

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-39062

FREQUENCY THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
75 Hayden Avenue, Suite 300
Lexington, MA
(Address of principal executive offices)

47-2324450
(I.R.S. Employer
Identification No.)

02421
(Zip Code)

(781) 315-4600

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	FREQ	The Nasdaq Stock Market LLC (The Nasdaq Global Select Market)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 1, 2023, the registrant had 36,926,285 shares of common stock, \$0.001 par value per share, outstanding.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding the transactions contemplated by the Agreement and Plan of Merger, or the Merger Agreement, dated as of July 14, 2023, by and among us, Korro Bio, Inc., or Korro Bio, and our wholly owned subsidiary, Frequency Merger Sub, Inc., or Merger Sub, pursuant to which Merger Sub will merge with and into Korro Bio, with Korro Bio surviving as our direct, wholly owned subsidiary, and the surviving corporation of the merger, or the Merger, the combined company following the Merger, our expectations regarding future funding needs and expenses, and our business strategy, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties and assumptions described under the sections in this Quarterly Report titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements are subject to numerous risks, including, without limitation, that the failure to complete, or delays in completing, the Merger could expose us to operational and financial risks.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Frequency Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 41,723	\$ 51,954
Short-term marketable securities	—	31,143
Prepaid expenses and other current assets	423	4,396
Assets held for sale	354	—
Total current assets	<u>42,500</u>	<u>87,493</u>
Property and equipment, net	543	2,739
Right of use assets	1,339	28,980
Restricted cash	1,967	1,699
Other long-term assets	—	327
Total assets	<u>\$ 46,349</u>	<u>\$ 121,238</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 338	\$ 3,114
Accrued expenses	7,847	5,891
Lease liabilities, current portion	1,427	2,021
Term loan, current portion	—	10,000
Total current liabilities	<u>9,612</u>	<u>21,026</u>
Lease liabilities, net of current portion	—	26,761
Term loan, net of current portion	—	4,167
Other long-term liabilities	—	89
Total liabilities	<u>9,612</u>	<u>52,043</u>
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, no shares issued or outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized, 36,926,285 and 35,262,083 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	37	35
Additional paid-in capital	340,308	331,023
Accumulated other comprehensive gain (loss)	10	(198)
Accumulated deficit	<u>(303,618)</u>	<u>(261,665)</u>
Total stockholders' equity	<u>36,737</u>	<u>69,195</u>
Total liabilities and stockholders' equity	<u>\$ 46,349</u>	<u>\$ 121,238</u>

See accompanying notes.

Frequency Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 2,560	\$ 11,715	\$ 18,509	\$ 38,769
General and administrative	10,105	8,560	26,498	26,037
Total operating expenses	<u>12,665</u>	<u>20,275</u>	<u>45,007</u>	<u>64,806</u>
Loss from operations	(12,665)	(20,275)	(45,007)	(64,806)
Interest income	448	351	1,317	871
Interest expense	—	(263)	(284)	(649)
Other income, net	596	617	2,043	357
Loss before income taxes	(11,621)	(19,570)	(41,931)	(64,227)
Income tax	7	23	(22)	9
Net loss	<u>\$ (11,614)</u>	<u>\$ (19,547)</u>	<u>\$ (41,953)</u>	<u>\$ (64,218)</u>
Net loss per share attributable to common stockholders-basic and diluted	<u>\$ (0.31)</u>	<u>\$ (0.55)</u>	<u>\$ (1.17)</u>	<u>\$ (1.83)</u>
Weighted-average shares of common stock outstanding-basic and diluted	<u>36,922,236</u>	<u>35,247,680</u>	<u>36,005,269</u>	<u>35,013,189</u>

See accompanying notes.

Frequency Therapeutics, Inc.
Consolidated Statements of Comprehensive Loss
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	\$ (11,614)	\$ (19,547)	\$ (41,953)	\$ (64,218)
Other comprehensive gain (loss):				
Unrealized gain (loss) on marketable securities and money market funds	16	16	208	(314)
Total other comprehensive gain (loss)	16	16	208	(314)
Comprehensive loss	<u>\$ (11,598)</u>	<u>\$ (19,531)</u>	<u>\$ (41,745)</u>	<u>\$ (64,532)</u>

See accompanying notes.

