UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934

For the month of August 2023

(Commission File No. 001-39431)

Freeline Therapeutics Holdings plc

(Exact Name of Registrant as Specified in Its Charter)

Sycamore House
Gunnels Wood Road
Stevenage, Hertfordshire SG1 2BP
United Kingdom
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.
Form 20-F ☒ Form 40-F ☐

This Report on Form 6-K (other than the information contained in the press release furnished as Exhibit 99.1 to this Report on Form 6-K) shall be deemed to be incorporated by reference into the registration statement on Form F-3 (File No. 333-259444) and registration statements on Form S-8 (File Nos. 333-242129, 333-242133, 333-259852 and 333-265634) of Freeline Therapeutics Holdings plc and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

The information contained in the press release furnished as Exhibit 99.1 to this Report on Form 6-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

INDEX

PART I

FREELINE THERAPEUTICS HOLDINGS PLC

Unaudited Condensed Consolidated Balance Sheets

(in thousands, except share and per share amounts)

(expressed in U.S. Dollars, unless otherwise stated)

	June 30, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 38,797	$ 47,279
License receivable	631	—
Prepaid expenses and other current assets	6,385	6,235
Assets held for sale	—	14,113
Total current assets	45,813	67,627
Non-current assets:		
Property and equipment, net	9,284	9,007
Operating lease right of use assets	4,792	6,014
Other non-current assets	2,764	3,993
Total assets	$ 62,653	$ 86,641
Liabilities and shareholders' equity		
Current Liabilities:		
Accounts payable	$ 6,875	$ 10,058
Accrued expenses and other current liabilities	8,963	7,908
Operating lease liabilities, current	2,842	2,663
Liabilities related to assets held for sale	—	10,337
Total current liabilities	18,680	30,966
Non-current liabilities:		
Operating lease liabilities, non-current	1,957	3,261
Total liabilities	$ 20,637	$ 34,227
Commitments and contingencies (Note 12)		
Shareholders’ equity:		
Ordinary shares, £0.00001 par value, 400,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 65,369,417 and 65,113,575 issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	—	—
Deferred shares, £0.00001 par value; 37,402 and 24,812 shares authorized, issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	—	—
Deferred shares, £100,000 par value; 1 authorized, issued and outstanding as of June 30, 2023 and December 31, 2022	137	137
Additional paid-in capital	502,861	500,781
Accumulated other comprehensive loss	(784)	(3,151)
Accumulated deficit	(460,198)	(445,353)
Total shareholders’ equity	42,016	52,414
Total liabilities and shareholders' equity	$ 62,653	$ 86,641

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

FREELINE THERAPEUTICS HOLDINGS PLC

Unaudited Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)

(expressed in U.S. Dollars, unless otherwise stated)

	For the Six Months Ended June 30,	
	2023	2022
License revenue	$ 617	$ —
Operating expenses:		
Research and development	$ 19,720	$ 38,785
General and administrative	17,581	16,278
Gain on legal settlement	(2,227)	—
Restructuring expense	1,276	—
Total operating expenses	36,350	55,063
Loss from operations:	(35,733)	(55,063)
Other income, net:		
Gain on sale of Freeline Therapeutics GmbH	20,279	—
Other income, net	73	2,973
Interest income, net	240	335
Benefit from R&D tax credit	464	721
Total other income, net	21,056	4,029
Net loss before income taxes	(14,677)	(51,034)
Income tax expense	(168)	(46)
Net loss	$ (14,845)	$ (51,080)
Net loss per share attributable to ordinary shareholders—basic and diluted	(0.23)	(0.95)
Weighted average ordinary shares outstanding—basic and diluted	65,140,334	53,587,167

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

FREELINE THERAPEUTICS HOLDINGS PLC

Unaudited Condensed Consolidated Statements of Comprehensive Loss

(in thousands)

(expressed in U.S. Dollars, unless otherwise stated)

	For the Six Months Ended June 30,	
	2023	2022
Net loss	$ (14,845)	$ (51,080)
Other comprehensive loss:		
Foreign currency translation adjustment	2,212	(10,968)
Comprehensive loss	$ (12,633)	$ (62,048)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

FREELINE THERAPEUTICS HOLDINGS PLC

Unaudited Condensed Consolidated Statements of Shareholders' Equity

(in thousands, except share amounts)

(expressed in U.S. Dollars, unless otherwise stated)

	Ordinary £0.00001 Par Value		Deferred Shares £0.00001 Par Value		Deferred Shares £0.001 Par Value		Deferred Shares £100,000 Par Value		Additional Paid-in Capital	Accumulated other comprehensive gain (loss)	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Amount	Amount	Deficit	Equity
Balance at December 31, 2021	35,854,591	$ —	112,077	$ —	—	$ —	1	$ 137	$ 467,213	$ 9,472	$ (356,381)	$ 120,441
Shares issued under employee share purchase plan	149,254	—	—	—	—	—	—	—	110	—	—	110
Vesting of restricted share units	30,863	—	—	—	—	—	—	—	—	—	—	—
Forfeiture of ordinary shares	(4,826)	—	4,826			—	—	—	—	—	—	—
Issuance of ordinary shares, net of issuance cost of $2,600	28,848,968	—	—	—	—	—	—	—	28,291	—	—	28,291
Cancellation of deferred shares	—	—	(93,451)	—	—	—	—	—	—	—	—	
Non-cash share-based compensation	—	—	—	—	—	—	—	—	2,835	—	—	2,835
Unrealized loss on foreign currency translation	—	—	—	—	—	—	—	—	—	(10,968)	—	(10,968)
Net loss	—	—	—	—	—	—	—	—	—	—	(51,080)	(51,080)
Balance at June 30, 2022	64,878,850	$ —	23,452	$ —	—	$ —	1	$ 137	$ 498,449	$ (1,496)	$ (407,461)	$ 89,629
Balance at December 31, 2022	65,113,575	$ —	24,812	$ —	—	$ —	1	$ 137	$ 500,781	$ (3,151)	$ (445,353)	$ 52,414
Shares issued under employee share purchase plan	217,755	—	—	—	—	—	—	—	32	—	—	32
Vesting of restricted share units	50,677	—	—	—	—	—	—	—	—	—	—	—
Forfeiture of ordinary shares	(12,590)	—	12,590			—	—	—	—	—	—	—
Non-cash share-based compensation	—	—	—	—	—	—	—	—	2,048	—	—	2,048
Release of cumulative foreign currency translation adjustment, upon sale of Freeline Therapeutics GmbH	—	—	—	—	—	—	—	—	—	155	—	155
Unrealized gain on foreign currency translation	—	—	—	—	—	—	—	—	—	2,212	—	2,212
Net loss	—	—	—	—	—	—	—	—	—	—	(14,845)	(14,845)
Balance at June 30, 2023	65,369,417	$ —	37,402	$ —	—	$ —	1	$ 137	$ 502,861	$ (784)	$ (460,198)	$ 42,016

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

FREELINE THERAPEUTICS HOLDINGS PLC

Unaudited Condensed Consolidated Statements of Cash Flows

(in thousands)

(expressed in U.S. Dollars, unless otherwise stated)

	For the Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (14,845)	$ (51,080)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	753	1,020
Non-cash share-based compensation expense	2,048	2,835
(Gain) loss on disposal of property and equipment	(62)	226
Gain on sale of Freeline Therapeutics GmbH	(20,279)	—
Gain on legal settlement	(2,227)	—
Changes in components of operating assets and liabilities		
Prepaids and other current assets	(1,354)	1,083
Other non-current assets	—	(167)
Operating lease right of use assets	1,445	4,519
Accounts payable	(593)	3,443
Accrued expenses and other current liabilities	879	(7,425)
Operating lease liabilities, net	(1,484)	2,343
Net cash used in operating activities	(35,719)	(43,203)
Cash flows from investing activities:		
Purchase of property and equipment	(648)	(939)
Proceeds from the sale of equipment	62	—
Proceeds from the sale of Freeline Therapeutics GmbH, net of cash transferred with sale of $1,015	24,203	—
Net cash provided by (used in) investing activities	23,617	(939)
Cash flows from financing activities:		
Proceeds from issuance of ordinary shares	—	27,328
Proceeds from employee share purchase plan	32	110
Net cash provided by financing activities	32	27,438
Effect of exchange rate changes on cash, cash equivalents and restricted cash	1,958	(11,072)
Net decrease in cash, cash equivalents and restricted cash	(10,112)	(27,776)
Cash, cash equivalents and restricted cash		
Beginning of period	48,909	119,063
End of period	$ 38,797	$ 91,287
Supplemental disclosure of non-cash flow information:		
Commitment shares issued to Lincoln Park Capital Fund, LLC	—	963

The following table provides a reconciliation of the cash, cash equivalents and restricted cash balances as of each of the periods shown above:

	For the Six Months Ended June 30,	
	2023	2022
Cash and cash equivalents	$ 38,797	$ 89,998
Long-term restricted cash	—	1,289
Total cash, cash equivalents and restricted cash	$ 38,797	$ 91,287

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

1. Nature of the Business

Freeline Therapeutics Holdings plc (the "Company") is a clinical-stage biotechnology company developing transformative adeno-associated virus ("AAV") vector-mediated gene therapies for patients suffering from chronic debilitating diseases. The Company is headquartered in the United Kingdom ("U.K.") and has operations in the United States ("U.S."). The Company is a public limited company incorporated pursuant to the laws of England and Wales.

Going Concern

In accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, the ability to secure additional capital to fund operations, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with government regulations. Product candidates currently under development require significant additional research and development efforts, including clinical testing and regulatory approval, prior to any commercialization. These efforts require significant amounts of capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from any product sales.

The Company has funded its operations primarily with proceeds from the sale of its equity securities. As of June 30, 2023, the Company had unrestricted cash and cash equivalents of $38.8 million. The Company has incurred recurring losses since its inception including net losses of $14.8 million and $51.1 million for the six months ended June 30, 2023 and 2022, respectively. In addition, the Company had an accumulated deficit of $460.2 million as of June 30, 2023.

