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 August 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): ☐

Departure of Directors or Certain Officers; Election of Directors

On July 24, 2019, Vincent Sai Sing Cheung and Cheuk Kin Stephen Law resigned as members of the Board of Directors (the "Board") of Stealth BioTherapeutics Corp (the "Company"), effective immediately. Messrs. Cheung and Law's decision to resign from the Board was not due to a disagreement on any matter related to the Company's operations, policies or practices.

On July 24, 2019, the Board, acting in accordance with the recommendation of the Nominating Committee of the Board, appointed Louis Lange, M.D., Ph.D as a Class II director and as a member of the Audit Committee and Remuneration Committee, effective as of July 24, 2019.

Dr. Lange is currently a general partner at Asset Management Ventures, an investment firm, where he has worked since June 2009. Dr. Lange was the co-founder and served as the President and Chief Executive Officer of Cardiogen Sciences, Inc., a biotechnology company, from April 2014 until it was acquired by Audentes Therapeutics, Inc. (Nasdaq: BOLD) in August 2015. Dr. Lange also co-founded CV Therapeutics, Inc. in 1990 and served as the Chairman, Chief Executive Officer and Chief Scientific Officer until it was acquired by Gilead Sciences, Inc. (Nasdaq: GILD) in 2009. Dr. Lange has also served as the Chief of Cardiology and Professor of Medicine at Jewish Hospital at Washington University. Dr. Lange has served as a member of Audentes Therapeutics, Inc.'s board of directors since August 2015 and served on the board of directors of Maxygen, Inc. from December 2005 to August 2013, CymaBay Therapeutics, Inc. (Nasdaq: CBAY) from November 2003 to October 2015, and Esperion Therapeutics, Inc. (Nasdaq: ESPR) from February 2010 to May 2014. Dr. Lange also serves as a member of the Board of Trustees at the University of Rochester, The Gladstone Foundation, is a senior advisor to Gilead and was on the board of directors of BIO (the trade organization of biotech companies) from 1998 to 2009, as well as other private companies. Dr. Lange holds a B.A. from the University of Rochester, an M.D. from Harvard Medical School and a Ph.D. from Harvard University.

In accordance with the Company's director compensation program (the "Program"), Dr. Lange will receive (i) annual cash compensation of $40,000 for his service as a director, (ii) additional annual cash compensation of $5,000 as a member of the Audit Committee, (iii) additional annual cash compensation of $5,000 as a member of the Remuneration Committee and (iv) reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of the Board and committees thereof. In addition, in accordance with the Program, Dr. Lange was granted a stock option to purchase up to 150,000 shares of the Company's ordinary shares at a per share exercise price of $1.01 (which was the closing price of American Depositary Shares (the "ADSs") on the Nasdaq on July 24, 2019, the date of grant, divided by the ADS ratio as set pursuant to the Registration Statement on Form F-6 as filed by the Company with the United States Securities and Exchange Commission, rounded up to the penny), which option will vest as to 50% of the shares on July 24, 2020 and 50% of the shares on July 24, 2021, subject to Dr. Lange's continued service with the Company.

Earnings Release

On August 14, 2019, the Company issued a press release announcing its unaudited financial results for the three and six months ended June 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 August 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: August 14, 2019

Exhibit 99.1

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

- Louis Lange M.D., Ph.D. joins Board

BOSTON – August 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 three and six months ended June 30, 2019 and provided a corporate update, including the announcement of a new Board member, Dr. Louis G. Lange.

"As we move into the second half of 2019, we look forward to achieving key near-term milestones including completion of our Phase 3 study of elamipretide in primary mitochondrial myopathy, clarification around the path to registration for our Barth program, and progression of our next product candidate, SBT-272, into the clinic," said Reenie McCarthy, Chief Executive Officer. "We're also delighted to welcome Lou Lange to our Board of Directors, where his extensive scientific, industry, operating and investment experience will augment our efforts to bring first-in-class therapies to patients with rare mitochondrial diseases."

