report speak only as of the date hereof, and the Company specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

SELECTED CONSOLIDATED FINANCIAL DATA

We have derived the following selected consolidated statement of operations data for the fiscal years ended December 31, 2018, 2019 and 2020 and the selected consolidated balance sheet data as of December 31, 2019 and 2020 from our audited consolidated financial statements for the year ended December 31, 2020. The consolidated statements of operations data for the six months ended June 30, 2020 and 2021 and the consolidated balance sheet data as of June 30, 2021 have been derived from our unaudited condensed consolidated financial statements and have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information contained in those statements. Our historical results are not necessarily indicative of the results that should be expected for any future period. The selected consolidated financial data set forth below should be read together with our consolidated financial statements, as well as the sections of our Annual Report on Form 20-F filed with the Securities and Exchange Commission ("SEC") on April 6, 2021 for the fiscal year ended December 31, 2020 captioned "Item 5. Operating and Financial Review and Prospects".

	YEAR ENDED DECEMBER 31,			SIX MONTHS ENDED JUNE 30,	
	2018	2019	2020	2020	2021
(in thousands, except share and per share data)					
Consolidated Statement of Operations Data:					
Revenue	\$ —	\$ 21,087	\$ —	\$ —	\$ —
Operating expenses:					
Research and development	\$ 53,062	\$ 44,604	\$ 29,305	\$ 17,252	\$ 12,012
General and administrative	22,217	22,315	19,366	9,703	10,062
Total operating expenses	75,279	66,919	48,671	26,955	22,074
Loss from operations	(75,279)	(45,832)	(48,671)	(26,955)	(22,074)
Other expense, net	(21,433)	(25,896)	(8,786)	(954)	(4,021)
Net loss attributable to ordinary shareholders	<u>\$ (96,712)</u>	<u>\$ (71,728)</u>	<u>\$ (57,457)</u>	<u>\$ (27,909)</u>	<u>\$ (26,095)</u>
Net loss per share attributable to ordinary shareholders—basic and diluted	<u>\$ (1.41)</u>	<u>\$ (0.19)</u>	<u>\$ (0.10)</u>	<u>\$ (0.06)</u>	<u>\$ (0.04)</u>
Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders—basic and diluted	<u>68,476,149</u>	<u>375,669,759</u>	<u>556,169,255</u>	<u>506,055,526</u>	<u>663,833,037</u>

	AS OF DECEMBER 31,		AS OF
	2019	2020	JUNE 30, 2021
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 50,768	\$ 32,787	\$ 30,766
Working capital	18,448	13,991	18,195
Total assets	52,743	35,848	32,258
Total accumulated deficit	(497,997)	(555,454)	(581,549)
Total shareholders' equity (deficit)	17,267	(10,372)	(26,315)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes and other financial information contained in our Annual Report on Form 20-F for the fiscal year ended December 31, 2020 filed with the Securities and Exchange Commission ("SEC") on April 6, 2021. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of our Annual Report on Form 20-F for the fiscal year ended December 31, 2020, 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. 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 and Pfizer.

Our first clinical product candidate, elamipretide, is a small peptide that targets and binds reversibly to cardiolipin, an essential structural element of mitochondria, stabilizing the inner mitochondrial membrane under conditions of oxidative stress. This novel mechanism of action has shown potential clinical benefit in both rare genetic and common age-related ophthalmic and cardiac diseases entailing mitochondrial dysfunction. Elamipretide has been generally well tolerated in clinical trials with over 1,000 subjects systemically exposed to it to date.

We are studying elamipretide in the following indications:

- Barth Syndrome, or Barth, an inherited cardiomyopathic disease, for which we have conducted a Phase 3 retrospective natural history-controlled trial and a Phase 2/3 clinical trial in the United States; and
- Geographic atrophy or GA, an advanced form of dry age-related macular degeneration, for which we conducted a Phase 1 clinical trial in the United States and are currently conducting a Phase 2b clinical trial in the United States. Our Phase 2b trial was fully enrolled in February 2021, and we expect data from this trial during the first half of 2022.

We met with the Division of Cardiology and Nephrology at the U.S. Food and Drug Administration, or FDA, in November 2020, in February 2021 and April 2021 to discuss the clinical evidence to support a potential new drug application, or NDA, submission for Barth. We have had multiple recent communications with senior FDA officials in the Office of Cardiology, Hematology, Endocrinology and Nephrology and at the Division of Cardiology and Nephrology regarding our Barth syndrome program following the April 2021 meeting. We also received a petition signed by over 4,250 members of the Barth community requesting us to submit our NDA on the basis of our existing clinical data. The FDA expressed its view that the existing clinical data are insufficient to demonstrate substantial evidence of effectiveness and would not support NDA review. The FDA recommended that we collect additional controlled clinical data in this indication prior to an NDA submission. In May 2021, we submitted a randomized withdrawal clinical trial protocol to FDA. This design was previously suggested by multiple FDA review divisions, including most recently the Division of Cardiology and Nephrology. After reviewing our submission, FDA concluded that neither the proposed randomized withdrawal trial nor any new clinical trial data from the patients remaining on OLE would be likely to add meaningfully to the evidence to support an NDA. Due to the ultra-rare nature of Barth syndrome, neither the Company nor the FDA to date has been able to identify a feasible trial design to generate additional data. Despite FDA's view that the existing clinical data are insufficient to demonstrate substantial evidence of effectiveness and would not support NDA review, we believe that the data could support an NDA review and plan to submit our NDA to the FDA in August 2021, although there is no assurance that the FDA will file the NDA.

We are evaluating the potential for additional clinical trials of elamipretide in the following cardiac, ophthalmic and neurological diseases in which mitochondrial dysfunction is implicated:

- Duchenne cardiomyopathy, which is the heart muscle weakness associated with Duchenne's muscular dystrophy, or DMD, is the leading cause of early mortality in this disease;
- Friedreich's ataxia, or FRDA, which is associated with both cardiomyopathy and progressive decline in visual function;
- Leber's hereditary optic neuropathy, or LHON, an inherited disease of central blindness, for which we have conducted a Phase 2 clinical trial in the United States; and
- Primary mitochondrial disease caused by mutations in nuclear genes that encode for mitochondrial proteins, or nPMD.

Subject to discussions with the FDA, continued planning efforts and financing plans, we hope to initiate a clinical development program for elamipretide in DMD patients with cardiomyopathy during the first half of 2022, focusing primarily on cardiac endpoints. We plan to support an investigator-initiated Phase 2a open-label clinical trial of elamipretide assessing both visual and cardiac endpoints in FRDA, which is anticipated to commence enrollment in 2021, and we hope that results from this trial will help inform a pivotal trial design. We also plan to initiate a pivotal trial for elamipretide in patients with nPMD during the second half of 2021, subject to continued planning efforts and financing plans. Patients with nPMD comprised a prespecified subgroup of patients with nuclear DNA mutations in whom improvements were observed in our Phase 3 primary mitochondrial myopathy trial. Although we plan to initiate a Phase 3 global clinical trial for elamipretide in LHON, the initiation of this trial is subject to ongoing formulation studies expected to read out in early 2022, continued planning efforts, and financing plans.

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 and greater concentrations in the brain relative to elamipretide. We are developing SBT-272 for rare neurological diseases involving mitochondrial dysfunction. Preliminary results from a Phase 1 clinical trial in healthy human volunteers completed during 2020 did not reach desired drug exposure levels. We are conducting subcutaneous dosing studies and plan to commence longer term toxicology studies in 2021 to support the initiation of a Phase 1 clinical trial in early 2022 and the potential initiation of a Phase 2 clinical trial in patients in late 2022. We have conducted and continue to conduct preclinical studies in neurological disease models to inform our decisions regarding our first Phase 2 indication.