Net cash used in operating and investing activities was $12.1 million for the six months ended June 30, 2023. The Company expects to continue to incur significant expenses and generate operating losses for the foreseeable future. These conditions indicate that there is substantial doubt regarding the Company's ability to continue as a going concern for at least 12 months from the issuance date of these unaudited condensed consolidated financial statements.

As a result, the Company will need additional funding to support its continuing operations. There can be no assurances, however, that additional funding will be available on favorable terms, or at all. If adequate funds are not available, the Company will be required to further reduce headcount as well as spending and potentially delay, limit, reduce or terminate its product research and development efforts in order to enable it to meet its obligations as they fall due for the foreseeable future.

The accompanying unaudited condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the unaudited condensed consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, Summary of Significant Accounting Policies, to the consolidated financial statements as of and for the year ended December 31, 2022 in the Annual Report on Form 20-F. There have been no material changes to the significant accounting policies during the six months ended June 30, 2023, except as described below.

License Revenue

The Company accounts for its revenues pursuant to the provisions of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606").

The Company has no products approved for commercial sale and has not generated any revenue from commercial product sales. The revenue earned to date has been generated solely from an out-licensing agreement.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under the arrangement within the scope of ASC 606, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

License Fees and Multiple Element Arrangements

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license at such time as the license is transferred to the licensee and the licensee is able to use, and benefit from, the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligations to determine whether the combined performance obligations are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Appropriate methods of measuring progress include output methods and input methods. In determining the appropriate method for measuring progress, the Company considers the nature of service that the Company promises to transfer to the customer. When the Company decides on a method of measurement, the Company will apply that single method of measuring progress for each performance obligation satisfied over time and will apply that method consistently to similar performance obligations and in similar circumstances.

Contingent Research Milestone Payments

ASC 606 constrains the amount of variable consideration included in the transaction price in that either all, or a portion, of an amount of variable consideration should be included in the transaction price. The variable consideration amount should be included only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The assessment of whether variable consideration should be constrained is largely a qualitative one that has two elements: the likelihood of a change in estimate, and the magnitude thereof. Variable consideration is not constrained if the potential reversal of cumulative revenue recognized is not significant.

If the consideration in a contract includes a variable amount, the Company will estimate the amount of consideration in exchange for transfer of promised goods or services. The consideration also can vary if the Company's entitlement to the consideration is contingent on the occurrence or non-occurrence of a future event. The Company considers contingent research milestone payments to fall under the scope of variable consideration, which should be estimated for revenue recognition purposes at the inception of the contract and reassessed ongoing at the end of each reporting period.

The Company assesses whether contingent research milestones should be considered variable consideration that should be constrained and thus not part of the transaction price. This includes an assessment of the probability that all or some of the milestone revenue could be reversed when the uncertainty around whether or not the achievement of each milestone is resolved, and the amount of reversal could be significant.

The Company considers all relevant factors in accordance with U.S. GAAP when assessing whether variable consideration should be constrained and no one factor is determinative.

Royalty Revenue

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and in which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

3. Sale of Freeline Therapeutics GmbH

On February 8, 2023, the Company sold its German subsidiary, Freeline Therapeutics GmbH, and certain intellectual property rights to Ascend Gene & Cell Therapies Limited ("Ascend") pursuant to a definitive agreement entered into in November 2022 for an aggregate cash purchase price of $25.0 million, subject to purchase price adjustments, and a license back of certain intellectual property rights assigned to Ascend (the "Subsidiary Sale"). The Subsidiary Sale did not meet the criteria for reporting discontinued operations as there was not a strategic shift that has had, or will have, a major effect on the Company's operations. The Company recognized a gain on the Subsidiary Sale of $20.3 million in its unaudited condensed consolidated statement of operations during the six months ended June 30, 2023. Upon the closing of the Subsidiary Sale, the cumulative foreign currency translation losses totaling $0.2 million were released to earnings and included in the gain on the Subsidiary Sale.

In connection with the Subsidiary Sale, the Company and Ascend also entered into a transition services agreement (the "Transition Services Agreement"), pursuant to which Ascend will provide certain services in the area of development and manufacturing to the Company. As part of the Transition Services Agreement, the Company agreed to utilize no fewer than 15 full-time employee equivalents ("FTEs") per annum for a guaranteed period of 18 months following the Transition Services Agreement’s effective date of February 8, 2023. The Company also agreed to pay Ascend a guaranteed minimum of approximately $7.9 million in respect of FTE costs during such period, $2.6 million of which was paid in the three months ended March 31, 2023 and recorded as prepaid expenses. As of June 30, 2023, $0.8 million remained within prepaid and other current assets on the unaudited condensed consolidated balance sheet. The Company will make minimum guaranteed payments to Ascend of $4.8 million and $3.1 million for the years ending December 31, 2023 and 2024, respectively. The Transition Services Agreement will terminate three years after its effective date, unless earlier terminated by Freeline with 90 days' written notice, effective from the end of the 18-month guarantee period at the earliest, in accordance with its terms.

Concurrently with the closing of the Subsidiary Sale, the Company and Ascend entered into an intellectual property deed of assignment and license (the "IP Agreement"), pursuant to which the Company assigned certain intellectual property rights pertaining to the business of Freeline Therapeutics GmbH to Ascend, including certain patents and know-how related to chemistry, manufacturing and controls capabilities and technologies. Ascend granted a non-exclusive, royalty-free, perpetual, irrevocable, worldwide license back to the Company of the assigned rights necessary to develop or commercialize its then-current product candidates. There was no value assigned or recorded for the license back to the Company as the license is considered in-process research and development and had no alternative future use.

The table below sets forth the book value of the Freeline Therapeutics GmbH assets and liabilities sold along with the calculation of the gain on sale based on the cash consideration received.

	(in thousands)
Book value of assets sold	
Cash and cash equivalents	$ 1,015
Prepaid expenses and other current assets	414
Property and equipment, net	5,470
Operating lease right of use assets	8,455
Other non-current assets	3
Amounts attributable to assets sold	15,357
Book value of liabilities sold	
Accounts payable	230
Accrued expenses and other current liabilities	1,430
Operating lease liabilities, current	869
Operating lease liabilities, non-current	8,044
Amounts attributable to liabilities sold	10,573
Total identifiable net assets sold	4,784
Less: accumulated other comprehensive loss	(155)
Consideration, inclusive of cash transferred	25,218
Gain on sale of Freeline Therapeutics GmbH	$ 20,279

4. License Revenue

On March 24, 2023, the Company entered into an exclusive patent and know-how out-license agreement (the "Syncona Agreement") with Syncona IP Holdco (2) Limited ("Syncona Holdco"), a company controlled by Syncona Limited ("Syncona"). Under the terms of the Syncona Agreement, the Company granted Syncona Holdco an exclusive license under certain patent rights related to an immune-modifying protein (the "Patent"), an exclusive license under certain patent rights related to an assay (the "Assay Patent"), and a non-exclusive license to certain know-how (the "Assay Know-How") to develop and commercialize the technology other than in respect of liver-directed gene therapies. Upon execution of the Syncona Agreement, the Company made available the licensed intellectual property to Syncona Holdco for an upfront non-refundable payment of £0.5 million or $0.6 million. The Company has no further material performance obligations related to the Syncona Agreement.

The Company further granted to Syncona Holdco the option to take an assignment of the licensed intellectual property (the "Option"). Upon exercise of the Option, Syncona Holdco shall grant the Company a worldwide exclusive fully-paid up royalty free license to the assigned intellectual property. The Company determined that the Option is not considered a material right and does not give rise to a separate performance obligation.

The Company identified the following material promises relating to the Syncona Agreement. The Company determined that the licenses of the Patent, Assay Patent and Assay Know-How were not individually distinct because Syncona Holdco can only benefit from the licensed intellectual property rights when bundled together as one performance obligation. Based on these determinations, the Company identified one distinct performance obligation at the inception of the contract.

The Company further determined that the upfront license fee payable constitutes the transaction price at contract inception, which was allocated to one performance obligation. The amount of the transaction price allocated to the performance obligation is recognized as or when the Company satisfies the performance obligation. The Company determined that the performance obligation was recognized at a point-in-time, upon the delivery of the licenses to Syncona Holdco. The Company recognized total license revenue of £0.5 million or $0.6 million, related to the Syncona Agreement for the six months ended June 30, 2023.

The Company may receive further payments up to £12.5 million or $15.1 million upon the achievement of certain development and regulatory milestones, as well as low-single-digit percentage royalty payments based on net sales of certain licensed products covered by the licensed intellectual property. Future potential milestone payments were fully constrained as the risk of significant revenue reversal related to these amounts has not yet been resolved as of June 30, 2023. The achievement of the future potential milestones is not within the Company's control and is subject to certain research and development success or regulatory approvals and therefore carries significant uncertainty. The Company will reevaluate the likelihood of achieving future milestones at the end of each reporting period. As all performance obligations will have been satisfied in advance of the achievement of the milestone events, if the risk of significant revenue reversal is resolved, any future milestone revenue from the arrangement will be added to the transaction price (and thereby recognized as revenue) in the period the risk is resolved.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	June 30, 2023	December 31, 2022
U.K. R&D tax credit	$ 1,757	$ 1,230
VAT receivable	731	1,373
Insurance	312	1,702
Prepaid manufacturing costs	—	456
Prepaid transition services (note 3)	749	—
Other current assets	2,836	1,474
	$ 6,385	$ 6,235

6. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	June 30, 2023	December 31, 2022
Office equipment and computers	$ 961	$ 751
Furniture & Fixtures	2,756	2,584
Laboratory equipment	3,444	3,140
Leasehold improvements	8,118	7,549
	15,279	14,024
Less: accumulated depreciation	(5,995)	(5,017)
	$ 9,284	$ 9,007

Depreciation and amortization expense was $0.8 million and $1.0 million for the six months ended June 30, 2023 and 2022, respectively.

7. Other Non-current Assets

Other non-current assets consisted of the following (in thousands):

	June 30, 2023	December 31, 2022
Deferred offering costs	$ 2,222	$ 2,133
Restricted cash	—	1,327
Deferred tax asset	542	533
	$ 2,764	$ 3,993

Restricted cash consisted of collateral deposits for the office space leased by the Company's former wholly owned subsidiary, Freeline Therapeutics GmbH. This collateral was released upon the sale of Freeline Therapeutics GmbH in the six months ended June 30, 2023.

8. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following (in thousands):

	June 30, 2023	December 31, 2022
Employee compensation and benefits costs	$ 2,426	$ 4,178
Research and development expenses	4,237	1,923
Consulting and professional services	2,215	1,215
Other liabilities	85	592
	$ 8,963	$ 7,908

9. Shareholders' Equity

Ordinary Shares

As of June 30, 2023, the Company's authorized capital consisted of 400,000,000 ordinary shares with a par value of £0.00001 per share.

Each holder of ordinary shares is entitled to one vote per ordinary share and to receive dividends when and if such dividends are recommended by the board of directors and approved by the shareholders. As of June 30, 2023, the Company has not declared any dividends.

ADS Ratio Change

On May 12, 2023, the Company changed the ratio of its American Depositary Shares ("ADSs") to its ordinary shares (the "ADS Ratio") from the previous ADS Ratio of one ADS to one ordinary share to a new ADS Ratio of one ADS to fifteen ordinary shares. The change in the ADS Ratio had the same effect as a one-for-fifteen reverse ADS split and enabled the Company to regain compliance with the Nasdaq minimum bid price requirement. As all financial statement and disclosure information is presented in ordinary share amounts, not ADSs, there was no impact to the unaudited condensed consolidated financial statements and footnote disclosures. The Company paid depositary fees of $2.0 million in connection with the ADS Ratio change which is recorded within general and administrative expenses on the Company's unaudited condensed consolidated statements of operations during the six months ended June 30, 2023.

Registered Direct Offering

On March 10, 2022, the Company entered into a purchase agreement with its majority shareholder, Syncona Portfolio Limited, a subsidiary of Syncona, and certain other existing shareholders providing for the issuance and sale by the Company of ADSs representing 24,857,144 ordinary shares at a price of $1.05 per ordinary share for total gross proceeds of $26.1 million, in a registered direct offering. The offering closed on March 15, 2022. The Company received net proceeds of approximately $24.2 million from the offering, after deducting offering expenses payable by the Company.

Lincoln Park Capital

On March 18, 2022, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") under which the Company may at its discretion, sell to Lincoln Park up to $35.0 million of its ADSs over a 36-month period, subject to certain daily limits, applicable prices, and conditions. In addition, under the purchase agreement, the Company issued ADSs representing 954,208 ordinary shares as commitment shares to Lincoln Park as consideration for its commitment to purchase ADSs under the purchase agreement (the "Commitment Shares"). The Commitment Shares were valued using the closing price of the Company's ADSs on the date of the purchase agreement resulting in a fair market value of approximately $1.0 million. The fair value of the Commitment Shares as well as issuance costs of $0.2 million associated with the purchase agreement are classified as prepaid expenses and other current assets in the accompanying unaudited condensed consolidated balance sheet. As the Company's ADSs are sold in accordance with the purchase agreement, the fair value of the Commitment Shares and issuance costs will be reclassified to additional paid-in capital on the Company's condensed consolidated balance sheet. During the six months ended June 30, 2023, the Company did not issue any additional ADSs pursuant to the purchase agreement.

Open Market Sale Agreement℠

On November 17, 2021, the Company entered into an Open Market Sale Agreement℠ (the "Sales Agreement") with Jefferies LLC ("Jefferies") pursuant to which the Company may issue and sell ADSs having aggregate offering sales proceeds of up to $75.0 million, from time to time, in "at-the-market" offerings pursuant to which Jefferies will act as sales agent and/or principal. During the year ended December 31, 2022, the Company issued ADSs representing 3,037,616 ordinary shares pursuant to the Sales Agreement, raising approximately $3.2 million in net proceeds. During the six months ended June 30, 2023, the Company did not issue any additional ADSs pursuant to the Sales Agreement.

Deferred Shares

Deferred shares are a unit of equity that confer to their holder effectively no economic rights or any voting rights. The Company, without the consent of the shareholder, may transfer deferred shares at any time for nil consideration.

In the six months ended June 30, 2023, unvested Employee Shares were forfeited upon termination of employment, classified as additional deferred shares of £0.00001 each on the balance sheet and will be subsequently cancelled (see Note 10).

Deferred shares are not included in the Company's potentially dilutive securities as they are not ordinary shares and have no conversion rights.

The table below reflects the number of ordinary shares and deferred shares issued and outstanding at June 30, 2023 and December 31, 2022.

	June 30, 2023	December 31, 2022
Ordinary shares	65,369,417	65,113,575
Deferred shares of £0.00001	37,402	24,812
Deferred shares of £100,000	1	1
Total ordinary and deferred shares	65,406,820	65,138,388

10. Non-Cash Share-Based Compensation

2020 Equity Incentive Plan

On July 31, 2020, the Company adopted an equity incentive plan (the "2020 Plan"). The 2020 Plan provides for the grant of options, share appreciation rights ("SARs"), restricted shares, dividend equivalents, restricted share units ("RSUs"), and other share-based awards. The maximum number of equity awards originally authorized under the 2020 Plan was 5,898,625 shares. Additionally, the number of ordinary shares reserved for issuance under the 2020 Plan automatically increases on January 1st of each year, for a period of not more than ten years, by an amount equal to the lesser of (i) 4% of the total number of ordinary shares outstanding on December 31st of the prior calendar year or (ii) such fewer number of ordinary shares as the board of directors may designate prior to the applicable January 1st date. On January 1, 2023 and 2022, the number of shares reserved automatically increased by 2,596,620 and 1,434,184 shares, respectively. As of June 30, 2023, 2,125,701 shares are available for future issuance under the 2020 Plan.

Any equity awards granted under the 2020 Plan or any prior equity incentive plan that expire, lapse, or are terminated, exchanged for cash, surrendered, repurchased or cancelled, without having been fully exercised, or forfeited, will be added back to shares issuable under the 2020 Plan, subject to certain conditions.

The Company has typically granted equity awards under the 2020 Plan that vest over a four-year service period, with 25% of the award vesting on the first anniversary of the vesting commencement date, with the balance generally vesting periodically over the remaining three years. In the six months ended June 30, 2023, the Company granted equity awards under the 2020 Plan that vest over a three-year service period, subject to vesting acceleration upon achievement of two distinct milestones related to progression of the Company's FLT201 product candidate for the treatment of Gaucher disease Type 1 toward initiation of a Phase 3 clinical trial.

2021 Equity Inducement Plan

On September 27, 2021, the Company adopted an equity inducement plan (the “Inducement Plan”). The purpose of the Inducement Plan is to enhance the Company’s ability to attract employees who are expected to make important contributions to the Company by providing these individuals with equity ownership opportunities. Awards under the Inducement Plan are granted as an inducement material to employees entering into employment with the Company. The Inducement Plan provides for the grant of options, SARs, restricted shares, dividend equivalents, RSUs, and other share-based awards. The maximum number of equity awards authorized under the Inducement Plan is 3,400,000 shares. Any equity awards granted under the Inducement Plan that expire, lapse, or are terminated, exchanged for cash, surrendered, repurchased or cancelled, without having been fully exercised, or forfeited, will be added back to shares issuable under the Inducement Plan, subject to certain conditions. As of June 30, 2023, 1,655,600 shares are available for future issuance under the Inducement Plan.

2020 Employee Share Purchase Plan

On July 31, 2020, the Company adopted an employee share purchase plan (the “ESPP”). The purpose of the ESPP is to provide employees the opportunity to purchase ordinary shares or ADSs at 85% of the fair market value of the ADSs on the offering date or the exercise date, whichever is lower, for up to 15% of such employee’s compensation for each pay period. The Company reserved 347,447 ordinary shares for the ESPP. The ESPP provides for an annual increase beginning on January 1, 2022 in an amount equal to the least of (i) 347,447 ordinary shares, (ii) 1% of the total number of ordinary shares outstanding on December 31st of the prior calendar year or (iii) such fewer number of ordinary shares as the board of directors may designate prior to the applicable January 1st date. On January 1, 2023, the reserve automatically increased by 347,447 shares. During the six months ended June 30, 2023, 217,755 shares were purchased under the ESPP. As of June 30, 2023, 393,278 shares are available for future issuance under the ESPP.

The numbers of Employee Shares, share options and RSUs, the weighted average grant date fair values per Employee Share, share option and RSU, and the weighted average exercise prices are all shown below on a per ordinary share basis.

Option Repricing

On June 28, 2023, the Company's shareholders approved the amendment of the exercise price of each outstanding option granted to an employee on or after June 1, 2021 with an exercise price greater than or equal to $0.42 per ordinary share (or $6.27 per ADS) under the 2021 Equity Inducement Plan and 2020 Equity Incentive Plan (the "In-Scope Options") to a new replacement per ADS exercise price equal to $2.42, the closing sales price for ADSs as quoted on the Nasdaq Capital Market for June 29, 2023 (the "Repricing"). The Repricing was effective on June 30, 2023 (the "Repricing Date"). Share options held by the Company's non-executive directors were not included in the Repricing. The Repricing was deemed to be a Type I modification event under ASC 718, Compensation-Stock Compensation. No other terms of the In-Scope Options were modified, and the In-Scope Options will continue to vest according to their original vesting schedules and will retain their original expiration dates. The Repricing resulted in incremental share-based compensation expense of $0.4 million, of which $0.1 million related to vested share option awards and was expensed on the Repricing Date and $0.3 million related to unvested share option awards and will be amortized on a ratable basis over the remaining weighted-average vesting period of those awards.

Employee Shares

The Company measures all non-cash share-based awards using the fair value on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. Prior to the Company’s initial public offering (“IPO”), the Company granted share-based compensation in the form of ordinary shares, collectively referred to as Employee Shares, to employees and non-employees with both performance and service-based vesting conditions. The Company records expense for these awards using the straight-line method.

A summary of the changes in the Employee Shares from December 31, 2022 through June 30, 2023 is as follows.

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested balance as of December 31, 2022	16,309	$ 11.33
Granted	—	—
Vested	(3,487)	10.70
Forfeited	(11,431)	11.78
Unvested balance as of June 30, 2023	1,391	$ 13.49

As of June 30, 2023, there was less than $0.1 million of unrecognized compensation cost related to unvested Employee Shares outstanding, which is expected to be recognized over a weighted-average period of 1.2 years. Unvested Employee Shares are forfeited upon termination of employment, classified as deferred shares on the balance sheet and are subsequently cancelled.

