STEALTH BIOTHERAPEUTICS CORP

FORM 6-K
(Report of Foreign Issuer)

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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 2020

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
190 Elgin Avenue, George Town
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 333-237541 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Item 1.01 Entry into a Material Definitive Agreement

On July 28, 2020, Stealth Biotherapeutics Corp. (the "Company") and its wholly owned subsidiary, Stealth BioTherapeutics Inc. collectively, the "Borrowers" entered into a fifth Amendment to Loan and Security Agreement (the "Amendment") with Hercules Capital, Inc. ("Hercules") pursuant to which the Loan and Security Agreement June 30, 2017, as amended, was amended to, among other things, to extend the maturity date of the secured term loan facility from January 1, 2021 to July 1, 2021, subject to certain terms and conditions.

The foregoing description of the Amendment is qualified in its entirety by reference to the full text of the Amendment, a copy of which is attached hereto as Exhibit 10.1 and which is incorporated herein by reference.

Earnings Release

On August 6, 2020, Stealth BioTherapeutics Corp (the "Company") issued a press release announcing its unaudited financial results for the second quarter ended June 30, 2020 and operational progress. The press release issued by the Company in connection therewith is attached hereto as Exhibit 99.1.

EXHIBIT INDEX

Exhibit Number	Description
10.1	Fifth Amendment to Loan and Security Agreement dated as July 28, 2020, by and between Hercules Capital Inc and the Company
99.1	Press Release issued by the Company on August 6, 2020

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 6, 2020

Exhibit 10.1

FIFTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **FIFTH AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Fifth Amendment**"), dated as of July 28, 2020 (the "**Fifth Amendment Effective Date**"), is made among STEALTH BIOTHERAPEUTICS CORP, an exempted company incorporated with limited liability under the laws of the Cayman Islands with registered number 165223 ("**Stealth Cayman**"), STEALTH BIOTHERAPEUTICS INC., a Delaware corporation ("**Stealth Delaware**" and, together with Stealth Cayman, hereinafter individually and collectively referred to as "**Borrower**"), those certain banks and other financial institutions or entities from time to time party to the Loan and Security Agreement (collectively, referred to as "**Lender**"), and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, "**Agent**").

WHEREAS, Borrower, Agent and Lender are party to that certain Loan and Security Agreement dated as of June 30, 2017, as amended by that certain First Amendment to Loan and Security Agreement dated as of March 12, 2018, that certain Second Amendment to Loan and Security Agreement dated as of July 26, 2018, that certain Third Amendment to Loan and Security Agreement dated as of October 10, 2018, and that certain Fourth Amendment to Loan and Security Agreement dated as of March 29, 2019, in each case by and among Borrower, Lender and Agent (and as further amended from time to time, the "**Loan and Security Agreement**"); and

WHEREAS, the Borrower, Agent and Lender have agreed to certain amendments to the Loan and Security Agreement;

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency thereof being hereby acknowledged, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Fifth Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1 of the Loan and Security Agreement shall be applicable to this Fifth Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan and Security Agreement.

(a) **Amendment**. The Loan and Security Agreement shall be amended as follows effective as of the Fifth Amendment Effective Date:

(i) New Definitions. The following definitions are added to Section 1.1 in their proper alphabetical order:

"Aggregate Principal Amount" shall have the meaning assigned to such term in Section 7.21.

A/P Amount shall have the meaning assigned to such term in Section 7.21.

"End of Term Charge" shall have the meaning assigned to such term in Section 2.6(b).

"Fifth Amendment Effective Date" means July 28, 2020.

"First End of Term Charge" shall have the meaning assigned to such term in Section 2.6(a).

"Performance Milestone 11" means satisfaction of each of the following events: (a) no Event of Default has occurred and is continuing, and (b) Borrower has submitted a New Drug Application for the approval of elamipretide for the treatment of Barth Syndrome, which includes, for the avoidance of doubt, the full submission of all New Drug Application modules required by the FDA) (the "**Performance Milestone 11 New Drug Application**"); in each case, subject to verification by Agent in its reasonable discretion (including supporting documentation reasonably requested by Agent).

