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 2019

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 15, 2019, Stealth BioTherapeutics Corp (the "Company") issued a press release announcing its unaudited financial results for the quarter ended March 31, 2019 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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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 15, 2019

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by the Company on May 15, 2019

Exhibit 99.1

STEALTH BIOTHERAPEUTICS REPORTS FIRST QUARTER 2019 FINANCIAL RESULTS AND RECENT BUSINESS HIGHLIGHTS

BOSTON – May 15, 2019 – 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 quarter ended March 31, 2019.

"We expect 2019 to be a transformational year for Stealth and believe the milestones achieved during the first quarter attest to our ability to execute through this exciting period," said Reenie McCarthy, Chief Executive Officer at Stealth. "We opened the first quarter with our initial public offering, providing the foundation to implement our clinical strategy. During the quarter, we successfully initiated and dosed the first patient in our ReCLAIM-2 Phase 2b study in dry age-related macular degeneration with geographic atrophy and, more recently, announced completion of enrollment for our pivotal MMPOWER-3 study in primary mitochondrial myopathy. We look forward to sharing more news throughout 2019, including top-line data from MMPOWER-3 expected by year-end."

First Quarter 2019 and Recent Highlights

- **Presented positive results in dry age-related macular degeneration (AMD) and Leber's hereditary optic neuropathy (LHON)** at the Association for Research in Vision and Ophthalmology (ARVO) 2019 Annual Meeting. Results were from the ReCLAIM Phase 1 study in dry AMD and the open-label portion of the ReSIGHT Phase 2 study in LHON. In addition to improvements in measures of visual function and quality of life, elamipretide was well tolerated and most adverse events were mild to moderate in severity. A mid-year 2019 FDA meeting is expected to inform the regulatory path forward in LHON.
- **Completed enrollment for primary mitochondrial myopathy (PMM) Phase 3 study.** MMPOWER-3 is a Phase 3, randomized, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of daily subcutaneous injections of elamipretide in patients with PMM, followed by an open-label extension in which 90 of the 95 subjects who have completed the double-blind portion of the trial to date have elected to participate. The study is fully enrolled, with top-line data expected by year end.
- **Announced positive results from Barth syndrome Phase 2/3 open-label extension.** Data from the open-label portion of the TAZPOWER Phase 2/3 study in Barth syndrome demonstrated a significant (almost 40%) decrease in a biomarker which is diagnostic for the disease, with reductions from baseline observed in all ten open-label extension participants and further correlated with improvements in clinical endpoints. Elamipretide was well tolerated and most adverse events, including injection site reactions, were mild to moderate in severity. We anticipate further engagement with the FDA during the third quarter to discuss appropriate controls for the open-label extension data.
- **Dosed first patient in Phase 2b study of elamipretide in patients with dry AMD with geographic atrophy.** ReCLAIM-2 is a Phase 2b randomized, double-masked, placebo-controlled clinical study to evaluate the safety and efficacy of 48 weeks of subcutaneous injections of elamipretide in patients with dry AMD with geographic atrophy. Completion of enrollment is targeted for early 2020.

- **Completed initial public offering (IPO)** of 7,088,232 American Depositary Shares (ADSs) at a public offering price of $12.00 per ADS, which includes a partial exercise of the underwriters' over-allotment option. The total net proceeds, after deducting underwriting discounts and commissions and other offering expenses, were approximately $76.9 million.

Key Upcoming Milestones

- Meetings with FDA to discuss regulatory path for elamipretide in LHON and Barth syndrome during the second and third quarters of 2019.
- Report top-line data from Phase 3 clinical trial in PMM by the end of 2019.
- Initiate Phase 1 clinical trial of new pipeline candidate, SBT-272, by the end of 2019.

Financial Results for the Quarter Ended March 31, 2019

Cash Position: Cash and cash equivalents were $70.5 million at March 31, 2019, compared to $10.9 million at December 31, 2018. During the first quarter of 2019, the Company raised $76.9 million of net proceeds from its IPO.

Research and Development (R&D) Expenses: R&D expenses were $14.3 million for the first quarter of 2019, compared to $13.4 million for the first quarter of 2018. This increase was primarily due to a $1.7 million increase in headcount and consulting-related expenses as we continued to build our clinical, medical affairs and regulatory functions and a $1.1 million increase in contract manufacturing expenses for NDA-enabling activities, offset by a decrease of $1.9 million in clinical trial costs.

