STEALTH BIOTHERAPEUTICS CORP

FORM 6-K
(Report of Foreign Issuer)

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UNITED STATES
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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 December 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): ☐

Press Release

On December 20, 2019, Stealth BioTherapeutics Corp (the "Company") issued a press release providing an update on the results of its Phase 3 clinical trial in primary mitochondrial myopathy. 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.

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by the Company on December 20, 2019

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: December 20, 2019

Exhibit 99.1

Stealth BioTherapeutics Provides Update on Phase 3 Trial of Elamipretide in Primary Mitochondrial Myopathy

December 20, 2019

BOSTON, Dec. 20, 2019 /PRNewswire/ — Stealth BioTherapeutics (NASDAQ: MITO), a clinical-stage biotechnology company focused on the discovery, development and commercialization of novel therapies for diseases involving mitochondrial dysfunction, today announced top-line data from the Phase 3 MMPOWER-3 trial evaluating elamipretide for treatment of patients with primary mitochondrial myopathy (PMM). The study did not meet its primary endpoints assessing changes in the six-minute walk test and Primary Mitochondrial Myopathy Symptom Assessment (PMMSA) Total Fatigue Score. Safety results showed that treatment with elamipretide was well tolerated with most adverse events mild to moderate in severity.

“We are deeply grateful to our patients and families, our investigators and their teams, and our advocacy partners for their support of this study, and share their disappointment that it did not meet the promise of our earlier trials in this indication,” said Chief Executive Officer Reenie McCarthy. “We remain confident in the promise of our platform and committed to our mission of improving the lives of people living with diseases involving mitochondrial dysfunction. We plan to meet with the FDA in early 2020 regarding our Barth syndrome program, where we have observed significant improvement in cardiac stroke volume during open-label extension, and continue to enroll our Phase 2b clinical trial in geographic atrophy associated with dry age-related macular degeneration, in which we observed improvement in visual function during an earlier Phase 1 study. We are also progressing our pipeline of second-generation mitochondrial therapeutics, with lead pipeline compound SBT-272 entering Phase 1.”

The Company plans to review its operational resources to align them with its near-term priorities of progressing its Barth, AMD and pipeline programs, and expects to provide further guidance next month.

Conference Call Information

Stealth will host a conference call and webcast today at 8:30 a.m. ET to discuss the MMPOWER-3 trial. The call can be accessed by dialing 866-939-3921 (domestic) or 678-302-3550 (international) and referencing conference ID 49292088. 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 the MMPOWER-3 Clinical Trial

MMPOWER-3 was a randomized, double-blind, parallel-group, placebo-controlled trial to evaluate the efficacy and safety of elamipretide over 32 weeks in 218 patients with primary mitochondrial myopathy between the ages of 16 and 80. The trial was conducted at 28 clinical sites across North America, Europe and Australia.

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 and SBT-259, 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.

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