"Performance Milestone 12" means satisfaction of each of the following events: (a) no Event of Default has occurred and is continuing, (b) achievement of Performance Milestone 11, and (c) the FDA has accepted for review the Performance Milestone 11 New Drug Application; in each case, subject to verification by Agent in its reasonable discretion (including supporting documentation reasonably requested by Agent).

"Second End of Term Charge" shall have the meaning assigned to such term in Section 2.6(b).

(ii) Amended Definitions. The following definitions are hereby amended and restated as follows:

"New Amortization Date" means March 1, 2021.

"Term Loan Maturity Date" means July 1, 2021.

(iii) Section 2.2(d). Sections 2.2(d)(i) and 2.2(d)(ii) are hereby amended and restated as follows:

" (i) Borrower will pay interest in arrears on each Term Loan Advance on the first Business Day of each month, beginning the month after the Advance Date. Borrower shall repay the aggregate Term Loan principal balance that is outstanding on the day immediately preceding the Amortization Date, in equal monthly installments of principal and interest (mortgage style) beginning on the Amortization Date and continuing on the first Business Day of each month thereafter until the Fifth Amendment Effective Date. Agent and Lender acknowledges receipt of principal payments from Borrower in the amount of $10,972,740.15 as of the Fifth Amendment Effective Date resulting in a total remaining principal balance outstanding as of the Fifth Amendment Effective Date of $9,027,259.85.

(ii) Commencing on the Fifth Amendment Effective Date, (x) Borrower will pay interest in arrears on each Term Loan Advance on the first Business Day of each month; and (y) Borrower shall repay the aggregate Term Loan principal balance that is outstanding on the day immediately preceding the New Amortization Date, in equal monthly installments of principal and interest (mortgage style) beginning on the New Amortization Date and continuing on the first Business Day of each month thereafter until the Secured Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) are repaid. As an example, the payment schedules as of the Fifth Amendment Effective Date are reflected in Exhibit J attached hereto (as reflected on Schedule 1 therein for a New Amortization Date of March 1, 2021) and Agent may update such payment schedule from time to time in accordance with the terms of this Agreement (as amended from time to time, the "**Amortization Schedules**"). In the event of any inconsistency between the Amortization Schedules and the terms of this Agreement (including this Section 2.2), the terms of this Agreement shall prevail."

(iv) Section 2.5. The first sentence of Section 2.5 is hereby amended and restated as follows:

"At its option upon at least five (5) Business Days prior notice to Agent, Borrower may prepay all, but not less than all, of the outstanding Advances by paying the entire principal balance, all accrued and unpaid interest thereon, plus all fees and other amounts owing under the Loan Documents at such time (including, for the avoidance of doubt, any unpaid End of Term Charge), together with a prepayment charge equal to the following percentage of the Advance amount being prepaid: if such Advance amounts are prepaid in any of the first twelve (12) months following the Closing Date, 3.0%; after twelve (12) months but on or prior to March 31, 2020, 2.0%; and thereafter, 0.5% (each, a "**Prepayment Charge**")."

(v) Section 2.6. Section 2.6 is hereby amended and restated as follows.

"End of Term Charge.

(a) On the earliest to occur of (i) January 1, 2021, (ii) the date that Borrower prepays the outstanding Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) in full, or (iii) the date that the Secured Obligations become due and payable, Borrower shall pay Lender a charge in an amount equal to One Million Three Hundred Thirty-Five Thousand Dollars (U.S.$1,335,000) (the "**First End of Term Charge**"). Notwithstanding the required payment date of the First End of Term Charge, such charge shall be deemed earned by Lender as follows: U.S.$750,000 earned as of the Closing Date, U.S.$250,000 earned as of March 15, 2018, U.S.$200,000 earned as of the Second Amendment Effective Date, U.S.$50,000 earned as of the Third Amendment Date, U.S.$85,000 earned as of the Fourth Amendment Effective Date.