We have discovered and own over 100 compounds, including SBT-272 and the SBT-550 family, that also target the mitochondria and form the basis of our broad proprietary pipeline of mitochondrial-targeted product candidates. We are evaluating 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 program, in which they could potentially serve as scaffolds to deliver other beneficial compounds to the mitochondria.

As of December 31, 2020, we held exclusive worldwide rights or an option for exclusive worldwide rights under 393 issued patents and 188 patent applications to protect our platform and product candidates. We have exclusive worldwide rights to elamipretide and a second product candidate, SBT-20, both of which we licensed from Cornell Research Foundation, Inc., a subsidiary of Cornell University, or Cornell, and Institut de recherches cliniques de Montréal, or the 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 Boston Children's Hospital, Charité Berlin, Children's Hospital of Philadelphia, Columbia University, Cornell University, Duke University, Johns Hopkins University, Massachusetts General Hospital, Mayo Clinic, Stanford University, University of California Los Angeles, University of California San Diego, University of Colorado and University of Washington.

As of June 30, 2021, we had an accumulated deficit of \$581.5 million. Our net loss was \$96.7 million, \$71.7 million and \$57.5 million for the years ended December 31, 2018, 2019 and 2020, respectively, and \$26.1 million for the six months ended June 30, 2021. 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 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. We expect that our existing cash as of June 30, 2021 of \$30.8 million along with the \$22.0 million committed to be funded by Morningside Ventures (I) Investment Limited, or MVIL, in October and December 2021 under our Development Funding Agreement with MVIL, as amended, but exclusive of any other milestone payments under such Development Funding Agreement, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2022.

Beyond that point, we will need to raise additional capital to finance our operations, which cannot be assured. 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 six months ended June 30, 2021. See Note 1 to our unaudited interim condensed consolidated financial statements contained herein.

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.

In 2019 we received a non-refundable upfront payment of \$15.0 million under the terms of the option agreement and \$15.0 million under an equity agreement with Alexion Pharmaceutical, Inc or 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 option 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.

In 2019, 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 option agreement in January 2020 and, as such, no additional revenue was 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,		SIX MONTHS ENDED JUNE 30,	
	2019	2020	2020	2021
Product candidate expenses:				
Elamipretide	\$ 20,633	\$ 15,919	\$ 9,324	\$ 4,915
SBT-20	2	—	—	—
SBT-272	2,143	1,851	828	1,136
SBT-550	—	—	—	203
Total costs directly allocated to product candidates	<u>22,778</u>	<u>17,770</u>	<u>10,152</u>	<u>6,254</u>
Expenses not directly allocated to product candidates:				
Research and development programs	1,615	1,026	765	660
Consultants and professional expenses	6,547	1,965	986	1,315
Employee expenses including cash compensation, benefits and share-based compensation	<u>13,664</u>	<u>8,544</u>	<u>5,349</u>	<u>3,783</u>
Total expenses not directly allocated to product candidates	<u>21,826</u>	<u>11,535</u>	<u>7,100</u>	<u>5,758</u>
Total research and development expenses	<u><u>\$ 44,604</u></u>	<u><u>\$ 29,305</u></u>	<u><u>\$ 17,252</u></u>	<u><u>\$ 12,012</u></u>

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, insurance for directors and officers 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 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 cash and cash equivalents and changes in the fair value of our derivative liability.

Results of Operations

Comparison of the Six Months Ended June 30, 2020 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2020, and 2021, together with the dollar change in those items:

	SIX MONTHS ENDED JUNE 30,		DOLLAR CHANGE
	2020	2021	
	(in thousands)		
Operating expenses:			
Research and development	\$ 17,252	\$ 12,012	\$ (5,240)
General and administrative	9,703	10,062	359
Total operating expenses	26,955	22,074	(4,881)
Loss from operations	(26,955)	(22,074)	4,881
Other income (expense):			
Interest income	137	2	(135)
Interest expense	(1,091)	(488)	603
Gain (loss) from remeasurement of derivative liability	—	(3,535)	(3,535)
Total other expenses, net	(954)	(4,021)	(3,067)
Net loss	<u>\$ (27,909)</u>	<u>\$ (26,095)</u>	<u>\$ (1,814)</u>

Research and Development Expenses

R&D expenses were \$12.0 million for the six months ended June 30, 2021, compared to \$17.3 million for the same period in 2020. This decrease was due to a net decrease of \$4.0 million in clinical costs primarily driven by the closeout of our Primary Mitochondrial Myopathy development efforts, a decrease of \$1.5 million in employee related costs due to the strategic repositioning in 2020 offset in part by a \$0.3 million increase in consultant costs and a decrease of \$0.9 million in manufacturing cost offset in part by a \$0.6 million increase in preclinical costs and a \$0.2 million net increase in regulatory costs.

General and Administrative Expenses

G&A expenses were \$10.1 million for the six months ended June 30, 2021, compared to \$9.7 million for the same period in 2020. The increase was primarily attributable a \$0.4 million increase in costs of insurance and \$0.3 million increase in precommercial activities offset in part by a net decrease of \$0.3 million in employee and consultant related costs.

Other Expense

Other expense was \$4.0 million for the six months ended June 30, 2021, compared to other expense of \$1.0 million for the same period in 2020. Other expense in 2021 consisted of a \$3.5 million loss due to the change in fair value of the derivative liability and \$0.5 million in interest expense. Other expense in 2020 consisted of a \$1.1 million in interest expense offset by \$0.1 million in interest income.

Comparison of the Years Ended December 31, 2019 and 2020

A discussion of our results of operations for the years ended December 31, 2019, and 2020 may be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Comparison of the Years Ended December 31, 2020 and 2019" in our Annual Report on Form 20-F for the fiscal year ended December 31, 2020 filed with the SEC on April 6, 2021.

Liquidity and Capital Resources

Overview

We have funded our operations from inception through June 30, 2021, primarily through aggregate gross proceeds from the sale of Series A convertible preferred shares, the issuance of convertible promissory notes, a term loan, the sale of ordinary shares, the sale and issuance of ADSs, proceeds from the Development Funding Agreement, as well as gross proceeds received from Alexion. As of June 30, 2021, we had cash and cash equivalents of \$30.8 million.

Indebtedness

Term Loan Facility. On June 30, 2017, we entered into a loan and security agreement 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, July 2020, and April 2021. We have borrowed an aggregated principal amount of \$20.0 million and have an outstanding principal balance of \$5.5 million as of June 30, 2021.

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 5.50% or (ii) 9.50%. In an event of default, as defined in the loan and security agreement, 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 December 31, 2021, the total principal and final end of term charge is payable on the maturity date of January 1, 2022.

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, of 0.5% of the outstanding principal at the time the prepayment is made. On January 1, 2021, we paid the end of term charge of \$1.3 million. An additional end of term charge of \$0.2 million is due upon the earlier to occur of July 1, 2021, the acceleration or prepayment of all outstanding principal, or the termination of the Term Loan Facility. An additional end of term charge of \$0.1 million is due upon the earlier to occur of January 1, 2022, 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 June 30, 2021.

In connection with our entry into the Term Loan Facility, we issued to Hercules a warrant to purchase our ordinary shares. See “Description of Share Capital and Articles of Association—Warrant” for a description of the warrant.

