# 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 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

Except as otherwise setforth below, 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

**Earnings Release**

On November 11, 2021, the Company issued a press release announcing its unaudited financial results for the three months ended September 30, 2021, and operational progress. The press release issued by the Company in connection therewith is attached hereto as Exhibit 99.1. The information in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, nor shall be deemed incorporated by reference in any filing under the Securities Act 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 11, 2021 |

**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 12, 2021

# STEALTH BIOTHERAPEUTICS REPORTS THIRD QUARTER 2021 FINANCIAL RESULTS AND RECENT BUSINESS HIGHLIGHTS

*ReCLAIM-2 Phase 2b extrafoveal geographic atrophy data on track for first half of 2022*

*Barth syndrome Type A meeting with Division of Cardiology and Nephrology (DCN) requested*

*Pre-IND meeting granted by DCN to discuss Duchenne muscular dystrophy development plan*

*NuPOWER Phase 3 clinical trial in patients with primary mitochondrial myopathy due to nDNA mutations (nPMM) expected to initiate by year-end*

*Clinical expansion efforts in Friedreich's ataxia and neurology indications ongoing*

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

BOSTON –November 11, 2021 – 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 months ended September 30, 2021 and announced recent business highlights.

"We are excited to broaden our clinical development efforts with multiple new trial initiations expected over the coming months," said Reenie McCarthy, Chief Executive Officer at Stealth. "We are highly enthusiastic about the potential of elamipretide to treat extrafoveal geographic atrophy ahead of our ReCLAIM-2 data read-out, which is expected during the first half of next year, and are increasingly optimistic about the feasibility of our intravitreal development efforts which we hope will support potential partnering discussions. While we are disappointed that the FDA declined to file our new drug application for Barth syndrome, despite the significant unmet need and the appeal from the patient community, we are looking forward to our meeting with the FDA later this quarter to discuss a potential path forward. We are also moving forward with our development efforts in several other rare disease indications, including our planned initiation of our NuPOWER Phase 3 clinical trial in patients with primary mitochondrial myopathy due to nuclear DNA mutations and our scheduled pre-IND meeting with DCN to discuss our development efforts in Duchenne muscular dystrophy. We're also thrilled to be bringing SBT-272, which is the cornerstone of our growing neurology franchise, back into the clinic in a Phase 1 clinical trial expected to start early next year."

**Third Quarter 2021 and Recent Highlights**

**Ophthalmology franchise.**

*ReCLAIM-2 in extrafoveal geographic atrophy.* The Company presented data from its ophthalmology clinical trials at recent conferences, including EURETINA 2021 Virtual Congress, the Annual Scientific Session of The Retina Society, and the American Society of Retina Specialist (ASRS) Annual Scientific Meeting. These data included analyses from the Company's Phase 1 ReCLAIM clinical trial demonstrating that elamipretide-mediated improvement of visual function was significantly associated with baseline retinal mitochondrial health and baseline patient characteristics from the Company's fully-enrolled ReCLAIM-2 clinical trial. The Company expects to announce top-line clinical trial results from ReCLAIM-2 during the first half of 2022.

**Cardiomyopathy franchise.**

*Barth syndrome.* In August 2021, the Company submitted its new drug application (NDA) for Barth syndrome, for which it received a Refusal to File letter from the FDA in October 2021. The

Company requested and the FDA granted a Type A meeting with DCN to discuss why SPIBA-001, the Company's positive Phase 3 trial comparing SPIBA-201 results to a retrospective natural history control and the primary basis for the NDA submission, was not sufficient to support the filing of the NDA. At the meeting, which is scheduled for later this quarter, the Company also plans to propose alternative steps to generate additional evidence of elamipretide's effectiveness in Barth syndrome and hopes to reach agreement with DCN on a viable path forward.

*Duchenne muscular dystrophy (DMD).* In September 2021, the Company presented positive elamipretide data showing improvements in mitochondrial respiration and heart muscle function in explanted tissue from failing pediatric human hearts at the International Society for Heart Research North American Section Meeting 2021. The study also demonstrated that elamipretide treatment improved mitochondrial respiration, contraction and relaxation in muscle fibers isolated from failing hearts of children with dilated cardiomyopathy. The lead author of the study indicated that these data were consistent with observed effects of elamipretide in metabolic (muscular dystrophy) cardiomyopathy. In October 2021, the Company's request for a pre-IND meeting to discuss its DMD development plan was granted by DCN, and a meeting is scheduled for later this year.