Share Options Valuation

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the share options granted to employees and directors during the six months ended June 30, 2023 were as follows:

	For the Six Months Ended June 30, 2023
Expected option life (years)	5.8
Expected volatility	71.7%
Risk-free interest rate	3.6%
Expected dividend yield	—

Share Options

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	7,918,500	$ 4.76	8.40	$ —
Granted	4,015,796	0.55	—	—
Exercised	—	—	—	—
Expired	(647,516)	13.22	—	—
Canceled or Forfeited	(1,665,323)	2.94	—	—
Outstanding as of June 30, 2023	9,621,457	$ 2.64	8.44	$ 2
Exercisable as of June 30, 2023	2,608,080	5.92	6.53	—
Vested and expected to vest as of June 30, 2023	9,621,457	$ 2.64	8.44	$ 2

The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Company's ordinary shares for those share options that had exercise prices lower than the fair value of the Company's ordinary shares.

The weighted-average grant-date fair value for the share options granted during the six months ended June 30, 2023 and 2022 was $0.36 per share and $0.77 per share, respectively. The weighted-average grant-date fair value for the share options vested during the six months ended June 30, 2023 and 2022 was $3.71 per share and $7.93 per share, respectively.

As of June 30, 2023, there was $5.9 million of unrecognized compensation cost related to unvested share options outstanding, which is expected to be recognized over a weighted-average period of 2.2 years.

Restricted Share Units

The Company has granted (i) RSUs that generally vest over a period of three or four years from the date of grant and (ii) RSUs to certain new employees in order to compensate them for equity awards forfeited to their previous employers which generally vest over a period of less than one year from the date of grant. The Company granted share options and RSUs as its annual equity incentive awards to employees during the six months ended June 30, 2023. The following table summarizes the activity related to RSUs from December 31, 2022, through June 30, 2023:

	Number of RSUs	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2022	445,590	$ 0.98
Granted	1,157,989	0.58
Vested and settled	(89,340)	1.08
Canceled or Forfeited	(317,531)	0.84
Outstanding as of June 30, 2023	1,196,708	$ 0.64

As of June 30, 2023, there was $0.6 million of unrecognized compensation cost related to unvested share options outstanding, which is expected to be recognized over a weighted-average period of 2.6 years.

Share-based Compensation Expense

Non-cash share-based compensation expense recorded as research and development and general and administrative expenses is as follows (in thousands):

	For the Six Months Ended June 30,	
	2023	2022
Research and development	$ 539	$ 1,170
General and administrative	1,509	1,665
	$ 2,048	$ 2,835

11. Net Income (Loss) Per Share

Basic and diluted net loss per share attributable to ordinary shareholders was calculated as follows (in thousands, except share and per share amounts):

	June 30,	
	2023	2022
Numerator		
Net loss	$ (14,845)	$ (51,080)
Net loss attributable to ordinary shareholders—basic and diluted	$ (14,845)	$ (51,080)
Denominator		
Weighted-average number of ordinary shares used in net loss per share - basic and diluted	65,140,334	53,587,167
Net loss per share attributable to ordinary shareholders— basic and diluted	$ (0.23)	$ (0.95)

The Company used the treasury stock method to determine the number of dilutive shares. The Company excluded the following potential ordinary shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to ordinary shareholders for the six months ended June 30, 2023 and 2022 because including them would have had an anti-dilutive effect:

	June 30,	
	2023	2022
Unvested ordinary shares	1,391	27,029
Share options	9,621,457	8,311,290
Restricted share units	1,196,708	535,117
Total	10,819,556	8,873,436

12. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may be a party to litigation or arbitration or subject to claims incident to the ordinary course of business. Regardless of the outcome, litigation and arbitration are subject to inherent uncertainties and could adversely impact the Company's reputation, operations, and its operating results or overall financial condition. As of June 30, 2023, except as set forth below, there were no pending material legal proceedings to which the Company was a party or to which any of its property was subject, and the Company did not have contingency reserves established for any liabilities as of June 30, 2023 and December 31, 2022. When appropriate in management's estimation, the Company will record adequate reserves in its financial statements for pending litigation or arbitration.

In June 2020, the Company entered into a dedicated manufacturing and commercial supply agreement (the "Manufacturing Agreement") with Brammer Bio MA, LLC ("Brammer") pursuant to which Brammer was obligated to reserve certain amounts of manufacturing capacity in its manufacturing facility to supply the Company with its product candidate FLT180a for the treatment of hemophilia B. As consideration for the reserved manufacturing capacity, the Company was required to pay Brammer an annual capacity access fee of $10.0 million, subject to inflationary annual increases, excluding any purchase commitment or other fees.

The Company committed to an annual minimum purchase commitment equivalent to $6.0 million throughout the term of the Manufacturing Agreement. The term of the Manufacturing Agreement was effective as of June 30, 2020 and was to continue until December 31, 2027.

On May 18, 2023, the Company entered into a Mutual Release and Settlement Agreement (the "Settlement Agreement") with Brammer to resolve the Company's claims and Brammer's counterclaims in an arbitration brought by the Company before the American Arbitration Association in New York arising from the Manufacturing Agreement. Pursuant to the terms of the Settlement Agreement, the Company paid to Brammer a total of $2.25 million. Subject to specified conditions and exceptions, the parties dismissed the arbitration, and each party released the other party from any and all claims arising from the parties' business relationship. As a result of the Settlement Agreement, the Company reversed $5.1 million of discharged liabilities and $0.6 million of prepaid expenses, which resulted in a net gain on legal settlement of $2.2 million on the unaudited condensed consolidated statements of operations.

As a result of the mutual termination of the Manufacturing Agreement in August 2022, the Company derecognized the associated operating lease assets and liabilities (see "Operating Lease Agreements" below) and no longer recognizes the annual minimum purchase commitment as a contractual obligation.

Operating Lease Agreements

The following table summarizes the Company's costs included in the statements of operations related to right of use lease assets entered into through June 30, 2023 and 2022 (in thousands):

	For the Six Months Ended June 30,	
Lease Cost	**2023**	**2022**
Operating lease cost		
Research and development	$ 1,196	$ 4,287
General and administrative	541	3,641
Short-term lease cost	6	139
Sublease income	(49)	(128)
Total lease cost	$ 1,694	$ 7,939

	For the Six Months Ended June 30,	
Other Information	**2023**	**2022**
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ 1,535	$ 6,229
Weighted-average remaining lease term-operating leases	5.80	5.70
Weighted-average discount rate-operating leases	9.58%	11.15%

In August 2022, in connection with the termination of the Manufacturing Agreement, the Company terminated the operating lease in connection with the dedicated capacity at the Brammer facility. The Company derecognized the related right-of-use asset of approximately $35.6 million and accordingly the operating lease liabilities of $40.3 million, resulting in a gain of $5.3 million for the year ended December 31, 2022.

Contractual Obligations

The following table summarizes the Company's contractual obligations as of June 30, 2023, and the effects that such obligations are expected to have on its liquidity and cash flows in future periods (in thousands):

Maturity of Operating Leases

Years Ended December 31,	**Operating Leases**
2023 (excluding the six months ended June 30, 2023)	1,537
2024	2,008
2025	698
2026	676
2027	337
Thereafter	—
Total payments	5,256
Less: imputed interest	(481)
Less: foreign exchange (gain)/loss	24
Total	$ 4,799

In connection with the Subsidiary Sale, the Company and Ascend entered into the Transition Services Agreement whereby the Company agreed to pay Ascend a guaranteed minimum of approximately $7.9 million in respect of FTE costs. The Company will make remaining minimum guaranteed payments of $2.2 million and $3.1 million for the years ending December 31, 2023 and 2024, respectively. See Note 3, Sale of Freeline Therapeutics GmbH.

Indemnification Agreements

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with the Articles of Association in force on June 30, 2023, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date, and the Company has director and officer insurance that may enable it to recover a portion of any amounts paid for future potential claims.

13. Related Party Transactions

The Company analyzed its transactions with related parties for the six months ended June 30, 2023 and 2022, and determined it had the following material transactions.

Syncona

On March 10, 2022, the Company entered into a purchase agreement with its majority shareholder, Syncona Portfolio Limited, a subsidiary of Syncona Limited, and certain other existing shareholders providing for the issuance and sale by the Company of $26.1 million of the Company's ADSs at a price of $1.05 per ordinary share, in a registered direct offering. The offering closed on March 15, 2022. The Company received net proceeds of approximately $24.2 million from the offering, after deducting offering expenses payable by the Company.

Forcefield Therapeutics Limited

On March 21, 2023, the Company entered into an exclusive patent and know-how in-license agreement with Forcefield Therapeutics Limited ("Forcefield"), a company controlled by Syncona. Under the terms of the agreement, Forcefield granted the Company an exclusive license under certain patent rights to develop and commercialize AAV gene therapies for certain cardiac conditions and a non-exclusive license to certain know-how.

The Company has committed to an upfront fee of £0.5 million or $0.6 million and may be obligated to make up to £18.3 million or $22.0 million in development and regulatory milestone payments, and pay Forcefield a mid-single-digit percentage royalty on net sales of certain royalty products on a product-by-product and country-by-country basis, until the later of (a) the expiration of the last valid licensed patent claim covering such product in such country or (b) ten years from the first commercial sale of such product sold in that country or twenty years from the date upon which the agreement was signed. The Company considers the development and regulatory milestones probable when actually achieved. During the six months ended June 30, 2023, the Company recorded expense of $0.6 million within research and development on the Company's unaudited condensed consolidated statements of operations related to the license agreement with Forcefield.

Syncona IP Holdco (2) Limited

See Note 4, License Revenue.

14. Restructuring Charges

During the first quarter of 2023, the Company completed a financial and organizational assessment to increase efficiencies and reduce operating expenses. As a result of this assessment, the Company reduced its U.S. and U.K. workforce by nearly 30%. For the six months ended June 30, 2023, the Company incurred total expenses of $1.3 million, consisting of severance and termination-related costs, which were recognized as operating expenses.