Frequency Therapeutics, Inc.
Consolidated Statements Stockholders' Equity
(in thousands, except share and per share amounts)
(unaudited)

	Common shares issued	Common par value	Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
Balance, June 30, 2022	34,976,409	\$ 35	\$ 320,966	\$ (392)	\$ (224,756)	\$ 95,853
Stock-based compensation expense	-	-	5,595	-	-	5,595
Purchase of common stock under Employee Stock Purchase Plan	44,774	-	57	-	-	57
Issuance of common stock, net	200	-	(1)	-	-	(1)
Issuance of common stock pursuant to restricted stock units	240,850	-	-	-	-	-
Other comprehensive gain	-	-	-	16	-	16
Net loss	-	-	-	-	(19,547)	(19,547)
Balance, September 30, 2022	<u>35,262,233</u>	<u>\$ 35</u>	<u>\$ 326,617</u>	<u>\$ (376)</u>	<u>\$ (244,303)</u>	<u>\$ 81,973</u>
Balance, June 30, 2023	35,963,706	\$ 36	\$ 337,382	\$ (6)	\$ (292,004)	\$ 45,408
Stock-based compensation expense	-	-	2,925	-	-	2,925
Purchase of common stock under Employee Stock Purchase Plan	6,329	-	2	-	-	2
Issuance of common stock pursuant to restricted stock units	956,250	1	(1)	-	-	-
Other comprehensive gain	-	-	-	16	-	16
Net loss	-	-	-	-	(11,614)	(11,614)
Balance, September 30, 2023	<u>36,926,285</u>	<u>\$ 37</u>	<u>\$ 340,308</u>	<u>\$ 10</u>	<u>\$ (303,618)</u>	<u>\$ 36,737</u>
Balance, December 31, 2021	34,611,213	\$ 35	\$ 310,936	\$ (62)	\$ (180,085)	\$ 130,824
Stock-based compensation expense	-	-	15,425	-	-	15,425
Purchase of common stock under Employee Stock Purchase Plan	76,606	-	196	-	-	196
Issuance of common stock, net	22,964	-	61	-	-	61
Issuance of common stock pursuant to restricted stock units	551,450	-	(1)	-	-	(1)
Other comprehensive loss	-	-	-	(314)	-	(314)
Net loss	-	-	-	-	(64,218)	(64,218)
Balance, September 30, 2022	<u>35,262,233</u>	<u>\$ 35</u>	<u>\$ 326,617</u>	<u>\$ (376)</u>	<u>\$ (244,303)</u>	<u>\$ 81,973</u>
Balance, December 31, 2022	35,262,083	\$ 35	\$ 331,023	\$ (198)	\$ (261,665)	\$ 69,195
Stock-based compensation expense	-	-	9,253	-	-	9,253
Purchase of common stock under Employee Stock Purchase Plan	31,083	-	33	-	-	33
Issuance of common stock, net	2,969	-	-	-	-	-
Issuance of common stock pursuant to restricted stock units	1,630,150	2	(1)	-	-	1
Other comprehensive gain	-	-	-	208	-	208
Net loss	-	-	-	-	(41,953)	(41,953)
Balance, September 30, 2023	<u>36,926,285</u>	<u>\$ 37</u>	<u>\$ 340,308</u>	<u>\$ 10</u>	<u>\$ (303,618)</u>	<u>\$ 36,737</u>

See accompanying notes.

Frequency Therapeutics, Inc.
Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (41,953)	\$ (64,218)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	9,253	15,425
Depreciation expense	1,879	2,094
Non-cash lease expense	1,901	1,763
Non-cash interest (income) expense	(214)	421
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,973	3,193
Accounts payable	(2,776)	459
Lease liabilities	(1,615)	(1,359)
Accrued expenses	2,194	(396)
Net cash used in operating activities	<u>(27,358)</u>	<u>(42,618)</u>
Cash flows from investing activities:		
Sale of property and equipment	63	18
Purchase of property and equipment	(100)	—
Purchase of marketable securities	(1,978)	(46,914)
Redemption of marketable securities	33,543	53,469
Net cash provided by investing activities	<u>31,528</u>	<u>6,573</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	1	60
Proceeds from Employee Stock Purchase Plan	33	196
Repayment of Term Loan	(14,167)	—
Net cash (used in) provided by financing activities	<u>(14,133)</u>	<u>256</u>
Net decrease in cash, cash equivalents and restricted cash	(9,963)	(35,789)
Cash, cash equivalents, and restricted cash at beginning of period	53,653	81,334
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 43,690</u>	<u>\$ 45,545</u>
Non-cash items:		
Reduction of right of use assets	<u>\$ 25,740</u>	<u>\$ —</u>
Reduction of lease liabilities	<u>\$ 25,470</u>	<u>\$ —</u>