*Friedreich's ataxia.* The investigator is awaiting Institutional Review Board approval of the planned Phase 2a clinical trial in patients with Friedreich's ataxia and expects to begin enrollment in early 2022.

**Neurology franchise.**

*NuPOWER initiation*. In July 2021, the Company reached alignment with Division of Rare Diseases and Medical Genetics on the design of NuPOWER, its planned Phase 3 clinical trial in patients with mitochondrial disease associated with pathogenic nDNA mutations (nPMM). Trial initiation is expected by year-end.

*SBT-272*. In October 2021, the Company announced that promising data from a study evaluating the effects of SBT-272 in a murine model of amyotrophic lateral sclerosis (ALS) were presented at the virtual 2021 Annual Northeast Amyotrophic Lateral Sclerosis (NEALS) Meeting. The study demonstrated that sustained SBT-272 levels across different regions of the brain protected mitochondria against ischemic stress. In primary motor neuron cultures, treatment with SBT-272 improved mitochondrial motility in a dose-dependent manner, reduced mitochondrial ultrastructural defects and was associated with improved axon outgrowth. In September 2021, the Company announced that promising data from a study evaluating the effects of SBT-272 in a murine model of Parkinson's disease were presented at the International Parkinson and Movement Disorder Society Virtual Congress 2021. Systemic daily administration of SBT-272 doses significantly protected against the loss of dopaminergic neurons and the aggregation of pathological alpha-synuclein and reduced two markers of neuroinflammation in this model.

**Financial updates**

In September 2021, the Company and its wholly owned subsidiary, Stealth BioTherapeutics Inc., entered into a Venture Loan and Security Agreement ("LSA") with Horizon Technology Finance Corporation and Powerscourt Investments XXV, LP, which provided the Company and its subsidiary with a senior secured credit facility in an aggregate principal amount of $25.0 million. On September 30, 2021, upon the closing of the LSA, $15.0 million was drawn by the Company, of which approximately $5.7 million was utilized to payoff the existing term loan with Hercules Capital, Inc. The additional $10 million available under the LSA may be funded upon the achievement of a predetermined milestone.

In September 2021, the Company received $11.0 million under the Development Funding Agreement with Morningside Venture (I) Investments Limited ("Morningside").

**Key Upcoming Milestones**

- **Ophthalmology franchise:** Data from ReCLAIM will be presented at the American Academy of Ophthalmology meeting in November. The Company expects data from ReCLAIM-2 during the first half of 2022. The Company also expects to have further data regarding feasibility of its ongoing intravitreal formulation development efforts concurrently with the ReCLAIM-2 data read-out.

- **Cardiomyopathy franchise:** The Company looks forward to its Type A meeting with FDA, which has been granted, to discuss Barth syndrome development plans with DCN. The Company's pre-IND meeting with DCN to discuss its DMD development program is scheduled for later this year. The Company also looks forward to the commencement of an investigator-initiated Phase 2a clinical trial in Friedreich's ataxia by early 2022.

- **Neurology franchise:** The Company expects to initiate NuPOWER, its Phase 3 clinical trial in the enriched population of patients with primary mitochondrial myopathy due to nuclear DNA mutations who responded to elamipretide therapy in the Company's MMPOWER-3 trial, by year end. The Company plans to initiate a Phase 1 single and multiple ascending dose trial of subcutaneous SBT-272 in early 2022 as it continues to work toward indication selection.

**Financial Results for the three months ended September 30, 2021**

**Cash Position:** Cash and cash equivalents were $42.3 million at September 30, 2021, compared to $32.8 million at December 31, 2020. In September 2021, the Company received $11.0 million of the remaining $27.0 million total due during the second half of 2021 from Morningside under the Development Funding Agreement, which includes the $5.0 million milestone payable upon Barth NDA submission and the $22.0 million balance that was committed as additional financing in May 2021. In October 2021, the Company received $5.0 million of the additional financing, and expects to receive the remaining $11.0 million on or around December 1, 2021. The Company expects that its cash, cash equivalents and investments as of September 30, 2021, together with the $5.0 million of additional financing received in October and $11.0 million of additional financing expected in December will be sufficient to enable it to fund its planned operations into the third quarter of 2022.