Lincoln Park Agreement. In June 2020, we entered into a \$20.0 million purchase agreement, or the Purchase Agreement, together with a registration rights agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park. Under the terms and subject to the conditions of the Purchase Agreement, we have the right to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to \$20.0 million of our ordinary shares, subject to certain limitations, from time to time, over the 36-month period commencing on June 22, 2020. As of June 30, 2021, pursuant to the Purchase Agreement a total of 25,380,000 ordinary shares were sold to Lincoln Park for aggregate gross proceeds totaling \$3.2 million.

ATM Offering Agreement. In August 2020, we and Wainwright, entered into an At The Market Offering Agreement pursuant to which we may offer and sell, from time to time, through Wainwright, ADSs, each representing 12 ordinary shares, with a nominal or par value of \$0.0003 per share. We have no obligation to sell any ADSs pursuant to the agreement and may at any time suspend sales pursuant to the agreement. Each party may terminate the agreement at any time without liability. As of June 30, 2021, we have not sold any shares under the ATM Offering Agreement, and we suspended our ability to sell under the facility as of November 19, 2020.

Development Funding Agreement. In October 2020, we entered into the Development Agreement, under which MVIL agreed to provide funding to support our efforts to secure regulatory approval for elamipretide and to develop elamipretide for the treatment of Barth, dry AMD, FRDA, DMD, nPMD and LHON. We received initial cash proceeds of \$20.0 million pursuant to the Development Funding Agreement and in February 2021 we received a milestone payment of \$10.0 million. We may receive up to an additional \$5.0 million upon the completion of a final milestone. We may agree to add additional investors to the Development Funding Agreement, subject to the prior written consent of MVIL, on the same terms and subject to the same conditions as MVIL’s initial commitments, prior to the completion of the final milestone. We are obligated to make success payments to MVIL upon receipt of certain regulatory approvals of elamipretide in the designated indications. In May, 2021, we amended the Development Funding Agreement, and under the amended Development Funding Agreement. MVIL paid \$8.0 million to us in May 2021 and has agreed to pay us additional funding of (i) \$11.0 million on or about October 1,

2021 and (ii) \$11.0 million on or about December 1, 2021. The amended Development Funding Agreement is subject to the same terms and condition as MVIL's initial commitment.

Registered Direct Offerings. In November 2020, we entered into a Securities Purchase Agreement with certain institutional investors for a registered public offering, or the 2020 Public Offering, of an aggregate of 2,844,446 ADSs at a public offering price of \$1.125 per ADS for net proceeds of approximately \$2.6 million. In February 2021, we entered into a Securities Purchase Agreement with certain institutional investors for a registered direct offering, or the 2021 Public Offering, of an aggregate of 2,339,000 ADSs at a public offering price of \$2.00 per ADS for net proceeds of approximately \$4.1 million.

Cash Flows

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

	SIX MONTHS ENDED JUNE 30,	
	2020	2021
Net cash (used in) provided by:		
Operating activities	\$ (32,900)	\$ (23,280)
Investing activities	(14)	245
Financing activities	13,980	21,014
Net increase (decrease) in cash and cash equivalents	<u>\$ (18,934)</u>	<u>\$ (2,021)</u>

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 \$9.7 million to \$23.3 million during the six months ended June 30, 2021 from \$32.9 million during the six months ended June 30, 2020. Cash used in operating activities during the six months ended June 30, 2021, consisted of our net loss of \$26.1 million, partially offset by non-cash charges of \$5.9 million which includes, \$3.5 million loss driven by change in fair value of the derivative liability, \$2.2 million in shared-based compensation expense, and \$0.2 million in other non-cash items. Changes in operating assets and liabilities included \$4.3 million decrease in accounts payable, accrued expenses and other current liabilities offset in part by a \$1.2 million decrease in prepaid expenses and other current assets. Cash used in operating activities during the six months ended June 30, 2020, consisted of our net loss of \$27.9 million, partially offset by non-cash charges of \$2.5 million which includes \$2.0 million in share-based compensation, \$0.2 million in amortization of the debt discount, \$0.2 million in non-cash interest expense and \$0.1 million in depreciation and amortization. Changes in operating assets and liabilities included \$8.0 million in decreases in accounts payable, accrued expenses and other current liabilities offset in part by a \$0.5 million decrease in prepaid expenses and other current assets.

Net Cash Used in Investing Activities

Net cash used in investing activities increased by \$0.2 million during the six months ended June 30, 2021 from \$14,000 during the six months ended June 30, 2020. The increase was primarily driven by refund of a security deposit from the previous facility lease.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$21.0 million during the six months ended June 30, 2021, compared to \$14.0 million during the six months ended June 30, 2020. Cash provided by financing activities during the six months ended June 30, 2021, was primarily attributable to the receipt of \$18.0 million from the development funding agreement milestone payment and additional funding under the amended development funding agreement and \$6.9 million in connection with the issuance of ordinary shares as part of our financing activities, offset in part by \$3.6 million of principal payments made on the Term Loan Facility and \$0.3 million of payment of offering cost.

Comparison of the Years Ended December 31, 2019 and 2020

A discussion of our results of cash flows for the years ended December 31, 2019 and 2020 may be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity

and capital resources—Cash Flows—Comparison of the Years Ended December 31, 2020 and 2019” in our Annual Report on Form 20-F for the fiscal year ended December 31, 2020 filed with the SEC on April 6, 2021.

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. 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.

As of June 30, 2021, we had cash and cash equivalents of \$30.8 million and together with our existing cash and cash equivalents and the \$22.0 million committed to be funded by MVIL, in October and December 2021 under our Development Funding Agreement with MVIL, as amended, but exclusive of any other milestone payments under such Development Funding Agreement, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2022. Our capital expenditures for the six months ended June 30, 2021 and for the years ended December 31, 2020 and 2019 amounted to \$0.01 million, \$0.1 million and \$0.13 million, respectively.

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.

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 contained in our Annual Report on Form 20-F for the fiscal year ended December 31, 2020 filed with the SEC on April 6, 2021, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our 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.

Development Derivative Liability

Under the Development Funding Agreement, MVIL paid us \$20.0 million upon execution of the Agreement, and in February 2021, paid us \$10.0 million upon completing enrollment of our ReCLAIM 2 Phase 2 clinical trial of elamipretide for the treatment of dry AMD, or Tranche 2 Milestone Event. MVIL has also agreed to pay us \$5.0 million within 15 days of our submission of a new drug application to the FDA for elamipretide for the treatment of Barth, or Tranche 3 Milestone Event. Upon receipt of funding for each Tranche 2 Milestone Event and Tranche 3 Milestone Event, we are required to issue a warrant, or the Future Warrants, exercisable for ordinary shares at an exercise price that is 115% of the implied price of our ordinary shares on the date of issuance, with such number of ordinary shares being equal to the quotient of 30% of the amount of each funding received divided by the exercise price. Upon execution of the Development Funding Agreement, we issued a warrant to MVIL exercisable for 46,153,846 ordinary shares or the Initial Warrant, at an exercise price of \$0.13 with such number of ordinary shares being equal to the quotient of 30% of the amount of MVIL's commitment divided by the exercise price. The Initial Warrant was immediately exercisable and has a term of three years.

The Development Funding Agreement is presented as a derivative liability on our consolidated balance sheet as of December 31, 2020 and June 30, 2021. The success payments feature in the Development Funding Agreement meets the criteria for derivative accounting as it has multiple underlyings, payment provisions, nominal initial net investment and a net settlement provision. The Development Funding Agreement also includes provisions that allow for the issuance of Future Warrants upon receipt of additional funding. At inception, the Future Warrants were not considered "fixed-for-fixed" as the exercise price and number of ordinary shares are dependent on the date and share price at the date of issuance. As such the Future Warrants were deemed to be liability classified. The Development Funding Agreement and the Future Warrants are considered to be a hybrid instrument recorded as the development derivative liability on our consolidated balance sheets.