15. Subsequent Events

The Company evaluated subsequent events through August 15, 2023, the date on which these unaudited condensed consolidated financial statements were issued. The Company has concluded that no subsequent event has occurred that requires disclosure.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 6-K contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements are any statements other than statements of historical fact. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements contained in this report are based upon information available to us as of the date of this report and, while we believe we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- our ability to raise additional capital;
- our estimates regarding future expenses, the period for which we expect that our current cash and cash equivalents will be sufficient to fund operations and our needs for additional funding;
- our ability to advance our product candidates into, and successfully complete, clinical trials;
- the development of our product candidates, including statements regarding the timing of initiation, enrollment, continuation, completion and the outcome of preclinical studies or clinical trials and related preparatory work, the period during which interim data from, or the final results of, the studies or trials will become available and our research and development programs;
- our ability to obtain and maintain regulatory approval of our product candidates in the indications for which we plan to develop them, and any related restrictions, limitations or warnings in the label of an approved drug or therapy;
- our ability to license additional intellectual property relating to our product candidates from third parties and to comply with our existing license agreements;
- our plans to research, develop, manufacture and commercialize our product candidates;
- the timing of our regulatory filings for our product candidates, along with regulatory developments in the United States, European Union and other foreign countries;
- the size and growth potential of the markets for our product candidates, if approved, and the rate and degree of market acceptance of our product candidates, including pricing and reimbursement that may be agreed with payors;
- the impact of changes in economic, capital market and political conditions, including fluctuations in commodity prices, inflation, interest rates and foreign currency exchange rates, disruptions in global supply chains and labor markets, geopolitical risks and global hostilities, including Russia's invasion of Ukraine;
- our expectations regarding our ability to obtain and maintain intellectual property protection;
- our ability to attract and retain qualified employees and key personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the scalability and commercial viability of our manufacturing methods and processes;
- the success of competing therapies that are or may become available;
- our ability to realize the anticipated benefits of any acquisitions, joint ventures or divestitures; and
- whether we are classified as a passive foreign investment company, or PFIC, for current and future periods.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. The forward-looking statements contained in this report speak only as of the date of this report. You should refer to the section titled “Risk Factors” elsewhere in this report on Form 6-K and Item 3.D. “Key Information—Risk Factors” in our Annual Report on Form 20-F for the year ended December 31, 2022, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this report.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") for Freeline Therapeutics Holdings plc ("us," "we," "our," "Freeline," or "the Company"), together with our unaudited condensed consolidated financial statements as of and for the six months ended June 30, 2023 and June 30, 2022 and accompanying notes thereto, included elsewhere in this report on Form 6-K, and our audited consolidated financial statements and the related notes as of and for the fiscal year ended December 31, 2022 included in our Annual Report on Form 20-F for the year ended December 31, 2022 (the "Annual Report"), which is available through the U.S. Securities and Exchange Commission's ("SEC") Electronic Data Gathering and Analysis Retrieval ("EDGAR") system at http://www.sec.gov.

Some of the information contained in this MD&A, including, but not limited to, information with respect to our plans and strategy for our business and our expectations with respect to liquidity and capital resources, includes forward-looking statements. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, those risks and uncertainties described in the section titled "Risk Factors" elsewhere in this report on Form 6-K and Item 3.D. "Key Information—Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in our Annual Report. Our actual results could differ materially from the results described in or implied by these forward-looking statements.

Overview

We are a clinical-stage biotechnology company with the ambition of developing transformative AAV vector-mediated gene therapies. We are dedicated to improving patient lives through innovative, potential one-time treatments for chronic debilitating diseases. We use our proprietary, rationally designed AAV vector and capsid (AAVS3) along with novel promoters and transgenes to deliver a functional copy of a therapeutic gene into human liver cells, thereby expressing a persistent functional level of the missing or dysfunctional protein into the patient's bloodstream. Our pipeline includes a program in the clinic for Gaucher disease and research programs targeting GBA1-linked Parkinson's disease and other novel applications for gene therapy, for which we have, through owned and in-licensed intellectual property rights, development and worldwide commercial rights. In an effort to ensure we are investing our resources in highest-value programs, we have deprioritized product candidates in Fabry disease and hemophilia B.

Since our inception in May 2015, we have devoted substantially all of our resources to conducting preclinical studies and clinical trials, organizing and staffing our company, planning our business initiatives, raising capital and establishing our intellectual property portfolio. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily with proceeds from the sale of our equity securities, including net proceeds from our initial public offering, or IPO, in August 2020, and subsequent issuances. Through June 30, 2023, we had received net cash proceeds of approximately $474.1 million from sales of our equity securities.

As of June 30, 2023, we had unrestricted cash and cash equivalents of $38.8 million. We have incurred operating losses since inception including net losses of $14.8 million and $51.1 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $460.2 million. We expect to continue to incur significant expenses and generate operating losses for the foreseeable future as we advance our FLT201 product candidate through clinical development, seek regulatory approval, invest further in our gene therapy platform and seek to identify new gene therapy product candidates. These conditions indicate that there is substantial doubt regarding our ability to continue as a going concern for at least 12 months from the issuance date of the accompanying unaudited condensed consolidated financial statements. See "—Liquidity and Capital Resources—Funding Requirements" below for additional information.

Recent Developments

Clinical Trial Updates

On August 15, 2023, we announced that the second patient has been dosed in the Phase 1/2 GALILEO-1 clinical trial evaluating FLT201, our adeno-associated virus gene therapy candidate, in Gaucher disease type 1, marking the completion of dosing in the first cohort. We expect to report initial data, including assessments of safety and enzyme activity, in the third quarter of 2023.

Option Repricing

On June 28, 2023, our shareholders approved the amendment of the exercise price of each outstanding option granted to an employee on or after June 1, 2021 with an exercise price greater than or equal to $0.42 per ordinary share (or $6.27 per American Depositary Share, or ADS) under the 2021 Equity Inducement Plan and 2020 Equity Incentive Plan, or the In-Scope Options, to a new replacement per ADS exercise price equal to $2.42, the closing sales price for ADSs as quoted on the Nasdaq Capital Market for June 29, 2023. Share options held by non-employee directors of our board of directors were not included in the repricing. Except for the modified exercise price, all other terms and conditions of the In-Scope Options remain in full force and effect.

Strategic Prioritization

As previously announced in April 2023, following an assessment of our strategic priorities based on our financial position and the capital needs associated with advancing two clinical-stage programs in parallel, we decided to focus our resources on the development of our candidate FLT201 in Gaucher disease and pause development of FLT190 in Fabry disease. In parallel, we restructured the organization to align with our focus on FLT201 and to increase efficiencies and reduce operating expenses. We reduced our workforce by nearly 30 percent, bringing our headcount to approximately 65 employees. We incurred $1.3 million in restructuring charges, consisting of severance and termination-related costs, which have been recognized as operating expenses.

Brammer Dispute

On May 18, 2023, we entered into a Mutual Release and Settlement Agreement, or the Settlement Agreement, with Brammer Bio MA, LLC, or Brammer, to resolve the arbitration arising from the Dedicated Manufacturing and Commercial Supply Agreement, dated June 30, 2020, by and between Freeline Therapeutics Limited and Brammer.

Pursuant to the terms of the Settlement Agreement, we paid Brammer a total of $2.25 million. Subject to specified conditions and exceptions, the parties dismissed the arbitration, and each party released the other party from any and all claims arising from the parties' business relationship. As a result of the Settlement Agreement, we reversed $5.1 million of discharged liabilities and $0.6 million of prepaid expenses, which resulted in a net gain on legal settlement of $2.2 million.

ADS Ratio Change

On May 12, 2023, we changed the ratio of our ADSs to our ordinary shares, or the ADS Ratio, from the previous ADS Ratio of one ADS to one ordinary share to a new ADS Ratio of one ADS to fifteen ordinary shares. The change in the ADS Ratio had the same effect as a one-for-fifteen reverse ADS split and enabled the Company to regain compliance with the Nasdaq minimum bid price requirement. We also paid to the depositary $2.0 million of fees in connection with the ADS Ratio change.

Components of Our Results of Operations

Revenue

The total revenue to date has been generated from our out-license agreement with Syncona Holdco. We have not generated any revenue from product sales and do not know when or if we will generate revenue from our product sales. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of our product candidates. Research and development expenses consist of:

- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with clinical research organizations, or CROs;
- the costs of contract manufacturing organizations, or CMOs, that manufacture drug products for use in our preclinical studies and clinical trials;
- employee-related expenses, including salaries, related benefits, travel and non-cash share-based compensation expense for employees engaged in research and development functions;
- costs of outside consultants engaged in research and development activities, including their fees, non-cash share-based compensation and related travel expenses;
- costs of laboratory supplies;
- costs related to compliance with regulatory requirements;
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of research and development facilities and other operating costs; and
- upfront, milestone and management fees for maintaining licenses under our third-party licensing agreements.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as a prepaid expense or accrued research and development expenses.

Certain of our direct research and development expenses are not tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants, CROs and CMOs in connection with our preclinical development, manufacturing and clinical development activities. License fees and other costs incurred after a product candidate has been selected that are directly related to a product candidate are included in direct research and development expenses for that program. License fees and other costs incurred prior to designating a product candidate are included in other program expense. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to oversee research and discovery as well as to manage our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

Research and development activities are central to our business model. Our research and development expenses may decrease in the near term as a result of the program prioritization and workforce reductions announced previously. However, product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials and related product manufacturing expenses. As a result, we expect that our research and development expenses will continue to increase over the mid- to long-term as we seek to: (i) expedite clinical development and attempt to obtain marketing approval for our product candidates; (ii) initiate additional clinical trials of our product candidates; (iii) improve the efficiency and scalability of our manufacturing processes and supply chain; (iv) continue to discover and develop additional product candidates; and (v) prepare for regulatory filings related to our product candidates. We also expect to incur additional expenses related to milestone, royalty payments and maintenance fees payable to third parties with whom we have entered into license agreements to acquire the rights related to our product candidates.

