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 October 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
One Nexus Way, Camana Bay
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 333-253601, 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

On October 18, 2021, Stealth BioTherapeutics Corp (the "Company") received a Refusal to File letter from the U.S. Food and Drug Administration (the "FDA") regarding the Company's new drug application (the "NDA") for elamipretide, a mitochondria-targeted therapy for the treatment of Barth syndrome. The FDA determined, upon its preliminary review, that the NDA was not sufficiently complete to permit a substantive review. In the letter, the FDA stated that the NDA does not contain an adequate and well-controlled trial that provides evidence of effectiveness, noting that the SPIBA-201 Phase 2 clinical trial of elamipretide for the treatment of Barth syndrome was negative during the randomized, double-blind portion of the study and that the FDA does not consider the open label extension of the SPIBA-201 trial to be adequate and well-controlled.

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: October 20, 2021