(b) On the earliest to occur of (i) the Term Loan Maturity Date, (ii) the date that Borrower prepays the outstanding Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) in full, or (iii) the date that the Secured Obligations become due and payable, Borrower shall pay Lender a charge in an amount equal to Two Hundred Three Thousand One Hundred Thirteen Dollars (U.S.$203,113) (the "**Second End of Term Charge**" and together with the First End of Term Charge, collectively, the "**End of Term Charge**"). Notwithstanding the required payment date of the Second End of Term Charge, such charge shall be deemed earned by Lender as of the Fifth Amendment Effective Date."

(vi) Section 7.21. Section 7.21 is hereby amended and restated as follows:

"Minimum Cash. Borrower shall maintain at all times Unrestricted Cash in an amount greater than or equal to 100% of the aggregate unpaid principal amount of the Term Loan Advances then outstanding at such time (the "**Aggregate Principal Amount**") plus the amount of Borrower's accounts payable under GAAP not paid after the 90th day following the invoice date for such accounts payable (the "**A/P Amount**"); *provided that*, upon the occurrence of Performance Milestone 11, Borrower shall maintain at all times thereafter Unrestricted Cash in an amount greater than or equal to 60% of the Aggregate Principal Amount plus the A/P Amount; *provided further that*, upon the occurrence of Performance Milestone 12, Borrower shall maintain at all times thereafter Unrestricted Cash in an amount greater than or equal to 25% of the Aggregate Principal Amount plus the A/P Amount. Borrower shall provide Agent evidence of compliance with the financial covenants under this Section 7.21 in each Compliance Certificate to be executed by an Authorized Signatory of the Borrower and upon request in form and substance reasonably acceptable to Agent and supporting documentation reasonably requested by Agent."

(vii) Section 9.3. Section 9.3 is hereby amended and restated as follows:

"Material Adverse Effect. A circumstance has occurred that has had a Material Adverse Effect; provided that solely for purposes of this Section 9.3, the failure to achieve Performance Milestone 1, Performance Milestone 2, Performance Milestone 3, Performance Milestone 4, Performance Milestone 5, Performance Milestone 6, Performance Milestone 7, Performance Milestone 8, Performance Milestone 9, Performance Milestone 10, Performance Milestone 11 and Performance Milestone 12 in each case in and of itself, shall not constitute a Material Adverse Effect; or"

(viii) Section 10.1. Section 10.1 is hereby amended and restated as follows:

"General. Upon and during the continuance of any one or more Events of Default, (i) Agent may, and at the direction of the Required Lenders shall, accelerate and demand payment of all or any part of the Secured Obligations together with a Prepayment Charge and declare them to be immediately due and payable (provided, that upon the occurrence of an Event of Default of the type described in Section 9.5, all of the Secured Obligations (including, without

limitation, the Prepayment Charge and any unpaid End of Term Charge) shall automatically be accelerated and made due and payable, in each case without any further notice or act), (ii) Agent may, at its option, sign and file in Borrower's name any and all collateral assignments, notices, control agreements, security agreements and other documents it deems necessary or appropriate to perfect or protect the repayment of the Secured Obligations, and in furtherance thereof, Borrower hereby grants Agent an irrevocable power of attorney coupled with an interest, and (iii) Agent may notify any of Borrower's account debtors to make payment directly to Agent, compromise the amount of any such account on Borrower's behalf and endorse Agent's name without recourse on any such payment for deposit directly to Agent's account. Agent may, and at the direction of the Required Lenders shall, exercise all rights and remedies with respect to the Collateral under the Loan Documents or otherwise available to it under the UCC and other applicable law, including the right to release, hold, sell, lease, liquidate, collect, realize upon, or otherwise dispose of all or any part of the Collateral and the right to occupy, utilize, process and commingle the Collateral. All Agent's rights and remedies shall be cumulative and not exclusive."