The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with development and commercialization, including the following:

- completing research and preclinical development of our product candidates and identifying new gene therapy product candidates and investing in our gene therapy platform;
- establishing an appropriate safety profile with IND- and CTA-enabling studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities and reimbursement and market access from third-party payors;
- our ability to maintain suitable arrangements with third-party manufacturers for our product candidates, including our ability to meet CMC and other regulatory requirements relating to the manufacture of product candidates;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- defending against third-party infringement, misappropriation or other violation of intellectual property rights claims;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates could mean a significant change in the costs and timing associated with such development. For example, if the U.S. Food and Drug Administration, the European Medicines Agency, the U.K. Medicines and Healthcare products Regulatory Agency or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to commit significant additional financial resources and time to the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, non-cash share-based compensation expense, travel and other expenses incurred by personnel in executive, finance and administrative functions. These expenses include professional fees for legal, consulting, accounting and audit services and other costs associated with being a public company.

Other Income (Expense), Net

Other Income (Expense), Net

Other income *(expense)*, net consists primarily of realized and unrealized gains and losses from foreign currency denominated cash balances, vendor payables and receivables.

Interest Income, Net

Interest income, net consists of interest income on cash and cash equivalents held in our banking institutions.

Income Tax Expense

We are subject to corporate taxation in the United States, Ireland and the United Kingdom and through the closing of the Subsidiary Sale, in Germany. Due to the nature of our business, we have generated losses since inception and therefore have not paid corporation tax in either the United Kingdom or Ireland. Our income tax expense represents income taxes in the United States and Germany.

Unsurrendered U.K. losses may be carried forward indefinitely to be offset against future taxable profits, subject to numerous utilization criteria and restrictions. The amount that can be offset each year is limited to £5.0 million plus an incremental 50% of U.K. taxable profits. We had accumulated tax losses for carry forward in the United Kingdom of $310.8 million as of December 31, 2022. We have not recognized any deferred tax assets to date in relation to U.K. losses. This treatment is based on the Company incurring losses while the clinical programs are not at a commercial stage. We believe there is no reasonable certainty that sufficient future taxable income will be available against which such deferred tax assets can be realized. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

Benefit from R&D Tax Credit

As a company that carries out extensive research and development activities, we seek to benefit from the U.K. research and development tax credit cash rebate, or U.K. R&D tax credit, regimes. The amount of benefits received depends on whether we qualify for a tax credit under the Research and Development Expenditure Credit, or RDEC, program. We record the U.K. R&D tax credit benefit within other income (expense), net. The U.K. R&D tax credit is fully refundable to us and is not dependent on current or future taxable income. As a result, we have recorded the entire benefit from the U.K. R&D tax credit as a benefit, which is included in our net loss before income tax and accordingly, not reflected as part of the income tax provision. If, in the future, any U.K. R&D tax credits generated are needed to offset a corporate income tax liability in the UK, that portion would be recorded as a benefit within the income tax provision and any refundable portion not dependent on taxable income would continue to be recorded within other income (expense), net.

Under the RDEC scheme, we are able to surrender some of our trading losses that arise from qualifying research and development activities for a cash rebate of up to 10.53% (or, from April 2023, 15%) of such qualifying research and development expenditure. Qualifying expenditures largely comprise employment costs for research staff, consumables and certain internal overhead costs incurred as part of research projects for which we do not receive income. Based on criteria established by HM Revenue & Customs, or HMRC, we expect a portion of expenditures being carried out in relation to our pipeline research and development, clinical trials management and manufacturing development activities to be eligible for the RDEC regime for the six months ended June 30, 2023 and 2022.

Results of Operations

Comparison of the Six Months Ended June 30, 2023 and 2022

The following table summarizes our results of operations for the six months ended June 30, 2023 and 2022 (in thousands):

	Six Months Ended June 30,		
	2023	2022	Change
License revenue	$ 617	$ —	$ 617
Operating expenses:			
Research and development	$ 19,720	$ 38,785	$ (19,065)
General and administrative	17,581	16,278	1,303
Gain on legal settlement	(2,227)	—	(2,227)
Restructuring expense	1,276	—	1,276
Total operating expenses	36,350	55,063	(18,713)
Loss from operations	(35,733)	(55,063)	19,330
Other income, net			
Gain on sale of Freeline Therapeutics GmbH	20,279	—	20,279
Other income, net	73	2,973	(2,900)
Interest income, net	240	335	(95)
Benefit from R&D tax credit	464	721	(257)
Total other income, net	21,056	4,029	17,027
Net loss before income taxes	(14,677)	(51,034)	36,357
Income tax expense	(168)	(46)	(122)
Net loss	$ (14,845)	$ (51,080)	$ 36,235

License Revenue

License revenue increased to $0.6 million for the six months ended June 30, 2023, due to the execution of our out-license agreement with Syncona Holdco which included recognition of a non-refundable upfront license fee payable to us. During the six months ended June 30, 2022, we did not recognize any license revenue.

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2023 and 2022 (in thousands):

	Six Months Ended June 30,		
	2023	2022	Change
Direct research and development expenses by program:			
FLT201	$ 2,188	$ 3,054	$ (866)
FLT180a	1,813	7,303	(5,490)
FLT190	2,696	3,350	(654)
Pre-clinical and discovery	3,855	2,947	908
Unallocated research and development expenses:			
Personnel expenses	6,409	11,544	(5,135)
Facilities and other expenses	2,220	9,417	(7,197)
Non-cash share-based compensation expense	539	1,170	(631)
Total research and development expenses	$ 19,720	$ 38,785	$ (19,065)

Research and development, or R&D, expenses were $19.7 million for the six months ended June 30, 2023, a decrease of approximately $19.1 million, from $38.8 million for the six months ended June 30, 2022. The decrease in research and development expenses was primarily attributable to the following:

- a $0.9 million decrease in spending related to FLT201, our product candidate for the treatment of Gaucher disease Type 1, primarily related to a decrease in our CRO expense resulting from the timing of milestone payments in 2023;
- a $5.5 million decrease in spending related to FLT180a, our deprioritized product candidate for the treatment of hemophilia B, primarily due to our decision to halt further development of FLT180a, offset by clinical trial wind-down costs and long-term follow up;
- a $0.7 million decrease in spending related to FLT190, our deprioritized product candidate targeting Fabry disease, primarily related to lower clinical trial costs and related activities for our Phase 1/2 MARVEL-1 clinical trial in 2023;
- a $0.9 million increase in spending related to preclinical and discovery activities, primarily related to increased external research and development costs in connection with the Transition Services Agreement with Ascend Gene and Cell Therapies Limited, partially offset by cost savings associated with the sale of Freeline Therapeutics GmbH, or the Subsidiary Sale;
- a $5.1 million decrease in personnel expenses, primarily related to a reduction of R&D and manufacturing personnel in connection with the October 2022 and April 2023 reductions in workforce and the sale of Freeline Therapeutics GmbH;
- a $7.2 million decrease in facilities and other expenses, mainly due to a reduction in CMO capacity fees and consulting expenses; and
- a $0.6 million decrease in non-cash share-based compensation expense, primarily due to reduced R&D personnel in connection with the October 2022 and April 2023 reductions in workforce offset by incremental expense as a result of the option repricing.

We generally expect these costs to increase year over year to support our plan to advance FLT201 through clinical development and our research programs targeting GBA1-linked Parkinson's disease and other novel applications for gene therapy, although certain of these costs may decrease during the next twelve months due to our strategic prioritizations, reduced expenses due to the sale of Freeline Therapeutics GmbH and reductions in workforce.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for six months ended June 30, 2023 and 2022 (in thousands):

	Six Months Ended June 30,		
	2023	2022	Change
Personnel expenses	$ 4,152	$ 6,159	$ (2,007)
Legal and professional fees	4,608	4,585	23
Facilities and other expense	3,093	3,869	(776)
Non-cash share-based compensation expense	1,509	1,665	(156)
Cost related to sale of Freeline Therapeutics GmbH	2,237	—	2,237
Depositary fees in connection with ADS Ratio change	1,982	—	1,982
Total general and administrative expenses	$ 17,581	$ 16,278	$ 1,303

General and administrative, or G&A, expenses were $17.6 million for the six months ended June 30, 2023, an increase of $1.3 million from $16.3 million for the six months ended June 30, 2022. The increase in general and administrative expenses was primarily attributable to the following:

- a $2.0 million decrease in personnel expenses, primarily as a result of the October 2022 and April 2023 reductions in workforce;
- a $0.8 million decrease in facilities and other expense resulting primarily from a decrease in D&O insurance expense;
- a $0.2 million decrease in non-cash share-based compensation expense, primarily as a result of reduced G&A personnel in connection with the October 2022 and April 2023 reductions in workforce offset by incremental expenses as a result of the option repricing; and
- offset by costs incurred of $2.2 million associated with the sale of Freeline Therapeutics GmbH and $2.0 million associated with the ADS depositary fees in connection with the ADS Ratio change.

Gain on Legal Settlement

Gain on legal settlement of $2.2 million for the six months ended June 30, 2023, represents the net gain from the Settlement Agreement with Brammer. We released approximately $5.1 million of discharged liabilities, which was offset by the write-off of prepaid expenses of approximately $0.6 million and a cash payment of $2.25 million. There was no gain on legal settlement during the six months ended June 30, 2022.

Total Other Income, Net

Total other income, net was $21.1 million for the six months ended June 30, 2023, an increase of $17.0 million, from total other income, net of $4.0 million for the six months ended June 30, 2022, primarily due to the gain of $20.3 million on the sale of Freeline Therapeutics GmbH.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses in each period and on an aggregate basis. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. We have funded our operations to date primarily with proceeds from the sale of preferred shares, ordinary shares and ADSs. Through June 30, 2023, we had received aggregate net cash proceeds of $474.1 million from sales of our equity securities.

On September 10, 2021, we filed a shelf registration on Form F-3 (File No. 333-259444) with the SEC, which was declared effective on September 22, 2021, or the Shelf Registration. Under the Shelf Registration, we may offer and sell up to $250.0 million of a variety of securities including ordinary shares (including ordinary shares represented by ADSs), preference shares, purchase contracts, warrants, units or any combination of such securities from time to time during the three-year period that commenced upon the Shelf Registration becoming effective.

