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 April 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
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): ☐

Earnings Release

On April 6, 2021, Stealth BioTherapeutics Corp (the "Company") issued a press release announcing its unaudited financial results for the year ended December 31, 2020 and operational progress. The press release issued by the Company in connection therewith is attached hereto as Exhibit 99.1 The information in this Form 6-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by the Company on April 6, 2021

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: April 6, 2021

Exhibit 99.1

STEALTH BIOTHERAPEUTICS REPORTS FISCAL YEAR 2020 FINANCIAL RESULTS AND RECENT BUSINESS HIGHLIGHTS

Phase 2b dry AMD patient recruitment completed with topline data expected Q2 2022

NDA submission for elamipretide for cardiomyopathy in Barth syndrome may be delayed based on recent FDA feedback and ongoing interactions

Clinical expansion efforts underway for elamipretide in rare metabolic cardiomyopathies and in rare mitochondrial disease caused by nuclear DNA mutations

Pipeline development ongoing with SBT-272, SBT-550, and other pipeline compounds

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

BOSTON –April 6, 2021 – 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 year ended December 31, 2020 and announced recent business highlights.

"As we look forward to data from our fully-enrolled Phase 2 program in dry age-related macular degeneration during the first half of 2022, we are poised to progress our planned clinical expansion into rare metabolic cardiomyopathies and neurological diseases, with multiple trial initiations expected this year," said Reenie McCarthy, Chief Executive Officer at Stealth. "Our recent and ongoing discussions with FDA may result in a delay in our Barth NDA submission, but helped identify options to generate additional data we believe may support a filing within a reasonable time-frame. We appreciate the strong engagement by senior Division and Office level FDA personnel, and we believe that our learnings from this program will help inform our approach to larger rare cardiomyopathic disease indications."

Fourth Quarter 2020 and Recent Highlights

- **Barth syndrome.** In January 2021, the Company announced that it had met with the Division of Cardiology and Nephrology (DCN) to discuss its Barth development program and planned submission of its New Drug Application (NDA) for the treatment of cardiomyopathy in Barth syndrome. In late February 2021 and in early April 2021, the Company met again with DCN to discuss both matters. FDA expressed its view that the existing clinical data are insufficient to demonstrate substantial evidence of effectiveness and do not support NDA review, and suggested potential paths forward to generate additional data, including by a randomized withdrawal of therapy from patients in the Company's ongoing open label extension trial and from additional potential patients the Company could enroll. The Company has not yet received a record of this meeting. The Company is evaluating the proposed withdrawal protocol among other potential next steps.
- In late 2020, the Barth Syndrome Foundation, which is the global advocacy group representing Barth patients, announced its petition requesting the Company to submit and the FDA to review an NDA for elamipretide for the treatment of Barth. On March 3, 2021, the Barth Syndrome Foundation announced that DCN and other FDA representatives attended a March 3 listening session requested by members of the Barth syndrome community. The listening session was a first-of-its-kind engagement in which the FDA sought to understand the level of uncertainty Barth patients would accept regarding the effectiveness of new therapies, which is a type of flexibility FDA's December 2019 *Guidance for Industry: Demonstrating Substantial Evidence of Effectiveness* recommends the FDA consider in rare disease settings.

- **Geographic atrophy.** In February 2021, the Company announced that it had completed enrollment of 176 patients in its ReCLAIM-2 Phase 2b clinical trial in patients with geographic atrophy. This milestone triggered the payment of an additional $10 million of development funding to the Company under the Development Funding Agreement announced in November 2020. Design and preliminary baseline demographics for the ReCLAIM-2 trial were presented at Angiogenesis, Exudation, and Degeneration 2021 in February 2021.

- **SBT-272.** As previously reported, data presented at the 2020 Annual NEALS Meeting demonstrated that SBT-272 improved neurite length and branching in mutant TDP43 primary upper motor neurons. TDP43 pathology, which is believed to play a role in neuronal cell death, has been observed in multiple neurodegenerative diseases, including

Amyotrophic Lateral Sclerosis, Frontotemporal Lobar Degeneration, Lewy Body Dementia, Progressive Supranuclear Palsy, and Alzheimer's Disease. The Company is conducting toxicology studies to support a potential Phase 2a clinical study in patients with neurological disease in 2022.

- **Development Funding Agreement.** In November 2020, the Company announced the first closing under a Development Funding Agreement to support the clinical development of elamipretide. To date, the Company has received $30 million and is eligible to receive an additional $5 million on submission of an NDA for the treatment of cardiomyopathy in Barth syndrome.
- **Registered Direct Offerings.** In November 2020, the Company received gross proceeds of $3.2M from the registered direct offering of 2,844,446 ADSs. In February 2021, the Company received gross proceeds of $4.7 million from the registered direct offering of 2,339,000 ADSs.

Key Upcoming Milestones

- **Geographic atrophy:** Data expected in Q2 2022.
- **Expansion of cardiomyopathy franchise:** A Phase 2a investigator-initiated open-label clinical trial assessing elamipretide in a cohort of patients affected by visual decline and/or cardiomyopathy associated with Friedreich’s ataxia is expected to commence during Q2 2021. The Company anticipates that data from this trial will help inform pivotal trial design. A meeting with the FDA to discuss protocol design for a trial to evaluate elamipretide in patients with cardiomyopathy associated with Duchenne muscular dystrophy is expected during Q3 2021.
- **Initiation of Phase 3 clinical trial in rare mitochondrial diseases caused by nuclear DNA (nDNA) mutations:** The Company plans to meet with the FDA during Q2 2021 prior to initiating a Phase 3 clinical trial in the prespecified subgroup of primary mitochondrial disease patients with nDNA mutations who appeared to respond to elamipretide therapy in the Company’s Phase 3 trial in primary mitochondrial myopathy.
- **Expansion of neurology franchise:** The Company is continuing its neurology pipeline expansion efforts with SBT-272 and a group of compounds from its SBT-550 series and expects to announce results of SBT-272 preclinical studies and initiation of SBT-550 pre-IND enabling studies during 2021.