(ix) Exhibit F. Exhibit F is hereby amended and restated in the form attached hereto as Annex A.

(x) Exhibit J. Exhibit J is hereby amended and restated in the form attached hereto as Annex B.

(b) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Fifth Amendment.

SECTION 3 Conditions of Effectiveness. The effectiveness of this Fifth Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses**. Borrower shall have paid (i) all attorney fees and other costs and expenses then due in accordance with Section 5(e) of this Amendment, and (ii) all other fees, costs and expenses, if any, due and payable as of the Fifth Amendment Effective Date under the Loan and Security Agreement.

(b) **This Fifth Amendment**. Agent shall have received this Fifth Amendment, executed by Agent, Lender and Borrower.

(c) **Representations and Warranties; No Default**. On the Fifth Amendment Effective Date, after giving effect to the waivers under and amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 of this Fifth Amendment shall be true and correct on and as of the Fifth Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 4 Representations and Warranties. To induce the Agent and Lender to enter into this Fifth Amendment, Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; (b) no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing. For the purposes of this Section 4, (i) each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Fifth Amendment, and (ii) any representations and warranties which relate solely to an earlier date shall not be deemed confirmed and restated as of the date hereof (provided that such representations and warranties shall be true, correct and complete as of such earlier date).

SECTION 5 Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation**. Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. Lender's and Agent's execution and delivery of, or acceptance of, this Fifth Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future. Borrower hereby reaffirms the grant of security under Section 3 of the Loan and Security Agreement and hereby reaffirms that such grant of security in the Collateral secures all Secured Obligations under the Loan and Security Agreement, including without limitation any Term Loans funded on or after the Fifth Amendment Effective Date, as of the date hereof.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 33, each Lender that has signed this Fifth Amendment (which constitute all Lenders) shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender.

(c) **Release**. In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lender and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Fifth Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan and Security Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the

release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above. Borrower waives the provisions of California Civil Code Section 1542, which states:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

(d) **No Reliance**. Borrower hereby acknowledges and confirms to Agent and Lender that Borrower is executing this Fifth Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(e) **Costs and Expenses**. Borrower agrees to pay to Agent within ten (10) days of its receipt of an invoice (or on the Fifth Effective Amendment Date to the extent invoiced on or prior to the Fifth Amendment Effective Date), the out-of-pocket costs and expenses of Agent and Lender party hereto, and the fees and disbursements of counsel to Agent and Lender party hereto (including allocated costs of internal counsel), in connection with the negotiation, preparation, execution and delivery of this Fifth Amendment and any other documents to be delivered in connection herewith on the Fifth Amendment Effective Date or after such date.

(f) **Binding Effect**. This Fifth Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(g) **Governing Law**. **THIS FIFTH AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF CALIFORNIA (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE STATE OF CALIFORNIA), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

(h) **Complete Agreement; Amendments**. This Fifth Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Fifth Amendment and the Loan Documents merge into this Fifth Amendment and the Loan Documents.

(i) **Severability of Provisions.** Each provision of this Fifth Amendment is severable from every other provision in determining the enforceability of any provision.

(j) **Counterparts**. This Fifth Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Fifth Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(k) **Loan Documents**. This Fifth Amendment and the documents related thereto shall constitute Loan Documents.

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IN WITNESS WHEREOF, the parties hereto have duly executed this Fifth Amendment, as of the date first above written.