See accompanying notes

Frequency Therapeutics, Inc.
Notes to Unaudited Consolidated Financial Statements
(Amounts in thousands, except share and per share amounts)

1. Organization and basis of presentation

Organization

Frequency Therapeutics, Inc., together with its wholly owned subsidiaries, Frequency Therapeutics, PTY, LTD, and Frequency Therapeutics Securities Corporation (the Company) headquartered in Lexington, Massachusetts, was incorporated in November 2014 as a Delaware corporation. The Company is a preclinical-stage regenerative medicine company focused on developing therapeutics to activate a person's innate regenerative potential to restore function. On February 13, 2023, the Company announced a restructuring of the business which included the discontinuation of its hearing program and a downsizing of personnel by approximately 55%. On May 31, 2023, the Company announced an additional reduction in force of approximately 55% of its remaining personnel. On July 14, 2023, the Company, along with Frequency Merger Sub, Inc. (Merger Sub) and Korro Bio, Inc., (Korro Bio) entered into an Agreement and Plan of Merger (the Merger Agreement), pursuant to which, Merger Sub will merge with and into Korro Bio, with Korro Bio continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger.

Liquidity and capital resources

The Company has funded its operations primarily with proceeds from private and public securities financings, a term loan, and amounts received under a collaboration agreement. The Company has incurred recurring losses since its inception. In addition, as of September 30, 2023, the Company had an accumulated deficit of \$303,618. The Company expects to continue to generate operating losses for the foreseeable future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all. The Company believes that existing resources and the cost savings generated from the restructuring and reduction in force announced in February and May 2023, respectively, will be sufficient to fund planned operations for at least twelve months from the date the financial statements were available to be issued.

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that the Company follows to ensure its financial condition, results of operations, and cash flows are consistently reported. References to GAAP issued by the FASB in these notes to the consolidated financial statements are to the FASB Accounting Standards Codification (ASC).

Principles of consolidation

The consolidated financial statements include the accounts of Frequency Therapeutics, Inc. and its wholly owned subsidiaries Frequency Therapeutics Securities Corporation and Frequency Therapeutics PTY, LTD. All intercompany transactions and balances have been eliminated. The significant accounting policies used in preparation of these interim financial statements are consistent with those discussed in Note 2, "*Summary of significant accounting policies*," in the Company's Annual Report on Form 10-K (the Company's Form 10-K).

Unaudited interim financial information

The accompanying consolidated balance sheet as of September 30, 2023 and the consolidated statements of operations, the consolidated statements of comprehensive loss and the consolidated statements of stockholders' equity for the three and nine months ended September 30, 2023 and 2022 and the consolidated statements of cash flows for the nine months ended September 30, 2023 and 2022 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2023, the results of its operations for the three and nine months ended September 30, 2023 and

2022, and cash flows for the nine months ended September 30, 2023 and 2022. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2023 and 2022 are also unaudited. The results for the three and nine months ended September 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period. The consolidated balance sheet as of December 31, 2022 included herein was derived from the audited consolidated financial statements as of that date. These unaudited consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and the notes thereto for the year ended December 31, 2022 included in the Company’s Form 10-K.

2. Recently adopted and issued accounting standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company is an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the JOBS Act). The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company elected to avail itself of this extended transition period and, as a result, the Company will not be required to adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses* (Topic 326): Measurement of Credit Losses on Financial Instruments. The FASB has subsequently issued amendments to ASU 2016-13, which have the same effective date and transition date. These standards require that credit losses be reported using an expected losses model rather than the incurred losses model that was previously used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. These standards limit the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. The Company adopted the standard on January 1, 2023 and it did not have a material impact on the consolidated financial statements.

3. Fair value measurements

The Company’s financial assets are measured at fair value on a recurring basis by level within the fair value hierarchy at September 30, 2023 and December 31, 2022 are summarized as follows:

	September 30, 2023	
	Fair Value Hierarchy	Fair Market Value
Cash equivalents:		
Money market funds	Level 1	35,299
Investments:		
Short-term marketable securities	Level 2	—
		\$ 35,299
	December 31, 2022	
	Fair Value Hierarchy	Fair Market Value
Cash equivalents:		
Money market funds	Level 1	30,649
Investments:		
Short-term marketable securities	Level 2	31,143
		\$ 61,792

The carrying amounts reflected in the consolidated balance sheet for prepaid expenses and other current assets, accounts payable, accrued expenses, other liabilities, and term loan are shown at their historical values which approximate their fair values.

