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 November 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): ☐

Earnings Release

On November 14, 2019, Stealth BioTherapeutics Corp (the "Company") issued a press release announcing its unaudited financial results for the third quarter ended September 30, 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.

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by the Company on November 14, 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: November 14, 2019

Exhibit 99.1

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

BOSTON – November 14, 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 third quarter ended September 30, 2019 and provided a corporate update.

"We're approaching a transformational stage in our company's development, with our recently announced partnership with Alexion and our anticipated pivotal data in primary mitochondrial myopathy in January bringing us even closer toward our goal of delivering transformative therapies to patients with rare, mitochondrial diseases," said Reenie McCarthy, Stealth's Chief Executive Officer. "On the clinical front, the long-term data from our Barth open-label extension, now showing improvement across multiple parameters of cardiac function suggestive of cardiac remodeling, increases our optimism in elamipretide as a potential therapy for this devastating disease. We're also excited to usher our new investigational candidate, SBT-272, into the clinic, following recently announced data in an ALS model highlighting its neuro-protective potential."

Recent Highlights

- **Entered an option agreement with Alexion to co-develop and commercialize** the subcutaneous formulation of lead product candidate, elamipretide, which is currently in a Phase 3 study in primary mitochondrial myopathy (PMM). If exercised, the parties will enter into a 50-50 co-development and co-promote in the U.S. and Alexion will receive exclusive rights to develop and commercialize subcutaneous elamipretide outside the U.S. In October, Stealth received an initial payment of $30 million from Alexion for an equity investment, an option fee and development funding, and is entitled to receive additional option-related and milestone-dependent payments upon option exercise. Stealth has retained rights to develop all other pipeline product candidates, including SBT-272, which is poised to enter Phase 1 by year-end.
- **Presented new data from the open-label extension portion of the Phase 2/3 TAZPOWER trial** at the American Society of Human Genetics (ASHG) 2019 Annual Meeting in Houston, Texas. Data from 10 patients with Barth syndrome on the open-label extension showed a statistically significant ($p<0.05$) increase in average cardiac stroke volume, a primary determinant of cardiac output and overall heart function, from baseline to week 36 of the open-label extension.
- **Presented new preclinical data for SBT-272** at the 18th Annual Northeast Amyotrophic Lateral Sclerosis Consortium. Data from a mouse model of amyotrophic lateral sclerosis (ALS) demonstrated a statistically significant, dose-dependent delay in the onset of neurological symptoms as well as a reduction in neurofilament light chain, a systemic marker of neurodegeneration, and prolonged lifespan. SBT-272 is currently in pre-clinical development for treatment of ALS and other rare neurodegenerative diseases involving mitochondrial dysfunction and is expected to advance into Phase 1 by year-end.

Key Upcoming Milestones

- FDA submission of Phase 3 protocol for elamipretide in Leber's hereditary optic neuropathy (LHON) by year-end.
- Initiation of Phase 1 clinical trial of new pipeline candidate, SBT-272, by year-end.
- Reporting top-line data from MMPOWER-3, a Phase 3 clinical trial of elamipretide in PMM, in January 2020.
- Completing enrollment of Phase 2b clinical trial in geographic atrophy (GA) associated with dry age-related macular degeneration in first part of 2020.
- FDA end-of-phase meeting for Barth syndrome in first part of 2020.

Financial Results for the Quarter Ended September 30, 2019

Cash Position: Cash and cash equivalents were $37.2 million at September 30, 2019. In October 2019, we received a $30 million payment associated with the Alexion option and share purchase agreements announced on October 10, 2019.

Research and Development (R&D) Expenses:

R&D expenses were $9.8 million for the three months ended September 30, 2019, compared to $16.2 million for the same period in 2018. The decrease was primarily due to a $3.4 million net decrease in clinical trial costs due to timing of trials that ended in 2018, a $0.4 million decrease in discovery related expenses due to timing of activities and a $3.4 million decrease in contract manufacturing, offset in part by an increase of $0.8 million in employee and consultant related costs.

