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 May 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): ☐

On May 7, 2020, Stealth BioTherapeutics Corp (the "Company") issued a press release announcing its unaudited financial results for the three months ended March 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 May 7, 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: May 7, 2020

Exhibit 99.1

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

Further guidance on regulatory path for Barth syndrome expected summer 2020

Completion of Phase 2b dry AMD study enrollment expected by year-end

Clinical expansion efforts underway for elamipretide in rare metabolic cardiomyopathies

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

BOSTON – May 7, 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 first quarter ended March 31, 2020 and provided a corporate update.

"Our industry – and our global community – is facing unprecedented challenges due to the COVID-19 pandemic. In these trying times, Stealth is fortunate to have strong shareholder support, leaving us well-capitalized into 2021, with enthusiastic and focused employees, who have shown tremendous dedication to developing mitochondrial medicines for patients suffering from cardiomyopathic, ophthalmic, neurological and neuropathic disorders," said Reenie McCarthy, chief executive officer of Stealth. "Our team has rallied remarkably to work to ensure the continued progress of our ongoing clinical and regulatory efforts and the safety of our patients. We look forward to additional regulatory interactions regarding our Barth program, hopefully, over the summer and hope to see an uptick in enrollment in our Phase 2b study in dry AMD as various regions of the country reopen in the coming weeks. We are also continuing our efforts to expand our rare metabolic cardiomyopathy franchise and advance our pipeline of novel mitochondrial medicines."

COVID-19 Business Update:

Ongoing Clinical Trials

Stealth is committed to advancing its ongoing clinical programs in Barth and dry AMD. As previously announced, the Company anticipates completing enrollment for its Phase 2b trial in dry AMD by year-end and hopes to see an uptick in enrollment as various regions of the country reopen in the coming weeks. The Company is continually monitoring additional risks and potential delays in its clinical study sites and contract research organizations and will provide any further updates as appropriate.

Drug Supply

The Company believes that it has sufficient drug supply to complete its ongoing clinical studies and does not expect delays to its ongoing clinical trials due to manufacturing or supply-chain issues as a result of COVID-19.

First Quarter 2019 and Recent Highlights

- **Announced $20 million financing.** In April 2020, the Company closed a $20 million private placement with Morningside Venture (I) Investments Limited, extending its expected financial runway into 2021.
- **Type C meeting.** In March 2020, the Company had a productive Type C meeting with the Division of Rare Disease and Medical Genetics (DRDMG) of the U.S. Food and Drug Administration (FDA) to discuss its data in Barth syndrome. The Company has requested a follow-up Type C meeting with DRDMG, expected this summer, to present and discuss additional data requested by the DRDMG and to further clarify a potential path to NDA.
- **Announced improvement in cardiac function in Barth.** In March 2020, data presented at the American College of Cardiology (ACC) 2020 Virtual Annual Meeting showed that treatment through week 36 of the open-label extension study with elamipretide was associated with significant improvement in the slope of change from baseline for left ventricular stroke volume (p=0.0001), as well as significant improvements from baseline in 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.
- **Announced Barth rare pediatric designation.** In March 2020, the Company announced receipt of Rare Pediatric Disease (RPD) designation from the FDA for elamipretide for the treatment of Barth syndrome. Under this program, upon FDA priority review and approval of elamipretide for Barth syndrome, if any, the Company would be eligible for a voucher that could be used to obtain priority review for a subsequent human drug application.
- **Announced positive Barth data from efficacy study.** In February 2020, the Company announced positive results from its SPIBA-001 natural history comparative control efficacy study in Barth patients, demonstrating a greater than 80 meter improvement in the primary endpoint of 6 Minute Walk Test at one year compared to natural history controls (p=0.0005).
- **Expanded clinical pipeline.** In January 2020, the Company initiated a first-in-human Phase 1 trial evaluating its second-generation pipeline compound, SBT-272, in healthy subjects. The Company anticipates that preclinical data expected later this year in models of amyotrophic lateral sclerosis (ALS) and multiple system atrophy (MSA) will help inform SBT-272's clinical development pathway for rare neurodegenerative diseases.
- **Implemented strategic repositioning.** In January 2020, the Company implemented strategic actions to reduce costs and reposition its focus on Barth and other rare metabolic cardiomyopathies, in addition to its ophthalmic and pipeline neurology programs following the 2019 year-end announcement of its MMPOWER-3 clinical study results.