Silicon Valley Bank (SVB) was closed on March 10, 2023 by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. The FDIC then reopened SVB as Silicon Valley Bridge Bank, N.A. (SVBB). At September 30, 2023, SVBB holds the Company's sweep account and one of the Company's deposit accounts. The Company continues to decrease the balances held by SVBB.

4. Investments

The Company did not hold any investments at September 30, 2023. The following table summarizes the Company's investments at December 31, 2022, all of which are classified as available-for-sale and recorded at fair value:

	December 31, 2022		
	Amortization Cost	Unrealized Loss	Fair Market Value
Short-term marketable securities	31,280	(317)	31,143
	\$ 31,280	\$ (317)	\$ 31,143

The Company's short-term marketable securities were held in investment advisory accounts with SVB Asset Management (SAM). On March 27, 2023, following the closure of SVB, SAM's former parent company, and the creation of SVBB, the FDIC entered into a purchase and assumption agreement for certain assets of SVBB with First-Citizens Bank & Trust Company (FCB). As a result of this transaction, SAM became a wholly owned subsidiary of FCB. As of September 30, 2023, the Company does not hold any short-term marketable securities.

The Company determines the appropriate classification of investments at the time of purchase and reviews any investment when its fair value is less than its amortized cost and when evidence indicates that the investment's carrying amount is not recoverable within a reasonable period of time. The Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss may exist, the present value of cash flows expected to be collected from the investment is compared to its amortized cost basis. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded on the consolidated balance sheet, limited by the amount that the fair value is less than the amortized cost basis. Any impairment that is not related to a credit loss is recognized in other comprehensive (loss) income. The unrealized losses at September 30, 2023 and December 31, 2022 were attributable to changes in interest rates and do not represent credit losses.

At September 30, 2023, the Company did not own any debt securities. At December 31, 2022, the Company held 14 debt securities that were in an unrealized loss position. The Company does not sell the investments before recovery of their amortized cost bases, which may be at maturity. The following tables summarize the Company's debt securities in an unrealized loss position, aggregated by length of time in a continuous unrealized loss position.

	December 31, 2022					
	Less than 12 Months		More than 12 Months		Total	
	Fair Market Value	Unrealized Loss	Fair Market Value	Unrealized Loss	Fair Market Value	Unrealized Loss
Short-term marketable securities in unrealized loss position	\$ 17,303	\$ (78)	\$ 9,927	\$ (135)	\$ 27,230	\$ (213)
	\$ 17,303	\$ (78)	\$ 9,927	\$ (135)	\$ 27,230	\$ (213)

5. Property and equipment

Property and equipment include the following:

	September 30, 2023	December 31, 2022
Lab equipment	\$ 101	\$ 5,706
Furniture and office equipment	3,238	3,238
Software	291	291
Total	3,630	9,235
Accumulated depreciation	(3,087)	(6,496)
Property and equipment, net	<u>\$ 543</u>	<u>\$ 2,739</u>

The Company recognized \$385 and \$1,879 and \$679 and \$2,094 of depreciation expense for the three and nine months ended September 30, 2023 and 2022, respectively.

In connection with the Agreement and Plan of Merger with Korro Bio, Inc., the Company classified certain lab equipment as held for sale in September 2023. The carrying value of the lab equipment at September 30, 2023 has been removed from property and equipment, net and is presented as assets held for sale of \$354 within current assets on the consolidated balance sheets. The Company anticipates the items classified as held for sale to be disposed of in October 2023.