BORROWER:

STEALTH BIOTHERAPEUTICS CORP,
as Borrower

By: /s/ Reenie McCarthy
Name: Reenie McCarthy
Title: CEO

STEALTH BIOTHERAPEUTICS INC.,
as Borrower

By: /s/ Reenie McCarthy
Name: Reenie McCarthy
Title: CEO

AGENT:

HERCULES CAPITAL, INC,
as Agent

By: /s/ Jennifer Choe
Name: Jennifer Choe
Title: Associate General Counsel

LENDER:

HERCULES CAPITAL FUNDING TRUST 2018-1,
as Lender

By: /s/ Jennifer Choe
Name: Jennifer Choe
Title: Associate General Counsel

HERCULES CAPITAL FUNDING TRUST 2019-1,
as Lender

By: /s/ Jennifer Choe
Name: Jennifer Choe
Title: Associate General Counsel

Exhibit 99.1

STEALTH BIOTHERAPEUTICS REPORTS SECOND QUARTER 2020 FINANCIAL RESULTS AND RECENT BUSINESS HIGHLIGHTS

Additional Barth clinical data requested by the FDA; protocol development and NDA preparation ongoing

Phase 2b dry AMD study on-track to complete enrollment by year-end

Elamipretide clinical expansion efforts underway in rare metabolic cardiomyopathies and mitochondrial diseases caused by nuclear mutations affecting DNA synthesis

Additional preclinical data for SBT-272 expected in Second Half 2020

Management to host conference call today at 8:30am ET

BOSTON – August 6, 2020 – Stealth BioTherapeutics Corp (Nasdaq: MITO), a clinical-stage biotechnology company focused on the discovery, development and commercialization of novel therapies for diseases involving mitochondrial dysfunction, today reported financial results for the second quarter ended June 30, 2020 and provided a corporate update.

"The clinical efficacy data observed in Barth and other mitochondrial diseases caused by nuclear DNA mutations confirm our confidence in developing elamipretide to treat rare genetic diseases with no approved therapies," said Reenie McCarthy, chief executive officer of Stealth. "We are keenly aware that time is not on the side of patients suffering from these devastating conditions, with recent cardiac-related fatalities of young boys and men in the Barth community underscoring the urgency of effective treatment options. While the FDA recommends that we bolster our clinical evidence package in Barth prior to submission of an NDA, we remain committed to moving as quickly as possible to address this serious unmet need, and accordingly hope to address the FDA's concern with a proposed post-marketing protocol and potential NDA submission later this year."

COVID-19 Pandemic Business Update:

Ongoing Clinical Trials

Stealth is committed to advancing its ongoing clinical programs for elamipretide in Barth and dry AMD and to initiating new development efforts in other rare metabolic cardiomyopathies.

- The Company reiterates its previous guidance that full enrollment of its Phase 2b trial in dry AMD is expected at year-end. The trial is over seventy-five percent enrolled, with additional sites expected to open in the coming months to optimize efforts to achieve timely completion. Alternative safety monitoring procedures have been implemented to address COVID-19 related disruptions to normal site visits.
- The Company's Phase 1 trial of SBT-272 in healthy volunteers has recommenced dosing, following a pause due to the COVID-19 pandemic.
- The COVID-19 pandemic poses unique challenges to individuals with Barth, whose neutropenia meaningfully increases their susceptibility to infection and whose cardiovascular disease increases the risk of respiratory disease severity. Pandemic safety guidelines published by the Barth Syndrome Foundation include a recommendation that affected individuals stay home to limit exposures to people who may be infected but do not have symptoms. The principal investigator for the TAZPOWER trial has suspended all ongoing regular clinic visits in accordance with this guidance, and the Company has implemented alternative safety monitoring procedures, as a result. These safety considerations around patient travel for clinic visits further compromise the practicability of collecting additional controlled clinical data prior to Barth NDA submission.

Second Quarter 2020 and Recent Clinical and Regulatory Highlights

- **Type C Meeting.** In July 2020, the Company had a Type C interaction with the Division of Rare Diseases and Medical Genetics (DRDMG) of the FDA regarding the Company's data in Barth syndrome. DRDMG did not agree that the current data package is sufficient to support an NDA submission and recommended that the Company collect additional controlled clinical data in this indication prior to an NDA submission. Nevertheless, the Company believes that, with the expanded data and analyses that are provided in an NDA submission, the existing data could meet the requirements for an NDA. Additionally, although COVID-19-related safety considerations around patient travel for clinic visits further compromise the practicability of collecting additional controlled clinical data at this time, the Company is evaluating protocol designs for a potential post-approval confirmatory study. Potential trial designs may include a randomized withdrawal trial design and potential additional pediatric dosing initiatives in light of the rare pediatric designation granted by the FDA in February 2020. The Company plans to initiate such a study following a potential NDA submission later this year, so it would be ongoing

should the DRDMG determine that the expanded data and analyses in the Company's NDA support accelerated approval of elamipretide.