At the inception of the arrangement, we identified two units of account (i) the Initial Warrant and (ii) derivative liability, which included the success payments feature and the Future Warrants. The derivative liability was initially recorded at the value of \$18.1 million, the estimated fair value at inception of the arrangement, and is remeasured at fair value at each reporting date. The remaining amount of \$1.9 million of the initial cash received of \$20.0 million was attributed to the Initial Warrant, which met the criteria for equity classification.

In February 2021, we received a milestone payment of \$10.0 million from MVIL, in accordance with Development Agreement, upon completion of enrollment for the ReCLAIM-2 Phase 2 clinical trial of elamipretide for the treatment of dry AMD. We issued a warrant to MVIL exercisable for 18,750,000 ordinary shares at an exercise price of \$0.16 with such number of ordinary shares being equal to the quotient of 30% of the amount of MVIL's commitment divided by the exercise price. The warrant was immediately exercisable and has a term of three years. Upon the receipt of the milestone payment, the warrant met the criteria for equity classification as it was considered "fixed-for-fixed" and was recognized as a component of additional paid in capital and was not remeasured.

On May 17, 2021, we and MVIL amended the Development Agreement. Under the amended Development Agreement, we received \$8 million in May 2021 and will receive an additional (i) \$11.0 million on or about October 1, 2021 and (ii) \$11.0 million on or about December 1, 2021. We are required to issue a warrant to MVIL, in connection with each such additional funding, under the same terms and conditions as the initial commitment. In connection with the funding received in May 2021, we issued a warrant to MVIL exercisable for 18,461,538 ordinary shares at an exercise price of \$0.13 with such number of ordinary shares being equal to the quotient of 30% of the amount of MVIL's commitment divided by the exercise price. The warrant was immediately exercisable and has a term of three years. Upon the receipt of the funding tranche, the warrant met the criteria for equity classification as it was considered "fixed-for-fixed" and was recognized as a component of additional paid in capital and was not remeasured.

The development derivative liability is considered a level 3 fair value measurement, as it is dependent upon significant unobservable inputs. The derivative is valued using a scenario-based discounted cash

flow method, whereby each scenario makes assumptions regarding the probability and timing of cash flows, and the present value of such cash flows is determined valued using a risk-adjusted discount rate. See Note 3 to our consolidated financial statements contained in our Annual Report on Form 20-F for the fiscal year ended December 31, 2020 and our unaudited interim condensed consolidated financial statements contained herein for additional information.

If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

Contractual Obligations

The following table summarizes our outstanding contractual obligations as of payment due date by period at December 31, 2020:

	TOTAL	LESS THAN 1 YEAR	1 TO 3 YEARS	3 TO 5 YEARS	MORE THAN 5 YEARS
	(in thousands)				
Operating leases	\$ 265	\$ 139	\$ 126	\$ —	\$ —
Term Loan Facility (1)	10,565	10,565	—	—	—
Total	\$ 10,830	\$ 10,704	\$ 126	\$ —	\$ —

(1) Represents principal amount of the outstanding term loan as of December 31, 2020 as well as an end of term charge of \$1.5 million due under the Term Loan Facility, of which \$1.3 million was paid on January 1, 2021. The loan is subject to variable interest that will be calculated as payments become due.

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. These contracts are not included in the table above as they provide for termination on notice and, therefore, are cancelable contracts and do not include any minimum purchase commitments.

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, annual fees of approximately \$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.

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.

Recent Accounting Pronouncements

Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to the interim condensed consolidated financial statements includes a discussion of recent accounting pronouncements. There were no new accounting pronouncements adopted during 2020 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.

Qualitative and Quantitative Disclosures about Market Risk

We are minimally exposed to market risk related to changes in interest rates. As of June 30, 2021, we had cash and cash equivalents of \$30.8 million, consisting primarily of U.S. Treasury 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 treasury 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 5.50% or (ii) 9.50%, which exposes us to market interest rate risk when we have outstanding borrowings. As of June 30, 2021, we had \$5.5 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 by 1%, our annual interest expense would increase by \$0.1 million.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

**Index to Unaudited Interim Condensed Consolidated Financial Statements as of
December 31, 2020 and June 30, 2021 and for the Six Month Periods Ended June 30,
2020 and 2021**

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STEALTH BIOTHERAPEUTICS CORP
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	DECEMBER 31, 2020	JUNE 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,787	\$ 30,766
Prepaid expenses and other current assets	2,253	844
Total current assets	<u>35,040</u>	<u>31,610</u>
Property and equipment, net	106	72
Deferred financing cost and other assets	702	576
Total assets	<u>\$ 35,848</u>	<u>\$ 32,258</u>
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	\$ 3,526	\$ 2,566
Accrued expenses and other current liabilities	7,024	5,134
Accrued interest payable	1,499	263
Current portion of debt	9,000	5,452
Total current liabilities	<u>21,049</u>	<u>13,415</u>
Long-term deferred rent, less current portion	16	6
Development derivative liability -related party	25,155	45,152
Total liabilities	<u>46,220</u>	<u>58,573</u>
Shareholders' deficit:		
Ordinary shares, \$.0003 nominal or par value; 1,200,000,000 shares authorized and 635,092,150 shares issued and outstanding at December 31, 2020; 1,200,000,000 shares authorized and 690,993,790 shares issued and outstanding at June 30, 2021	191	207
Additional paid-in capital	544,891	555,027
Accumulated deficit	(555,454)	(581,549)
Total shareholders' deficit	<u>(10,372)</u>	<u>(26,315)</u>
Total liabilities and shareholders' deficit	<u>\$ 35,848</u>	<u>\$ 32,258</u>

See the accompanying notes to these unaudited condensed consolidated financial statements.

STEALTH BIOTHERAPEUTICS CORP
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share amounts)

	SIX MONTHS ENDED JUNE 30,	
	2020	2021
Operating expenses:		
Research and development	\$ 17,252	\$ 12,012
General and administrative	9,703	10,062
Total operating expenses	26,955	22,074
Loss from operations	(26,955)	(22,074)
Other income (expense):		
Interest income	137	2
Interest expense	(1,091)	(488)
Gain (loss) from remeasurement of derivative liability	—	(3,535)
Total other expense, net	(954)	(4,021)
Net loss attributable to ordinary shareholders	\$ (27,909)	\$ (26,095)
Net loss per share attributable to ordinary shareholders—basic and diluted	\$ (0.06)	\$ (0.04)
Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders—basic and diluted	506,055,526	663,833,037

See the accompanying notes to these unaudited condensed consolidated financial statements.