6. Accrued expenses

Accrued expenses consist of the following:

	September 30, 2023	December 31, 2022
Payroll and employee related expenses	\$ 1,868	\$ 4,216
Professional fees	3,895	377
Third-party research and development expenses	29	773
Legal settlements	1,675	—
Other	380	525
Total	<u>\$ 7,847</u>	<u>\$ 5,891</u>

7. Debt

On December 11, 2020, the Company entered into a Loan and Security Agreement (Loan Agreement) with Silicon Valley Bank for a term loan with a principal balance of \$15,000. The Company made monthly interest only payments through November 30, 2022. The principal balance and interest were to be repaid in equal monthly installments after the interest only period and continue through May 1, 2024 (Loan Maturity Date). On April 3, 2023, the Company prepaid the remaining \$11,667 due under the Loan Agreement. As such, there was no interest expense for the three months ended September 30, 2023. Interest expense related to the Loan Agreement was \$284 for the nine months ended September 30, 2023 and \$263 and \$649 for the three and nine months ended September 30, 2022, respectively.

The final payment of \$150, which the Company had been accruing over the term of the loan, was also paid on April 3, 2023. The Company was not subject to any prepayment premium as the prepayment occurred after the second anniversary of the closing date.

8. Net loss per share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock. Diluted net loss per share is the same as basic net loss per share for the three and nine months ended September 30, 2023 and 2022 since all potential shares of common stock instruments are anti-dilutive as a result of the loss for such periods.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net Loss	\$ (11,614)	\$ (19,547)	\$ (41,953)	\$ (64,218)
Denominator:				
Weighted-average shares of common stock outstanding-basic and diluted	36,922,236	35,247,680	36,005,269	35,013,189
Net loss per share attributable to common stockholders-basic and diluted	\$ (0.31)	\$ (0.55)	\$ (1.17)	\$ (1.83)

The Company excluded the following potential shares of common stock from the computation of diluted net loss per share because including them would have had an anti-dilutive effect.

	Nine Months Ended September 30,	
	2023	2022
Unvested restricted stock units	1,930,150	3,101,650
Outstanding stock options	4,662,721	5,753,361
Total	6,592,871	8,855,011

9. Stockholders' equity

Preferred stock

The Company has authorized 10,000,000 shares of \$0.001 par value preferred stock of which no shares were issued or outstanding as of September 30, 2023.

Common Stock

The Company has authorized 200,000,000 shares of \$0.001 par value common stock of which there were 36,926,285 and 35,262,083 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively. Common shares are voting, and dividends may be paid when, as and if declared by the Board of Directors.

The Company has reserved the following shares of common stock for future issuance as of September 30, 2023 and December 31, 2022:

	September 30, 2023	December 31, 2022
Stock options outstanding	4,662,721	5,742,053
Shares available for future grant under incentive plans	3,016,412	988,216
	<u>7,679,133</u>	<u>6,730,269</u>

Equity Offerings

On December 10, 2021, the Company entered into an Equity Distribution Agreement (the Sales Agreement) with Oppenheimer & Co. Inc. (the Sales Agent) to sell shares of the Company's common stock, par value \$0.001 per share, with aggregate gross sales proceeds of up to \$125,000, from time to time, through an "at the market" equity offering program.

During the nine months ended September 30, 2022, the Company sold 12,767 shares of common stock under the ATM program for net proceeds of approximately \$50. No shares were sold during the three or nine months ended September 30, 2023. On September 26, 2023, the Company's ATM was terminated.

10. Stock-based compensation

Stock options

The below summary includes stock option activity within the Company's 2014 Stock Incentive Plan and 2019 Incentive Award Plan for the nine months ended September 30, 2023:

	Number of shares in Plans	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding as of December 31, 2022	5,742,053	\$ 2.35	6.69	\$ 9,114
Granted	27,350	4.66	4.66	—
Exercised	(2,969)	0.07	—	\$ 1
Forfeited	(1,103,713)	2.45	—	—
Outstanding as of September 30, 2023	<u>4,662,721</u>	\$ 2.34	6.20	\$ 3
Options exercisable as of September 30, 2023	<u>4,324,933</u>	\$ 2.35	5.92	\$ 3
Options unvested as of September 30, 2023	<u>337,788</u>	\$ 2.23	7.28	\$ —

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

Stock option valuation

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors were as follows, presented on a weighted average basis:

	September 30, 2023
Risk-free interest rate	3.6%
Expected term (in years)	6.0
Expected volatility	92.0%
Expected dividend yield	0.0%

The weighted-average grant date fair value of options granted during the three and nine months ended September 30, 2023 was \$0 and \$3.58, respectively. The weighted-average grant date fair value of options granted during the three and nine months ended September 30, 2022 was \$1.40 and \$1.60, respectively.