On November 17, 2021, we entered into an Open Market Sale AgreementSM, or Sales Agreement, with Jefferies LLC, or Jefferies, pursuant to which we may issue and sell ADSs having aggregate offering sales proceeds of up to $75.0 million, from time to time, in "at-the-market" offerings pursuant to which Jefferies will act as sales agent and/or principal. During the year ended December 31, 2022, we issued ADSs representing 3,037,616 ordinary shares pursuant to the Sales Agreement, raising approximately $3.2 million in net proceeds.

On March 10, 2022, we entered into a purchase agreement with our majority shareholder, Syncona Portfolio Limited, a subsidiary of Syncona Limited, and certain other existing shareholders providing for the issuance and sale of $26.1 million of our ADSs at a price of $1.05 per ordinary share in a registered direct offering. The offering closed on March 15, 2022. We received net proceeds of approximately $24.2 million from the offering, after deducting offering expenses payable by us.

On March 18, 2022, we entered into a purchase agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park, under which we may at our discretion, sell to Lincoln Park up to $35.0 million of our ADSs over a 36-month period, subject to certain daily limits, applicable prices, and conditions. In addition, under the purchase agreement, we issued ADSs representing 954,208 ordinary shares to Lincoln Park as consideration for its commitment to purchase ADSs under the purchase agreement. During the six months ended June 30, 2023, we did not issue any additional ADSs pursuant to the purchase agreement.

On February 8, 2023, we received proceeds of approximately $25.0 million from the Subsidiary Sale, subject to purchase price adjustments and related transaction costs.

We currently have no ongoing material commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than our operating lease agreements and our Transition Services Agreement described in Note 12 to the unaudited condensed consolidated financial statements.

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2023 and 2022 (in thousands):

	For the Six Months Ended June 30,	
	2023	**2022**
Net cash used in operating activities	$ (35,719)	$ (43,203)
Net cash provided by (used in) investing activities	23,617	(939)
Net cash provided by financing activities	32	27,438
Effect of exchange rate changes on cash, cash equivalents and restricted cash	1,958	(11,072)
Net decrease in cash, cash equivalents and restricted cash	$ (10,112)	$ (27,776)

Net Cash Used in Operating Activities

Net cash used in operating activities was $35.7 million for the six months ended June 30, 2023, a decrease of $7.6 million, from $43.2 million for the six months ended June 30, 2022, primarily resulting from a decrease of $36.3 million in our net loss to $14.8 million from $51.1 million, offset by non-cash benefits of $19.8 million and the net cash in our operating assets and liabilities of $1.1 million. The net non-cash benefit primarily related to the gain on the sale of Freeline Therapeutics GmbH of $20.3 million and the gain on legal settlement of $2.2 million, partially offset by non-cash share-based compensation of $2.0 million and depreciation of $0.8 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $23.6 million for the six months ended June 30, 2023, an increase of $24.6 million, from $0.9 million used in investing activities for the six months ended June 30, 2022, primarily driven by proceeds from the disposal of Freeline Therapeutics GmbH.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was less than $0.1 million for the six months ended June 30, 2023. Net cash provided by financing activities was $27.4 million for the six months ended June 30, 2022, which was related to proceeds from the issuance of ordinary shares.

Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash

The effect of exchange rate changes on cash, cash equivalents and restricted cash was $2.0 million and $(11.1) million for the six months ended June 30, 2023 and 2022, respectively, primarily related to foreign currency gains arising from the translation of cash balances that were maintained in U.S. dollars, which is different from the legal entity's functional currency (pound sterling). Currently, our U.S. dollar balances are held in a pound sterling functional currency legal entity and converted as required into pound sterling because the predominant cash outflows are pound sterling.

Funding Requirements

We expect our expenses to decrease in connection with our ongoing activities in the near term as a result of our program prioritization and workforce reductions. However, our expenses will increase over the mid- to long-term as we:

- continue our development of our FLT201 product candidate, including conducting our ongoing Phase 1/2 GALILEO-1 clinical trial of FLT201 for the treatment of Gaucher disease Type 1 and any other clinical trials that may be required to obtain marketing approval;
- conduct research and development activities with respect to our research programs targeting GBA1-linked Parkinson's disease and other novel applications for gene therapy;
- initiate preclinical studies for future product candidates;
- develop the necessary processes, controls and manufacturing data to obtain marketing approval for our product candidates and to support manufacturing on a commercial scale;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire and retain additional personnel, such as clinical operations and affairs, pharmacovigilance, quality assurance, regulatory affairs, manufacturing, distribution, legal and compliance, medical affairs, finance, general and administrative, commercial and scientific personnel.

As of June 30, 2023, we had unrestricted cash and cash equivalents of $38.8 million. Based on our recurring losses, expectation of continuing operating losses and negative cash flows from operations in the foreseeable future, the need to raise additional capital to finance future operations, we have concluded that there is substantial doubt about our ability to continue as a going concern for at least 12 months from the issuance date of the unaudited condensed consolidated financial statements. The accompanying unaudited condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the unaudited condensed consolidated financial statements have been prepared on a basis that assumes we will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

As a result, we will need additional funding to support our continuing operations. We will need to obtain this additional funding through private and public equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic collaborations or licensing arrangements. To the extent that we raise additional capital through the sale of equity, current ownership interests will be diluted. If we raise additional funds through government or third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. However, there can be no assurances that additional funding will be available at all. If we are unable to raise additional funds when needed, we will be required to reduce spending and potentially delay, limit, reduce or terminate our product research and development efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Because of the numerous risks and uncertainties associated with research and development of product candidates and programs, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of drug discovery, laboratory testing, preclinical and clinical development for our current and future product candidates as well as further development of our gene therapy platform;
- our ability to enroll clinical trials in a timely manner and to quickly resolve any delays or clinical holds that may be imposed on our development programs;
- whether we elect to invest in and develop technology with the potential for further discovery and innovation, prioritize, delay or modify certain clinical programs, or implement any other strategic, scientific or operational changes;
- the costs, timing and outcome of regulatory review of our product candidates; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with the accounting principles generally accepted in the United States ("U.S. GAAP"). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue recognition, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. There have been no changes to our critical accounting estimates since December 31, 2022.

Internal Control over Financial Reporting

We have evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Our disclosure controls and procedures are designed to ensure that the information we are required to disclose in the reports we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2023, our disclosure controls and procedures were effective.

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this report on Form 6-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Emerging Growth Company Status Accounting Election

As an emerging growth company, we have elected to use the extended transition period under the JOBS Act until the earlier of the date we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We intend to rely on certain of the other exemptions and reduced reporting requirements provided by the JOBS Act. As an emerging growth company, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), and (ii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis).

RISK FACTORS

Except as set forth below, there have been no material changes to the Company's risk factors as disclosed in Item 3.D. "Key Information—Risk Factors," in our Annual Report on Form 20-F for the fiscal year ended December 31, 2022.

We will need substantial additional funding to complete the development, obtain regulatory approval and commence commercialization of our product candidates, which may not be available on acceptable terms, if at all. Failure to obtain additional funding when required may force us to delay, limit or terminate our product development efforts or other operations.

In our unaudited condensed consolidated financial statements for the six months ended June 30, 2023, included elsewhere in this report, we note that there is substantial doubt about our ability to continue as a going concern. In order to continue operating as a going concern, we will need to raise additional capital. We will need to obtain this additional funding through private and public equity offerings, debt financings, government or other third-party funding, strategic collaborations or licensing arrangements. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. Adverse conditions in the industry or the domestic and global financial markets, including due to interest rate increases or inflation, could increase our costs for additional financing. If we are unable to raise the requisite funds on a timely basis, we will be required to reduce spending and potentially delay, limit, reduce or terminate our product research and development efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, any of which could harm our business and potentially cause us to discontinue operations.

As of June 30, 2023, we had approximately $38.8 million in unrestricted cash and cash equivalents. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate further clinical trials of and seek marketing approval for our product candidates. In addition, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, laboratory testing, preclinical and clinical development for our current and future product candidates, as well as further development of our gene therapy platform;
- our ability to enroll clinical trials in a timely manner and to quickly resolve any delays or clinical holds that may be imposed on our development programs;
- whether we elect to invest in and develop technology with the potential for further discovery and innovation, prioritize, delay or modify certain clinical programs, or implement any other strategic, scientific or operational changes;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations and license agreements on favorable terms, if at all;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire technologies;
- the costs, timing and outcome of potential future commercialization activities, including manufacturing, marketing, sales and distribution for any product candidates for which we receive marketing approval;

- the sales price and availability of adequate third-party coverage and reimbursement for our product candidates, if and when approved;
- the costs of operating as a public company; and
- the cost of using contract manufacturers.

Even if we are able to obtain additional funding to alleviate the substantial doubt about our ability to continue operating as a going concern in the near term, developing product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our product revenues, if any, will be derived from or based on sales of product candidates that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on substantial additional financing to achieve our long-term business objectives. Adequate additional financing may not be available to us on acceptable terms, if at all.

EXHIBIT INDEX

Exhibit	Description
99.1*	Press Release dated August 15, 2023, “Freeline Reports Second Quarter 2023 Financial Results and Business Highlights"
101	The following materials formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Unaudited Condensed Consolidated Balance Sheets as of June, 2023 and 2022, (ii) Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss for the six month periods ended June 30, 2023 and 2022 and, (iii) Unaudited Condensed Consolidated Statements of Cash Flows for the six month periods ended June 30, 2023 and 2022 and (iv) Notes to Unaudited Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Furnished herewith.

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, thereto duly authorized.

FREELINE THERAPEUTICS HOLDINGS PLC

By: /s/ Michael J. Parini
Name: Michael J. Parini
Title: Chief Executive Officer

By: /s/ Paul M. Schneider
Name: Paul M. Schneider
Title: Chief Financial Officer

Date: August 15, 2023

FREELINE

Freeline Reports Second Quarter 2023 Financial Results and Business Highlights

Completed dosing in first cohort of Phase 1/2 GALILEO-1 trial of FLT201 in Gaucher disease; expect to report initial clinical data in third quarter of 2023

Extending impact of its novel GCase variant with research program for GBA1-linked Parkinson's disease

Management to host conference call at 8:00 a.m. ET today

LONDON, August 15, 2023 – Freeline Therapeutics Holdings plc (Nasdaq: FRLN) today reported financial results for the second quarter of 2023 and provided a business update.