STEALTH BIOTHERAPEUTICS CORP

Condensed Consolidated Statements of Shareholders' Deficit

(unaudited)

(in thousands, except share and per share amounts)

	ORDINARY SHARES		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TOTAL SHAREHOLDERS' EQUITY (DEFICIT)
	SHARES	AMOUNT			
Balance at December 31, 2019	436,720,810	\$ 131	\$ 515,133	\$ (497,997)	\$ 17,267
Share-based compensation expense	—	—	2,000	—	2,000
Issuance of ordinary shares, net of issuance cost of \$0	152,858,460	46	19,954	—	20,000
Ordinary share issued under share incentive plan upon vesting of restricted stock units	2,290,440	1	(1)	—	—
Issuance of commitment shares	2,203,812	—	227	—	227
Net loss	—	—	—	(27,909)	(27,909)
Balance at June 30, 2020	<u>594,073,522</u>	<u>\$ 178</u>	<u>\$ 537,313</u>	<u>\$ (525,906)</u>	<u>\$ 11,585</u>
Balance at December 31, 2020	635,092,150	\$ 191	\$ 544,891	\$ (555,454)	\$ (10,372)
Issuance of ordinary shares, net of issuance cost of \$789	48,768,000	14	6,380	—	6,394
Ordinary share issued under share incentive plan upon vesting of restricted stock units	7,133,640	2	(2)	—	—
Equity classified warrants	—	—	1,538	—	1,538
Share-based compensation expense	—	—	2,220	—	2,220
Net loss	—	—	—	(26,095)	(26,095)
Balance at June 30, 2021	<u>690,993,790</u>	<u>\$ 207</u>	<u>\$ 555,027</u>	<u>\$ (581,549)</u>	<u>\$ (26,315)</u>

See the accompanying notes to these unaudited condensed consolidated financial statements.

STEALTH BIOTHERAPEUTICS CORP
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	SIX MONTHS ENDED	
	JUNE 30,	
	2020	2021
Cash flows from operating activities:		
Net loss	\$ (27,909)	\$ (26,095)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	136	39
Change in fair value of derivative liability	—	3,535
Amortization of debt discount	188	23
Non-cash interest expense	188	130
Share-based compensation	2,000	2,220
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	547	1,157
Accounts payable	(4,805)	(1,020)
Accrued expenses, accrued interest payable and other current liabilities	(3,245)	(3,269)
Net cash used in operating activities	<u>(32,900)</u>	<u>(23,280)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(14)	(5)
Receipt for security deposit	—	250
Net cash provided (used) in investing activities	<u>(14)</u>	<u>245</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock net of commissions and underwriters' fees	20,000	6,903
Proceeds from development funding agreement	—	18,000
Payment of offering costs	—	(318)
Principal payments on term debt	(6,020)	(3,571)
Net cash provided by financing activities	<u>13,980</u>	<u>21,014</u>
Net decrease in cash and cash equivalents	(18,934)	(2,021)
Cash and cash equivalents, beginning of period	50,768	32,787
Cash and cash equivalents, end of period	<u>\$ 31,834</u>	<u>\$ 30,766</u>
Supplemental cash flow information:		
Cash paid for end of term charge for the term debt	\$ —	\$ 1,335
Cash paid for interest	<u>\$ 747</u>	<u>\$ 361</u>
Supplemental disclosure of noncash investing and financing activity:		
Offering costs included in accounts payable and accrued expenses	<u>\$ 307</u>	<u>\$ 64</u>
Commitment shares issued to LPC	<u>\$ 227</u>	<u>\$ —</u>
Reclassification of deferred offering costs to additional paid-in capital	<u>\$ —</u>	<u>\$ 126</u>

See the accompanying notes to these unaudited condensed consolidated financial statements.

STEALTH BIOTHERAPEUTICS CORP

Notes to Unaudited Condensed Consolidated Financial Statements

Six months ended June 30, 2020 and 2021

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. In 2020, Stealth BioTherapeutics (Shanghai) limited was dissolved. Hereinafter, Stealth BioTherapeutics Corp, Stealth BioTherapeutics Inc., and Stealth BioTherapeutics (HK) 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, 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 June 30, 2021, MVIL and certain entities associated with MVIL together beneficially owned approximately 72.5% of the Company’s outstanding shares.

The Company has incurred net losses and negative cash flows from operations and had an accumulated deficit of \$581.5 million as of June 30, 2021. The Company has financed its operations to date through its issuance of preferred shares, initial public offering (“IPO”), issuance of ordinary shares, American depositary shares (“ADS”) offerings, convertible debt and long-term debt.

Liquidity and Going Concern

These condensed 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 \$26.1 million for the six months ended June 30, 2021. The Company expects to continue to incur operating losses in the foreseeable future.

Management believes that cash and cash equivalents of \$30.8 million at June 30, 2021, together with the proceeds of \$22.0 million committed to be funded by MVIL, will not be sufficient to fund operating expenses for twelve months from the date these interim condensed consolidated financial statements are issued. 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 condensed 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 Company’s significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2020, incorporated by reference in this prospectus. Since the date of those financial statements, there have been no changes to its significant accounting policies. There were no new accounting pronouncements adopted during 2021 that had a material effect on our consolidated financial statements.

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States for interim financial reporting and as required by Regulation S-X, Rule 10-01. The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial position as of June 30, 2021, and the results of its operations and its cash flows for the six months ended June 30, 2020, and 2021. The financial data and other information disclosed in these notes related to the six months ended June 30, 2020, and 2021 are unaudited. The results for the six months ended June 30, 2021, are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods, or any future year or period. Accordingly, these condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto incorporated by reference in this prospectus and included in the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2020 filed with the SEC on April 6, 2021.

3. Fair Value of Financial Assets and Liabilities

Fair Value Hierarchy

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 following tables present 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, 2020, and June 30, 2021 (in thousands):

	FAIR VALUE MEASUREMENTS AS OF DECEMBER 31, 2020 USING:			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Short-term money market funds	\$ 32,643	\$ —	\$ —	\$ 32,643
Total financial assets	\$ 32,643	\$ —	\$ —	\$ 32,643
Liabilities:				
Development Derivative liability	\$ —	\$ —	\$ 25,155	\$ 25,155
Total financial liability	\$ —	\$ —	\$ 25,155	\$ 25,155

FAIR VALUE MEASUREMENTS AS OF JUNE 30, 2021 USING:

	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Short-term money market funds	\$ 30,666	\$ —	\$ —	\$ 30,666
Total financial assets	<u>\$ 30,666</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 30,666</u>
Liabilities:				
Development Derivative liability	\$ —	\$ —	\$ 45,152	\$ 45,152
Total financial liability	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 45,152</u>	<u>\$ 45,152</u>

As of December 31, 2020, and June 30, 2021, 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, 2020, and June 30, 2021.

As of December 31, 2020, and June 30, 2021, the outstanding debt from Term Loan bears interest at a rate which approximate prevailing market rate for an instrument with similar characteristics and, accordingly, the carrying value for this instrument approximates fair value.

There have been no transfers between fair value measure levels during the years ended December 31, 2020, and 2021.

Development Derivative Liability

On October 30, 2020, the Company entered into a development funding agreement ("Development Agreement") with MVIL under which MVIL agreed to provide funding to us to support our efforts to secure regulatory approval for elamipretide and to develop elamipretide for the treatment of Barth syndrome ("Barth"), geographic atrophy, an advanced form of dry-age related macular degeneration ("dry AMD"), Friedreich's ataxia ("FRDA"), Duchenne cardiomyopathy ("DMDC"), Leber's hereditary optic neuropathy ("LHON") and mitochondrial replisome-related disorders, which we collectively refer to as the Designated Indications.

Under the Development Agreement, MVIL has paid \$20.0 million to the Company upon execution of the Agreement, and in February 2021 paid \$10.0 million to the Company upon completing enrollment of its ReCLAIM 2 Phase 2 clinical trial of elamipretide for the treatment of dry AMD (the "Tranche 2 Milestone Event"). MVIL has also agreed to pay \$5.0 million within 15 days of the submission by the Company of a new drug application to the U.S. Food and Drug Administration (the "FDA") for elamipretide for the treatment of Barth (the "Tranche 3 Milestone Event"). Upon receipt of funding for each Tranche 2 Milestone Event and Tranche 3 Milestone Event, the Company is required to issue a warrant exercisable for ordinary shares at an exercise price that is 115% of the implied price of the Company's ordinary shares on the date of issuance, with such number of ordinary shares being equal to the quotient of 30% of the amount of each funding received divided by the exercise price ("Future Warrants").