The total grant date fair value of options vested during the three and nine months ended September 30, 2023 was \$2,171 and \$6,672, respectively. The total grant date fair value of options vested during the three and nine months ended September 30, 2022 was \$3,100 and \$11,390, respectively.

Repricing of stock options

On August 17, 2022, the Board of Directors approved the repricing of all options granted under the 2019 Incentive Award Plan that were held by then current employees, executives, directors, and consultants for which the exercise price per share was greater than the closing price per share of the Company's common stock on August 17, 2022 (Underwater Options) by reducing the exercise price of each Underwater Option to \$2.14, the closing price per share of the Company's common stock on August 17, 2022. Except for the modification of the exercise price, all other terms and conditions of the Underwater Options remain in effect.

The option repricing resulted in incremental stock-based compensation of \$2,505, of which \$179 and \$518 was recorded as expense in the three and nine months ended September 30, 2023, respectively. At September 30, 2023, \$357 incremental expense remains which will be recognized as expense over the requisite service period in which the options vest.

Restricted stock units

The below summary includes restricted stock unit activity within the Company's 2019 Incentive Award Plan for the nine months ended September 30, 2023:

	Number of shares	Weighted average fair value
Unvested, December 31, 2022	3,101,650	\$ 2.51
Awarded	1,666,340	4.78
Vested	(1,630,150)	2.91
Forfeited	(1,207,690)	3.58
Unvested as of September 30, 2023	<u>1,930,150</u>	<u>\$ 3.47</u>

Stock-based compensation

The Company recognized stock-based compensation within the accompanying consolidated statements of operations as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	\$ 750	\$ 2,095	\$ 1,760	\$ 5,994
General and administrative	2,175	3,500	7,493	9,431
Total	<u>\$ 2,925</u>	<u>\$ 5,595</u>	<u>\$ 9,253</u>	<u>\$ 15,425</u>

As of September 30, 2023, total unrecognized stock-based compensation expense relating to unvested stock options and restricted stock units was \$9,454. This amount is expected to be recognized over a weighted-average period of 1.52 years.

11. Employee stock purchase plan

On September 20, 2019, the Company's board of directors and stockholders approved and adopted the 2019 Employee Stock Purchase Plan (the ESPP) which became effective on the date of the Company's initial public offering of shares of its common stock. The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. The number of shares of common stock available for issuance under the ESPP will be automatically increased on the first day of each calendar year during the first ten years of the term of the ESPP, beginning with January 1, 2020 and ending with January 1, 2029, by an amount equal to 1% of the outstanding number of shares of the Company's common stock on December 31 of the preceding calendar year or such lesser amount as determined by the Company's board of directors.

31,832 shares were purchased under the ESPP in January 2022 related to the second offering period of 2021, which concluded on December 31, 2021. 24,754 shares were purchased in January 2023 related to the second offering period of 2022, which concluded on December 31, 2022. 6,329 shares were purchased in July 2023 related to the first offering period of 2023, which concluded on June 30, 2023. As of September 30, 2023, a total of 1,547,065 shares remain available for future issuance under the ESPP.

12. Income taxes

The Company's total provision is based on the United States statutory rate of 21%, increased by state taxes and reduced by a full valuation allowance on the Company's deferred tax assets. The income tax expense for the three and nine months ended September 30, 2023 and 2022 represents state taxes on interest income earned by the Company's subsidiary, Frequency Therapeutics Securities Corporation, a Massachusetts Securities Corporation.

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a valuation allowance against its deferred tax assets at September 30, 2023 and December 31, 2022 because the Company's management has determined that it is more likely than not that the Company will not recognize the benefits of its federal and state deferred tax assets primarily due to its cumulative loss position.

Since inception in 2014, the Company has generated cumulative federal and state net operating loss and research and development credit carryforwards for which no net tax benefit has been recorded due to uncertainty around utilizing these tax attributes within the respective carryforward periods.

13. Collaboration agreement

In July 2019, the Company entered into a License and Collaboration Agreement with Astellas (the Astellas Agreement), under which the Company granted Astellas an exclusive, royalty-bearing, sub-licensable, nontransferable license to certain patent rights to research, develop, manufacture, have manufactured, use, seek and secure regulatory approval for, commercialize, offer for sale, sell, have sold and import, and otherwise exploit licensed products containing both a GSK-3 inhibitor and an HDAC inhibitor, (the Astellas Licensed Products), including the product candidate FX-322, outside of the United States. The Company also granted Astellas a right of first negotiation and a right of last refusal if it entered into any negotiation or agreement of any kind (other than an acquisition of all of the stock or assets of the Company) with any third party under which such third party would obtain the right to develop, manufacture, or commercialize Astellas Licensed Products in the United States.