Recent Highlights

- **Announced changes to Board composition** , including the appointment of Dr. Lange as an independent director and member of the audit and compensation committees, and the resignations of Stephen Law and Vincent Cheung, whose service to date was recognized with gratitude. Dr. Lange has more than 20 years of experience in academic medicine at Harvard and Washington University, extensive industry experience as a founder, Chairman, CEO and Chief Scientific Officer of CV Therapeutics prior to its 2009 sale to Gilead Sciences, and extensive biotechnology operating and investment experience with Gilead Sciences, Pitch Johnson and Asset Management Ventures.
- **Shared positive results in dry age-related macular degeneration (AMD)** at the American Society of Retina Specialists 2019 Annual Meeting, featuring two oral presentations and one poster regarding data from the ReCLAIM Phase 1 study in dry AMD, a Phase 1 open-label study evaluating daily subcutaneous elamipretide for 24 weeks in patients with dry AMD with non-central geographic atrophy or high risk drusen. Results showed that patients who completed treatment in both cohorts (n=34) experienced an increase in low-luminance visual acuity, best-corrected visual acuity, low-luminance smallest line read correctly and patient-reported outcomes. The poster presentation, captioned *Effects of the Mitochondria-Targeted Drug Elamipretide on Leakage-Independent Vision Loss in Fellow Eyes with Neovascular AMD in the ReCLAIM Study* , and based on a post-hoc analysis demonstrating improvement in visual function in fellow (non-study) eyes with neovascular AMD, was the Second-Place Poster Award winner.

- **Shared ophthalmic program updates** at the Ophthalmology Innovation Summit preceding the American Society of Retina Specialists 2019 Annual Meeting, with an estimated 300 industry, entrepreneurial and clinical leaders in attendance.
- **Presented multiple updates on rare mitochondrial disease programs** at the United Mitochondrial Disease Foundation Symposium 2019, including platform presentations by:
    - Dr. Amel Karaa presented demographics of MMPOWER-3 Phase 3 trial in primary mitochondrial myopathy (PMM)
    - Dr. Bruce Cohen presented assessments in MMPOWER open label extension for patients enrolled in earlier phase trials in PMM
    - Dr. Hilary Vernon presented data from TAZPOWER Phase 2/3 trial and open label extension in Barth syndrome
    - Dr. Rustum Karanjia presented data from Phase 2 clinical trial and open-label extension in Leber's hereditary optic neuropathy

  Other posters included presentations on the TAZPOWER design, TAZPOWER data, primary mitochondrial myopathy natural history, primary mitochondrial myopathy open-label extension data, and MMPOWER primary mitochondrial myopathy Phase 1/2 metabolomics data.
- **Reached alignment with the Division of Ophthalmology Products at FDA** regarding key aspects of the planned Phase 3 trial design in LHON. We expect to submit the Phase 3 protocol by year-end.
- **Shared positive results in Leber's hereditary optic neuropathy (LHON) open-label extension** at the 14 th meeting of the European Neuro-ophthalmology Society. Results were from 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.
- **Announced transfer to Division of Gastroenterology and Inborn Errors of Metabolism Products (DGIEP) at FDA** with respect to Barth syndrome program, previously assigned to the Division of Neurology Products. Stealth expects to interact with DGIEP this fall to discuss the regulatory path for elamipretide in Barth syndrome.

Key Upcoming Milestones

- Interactions with the FDA's DGIEP to discuss the regulatory path for elamipretide in Barth syndrome during the second half of 2019.
- FDA submission of Phase 3 protocol for elamipretide in LHON by year-end 2019.
- Initiation of a Phase 1 clinical trial of new pipeline candidate, SBT-272, by year-end 2019.
- Reporting top-line data from MMPOWER-3, a Phase 3 clinical trial in PMM in early 2020 (data expected year-end 2019).
- Anticipated completion of enrollment in ReCLAIM 2b, a Phase 2b clinical trial in dry AMD with geographic atrophy, in early 2020.