General and Administrative (G&A) Expenses: G&A expenses were $4.2 million for the first quarter of 2019, compared to $3.5 million for the first quarter of 2018. The increase in administrative expenses of $0.7 million was primarily attributable to an increase in pre-commercial activities, including medical affairs, marketing and payer reimbursement activities and expenses related to public company activities, including director fees, and directors' and officers' liability insurance.

Other expense, net: Other first quarter expense of $24.7 million, compared to $3.4 million for the first quarter of 2018, was primarily attributable to a non-cash $22.7 million loss on extinguishment of debt due to the conversion of convertible notes into ordinary shares in connection with our IPO and a $1.3 million increase in interest expense associated with the notes, offset by $2.7 million of other income due to the change in fair value of the derivative liability associated with the notes.

Net Loss: Net loss for the first quarter of 2019 was $43.2 million, or $0.20 basic and diluted net loss per ordinary share, as compared to $20.3 million for the first quarter of 2018, or $0.30 basic and diluted net loss per ordinary share. The increased loss was primarily attributable to the aforementioned $22.7 million non-cash loss associated with the conversion of convertible notes.

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, collectively known as primary mitochondrial diseases, and are also involved in many common age-related diseases. We believe our lead product candidate, elamipretide, has the potential to treat both rare genetic and common age-related mitochondrial diseases. We are studying elamipretide in the following primary mitochondrial diseases: primary mitochondrial myopathy, Barth syndrome and Leber's hereditary optic neuropathy. We are also studying elamipretide in dry age-related macular degeneration. Our other pipeline candidates include SBT-272, which we are evaluating for rare neurodegenerative disease indications, and SBT-20, which we are evaluating for rare peripheral neuropathies. We have optimized our discovery platform to identify novel mitochondrial-targeted compounds, which may be nominated as therapeutic product candidates or utilized as scaffolds to deliver other compounds to mitochondria. We have assembled a highly experienced management team, board of directors and group of scientific advisors to help us achieve our mission of leading mitochondrial medicine.

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; the potential benefits of Stealth BioTherapeutics' product candidates; its key milestones for 2019; and its plans regarding future data presentations and regulatory interactions. 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; 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 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 March 31,	
	2019	2018
Operating expenses:		
Research and development	$ 14,328	$ 13,436
General and administrative	4,157	3,496
Total operating expenses	18,485	16,932
Loss from operations	(18,485)	(16,932)
Other income (expense):		
Loss on extinguishment of debt	(22,700)	—
Change in fair value of derivative liability	2,782	(52)
Change in fair value of warrant liability	(300)	(1)
Interest expense	(4,683)	(3,378)
Interest income	208	22
Total other income (expense), net	(24,693)	(3,409)
Net loss attributable to ordinary shareholders	$ (43,178)	$ (20,341)
Net loss per share attributable to ordinary shareholders — basic and diluted	$ (0.20)	$ (0.30)
Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders — basic and diluted	220,035,294	68,474,614

STEALTH BIOTHERAPEUTICS CORP

Condensed Consolidated Balance Sheets

(in thousands)

(unaudited)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 70,497	$ 10,855
Prepaid expenses and other current assets	1,597	2,438
Total current assets	72,094	13,293
Property and equipment, net	433	499
Deferred offering costs	—	1,325
Other non-current assets	331	406
Total assets	$ 72,858	$ 15,523
Liabilities, convertible preferred shares and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 9,605	$ 11,023
Accrued expenses and other current liabilities	11,726	13,826
Accrued interest payable	914	7,297
Current portion of long-term debt	4,235	8,465
Total current liabilities	26,480	40,611
Long-term debt, less current portion	12,455	10,317
Convertible notes payable	—	103,257
Derivative liability	—	36,567
Warrant liability	—	100
Total liabilities	38,935	190,852
Series A convertible preferred shares	—	211,377
Total shareholders' equity (deficit)	33,923	(386,706)
Total liabilities, convertible preferred shares and shareholders' equity (deficit)	$ 72,858	$ 15,523