
**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 November 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):

Earnings Release

On November 5, 2020, Stealth BioTherapeutics Corp (the “Company”) issued a press release announcing its unaudited financial results for the three months ended September 30, 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by the Company on November 5, 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: November 5, 2020

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

Secured a development funding agreement related to elamipretide

Phase 2b dry AMD study enrollment completion targeted by year-end

Barth NDA preparation underway

SBT-272 shows promise in additional neurological preclinical disease models

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

BOSTON – November 5, 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 third quarter ended September 30, 2020 and provided a corporate update.

“As we move into the fourth quarter, we are proud that our team has stayed focused, execution-oriented, excited about our platform potential, and dedicated to the patients we serve during what has been a challenging year,” said Reenie McCarthy, chief executive officer of Stealth. “We have learned important lessons that both inform our future development of elamipretide for diseases of mitochondrial dysfunction and stoke our enthusiasm in our deep pipeline of mitochondrial therapeutics. We are thrilled that with Morningside’s continued financial support under our recently announced development funding agreement, we are well-positioned to progress our first-in-class development efforts in 2021.”

Third Quarter 2020 Program Highlights

Geographic atrophy. The ReCLAIM-2 Phase 2b clinical trial in patients with geographic atrophy associated with dry age-related macular degeneration is approximately 90% enrolled, with complete enrollment targeted for year-end 2020. Several additional trial sites have been added, and the Company has implemented best practices measures, including availability of night and weekend visits and visiting nurses, to alleviate COVID-19 related challenges. The Company is closely monitoring any COVID-19 related discontinuations in light of increased reported incidence in the United States and may elect to upsize target enrollment if discontinuations increase during the fourth quarter. If enrollment is increased, completion of enrollment could extend into the first quarter of 2021.

Barth syndrome. More than 4,250 members of the Barth syndrome community have signed a petition asking the FDA and the Company to work together to provide Barth syndrome patients access to elamipretide, and for the FDA to review and approve a New Drug Application (NDA) for elamipretide to treat this ultra-rare disease. In their petition, patients expressed serious concern regarding delays anticipated by the FDA’s July 2020 Type C written response recommending that the Company conduct additional controlled clinical trials prior to NDA submission. In response, the Company has reiterated its commitment to the Barth community and its plan to submit its NDA by year-end.

Following FDA’s July 2020 recommendation, the Company also plans to submit a protocol for a randomized withdrawal study of the patients remaining on open-label extension. While the Company believes that a post-approval, long-term cardiac outcome trial would be most appropriate to provide confirmatory evidence of efficacy in this ultra-rare disease, the randomized withdrawal trial remains a near-term potential approach to address FDA feedback.

Data from SPIBA-001, the Company’s pivotal Phase 3 natural history control trial, and SPIBA-201, the Company’s Phase 2/3 double-blind placebo-controlled crossover trial and open label extension, were presented at the Barth Syndrome Foundation’s July 2020 Symposium and the American Society of Genetics in Medicine (ASGM) in October. These data showed that long-term treatment with elamipretide resulted in statistically significant improvements from baseline (with respect to SPIBA-201) and compared to natural history controls (with respect to SPIBA-001) in cardiac function, metabolic function, skeletal muscle function, and patient and clinician reported outcomes. Echocardiographic assessments suggest that prolonged treatment with elamipretide may lead to cardiac reverse remodeling. Data from SPIBA-201 were published in *Genetics in Medicine* in October 2020.

SBT-272. In a Phase 1 clinical trial, orally administered SBT-272 showed a favorable safety profile in healthy human volunteers. With these encouraging results, the Company is assessing drug exposure to inform decisions regarding oral formulation and utility of

exploring subcutaneous dosing. Long term toxicology studies are expected to be conducted in 2021 to enable progression into Phase 2 trials.

As previously reported, the Company has been evaluating SBT-272 in neurological disease preclinical models due to its improved blood brain barrier penetration and higher concentrations in the central nervous system relative to elamipretide. Data presented at the 2020 Annual NEALS Meeting in October demonstrated that SBT-272 improved neurite length and branching in mutant TDP43 primary upper motor neurons. TDP43 pathology has been observed in multiple neurodegenerative diseases, including ALS, Frontotemporal Lobar Degeneration (FTLD), Lewy Body Dementia (LBD), Progressive Supranuclear Palsy (PSP), and Alzheimer's Disease, and is believed to play a role in neuronal cell death.

Third Quarter 2020 and Recent Financial Highlights

Development Funding Agreement. In November 2020, the Company announced the first closing under a Development Funding Agreement to support the clinical development of elamipretide. Under the terms of the agreement, Stealth has received an upfront \$20 million from Morningside Venture (I) Investments Ltd., and expects to receive up to an additional \$15 million upon achievement of near-term clinical and regulatory milestones associated with its geographic atrophy and Barth programs. Additional investors may contribute up to an additional \$35 million in funding commitments at subsequent closings. The agreement also contemplates up to an additional \$35 million in funding upon mutual agreement of the parties. Stealth is obligated to make milestone payments following certain regulatory approvals, with most payments due in the 5th through 7th year following regulatory approval. No approval payments are owed should regulatory approval not be achieved for elamipretide in the indications currently under or planned for near-term development.

Amended Term Loan Facility with Hercules Capital, Inc. In July 2020, the Company amended its Term Loan Facility with Hercules Capital, Inc. to defer principal payment until March 1, 2021.

Key Upcoming Milestones

Barth syndrome: Submission of clinical protocols to generate post-approval-controlled data and potential NDA submission anticipated by year-end 2020.