- **Announced data regarding improvement in key metabolites in Barth.** In July 2020, the Company presented data at the Barth Syndrome Foundation's 2020 Symposium highlighting that treatment with elamipretide during the double-blind, placebo-controlled portion of the TAZPOWER clinical trial resulted in significant changes relative to placebo in several key metabolite classes including plasma acylcarnitines (fatty acid metabolism), ketones, amino acids and citric acid cycle intermediates, which are consistent with improved mitochondrial function. Elevated plasma acylcarnitines reflect impaired or incomplete mitochondrial fatty acid oxidation and have been linked to cardio-metabolic diseases, such as Barth.
- **Reported additional encouraging data regarding improvement in cardiac function in Barth.** In July 2020, investigators from Johns Hopkins presented data at the Barth Syndrome Foundation's 2020 Symposium showing that treatment with elamipretide through week 36 of the TAZPOWER open-label extension (OLE) was associated with significant improvement in the slope of change from baseline for left ventricular stroke volume ($p=0.0001$), left ventricular end diastolic ($p=0.0004$) and end systolic ($p=0.0098$) volumes, as well as trends toward improvement in other echocardiographic parameters. Together, the data suggest that prolonged treatment with elamipretide may lead to cardiac reverse remodeling. The Company has also shared data through week 72 of the TAZPOWER OLE showing durability of these cardiac improvements, including sustained significant improvement in the slope of change from baseline for left ventricular stroke volume ($p<0.0001$), and left ventricular end diastolic ($p<0.0001$) and end systolic ($p=0.0002$) volumes. An analysis comparing these improvements in left ventricular stroke volume to age-matched natural history controls ($n=12$) under the Company's natural history comparative control efficacy study confirmed that these improvements (+1.92mL at week 72 OLE) are not expected in the natural course of the disease, in which stroke volume is expected to decline (-4.8mL) over a comparable time-period ($p=0.002$). Stroke volume is a key component of ejection fraction and cardiac output, both of which have been correlated with cardiac outcomes in heart failure.
- **Announced improvement in replisome-related mitochondrial myopathies.** In June 2020, the Company announced at the United Mitochondrial Disease Foundation's PowerSurge 2020 Virtual Symposium that additional analyses of data from its Phase 3 trial in primary mitochondrial myopathy showcased trends toward improvement in six minute walk test (6MWT) in a pre-specified subgroup of patients with nuclear genetic mutations, with a significant increase ($p=0.05$) of 27.8 meters in elamipretide-treated patients relative to 3.7 meters in placebo-treated patients who met protocol requirements ($n=51$). Among these patients, those with nuclear DNA mutations affecting mitochondrial DNA replication, or replisome activity, which included patients with disorders arising from mutations in polymerase gamma, or POLG-related disorders, showed the greatest improvement. The Company is evaluating potential clinical development opportunities for these patients, whose clinical symptoms typically include mitochondrial myopathy, ataxia, peripheral neuropathy and chronic progressive ophthalmoplegia.
- **Metabolic cardiomyopathy clinical advisory board meeting.** In June 2020, the Company hosted a clinical advisory board meeting co-chaired by Dr. Eve E. Slater and chief clinical development officer of Stealth, Jim Carr and involving 16 external thought leaders with expertise in Duchenne muscular dystrophy (DMD), mitochondrial cardiomyopathy, and/or heart failure to discuss its planned development efforts in cardiomyopathy associated with DMD. The expert consensus from the meeting is that mitochondrial dysfunction is central to the pathology of DMD cardiomyopathy and that elamipretide may be beneficial to treat this devastating and life-limiting sequalae of the disease. The Company plans to launch early development efforts to commence a Phase 2 clinical trial in DMD in 2021.