**Research and Development (R&D) Expenses:** R&D expenses were $6.7 million for the three months ended September 30, 2021, compared to $6.2 million for the same period in 2020. The increase was due to a $1.2 million increase in preclinical costs to develop and expand our current pipeline, an increase of $0.6 million in headcount and related costs, and an increase of $0.1 million in manufacturing costs, offset by a net decrease of $1.4 million in clinical costs primarily driven by the closeout of the MMPOWER-3 clinical trial.

**General and Administrative (G&A) Expenses:** G&A expenses were unchanged at $4.7 million for the three months ended September 30, 2021 and for the same period in 2020. For the three months ended September 30, 2021, there was an increase of $0.3 million in pre-commercial costs offset by a $0.2 million decrease in facility related costs and a $0.1 million decrease in costs of professional services.

**Other Income (Expense):** Other income was $5.1 million for the three months ended September 30, 2021, compared to other expense of $0.3 million for the same period in 2020. Other income in 2021 consisted of a $5.4 million gain due to the change in fair value of the derivative liability,

offset by a $0.1 million loss due to extinguishment of the Hercules term loan and $0.2 million in interest expense. Other expense in 2020 consisted of $0.3 million in interest expense.

**Net Loss:** Net loss was $6.3 million, or $0.01 basic and diluted net loss per ordinary share, for the three months ended September 30, 2021, as compared to $11.2 million, or $0.02 basic and diluted net loss per ordinary share, for the same period in 2020.

**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 (domestic) or (201)-389-0921 (international) and referencing conference ID 13723309. 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 syndrome, DMD and Friedreich's ataxia, rare mitochondrial diseases entailing nuclear DNA mutations, 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 mitochondria-targeted vectors 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, planned clinical trial of SBT-272 and planned NuPOWER trial; its expectations regarding regulatory interactions, including its scheduled Type A meeting for Barth syndrome; the potential benefits of Stealth BioTherapeutics' product candidates; its key milestones for 2021 and 2022; and its plans regarding future data read-outs and presentations. 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 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
Janhavi Mohite, 212-362-1200
IR@StealthBT.com

**STEALTH BIOTHERAPEUTICS CORP**

**Condensed Consolidated Statements of Operations**

(in thousands, except share and per share data)
(unaudited)

| | Three months ending September 30, | | Nine months ending S | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | |
| Operating expenses: | | | | |
| Research and development | $ 6,739 | $ 6,211 | $ 18,751 | $ |
| General and administrative | 4,707 | 4,671 | 14,769 | |
| Total operating expenses | 11,446 | 10,882 | 33,520 | |
| Loss from operations | (11,446) | (10,882) | (33,520) | |
| Other income (expense): | | | | |
| Gain (Loss) from remeasurement of derivative liability | 5,431 | — | 1,896 | |
| Loss on extinguishment of debt | (86) | — | (86) | |
| Interest income | — | 2 | 2 | |
| Interest expense and other | (196) | (330) | (684) | |
| Total other income (expense) | 5,149 | (328) | 1,128 | |
| Net loss attributable to ordinary shareholders | $ (6,297) | $ (11,210) | $ (32,392) | $ |
| Net loss per share attributable to ordinary shareholders — basic and diluted | $ (0.01) | $ (0.02) | $ (0.05) | $ |
| Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders — basic and diluted | 692,513,064 | 596,900,696 | 673,498,101 | |

**STEALTH BIOTHERAPEUTICS CORP**

**Condensed Consolidated Balance Sheets**
(in thousands)
(unaudited)

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 42,277 | $ 32,787 |
| Prepaid expenses and other current assets | 1,163 | 2,253 |
| Total current assets | 43,440 | 35,040 |
| Property and equipment, net | 115 | 106 |
| Deferred financing costs and other non-current assets | 632 | 702 |
| Total assets | $ 44,187 | $ 35,848 |
| **Liabilities and shareholders' deficit** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,915 | $ 3,526 |
| Accrued expenses and other current liabilities | 5,743 | 7,024 |
| Accrued interest payable | — | 1,499 |
| Current portion of debt | — | 9,000 |
| Total current liabilities | 9,658 | 21,049 |
| Long-term deferred rent, less current portion | 2 | 16 |
| Long-term portion of debt | 13,542 | — |
| Development derivative liability - related party | 49,817 | 25,155 |
| Total liabilities | 73,019 | 46,220 |
| Total shareholders' deficit | (28,832) | (10,372) |
| **Total liabilities and shareholders' deficit** | $ 44,187 | $ 35,848 |