General and Administrative (G&A) Expenses:

G&A expenses were $6.3 million for the three months ended September 30, 2019, compared to $4.8 million for the same period in 2018. The increase in administrative expenses was primarily attributed to an increase of $0.6 million in employee and consultant related costs, associated in part with build-out of the pre-commercialization and compliance functions, $0.5 million in professional services for activities attributable to operating as a public company and $0.4 million in pre-commercial activities including building disease awareness.

Other Expense, Net:

Other expense was $0.4 million for the three months ended September 30, 2019, compared to $1.7 million for the same period in 2018. The decrease in other expense is primarily attributed to a $5.5 million decrease in interest expense related to convertible debt which was converted into ordinary shares in conjunction with our initial public offering, an increase in interest income of $0.1 million, offset in part by a $4.3 million change in period over period fair value adjustments of the derivative liability associated with the convertible debt.

Net Loss:

Net loss was $16.5 million, or $0.04 basic and diluted net loss per ordinary share for the three months ended September 30, 2019, as compared to $22.7 million, or $0.33 basic and diluted net loss per ordinary share for the same period in 2018.

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 (866) 451-7964 or (847) 944-7134 (international) and referencing conference ID 49191404. 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, collectively known as primary mitochondrial diseases, and are also involved in many common age-related diseases. We believe our lead product candidate, elamipretide, as well as pipeline candidates including SBT-272, have the potential to treat both rare genetic and common age-related mitochondrial diseases. We are studying elamipretide in primary mitochondrial myopathy, Barth syndrome and Leber's hereditary optic neuropathy, which are rare genetic diseases. We are also studying elamipretide in geographic atrophy associated with dry age-related macular degeneration. Our 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.

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 2020; 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 9,820	$ 16,222	$ 33,514	$ 41,758
General and administrative	6,269	4,755	16,490	12,541
Total operating expenses	16,089	20,977	50,004	54,299
Loss from operations	(16,089)	(20,977)	(50,004)	(54,299)
Other income (expense):				
Loss on extinguishment of debt	—	—	(22,700)	—
Change in fair value of derivative liability	—	4,331	2,782	(1,669)
Change in fair value of warrant liability	—	—	(300)	126
Interest income	223	60	773	141
Interest expense	(664)	(6,139)	(6,009)	(14,422)
Total other expense	(441)	(1,748)	(25,454)	(15,824)
Net loss attributable to ordinary shareholders	$ (16,530)	$ (22,725)	$ (75,458)	$ (70,123)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.04)	$ (0.33)	$ (0.21)	$ (1.02)
Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders – basic and diluted	420,399,807	68,474,614	355,634,626	68,474,614

STEALTH BIOTHERAPEUTICS CORP

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents (a)	$ 37,230	$ 10,855
Prepaid expenses and other current assets	1,688	2,438
Total current assets	38,918	13,293
Property and equipment, net	421	499
Deferred offering costs	—	1,325
Other non-current assets	250	406
Total assets	$ 39,589	$ 15,523
Liabilities, convertible preferred shares and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 7,284	$ 11,023
Accrued expenses and other current liabilities	10,652	13,826
Accrued interest payable	1,114	7,297
Current portion of long-term debt	8,745	8,465
Total current liabilities	27,795	40,611
Long-term debt, less current portion	8,099	10,317
Convertible notes payable	—	103,257
Derivative liability	—	36,567
Warrant liability	—	100
Total liabilities	35,894	190,852
Series A convertible preferred shares	—	211,377
Total shareholders' equity (deficit)	3,695	(386,706)
Total liabilities, convertible preferred shares and shareholders' equity (deficit)	$ 39,589	$ 15,523

(a) In October 2019, we received a $30 million payment associated with the Alexion option and share purchase agreements announced on October 10, 2019.