Prior to the occurrence of the Tranche 3 Milestone Event, the Company may agree to add additional investors to the Agreement (each, an "Additional Investor", and any such Additional Investors together with MVIL, the "Investors"), subject to the prior written consent of MVIL. The commitment from each such Additional Investor will be on the same terms and subject to the same conditions as the initial commitments, and, together with the commitment from MVIL, the aggregate commitments of the Investors will not exceed \$70.0 million without the consent of MVIL.

In addition, upon the mutual agreement of the Company and the Investors, at any time after the Company receives positive data from a clinical trial in a Designated Indication, the Company may request that the Investors make additional commitments of up to an additional \$35.0 million in the aggregate. Each Investor may agree to fund such commitment or not at its sole discretion.

The Company is required to make success payments to the Investors ("Success Payments") upon receipt of an approval of elamipretide (a "Regulatory Approval") of a NDA by the FDA or a marketing authorization application by the European Medicines Agency (the "EMA") for the treatment of (i) dry AMD

(a “Common Approval”) and (ii) Barth, FRDA, DMDC, replisome-related disorders or LHON (each, an “Orphan Approval”), subject to certain adjustments with most payments due in the 5th through 7th year following regulatory approval. No payments are owed should regulatory approval not be achieved for elamipretide in the designated indications.

If the first Regulatory Approval is an Orphan Approval, the Company will pay Success Payments of \$2 million upon approval and then an additional \$158 million in the aggregate in seven additional annual payments. All Success Payments will be proportionately adjusted in the event that the actual funding received by the Company from Investors is lower or greater than \$70.0 million including as a result of the payment of the Additional Funding. If the first Regulatory Approval is a Common Approval, or upon a second regulatory approval (whether a Common Approval or an Orphan Approval), the Company will make total Success Payments reflecting a 27% internal rate of return over a seven-year term following such approval.

If the Company’s board of directors determines to seek a Regulatory Approval from both the FDA and EMA, then 66% of each applicable Success Payment will be due upon Regulatory Approval by the FDA and each applicable anniversary thereof and 34% of each applicable Success Payment will be due upon Regulatory Approval by the EMA and each applicable anniversary thereof.

In addition, the Company has agreed that its obligations to the Investors under the Development Agreement will be subordinated to its existing indebtedness owed to Hercules Capital, Inc. (“Hercules”) under the Company’s Loan and Security Agreement, as amended (Note 7). The Company, Hercules and the Investors have entered in a customary subordination agreement.

Upon execution of the Development Agreement, the Company issued a warrant to MVIL exercisable for 46,153,846 ordinary shares (“Initial Warrant”) at an exercise price of \$0.13 with such number of ordinary shares being equal to the quotient of 30% of the amount of MVIL’s commitment divided by the exercise price. The warrant was immediately exercisable and has a term of three years.

The Development Agreement is presented as a derivative liability on the consolidated balance sheet as of December 31, 2020. The Success Payments feature in the Development Agreement meets the criteria for derivative accounting as it has multiple underlying, payment provisions, nominal initial net investment and a net settlement provision. The Development Agreement also includes provisions that allow for the issuance of Future Warrants upon receipt of additional funding. At inception, the Future Warrants were not considered “fixed-for-fixed” as the exercise price and number of ordinary shares are dependent on the date and share price at the date of the issuance. As such the Future Warrants were deemed to be liability classified. The Development Agreement and the Future Warrants are considered to be a hybrid instrument recorded as the development derivative liability on our consolidated balance sheets.

At the inception of the arrangement, the Company identified two units of account (i) the Initial Warrant and (ii) derivative liability, which included the Success Payments feature and the Future Warrants. The development derivative liability was initially recorded at the value of the \$18.1 million, the estimated fair value at inception of the arrangement, and is remeasured at fair value at each reporting date. The remaining amount of \$1.9 million of the initial cash received of \$20.0 million, was attributed to the Initial Warrant, which met the criteria for equity classification and was recognized as a component of additional paid in capital and was not remeasured.

In February 2021, the Company received a milestone payment of \$10.0 million from MVIL, in accordance with Development Agreement, upon completion of enrollment for the ReCLAIM-2 Phase 2 clinical trial of elamipretide for the treatment of dry AMD. The Company issued a warrant to MVIL exercisable for 18,750,000 ordinary shares at an exercise price of \$0.16 with such number of ordinary shares being equal to the quotient of 30% of the amount of MVIL’s commitment divided by the exercise price. The warrant was immediately exercisable and has a term of three years. Upon the receipt of the milestone payment, the warrant met the criteria for equity classification as it was considered “fixed-for-fixed” and was recognized as a component of additional paid in capital and was not remeasured.

On May 17, 2021, the Company and MVIL amended the Development Agreement. Pursuant to the amended Development Agreement the Company received \$8.0 million in May 2021 and will receive an additional (i) \$11.0 million on or about October 1, 2021 and (ii) \$11.0 million on or about December 1, 2021. The Company is required to issue a warrant to MVIL, in connection with each such additional funding, under the same terms and conditions as Development Agreement. Upon the MVIL commitment of \$30.0 million in additional funding the Company recognized a loss related to the development derivative liability of \$3.3 million. In connection with the funding received in May 2021, the Company issued a warrant to MVIL exercisable for 18,461,538 ordinary shares at an exercise price of \$0.13 with such number of ordinary shares being equal to the quotient of 30% of the amount of MVIL's commitment divided by the exercise price. Upon the receipt of the funding tranche of \$8.0 million, the related Future Warrant met the criteria for equity classification as it was considered "fixed-for-fixed" and was recognized as a component of additional paid in capital and was not remeasured. The warrant was immediately exercisable and has a term of three years.

During the six months ended June 30, 2021, the fair value of warrants recognized as a component of additional paid in capital was \$1.5 million based on a Black Scholes Merton model with the following ranges of assumptions: volatility of 67.61%-78.25%, share price of \$0.11-\$0.14, risk-free rate of 0.3%-0.34%, a term of 3 years and 11.5%-15.5% discount for lack of marketability.

The development derivative liability is considered a level 3 fair value measurement, as it is dependent upon significant unobservable inputs and as such is recorded at fair value and remeasured at each reporting period. The change in valuation of the development derivative liability of \$3.5 million was recorded as a loss for the six months ended June 30, 2021, on the condensed consolidated statement of operations. The development derivative liability has a remeasured fair value on June 30, 2021, of \$45.2 million.

The following table presents the development derivative liability measured at fair value using unobservable inputs (Level 3) as of the six months ended June 30, 2021 (in thousands):

Fair value at January 1, 2021	\$	25,155
Amounts received under the Development Agreement		10,000
Amounts received under the Development Agreement as amended		8,000
Loss from remeasurement of development derivative liability during the reporting period		3,535
Reclassification of equity classified warrants		(1,538)
Fair value at June 30, 2021	\$	<u>45,152</u>

The derivative liability is valued using a scenario-based discounted cash flow method, whereby each scenario makes assumptions regarding the probability and timing of cash flows, and the present value of cash flows is determined using a risk-adjusted discount rate.