Geographic atrophy: Completion of enrollment of Phase 2 clinical trial in dry AMD targeted for year-end 2020. Data expected in early 2022.

Friedreich's ataxia: 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 expected to commence in early 2021. The Company anticipates that data from this trial will help inform pivotal trial design.

Duchenne cardiomyopathy: Initiation of a pivotal trial in patients with cardiomyopathy associated with Duchenne muscular dystrophy targeted for the second half of 2021, subject to discussions with FDA, continued planning efforts, and financing plans.

Replisome-related mitochondrial myopathies: Initiation of a pivotal trial in the prespecified subgroup of patients that responded to elamipretide therapy in the Company's Phase 3 trial in primary mitochondrial myopathy targeted for the second half of 2021, subject to discussions with FDA, continued planning efforts, and financing plans.

SBT-272: Results from a study of SBT-272 in a model of α -synucleinopathy, a disease pathology associated with Parkinson's disease (PD), LBD, and multiple system atrophy (MSA), will be presented at an upcoming conference.

SBT-550: Initiation of IND-enabling studies for neurology candidates within SBT-550 series expected in 2021.

Financial Results for the Three Months Ended September 30, 2020

Cash Position:

Cash and cash equivalents were \$19.9 million at September 30, 2020, compared to \$50.8 million at December 31, 2019. The Company received an additional \$20.0 million in October 2020 upon execution of the Development Funding Agreement with Morningside Venture (I) Investments Limited.

Research and Development (R&D) Expenses:

R&D expenses were \$6.2 million for the three months ended September 30, 2020, compared to \$9.8 million for the same period in 2019. The decrease was primarily due to a \$3.2 million net decrease in employee and consultant related costs attributable to the strategic repositioning implemented in the first quarter of 2020, a \$0.7 million decrease in contract manufacturing, and a \$0.5 million

decrease in preclinical costs. These decreased costs were offset in part by a \$0.8 million net increase in clinical trial costs due to timing of trials.

General and Administrative (G&A) Expenses:

G&A expenses were \$4.7 million for the three months ended September 30, 2020, compared to \$6.3 million for the same period in 2019. The decrease in administrative expenses was attributed to a decrease of \$1.2 million in pre-commercial activities and a \$0.8 million net decrease in employee and consultant related costs, both primarily attributable to the strategic repositioning implemented in Q1 2020, offset in part by a \$0.4 million increase in professional services and activities attributable to the cost of various financing transactions and increased cost of insurance.

Other Expense, Net:

Other expense was \$0.3 million for the three months ended September 30, 2020, compared to \$0.4 million for the same period in 2019. The decrease in other expense is primarily attributed to a \$0.3 million decrease in interest expense offset in part by a \$0.2 million decrease in interest income.

Net Loss:

Net loss was \$11.2 million, or \$0.02 basic and diluted net loss per ordinary share, for the three months ended September 30, 2020, as compared to \$16.5 million, or \$0.04 basic and diluted net loss per ordinary share, for the same period in 2019. The decreased loss was primarily attributable to a decrease in operating costs of \$5.2 million and a net decrease in other expenses of \$0.1 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 (877) 407-0989 or (201) 389-0921 (international) and referencing conference ID 13710878 . 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, such as POLG-related disorders, 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 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 planned clinical trial of SBT-272; its plans for the potential submission of an NDA; expectations regarding regulatory interactions and funding for its plans to initiate additional clinical trials; the potential benefits of Stealth BioTherapeutics' product candidates; its key milestones for 2020 and 2021; its plans regarding future data presentations; 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

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STEALTH BIOTHERAPEUTICS CORP

Condensed Consolidated Statements of Operations

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 6,211	\$ 9,820	\$ 23,463	\$ 33,514
General and administrative	4,671	6,269	14,374	16,490
Total operating expenses	10,882	16,089	37,837	50,004
Loss from operations	(10,882)	(16,089)	(37,837)	(50,004)
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	2	223	139	773
Interest expense and other	(330)	(664)	(1,421)	(6,009)
Total other expense	(328)	(441)	(1,282)	(25,454)
Net loss attributable to ordinary shareholders	\$ (11,210)	\$ (16,530)	\$ (39,119)	\$ (75,458)
Net loss per share attributable to ordinary shareholders — basic and diluted	\$ (0.02)	\$ (0.04)	\$ (0.07)	\$ (0.21)
Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders — basic and diluted	596,900,696	420,399,807	536,558,283	355,634,626

STEALTH BIOTHERAPEUTICS CORP

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Assets		
Current assets:		
Cash and cash equivalents (a)	\$ 19,893	\$ 50,768
Prepaid expenses and other current assets	1,759	1,630
Total current assets	<u>21,652</u>	<u>52,398</u>
Property and equipment, net	169	345
Deferred financing costs and other assets	704	—
Total assets	<u>\$ 22,525</u>	<u>\$ 52,743</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 3,452	\$ 9,520
Accrued expenses and other current liabilities	6,406	8,495
Accrued interest payable	1,411	1,219
Current portion of long-term debt	8,982	14,716
Total current liabilities	<u>20,251</u>	<u>33,950</u>
Long-term debt, less current portion	—	1,526
Total liabilities	<u>20,251</u>	<u>35,476</u>
Total shareholders' equity	2,274	17,267
Total liabilities and shareholders' equity	<u>\$ 22,525</u>	<u>\$ 52,743</u>

- (a) An additional \$20.0 million was received in October 2020, pursuant to a Development Funding Agreement with Morningside Venture (I) Investments Limited.