Second Quarter 2020 and Recent Financial Highlights

- **Amended Term Loan Facility with Hercules Capital, Inc.** In July 2020, the Company amended its Term Loan Facility with Hercules Capital, Inc. to defer the current principal payments until the second quarter of 2021, instituting a seven month interest-only repayment schedule which extends the Company's financial runway further into 2021.
- **Announced up to $20 million Lincoln Park facility.** In June 2020, the Company entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC for up to $20 million, providing additional access to capital to strategically fund advancement of elamipretide and SBT-272 clinical development.
- **Closed $20 million private placement.** In April 2020, the Company closed a $20 million private placement with Morningside Venture (I) Investments Limited, extending the Company's financial runway into 2021.

Key Upcoming Milestones

- Initiation of an open-label clinical study in Friedreich's ataxia anticipated by year-end 2020.
- Submission of clinical protocol to generate post-approval controlled data in Barth syndrome and potential NDA submission anticipated by year-end 2020.
- Completion of enrollment of Phase 2 clinical trial in dry AMD expected by year-end 2020.

- Announcement of pre-clinical data for SBT-272 for the treatment of amyotrophic lateral sclerosis and multiple systems atrophy and for SBT-259 in Charcot-Marie-Tooth disease expected by year-end 2020.

Financial Results for the Three Months Ended June 30, 2020

Cash Position: Cash and cash equivalents were $31.8 million at June 30, 2020, compared to $50.8 million at December 31, 2019.

Research and Development (R&D) Expenses:

R&D expenses were $7.4 million for the three months ended June 30, 2020, compared to $9.4 million for the same period in 2019. The decrease was primarily due to a $2.8 million net decrease in employee and consultant related costs attributable to the strategic repositioning implemented by the Company in the first quarter of 2020, a $0.8 million decrease in contract manufacturing, and a $0.1 million decrease in regulatory costs. These decreased costs were offset in part by a $1.7 million net increase in clinical trial costs due to timing of trials.

General and Administrative (G&A) Expenses:

G&A expenses were $4.5 million for the three months ended June 30, 2020, compared to $6.1 million for the same period in 2019. The decrease in administrative expenses was attributed to a $0.9 million net decrease in employee and consultant related costs primarily attributable to the strategic repositioning implemented by the Company in the first quarter of 2020, and a decrease of $1.0 million in pre-commercial activities also driven by the strategic repositioning. These decreased costs were offset in part by a $0.3 million increase in professional services and activities attributable to operating as a public company.

Other Expense, Net:

Other expense was $0.4 million for the three months ended June 30, 2020, compared to $0.3 million for the same period in 2019. The increase in other expense is primarily attributed to a $0.3 million decrease in interest income offset in part by a $0.2 million decrease in interest expense.

Net Loss:

Net loss was $12.4 million, or $0.02 basic and diluted net loss per ordinary share, for the three months ended June 30, 2020, as compared to $15.8 million, or $0.04 basic and diluted net loss per ordinary share, for the same period in 2019. The decreased loss was primarily attributable to a decrease in operating costs of $3.5 million and a net increase in other expenses of $0.1 million.

Conference Call

Management will host a conference call today at 8:30 am ET to discuss the financial results and provide a general business update. The call can be accessed by dialing (800) 768-3395 or (212) 231-2919 (international) and referencing conference ID 21966839 . A live audio webcast of the event can be accessed by visiting the Investors & News section of Stealth's Investor website, https://investor.stealthbt.com/. A replay of the webcast will be archived on Stealth's website for 30 days following the event.