"FLT201 is a potential first- and best-in-class gene therapy for Gaucher disease Type 1, the most common type of the disease," said Michael Parini, Chief Executive Officer of Freeline. "Advancing the program is our top strategic priority, and we are extremely pleased with our recent progress and the momentum in the trial. The completion of dosing in the first cohort of our GALILEO-1 trial of FLT201 represents a significant milestone for the program, for Freeline and for the Gaucher community. We believe FLT201 has the opportunity to dramatically reduce the disease and treatment burden for people with Gaucher disease. We look forward to reporting initial clinical data in the third quarter of this year."

"In the second quarter, we also unveiled our lead research program in GBA1-linked Parkinson's disease, which leverages the same longer-acting GCase variant as FLT201," Parini continued. "As in Gaucher disease, *GBA1* mutations lead to a deficiency of the GCase enzyme and an accumulation of pathological substrates. Approximately 200,000 people with Parkinson's disease in the US, UK and four major European markets have *GBA1* mutations, making it the most common genetic risk factor for the disease. Our GBA1-linked Parkinson's disease program is a natural extension of our work in Gaucher and an opportunity to extend the therapeutic potential of our longer-acting GCase variant into a genetically defined patient population with a serious unmet need."

Anticipated Clinical Data for FLT201

- Initial clinical data, with a focus on assessments of safety and enzyme activity, from the first cohort of the GALILEO-1 Phase 1/2 trial of FLT201 is expected in the third quarter of 2023. GALILEO-1 is a first-in-human, international, multicenter Phase 1/2 dose-finding study assessing the safety, tolerability, and efficacy of a single intravenous dose of FLT201, the company's adeno-associated virus (AAV) gene therapy candidate for Gaucher disease Type 1.

Recent Corporate Highlights

- Today, Freeline announced the dosing of the second patient in its GALILEO-1 trial of FLT201, marking the completion of dosing in the first cohort.
- In June, the company announced the dosing of the first patient in its GALILEO-1 trial.

- Also in June, Freeline unveiled its research program in GBA1-linked Parkinson's disease. The program builds on its work in Gaucher disease, leveraging the same rationally engineered longer-acting GCase variant as used in FLT201 to develop a gene therapy candidate for a subset of Parkinson's disease patients with mutations in the *GBA1* gene. In preclinical studies, Freeline's GCase variant has demonstrated at least 20-fold greater activity levels compared to wildtype enzyme in various cell lines, including brain epithelial and neuroblastoma cells.

Q2 2023 Financial Results

- **Cash Position:** As of June 30, 2023, unrestricted cash and cash equivalents were $38.8 million, compared to $55.4 million as of March 31, 2023. Freeline expects its current level of cash and cash equivalents will enable the company to fund its planned operations into the second quarter of 2024.

- **Research and Development (R&D) Expenses:** R&D expenses were $19.7 million for the six months ended June 30, 2023, as compared to $38.8 million for the same period in 2022. The $19.1 million decrease was primarily attributable to a decrease in expenditures related to the company's deprioritized FLT180a and FLT190 programs, including CMC costs and capacity fees, and reduced headcount-related costs, including share-based compensation expense.

- **General and Administrative (G&A) Expenses:** G&A expenses for the six months ended June 30, 2023, were $17.6 million, as compared to $16.3 million for the same period in 2022. The increase of $1.3 million was driven by $2.2 million in costs associated with the sale of Freeline Therapeutics GmbH and $2.0 million associated with the ADS depositary fees in connection with the ADS ratio change. These increases were offset by reduced G&A headcount-related costs, including share-based compensation expense.

- **Gain on Settlement Agreement:** The company recorded a gain of $2.2 million due to the mutual release and settlement agreement with Brammer Bio MA, LLC announced in May, which included the release of approximately $4.5 million of discharged net liabilities offset by a settlement payment of $2.3 million.

- **Net Loss:** Net loss was $14.8 million, or $0.23 per ordinary share, for the six months ended June 30, 2023, as compared to a net loss of $51.1 million, or $0.95 per ordinary share, in the same period in 2022.

About Freeline Therapeutics
Freeline is a clinical-stage biotechnology company focused on developing transformative gene therapies for chronic debilitating diseases. Freeline uses its proprietary, rationally designed AAV vector and capsid (AAVS3), along with novel promoters and transgenes, to deliver a functional copy of a therapeutic gene into human liver cells, thereby expressing a persistent functional level of the missing or dysfunctional protein into a patient's bloodstream. The company is currently advancing FLT201, a highly differentiated gene therapy candidate that delivers a novel transgene, in a Phase 1/2 clinical trial in people with Gaucher disease type 1. Freeline has additional programs in research, including one focused on GBA1-linked Parkinson's disease that leverages the same novel transgene as FLT201. Freeline is headquartered in the UK and has operations in the United States. For more information, visit www.freeline.life or connect with Freeline on LinkedIn and Twitter.

Forward-Looking Statements

This press release contains statements that constitute “forward looking statements” as that term is defined in the United States Private Securities Litigation Reform Act of 1995, including statements that express opinions, expectations, beliefs, plans, objectives, assumptions or projections of Freeline Therapeutics Holdings plc (the “Company”) regarding future events or results, in contrast with statements that reflect historical facts. Examples include, among other topics, statements regarding the potential of FLT201 to be a first- and best-in-class gene therapy for Gaucher disease; the opportunity to extend the therapeutic potential of the Company’s longer-acting GCase variant into a genetically defined patient population with a serious unmet need; the Company’s expectations regarding its use of cash and cash runway; and the timing of data readouts from the Company’s GALILEO-1 Phase 1/2 clinical trial. In some cases, you can identify such forward-looking statements by terminology such as “anticipate,” “intend,” “believe,” “estimate,” “plan,” “seek,” “project,” “expect,” “may,” “will,” “would,” “could” or “should,” the negative of these terms or similar expressions. Forward-looking statements are based on management’s current beliefs and assumptions and on information currently available to the Company, and you should not place undue reliance on such statements. Forward-looking statements are subject to many risks and uncertainties, including the Company’s recurring losses from operations; the uncertainties inherent in research and development of the Company’s product candidates as well as risks associated with preclinical and clinical data, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the Company’s ability to design and implement successful clinical trials for its product candidates; whether the Company’s cash resources will be sufficient to fund the Company’s foreseeable and unforeseeable operating expenses and capital expenditure requirements for the Company’s expected timeline in light of management’s substantial doubt regarding the Company’s ability to continue as a going concern for at least 12 months from the issuance date of this press release; the Company’s failure to demonstrate the safety and efficacy of its product candidates; the Company’s ability to enroll patients in clinical trials for its product candidates; the possibility that one or more of the Company’s product candidates may cause serious adverse, undesirable or unacceptable side effects or have other properties that could delay or prevent their regulatory approval or limit their commercial potential; the Company’s ability to obtain and maintain regulatory approval of its product candidates; the Company’s limited manufacturing experience, which could result in delays in the development of its product candidates; and the Company’s ability to identify or discover additional product candidates, or failure to capitalize on programs or product candidates. A further list and description of risks, uncertainties, and other matters can be found in the Company’s Annual Report on Form 20-F for the fiscal year ended December 31, 2022, and in subsequent reports on Form 6-K, in each case including in the sections thereof captioned “Cautionary Statement Regarding Forward-Looking Statements” and “Item 3.D. Risk factors.” Many of these risks are outside of the Company’s control and could cause its actual results to differ materially from those it thought would occur. The forward-looking statements included in this press release are made only as of the date hereof. The Company does not undertake, and specifically declines, any obligation to update any such statements or to publicly announce the results of any revisions to any such statements to reflect future events or developments, except as required by law. For further information, please reference the Company’s reports and documents filed with the U.S. Securities and Exchange Commission (the “SEC”). You may review these documents by visiting EDGAR on the SEC website at www.sec.gov.

Unaudited Condensed Consolidated Statements of Operations
(in thousands of U.S. dollars, except per share data)

	For the Six Months Ended June 30,	
	2023	2022
License revenue	$ 617	$ —
OPERATING EXPENSES:		
Research and development	19,720	38,785
General and administrative	17,581	16,278
Gain on legal settlement	(2,227)	—
Restructuring expense	1,276	—
Total operating expenses	36,350	55,063
LOSS FROM OPERATIONS:	(35,733)	(55,063)
OTHER INCOME (EXPENSE) NET:		
Gain on sale of Freeline Therapeutics GmbH	20,279	—
Other (expense) income, net	73	2,973
Interest income, net	240	335
Benefit from R&D tax credit	464	721
Total other income, net	21,056	4,029
Net loss before income taxes	(14,677)	(51,034)
Income tax expense	(168)	(46)
Net loss	$ (14,845)	$ (51,080)
Net loss per share attributable to ordinary shareholders—basic and diluted	$ (0.23)	$ (0.95)
Weighted average ordinary shares outstanding—basic and diluted	65,140,334	53,587,167

Unaudited Condensed Consolidated Balance Sheets
(in thousands of U.S. Dollars)

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 38,797	$ 47,279
License receivable	631	—
Prepaid expenses and other current assets	6,385	6,235
Assets held for sale	—	14,113
Total current assets	45,813	67,627
NON-CURRENT ASSETS:		
Property and equipment, net	9,284	9,007
Operating lease right of use assets	4,792	6,014
Other non-current assets	2,764	3,993
Total assets	$ 62,653	$ 86,641
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 6,875	$ 10,058
Accrued expenses and other current liabilities	8,963	7,908
Operating lease liabilities, current	2,842	2,663
Liabilities related to assets held for sale	—	10,337
Total current liabilities	18,680	30,966
NON-CURRENT LIABILITIES:		
Operating lease liabilities, non-current	1,957	3,261
Total liabilities	20,637	34,227
SHAREHOLDERS' EQUITY:		
Deferred shares	137	137
Additional paid-in capital	502,861	500,781
Accumulated other comprehensive (loss) gain	(784)	(3,151)
Accumulated deficit	(460,198)	(445,353)
Total shareholders' equity	42,016	52,414
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 62,653	$ 86,641

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