Financial Results for the Six Months Ended June 30, 2019

Cash Position: Cash and cash equivalents were $53.2 million at June 30, 2019, compared to $10.9 million at December 31, 2018. In February 2019, the Company raised $76.9 million in net proceeds from its initial public offering (IPO).

Research and Development (R&D) Expenses: R&D expenses were $23.7 million for the six months ended June 30, 2019, compared to $25.5 million for the six months ended June 30, 2018. The decrease was primarily due to a $5.4 million decrease in clinical trial costs due to timing of trials that ended in 2018 and a $0.5 million decrease in discovery related expenses due to timing of activities, offset in part by increases of $1.6 million in headcount, $1.4 million in consulting related expenses related to the continued build-out of clinical, medical affairs and regulatory functions, and a $1.1 million increase in contract manufacturing expenses for NDA-enabling activities.

General and Administrative (G&A) Expenses: G&A expenses were $10.2 million for the six months ended June 30, 2019, compared to $7.8 million for the six months ended June 30, 2018. The increase in administrative expenses was primarily attributable to an increase of $1.3 million in pre-commercial activities including market awareness and payer reimbursement activities, a $0.7 million increase in professional services for activities attributable to operating as a public company, and a net $0.4 million increase in headcount and consulting related expenses.

Other Expense, Net: Other expense for the six months ended June 30, 2019 was $25.0 million, compared to $14.1 million for the six months ended June 30, 2018. The increase in other expense is primary attributable to a $22.7 million loss on extinguishment of debt recorded in conjunction with the IPO, offset by an $8.8 million change period over period in the fair value adjustments of the derivative liability associated with the convertible debt and a decrease in interest expense mostly related to the convertible debt of $2.9 million.

Net Loss: Net loss for the six months ended June 30, 2019 was $58.9 million, or $0.18 basic and diluted net loss per ordinary share, as compared to $47.4 million for the comparable period of 2018, or $0.69 basic and diluted net loss per ordinary share.

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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 9,366	$ 12,100	$ 23,694	$ 25,536
General and administrative	6,064	4,290	10,221	7,786
Total operating expenses	15,430	16,390	33,915	33,322
Loss from operations	(15,430)	(16,390)	(33,915)	(33,322)
Other income (expense):				
Loss on extinguishment of debt	—	—	(22,700)	—
Change in fair value of derivative liability	—	(5,948)	2,782	(6,000)
Change in fair value of warrant liability	—	127	(300)	126
Interest expense	(662)	(4,905)	(5,345)	(8,283)
Interest income	342	59	550	81
Total other income (expense)	(320)	(10,667)	(25,013)	(14,076)
Net loss attributable to ordinary shareholders	$ (15,750)	$ (27,057)	$ (58,928)	$ (47,398)
Net loss per share attributable to ordinary shareholders — basic and diluted	$ (0.04)	$ (0.40)	$ (0.18)	$ (0.69)
Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders — basic and diluted	420,399,807	68,474,614	320,771,044	68,474,614

STEALTH BIOTHERAPEUTICS CORP

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 53,200	$ 10,855
Prepaid expenses and other current assets	1,408	2,438
Total current assets	54,608	13,293
Property and equipment, net	437	499
Deferred offering costs	—	1,325
Other non-current assets	250	406
Total assets	$ 55,295	$ 15,523
Liabilities, convertible preferred shares and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 8,970	$ 11,023
Accrued expenses and other current liabilities	9,264	13,826
Accrued interest payable	1,013	7,297
Current portion of long-term debt	6,437	8,465
Total current liabilities	25,684	40,611
Long-term debt, less current portion	10,326	10,317
Convertible notes payable	—	103,257
Derivative liability	—	36,567
Warrant liability	—	100
Total liabilities	36,010	190,852
Series A convertible preferred shares	—	211,377
Total shareholders' equity (deficit)	19,285	(386,706)
Total liabilities, convertible preferred shares and shareholders' equity (deficit)	$ 55,295	$ 15,523