The fair value of the Future Warrants was estimated as of the inception of the agreement and as of each reporting period, using the Black Scholes Merton valuation model. As of June 30, 2021, the valuation used the ranges of assumptions: volatility of 69.9%, simulated share price of \$0.08-\$0.24 based on a Monte Carlo model, risk-free rate of 0.46%, a term of 3 years and a 15.4% discount for lack of marketability.

Key inputs to the level 3 fair value model at inception and as of the reporting date include (i) the probability and timing of achieving stated development milestones to receive the next tranches of funding and the related issuance of Future Warrants upon receipt of the respective tranches of funding (ii) the probability and timing of achieving FDA and EMA approval of the designated indications, and (iii) the Company's implied cost of borrowing (17.1% as of reporting period).

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	AS OF DECEMBER 31, 2020	AS OF JUNE 30, 2021
Research and development	\$ 357	\$ 199
Prepaid insurance	1,378	421
Other	518	224
Total	<u>\$ 2,253</u>	<u>\$ 844</u>

5. Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	AS OF DECEMBER 31, 2020	AS OF JUNE 30, 2021
Computer equipment and software	\$ 116	\$ 116
Furniture, fixtures and other	147	153
Laboratory equipment	289	289
Leasehold improvements	16	16
	<u>568</u>	<u>574</u>
Accumulated depreciation	(462)	(502)
Property and equipment, net	<u>\$ 106</u>	<u>\$ 72</u>

Depreciation expense for the six months ended June 30 2020, and 2021 was \$0.1 million and \$39,000, respectively.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	AS OF DECEMBER 31, 2020	AS OF JUNE 30, 2021
Research and development	\$ 3,098	\$ 2,558
Employee compensation costs	2,983	1,641
Consulting and professional services	647	528
Legal expenses	245	349
Deferred rent	6	19
Other	45	39
Total	<u>\$ 7,024</u>	<u>\$ 5,134</u>

7. Debt

Term Loan

In June 2017, the Company entered into a Loan and Security Agreement (the "LSA") with a lender that permits 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 June 30, 2021. 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 5% of the aggregate principal amount of all advances. The end of term charge is being accreted 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 June 30, 2021, the interest rate was 9.5%. 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. In July 2020, subsequent to the July principal payment, the Term loan was amended to defer the principal payments until March 1, 2021 and extend the maturity date from January 1, 2021 to July 1, 2021. In April 2021, subsequent to the April principal payment, the Term Loan was amended to extend the maturity date from July 1, 2021 to January 1, 2022 and all principal payments were deferred until the maturity date. For consideration of the amendments, the Company agreed to pay an additional end of term charge of \$0.1 million at maturity which is being accrued and recorded to interest expense over the life of the loan using the effective interest method. On January 1, 2021, the Company paid an end of term charge of \$1.3M. As of June 30, 2021, the total end of term charge was \$0.3 million.

The Company 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 of 0.5% of the outstanding principal at the time the prepayment is made. The end of term charge of \$0.2 million and \$0.1 million is due on July 1, 2021 and January 1, 2022, respectively or earlier if the Term Loan Facility is terminated prior the maturity of the loan. 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. 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 \$30.0 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 stock 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 Term Loan may be accelerated by the lender.

Future principal payments under the Term Loan, as amended, as of June 30, 2021, are as follows:

2022	\$	5,456
Total future principal payments		5,456
Less unamortized debt discount		4
Total balance as depicted on the balance sheet	\$	5,452
Term loan—current portion		5,452
Total balance as depicted on the balance sheet	\$	5,452

Interest expense related to the Term Loan for the six months ended June 30, 2020, and 2021 was \$1.1 million and \$0.5 million, respectively. Accrued interest as of June 30, 2021 was \$0.3 million.

8. Shareholders' Deficit

Ordinary Shares

At December 31, 2020 and June 30, 2021, 1,200,000,000 ordinary shares, \$0.0003 nominal or par value, were authorized for issuance and 635,092,150 and 690,993,790 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 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. 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").

On April 10, 2020, the Company entered into an ordinary share purchase agreement (the "Purchase Agreement"), pursuant to which the Company issued and sold to MVIL 152,858,460 ordinary shares, nominal or par value \$0.0003 per share (the "Shares"), at a price of \$0.13084 per share, for an aggregate purchase price of \$20.0 million.

In November 2020, the Company entered into a Securities Purchase Agreement with certain institutional investors for a registered public offering of an aggregate of 2,844,446 ADSs at a public offering price of \$1.125 per ADS for net proceeds of approximately \$2.6 million.

In February, 2021, the Company entered into a Securities Purchase Agreement with certain institutional investors for a registered public offering of an aggregate of 2,339,000 ADSs or 28,068,000 ordinary shares at a public offering price of \$2.00 per ADS for net proceeds of approximately \$4.1 million.

Lincoln Park Capital

On June 2, 2020, the Company entered into a \$20.0 million purchase agreement (the "LPC Purchase Agreement"), together with a registration rights agreement, with Lincoln Park Capital Fund, LLC ("LPC"). Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right to sell to and LPC is obligated to purchase up to \$20.0 million in shares of the Company's ordinary shares, subject to certain limitations, from time to time, over the 36-month period commencing on June 22, 2020.

The purchase price of the Ordinary Shares purchased by LPC under the LPC Purchase Agreement will be derived from prevailing market prices of the Company's ADSs immediately preceding the time of sale. The Company may direct LPC, at its sole discretion and subject to certain conditions, to purchase up to 900,000 ordinary shares on any business day on which the closing sale price of the Company's ADSs is not below \$1.00 per ADS (such purchases, a "Regular Purchase"). The maximum number of Ordinary Shares that the Company may direct LPC to purchase in any single Regular Purchase under the LPC Purchase Agreement increases, up to a maximum of 1,800,000 Ordinary Shares, if on the purchase date for such Regular Purchase the closing sale price of the Company's ADSs is above certain threshold prices set forth in the LPC Purchase Agreement, provided that LPC's total purchase obligation under any single Regular Purchase shall not exceed \$2,000,000. Additionally, as consideration for entering into the LPC Purchase Agreement, the Company paid LPC a commitment fee of 2,203,812 ordinary shares.

Sales of shares of ordinary shares to LPC under the LPC Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time of more than 4.99% of the outstanding Ordinary Shares. Furthermore, under

applicable rules of The Nasdaq Global Market, in no event may the Company issue or sell to LPC under the Purchase Agreement more than 19.99% of the Ordinary Shares outstanding immediately prior to the execution of the Purchase Agreement (the “Exchange Cap”), unless (i) the Company obtains shareholder approval to issue Ordinary Shares in excess of the Exchange Cap or (ii) the average price of ADSs that represent the equivalent of all applicable sales of Ordinary Shares to LPC under the Purchase Agreement equals or exceeds \$1.9674 per share, such that the transactions contemplated by the LPC Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules.

The LPC Purchase Agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions by, between and for the benefit of the parties. The Company agreed with LPC that it will not enter into any “variable rate” transactions with any third party for a period defined in the LPC Purchase Agreement. LPC has agreed not to cause or engage in any direct or indirect short selling or hedging of the Company’s ADSs. The LPC Purchase Agreement may be terminated by the Company at any time, at its sole discretion, without any cost or penalty.

Pursuant to the LPC Purchase Agreement, during the six months ended June 30, 2021, a total of 20,700,000 ordinary shares were sold to LPC for net proceeds totaling \$2.3 million. No ordinary shares were sold during the six months ended June 30, 2020. To date the Company has sold 25,380,000 ordinary shares to LPC for gross proceeds totaling \$3.2 million.