As consideration for the licensed rights under the Astellas Agreement, Astellas paid the Company an upfront payment of \$80,000 in July 2019 and had agreed to pay potential development milestone payments up to \$230,000 and commercialization milestones of up to \$315,000. The parties had agreed to share equally, on a 50/50 basis, all out-of-pocket costs and joint study costs for all the joint activities conducted pursuant to the development plans or the joint manufacturing plan.

On April 11, 2023, Astellas sent the Company a notice stating that Astellas would be terminating the Astellas Agreement on April 14, 2023. The Company agreed to the terms of the notice and on April 14, 2023, the Astellas Agreement was terminated. The Company was not subject to any payments or costs as a result of this termination.

The Astellas Agreement contained joint research and development activities that were not within the scope of ASC 606. The Company invoiced Astellas for all joint costs. In the three and nine months ended September 30, 2023 and 2022, the Company invoiced Astellas \$0 and \$81 and \$36 and \$337, respectively, for joint costs.

14. License agreements

Massachusetts Institute of Technology

In December 2016, the Company entered into an exclusive patent license agreement (MIT License Agreement) with the Massachusetts Institute of Technology (MIT), under which the Company received an exclusive, worldwide, royalty-bearing license to certain patent rights to develop, make, have made, use, sell, offer to sell, lease and import products (Licensed Products) and to develop and perform processes (Licensed Processes) which incorporate the licensed technology for the treatment of disease, including but not limited to the prevention and remediation of hearing loss. The Company also has the right to grant sublicenses of its rights under the MIT License Agreement.

On April 6, 2023, the Company sent MIT a notice stating that the Company would be terminating the MIT License Agreement in 3-months' time. The termination became final on July 6, 2023. The Company is not subject to any payments or costs as a result of this termination.

The Scripps Research Institute (California Institute for Biomedical Research)

In September 2018, the Company entered into a license agreement, (CALIBR License Agreement), with the California Institute for Biomedical Research, (CALIBR), under which the Company received an exclusive, worldwide, royalty-bearing license to certain patent rights to make, have made, use, sell, offer to sell, and import products (CALIBR Licensed Products) which incorporate the licensed technology for the treatment of MS. The Company also has the right to grant sublicenses of its rights under the CALIBR License Agreement. CALIBR reserves the right to use for itself and the right to grant non-exclusive licenses to other nonprofit or academic institutions, for any internal research and educational purposes.

On March 29, 2023, the Company sent CALIBR a notice stating that the Company would be terminating the CALIBR License Agreement in 30 days' time. On April 28, 2023 the CALIBR License Agreement was terminated. The Company is not subject to any payments or costs as a result of this termination.

Massachusetts Eye and Ear (Formerly Massachusetts Eye and Ear Infirmary)

In February 2019, the Company entered into an Non-Exclusive Patent License Agreement (MEE License Agreement) with the Massachusetts Eye and Ear (MEE) under which it received a non-exclusive, non-sublicensable, worldwide, royalty-bearing license to certain patent rights to develop, make, have made, use, sell, offer to sell, lease and import products and to develop and perform processes which incorporate the licensed technology for the treatment or prevention of hearing loss (MEE licensed products).

On February 21, 2023, the Company sent MEE a notice stating that the Company would be terminating the MEE License Agreement in 30 business days' time. On April 4, 2023, the MEE License Agreement was terminated. The Company is not subject to any payments or costs as a result of this termination.

15. Commitments and contingencies

Contract commitments

The Company also enters into contracts in the normal course of business with contract research organizations, contract manufacturing organizations, universities, and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. These contracts generally do not contain minimum purchase commitments and are cancelable by the Company upon prior written notice although, purchase orders for clinical materials are generally non-cancelable. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancelable obligations of the Company's service providers, up to the date of cancellation or upon the completion of a manufacturing run.

Guarantees

The Company has identified the guarantees described below as disclosable, in accordance with ASC 460, *Guarantees*.

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that should limit its exposure and enable it to recover a portion of any future amounts paid.