About Stealth

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 are involved in many common age-related diseases, typically involving organ systems with high energy demands such as the heart, the eye, and the brain. We believe our lead product candidate, elamipretide, has the potential to treat both rare metabolic cardiomyopathies, such as Barth, Duchenne and Becker muscular dystrophies and Friedreich's ataxia, rare mitochondrial diseases entailing nuclear DNA mutations, such as POLG-related disorders, as well as ophthalmic diseases entailing mitochondrial dysfunction, such as dry age-related macular degeneration and Leber's hereditary optic neuropathy. We are evaluating our second-generation clinical stage candidate, SBT-272, for rare neurodegenerative disease indications following promising preclinical data in amyotrophic lateral sclerosis, or ALS. We have optimized our discovery platform to identify novel mitochondria-targeted compounds, including SBT-259, the SBT-550 series of compounds, and other compounds which may be nominated as therapeutic product candidates or utilized as scaffolds to deliver other compounds to mitochondria.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding Stealth BioTherapeutics' plans, strategies and expectations for its preclinical and clinical advancement of its drug development programs, including its ongoing clinical trials of elamipretide and planned clinical trial of SBT-272; its plans for the potential submission of an NDA; the potential benefits of Stealth BioTherapeutics' product candidates; its key milestones for 2020 and 2021; its plans regarding future data presentations; and its financial guidance regarding the period in which it will have capital available to fund its operations. Statements that are not historical facts, including statements about Stealth BioTherapeutics' beliefs, plans and expectations, are forward-looking statements. The words "anticipate," "expect," "hope," "plan," "potential," "possible," "will," "believe," "estimate," "intend," "may," "predict," "project," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Stealth BioTherapeutics may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. 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: Stealth BioTherapeutics' 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 Stealth BioTherapeutics' product candidates and future product candidates; the preclinical and clinical results for Stealth BioTherapeutics' product candidates, which may not support further development and marketing approval; the potential advantages of Stealth BioTherapeutics' 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 Stealth BioTherapeutics product candidates; Stealth BioTherapeutics' ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials; unplanned cash requirements and expenditures; competitive factors; Stealth BioTherapeutics' 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 Stealth BioTherapeutics' 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. Forward-looking statements represent management's current expectations and are inherently uncertain. Except as required by law, Stealth BioTherapeutics does not undertake any obligation to update forward-looking statements made by us to reflect subsequent events or circumstances.

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STEALTH BIOTHERAPEUTICS CORP

Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 7,405	$ 9,366	$ 17,252	$ 23,694
General and administrative	4,523	6,064	9,703	10,221
Total operating expenses	11,928	15,430	26,955	33,915
Loss from operations	(11,928)	(15,430)	(26,955)	(33,915)
Other income (expense):				
Loss on extinguishment of debt	—	—	—	(22,700)
Change in fair value of derivative liability	—	—	—	2,782
Change in fair value of warrant liability	—	—	—	(300)
Interest income	14	342	137	550
Interest expense and other	(455)	(662)	(1,091)	(5,345)
Total other expense	(441)	(320)	(954)	(25,013)
Net loss attributable to ordinary shareholders	$ (12,369)	$ (15,750)	$ (27,909)	$ (58,928)
Net loss per share attributable to ordinary shareholders — basic and diluted	$ (0.02)	$ (0.04)	$ (0.06)	$ (0.18)
Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders — basic and diluted	575,390,241	420,399,807	506,055,526	320,771,044

STEALTH BIOTHERAPEUTICS CORP

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 31,834	$ 50,768
Prepaid expenses and other current assets	1,082	1,630
Total current assets	32,916	52,398
Property and equipment, net	224	345
Deferred financing costs	535	—
Total assets	$ 33,675	$ 52,743
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 5,003	$ 9,520
Accrued expenses and other current liabilities	5,333	8,495
Accrued interest payable	1,344	1,219
Current portion of long-term debt	10,410	14,716
Total current liabilities	22,090	33,950
Long-term debt, less current portion	—	1,526
Total liabilities	22,090	35,476
Total shareholders' equity	11,585	17,267
Total liabilities and shareholders' equity	$ 33,675	$ 52,743