At the Market Offering

On August 6, 2020, the Company and H.C. Wainwright & Co., LLC (“Wainwright”) entered into an At The Market Offering (“ATM”) Agreement pursuant to which the Company may offer and sell, from time to time, through Wainwright, ADSs, each representing 12 ordinary shares, with a nominal or par value of \$0.0003 per share. Any such sales would be effective pursuant to the Company’s registration statement on Form F-3 (File No. 333-237542), which was declared effective by the SEC on April 10, 2020. The Company has no obligation to sell any ADSs pursuant to the agreement and may at any time suspend sales pursuant to the agreement. Each party may terminate the agreement at any time without liability. The Company suspended the ATM as of November 19, 2020. As of June 30, 2021, the Company has not sold any shares under the ATM.

Development Agreement

On October 30, 2020, pursuant to the Development Agreement, the Company issued a warrant to MVIL exercisable for 46,153,846 ordinary shares at an exercise price of \$0.13 with such number of ordinary shares being equal to the quotient of 30% of the amount of MVIL’s initial funding divided by the exercise price. The warrant was immediately exercisable and has a term of three years.

In February 2021, in accordance with the Development Agreement, the Company received a milestone payment of \$10.0 million upon completion of enrollment for the ReCLAIM-2 Phase 2 clinical trial of elamipretide for the treatment of dry AMD. Pursuant to the Development Agreement, the Company issued warrants exercisable for 18,750,000 ordinary shares to MVIL, at an exercise price of \$0.16 with such number of ordinary shares being equal to the quotient of 30% of the amount of MVIL’s milestone funding divided by the exercise price. The warrant was immediately exercisable and has a term of three years.

In May 2021, in accordance with the Development Agreement, the Company received a payment of \$8.0 million upon the Amendment. Pursuant to the Development Agreement, the Company issued warrants exercisable for 18,461,538 ordinary shares to MVIL, at an exercise price of \$0.13 with such number of ordinary shares being equal to the quotient of 30% of the amount of MVIL’s milestone funding divided by the exercise price. The warrant was immediately exercisable and has a term of three years.

9. Share Incentive Plan

The Company’s 2006 Plan provided 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. The 2006 Plan expired in 2019 and no additional awards can be made under it.

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. On January 1, 2020, 17,468,832 ordinary shares were added to the 2019 Plan pursuant to the Evergreen Provision. In March 2020, upon shareholder approval the 2019 Plan was amended (“Amended 2019 Plan”) and the number of shares reserved under the plan was reduced by 24,999,996 shares, as those shares are now reserved under the 2020 ADS incentive plan (“2020 ADS Plan”). The Amended 2019 Plan provides for the grant of shares or other awards to employees, directors, advisors and consultants for the purchase of up to 55,898,342 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 Amended 2019 Plan.

In March 2020, upon shareholder approval, the Company adopted the 2020 ADS Plan to provide for grants of restricted ADSs, restricted ADS units and other ADS-based awards. The 2020 ADS Plan provides for the grant of ADS-based awards to employees, directors, advisors and consultants of up to 24,999,996 ordinary shares. Pursuant to the Evergreen Provision, effective January 1, 2021, an additional 22,228,225 ordinary shares were added to the Amended 2019 Plan and an additional 9,526,380 ordinary shares or 793,865 ADSs were added to the 2020 ADS Plan.

The fair value of each share option granted to employees and directors was estimated on the date of grant using the following assumptions:

	SIX MONTHS ENDED JUNE 30,	
	2020	2021
Risk-free interest rate	0.5% - 1.38%	0.51%-1.06%
Expected dividend yield	—	—
Expected term (in years)	5.23 - 6.98	5.46 - 6.72
Expected volatility	74% - 79%	76% - 79%

The following table summarizes share option activity for the Amended 2019 Plan for the six months ended June 30, 2021:

	NUMBER OF SHARES	WEIGHTED-AVERAGE EXERCISE PRICE	AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS)	AGGREGATE INTRINSIC VALUE
Outstanding at December 31, 2020	44,959,937	\$ 0.69	7.5	\$ 11,650
Granted	21,103,728	\$ 0.15		
Exercised	—	\$ —		
Cancelled or forfeited	(1,850,355)	\$ 0.83		
Outstanding at June 30, 2021	<u>64,213,310</u>	\$ 0.51	7.9	\$ 14,398
Exercisable at June 30, 2021	<u>27,225,923</u>	\$ 0.78	6.3	\$ 1,774
Vested and expected to vest at June 30, 2021	<u>59,336,318</u>	\$ 0.52	7.8	\$ 11,472

The weighted average grant date fair value per share for awards granted during the six months ended June 30, 2021, was \$0.10.

The following table summarizes restricted share unit activity for the 2020 ADS Plan for the six months ended June 30, 2021 (in ordinary shares):

	NUMBER OF SHARES	WEIGHTED- AVERAGE GRANT-DATE FAIR VALUE
Non-vested at December 31, 2020	15,013,296	\$ 0.11
Granted	6,054,492	\$ 0.15
Vested	(7,133,640)	\$ 0.11
Cancelled or forfeited	(199,548)	\$ 0.11
Non-vested as of June 30, 2021	<u>13,734,600</u>	<u>\$ 0.13</u>

The fair value of restricted share units is measured using the stock price on the date of grant and share-based compensation expense for the restricted stock units is recorded ratably over their vesting period.

Total share-based compensation expense as of June 30, 2020, and 2021 is as follows (in thousands):

	SIX MONTHS ENDED JUNE 30,	
	2020	2021
Research and development	\$ 536	\$ 646
General and administrative	1,464	1,574
Total	<u>\$ 2,000</u>	<u>\$ 2,220</u>

As of June 30, 2021, total unrecognized compensation expense related to non-vested share options and restricted stock units, net of related forfeiture estimates, was \$6.8 million. The Company expects to recognize its remaining unrecognized share-based compensation expense over a weighted-average period of approximately 2.2 years.

10. 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 an upfront license fee of \$60,000 and annual fees of approximately \$60,000. 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, the Company was required to commercialize a product by the date specified in the respective agreement, which with respect to the original Cornell agreement was 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. The Company believes that failure to commercialize is subject to the named exceptions, and to date has not received any notice of termination from the licensor. Any actual terminations of the license would be subject to cure periods and appeals before taking effect.

11. Income Taxes

During the year ended December 31, 2020 and six months ended June 30, 2021, the Company recorded a full valuation allowance on federal and state deferred tax assets since management does not forecast the Company to be in a profitable position in the near future.

12. 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):

	SIX MONTHS ENDED JUNE 30,	
	2020	2021
Numerator:		
Net loss attributable to ordinary shareholders	\$ (27,909)	\$ (26,095)
Denominator:		
Weighted average number of ordinary shares used in loss per share attributable to ordinary shareholders—basic and diluted	506,055,526	663,833,037
Net loss per share attributable to ordinary shareholders—basic and diluted	\$ (0.06)	\$ (0.04)

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:

	SIX MONTHS ENDED JUNE 30,	
	2020	2021
Ordinary share warrant	500,000	500,000
Ordinary share warrants issued to MVIL - related party	-	83,365,384
Outstanding ordinary share options	45,704,574	64,213,310
Non-vested restricted stock units	15,834,216	13,734,600
Total	62,038,790	161,813,294

13. Related Party

Except as disclosed elsewhere in the notes to the accompanying consolidated financial statements, there were no other material transactions with related parties.

14. Subsequent Events

On July 14, 2021, the shareholders approved the increase to the Company's authorized share capital from 1,200,000,000 ordinary shares of a nominal or par value of \$0.0003 each to 1,600,000,000 ordinary shares of a nominal or par value of \$0.0003 each.

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.