Financial Results for the year ended December 31, 2020

Cash Position: Cash and cash equivalents were $32.8 million at December 31, 2020, compared to $50.8 million at December 31, 2019. In February 2021, the Company received $10.0 million under the Development Funding Agreement with Morningside Venture (I) Investments Ltd., as a result of the tranche 2 milestone event upon completing enrollment in its ReCLAIM-2 Phase 2 clinical trial of elamipretide for the treatment of dry AMD and gross proceeds of $4.7 million from a registered direct offering of its ADSs.

Revenue: We did not have any revenue in 2020 compared to $21.1 million of revenue in 2019. Revenue in 2019 represents non-refundable upfront payments under the Alexion Arrangement that were recognized in full in accordance with applicable accounting standards as we completed our performance obligation in 2019. Alexion terminated the Agreement in January 2020, and as such, no additional revenue will be recognized under the Alexion Arrangement.

Research and Development (R&D) Expenses: R&D expenses decreased by $15.3 million to $29.3 million for the year ended December 31, 2020, from $44.6 million for the year ended December 31, 2019. This decrease was primarily due to a net decrease of $8.7 million in employee and consultant related costs attributable to the strategic repositioning implemented in Q1 2020, a $3.2 million decrease in contract manufacturing, a $1.8 million net decrease in clinical costs primarily driven by the closeout of our Primary Mitochondrial Myopathy development efforts which ended in December 2019, a $1.4 million decrease in preclinical costs and a $0.2 million net decrease in regulatory costs.

General and Administrative (G&A) Expenses: G&A expenses decreased by $2.9 million to $19.4 million for the year ended December 31, 2020, from $22.3 million for the year ended December 31, 2019. The increase was primarily attributable to a decrease of $4.3 million in pre-commercial activities offset in part by a $1.4 million increase in professional services for various financing transactions and increased costs of insurance.

Other Expense: Other expense decreased by $17.1 million to $8.8 million for the year ended December 31, 2020 from $25.9 million for the year ended December 31, 2019. Other expense in 2020 consisted of a $7.1 million non-cash expense due to the change in fair value of the derivative liability and $1.8 million in interest expense offset by $0.1 million in interest income. Other expense in 2019 consisted of a $22.7 million loss on extinguishment of debt recorded in conjunction with the IPO, $6.7 million in interest expense mostly related to convertible debt and $0.3 million loss due to the change in fair value of the warrant liability offset in part by a $2.8 million gain from the fair value adjustment of the derivative liability associated with the convertible debt and $1.0 million in interest income.

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 (877)-407-0989 (domestic) or (201)-389-0921 (international) and referencing conference ID 13717131. 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 muscular dystrophy and Friedreich's ataxia, rare mitochondrial diseases entailing nuclear DNA mutations, 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, and our new series of small molecules, SBT-550, for rare neurological disease indications following promising preclinical data. We have optimized our discovery platform to identify novel mitochondria-targeted compounds which may be nominated as therapeutic product candidates or utilized as mitochondria-targeted vectors 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 a potential submission of an NDA; its expectations regarding regulatory interactions, including its evaluation of the possibility that existing data and the data from the withdrawal protocol may provide sufficient evidence to support NDA review; the potential benefits of Stealth BioTherapeutics' product candidates; its key milestones for 2021 and 2022; and its plans regarding future data presentations. 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 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
Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Year Ended December 31,	
	2020	2019
Revenue	$ —	$ 21,087
Operating expenses:		
Research and development	29,305	44,604
General and administrative	19,366	22,315
Total operating expenses	48,671	66,919
Loss from operations	(48,671)	(45,832)
Other income (expense):		
Loss on extinguishment of debt	—	(22,700)
Change in fair value of derivative liability	(7,117)	2,782
Change in fair value of warrant liability	—	(300)
Interest income	139	988
Interest expense and other	(1,808)	(6,666)
Total other expense	(8,786)	(25,896)
Net loss attributable to ordinary shareholders	$ (57,457)	$ (71,728)
Net loss per share attributable to ordinary shareholders — basic and diluted	$ (0.10)	$ (0.19)
Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders — basic and diluted	556,169,255	375,669,759

STEALTH BIOTHERAPEUTICS CORP
Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents (a)	$ 32,787	$ 50,768
Prepaid expenses and other current assets	2,253	1,630
Total current assets	35,040	52,398
Property and equipment, net	106	345
Deferred financing costs and other non-current assets	702	—
Total assets	$ 35,848	$ 52,743
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,526	$ 9,520
Accrued expenses and other current liabilities	7,024	8,495
Accrued interest payable	1,499	1,219
Current portion of long-term debt	9,000	14,716
Total current liabilities	21,049	33,950
Long-term debt, less current portion	—	1,526
Long-term deferred rent, less current portion	16	—
Development derivative liability - related party	25,155	—
Total liabilities	46,220	35,476
Total shareholders' equity (deficit)	(10,372)	17,267
Total liabilities and shareholders' equity (deficit)	$ 35,848	$ 52,743

(a) Pursuant to the Development Funding Agreement, an additional $10.0M was received from Morningside Venture (I) Investments Ltd. upon the completion of enrollment of our RECLAIM-2 Phase 2 clinical trial of elamipretide for the treatment of Dry AMD in February 2021. Additionally, gross proceeds of $4.7 million from a registered direct offering of the Company's ADSs were also received in February 2021.