Key Upcoming Milestones

- Requesting follow-up Type C meeting with FDA to discuss additional data and regulatory path in Barth syndrome.
- Complete enrollment of Phase 2 clinical trial in dry AMD expected by year-end 2020.
- Pre-clinical data for SBT-272 in ALS and MSA and for SBT-259 in Charcot-Marie-Tooth disease expected by year-end 2020.

Financial Results for the Three Months Ended March 31, 2020

Cash Position: Cash and cash equivalents were $31.2 million at March 31, 2020, compared to $50.8 million at December 31, 2019. An additional $20.0 million was received in April 2020, pursuant to a private placement transaction with Morningside Venture (I) Investments Limited.

Research and Development (R&D) Expenses:

R&D expenses were $9.8 million for the three months ended March 31, 2020, compared to $14.3 million for the same period in 2019. The decrease was primarily due to a $1.7 million decrease in employee and consultant costs, offset by a net $0.5 million increase attributable to the strategic repositioning, a $1.5 million net decrease in clinical trial costs due to timing of trials, a $1.3 million decrease in contract manufacturing, a $0.3 million decrease in discovery related expenses due to timing of activities and a $0.2 million decrease in regulatory costs.

General and Administrative (G&A) Expenses:

G&A expenses were $5.2 million for the three months ended March 31, 2020, compared to $4.2 million for the same period in 2019. The increase in administrative expenses was attributed to a $0.8 million increase in professional services and activities attributable to operating as a public company, a $0.7 million increase in employee and consultant related costs primarily driven by share based compensation expense, and a net $0.4 million increase in employee costs attributable to its strategic repositioning, offset in part by a decrease of $0.9 million in pre-commercial activities attributable to the strategic repositioning.

Other Expense, Net:

Other expense was $0.5 million for the three months ended March 31, 2020, compared to $24.7 million for the same period in 2019. The decrease in other expense is primarily attributed to a non-cash $22.7 million loss on extinguishment of debt associated with the conversion of convertible notes into ordinary shares in connection with our 2019 IPO, a $4.0 million decrease in interest expense related to the convertible debt, a $0.3 million change in fair value of warrant liability. These decreases were offset in part by a $2.7 million change in fair value gain on the derivative liability associated with the convertible debt and a $0.1 million decrease in interest income.

Net Loss:

Net loss was $15.5 million, or $0.04 basic and diluted net loss per ordinary share, for the three months ended March 31, 2020, as compared to $43.2 million, or $0.20 basic and diluted net loss per ordinary share, for the same period in 2019. The decreased loss was primarily attributable to the $22.7 million non-cash loss associated with the conversion of convertible notes in connection with our 2019 IPO, decreased operating costs of $3.5 million and a net decrease in other expenses of $1.5 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 1 (866) 939-3921 or 1 (678) 302-3550 (international) and referencing conference ID 49677344. 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, 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 SBT-272; the potential benefits of Stealth BioTherapeutics' product candidates; its key milestones for 2020; its plans regarding future data presentations; its anticipated interactions with regulatory agencies; 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.

Investor Relations
Stern Investor Relations
Lauren Stival, 212-362-1200
IR@StealthBT.com

STEALTH BIOTHERAPEUTICS CORP

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

	Three months ending March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 9,847	$ 14,328
General and administrative	5,180	4,157
Total operating expenses	15,027	18,485
Loss from operations	(15,027)	(18,485)
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	123	208
Interest expense and other	(636)	(4,683)
Total other expense	(513)	(24,693)
Net loss attributable to ordinary shareholders	$ (15,540)	$ (43,178)
Net loss per share attributable to ordinary shareholders — basic and diluted	$ (0.04)	$ (0.20)
Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders — basic and diluted	436,720,810	220,035,294

STEALTH BIOTHERAPEUTICS CORP

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents (a)	$ 31,242	$ 50,768
Prepaid expenses and other current assets	620	1,630
Total current assets	31,862	52,398
Property and equipment, net	285	345
Total assets	$ 32,147	$ 52,743
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 6,513	$ 9,520
Accrued expenses and other current liabilities	7,270	8,495
Accrued interest payable	1,303	1,219
Current portion of long-term debt	14,634	14,716
Total current liabilities	29,720	33,950
Long-term debt, less current portion	—	1,526
Total liabilities	29,720	35,476
Total shareholders' equity	2,427	17,267
Total liabilities and shareholders' equity	$ 32,147	$ 52,743

(a) An additional $20.0 million was received in April 2020, pursuant to a private placement transaction with Morningside Venture (I) Investments Limited