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

The Company leases office space in Lexington, Massachusetts. On August 11, 2023, the Company entered into a termination agreement under which its operating lease will terminate on January 31, 2024. In connection with the termination agreement, the Company reduced the right of use asset and lease liabilities to reflect the remaining lease term. The \$1,699 security deposit for this lease is classified as restricted cash as of September 30, 2023. The Company has standard indemnification arrangements under this lease that require it to indemnify the landlord against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation, or nonperformance of any covenant or condition of the lease.

As of September 30, 2023, the Company had not experienced any losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves have been established.

Legal Contingencies

The Company accrues a liability for legal contingencies when it believes that it is both probable that a liability has been incurred and that the Company can reasonably estimate the amount of the loss. The Company reviews these accruals and adjusts them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and the views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in the Company's accrued liabilities would be recorded in the period in which such determination is made.

In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, the Company will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, the Company will provide disclosure to that effect. The Company expenses legal costs as they are incurred.

On June 3, 2021 and June 22, 2021, purported stockholders of the Company filed putative class action lawsuits in the U.S. District Court for the District of Massachusetts against the Company and the Company's Chief Executive Officer, President, and Director, David Lucchino. On March 21, 2022, the two lawsuits were consolidated into a single lawsuit, Quinones et al. v. Frequency Therapeutics, Inc. et al. and on May 16, 2022, the Company's Chief Development Officer, Dr. Carl LeBel, was added as a defendant. The plaintiffs alleged violations of Sections 10(b), 20(a) and Rule 10b5 of the Securities Exchange Act of 1934, as amended (the Exchange Act), due to allegedly false and misleading statements and omissions about the Company's Phase 2a clinical trial (FX-322-202) for its product candidate FX-322 in the Company's public disclosures between October 29, 2020 and March 22, 2021. The lawsuit sought, among other things, damages in connection with the Company's allegedly artificially inflated stock price between October 29, 2020 and March 22, 2021 as a result of those allegedly false and misleading statements and omissions, as well as interest, attorneys' fees and costs. The Company filed a motion to dismiss the Amended Complaint on July 15, 2022. On March 29, 2023, the Company's motion to dismiss was granted and the lawsuit was dismissed in its entirety. On April 27, 2023, Plaintiff filed a notice of appeal to the United States Court of Appeals for the First Circuit from the order dismissing the lawsuit. On August 2, 2023, Plaintiff-Appellant submitted its opening brief to the First Circuit. The Company filed its response brief on October 27, 2023. This matter is at the very early stages of the legal process, and as a result, the Company is not able to estimate a range of possible loss. Since an estimate of the possible loss or range of loss cannot be made at this time, no accruals have been recorded as of September 30, 2023.

On June 21, 2022, the Delaware Chancery Court dismissed a lawsuit brought by two purported stockholders against the Company and others. For previously reported information on this lawsuit, refer to Part I, Item 3, "Legal Proceedings" of the Company's 2021 Form 10-K. On August 16, 2022, these same two purported stockholders of the Company filed a similar lawsuit in Delaware Superior Court against (i) the Company, (ii) Computershare Inc., and (iii) Computershare Trust Company, N.A., entitled *The Gregory J. Parseghian Revocable Trust, et al. v. Frequency Therapeutics, Inc., et al.* The lawsuit alleges causes of action against the Company for breach of the statutory duty of care, negligence, conversion, and unjust enrichment, based on allegations that actions were taken to prevent the purported stockholders from selling their shares in the Company. The Company filed a motion to dismiss the complaint on November 14, 2022. On May 18, 2023, the Court issued an order granting in part and denying in part the Company's motion, dismissing the claims for breach of the statutory duty of care and unjust enrichment but leaving the remaining claims intact. On October 31, 2023, the parties reached an agreement to resolve all issues related to or arising from the allegations in the lawsuit. The Company agreed to pay \$1,675 to the two purported stockholders in exchange for a release of all claims. This payment is accrued as of September 30, 2023.

On June 30, 2022, a purported stockholder of the Company filed a shareholder derivative complaint in the U.S. District Court for the District of Delaware purportedly on the Company's behalf against members of the Company's board of directors and the Company as a nominal defendant, entitled *Dewey v. Cohen et al.* The complaint alleges (i) violations of Section 10(b) and Rule 10b5 of the Exchange Act, (ii) breach of fiduciary duty, (iii) aiding and abetting breach of fiduciary duty, (iv) unjust enrichment, and (v) waste of corporate assets. The claims are based on the same underlying allegations as the *Quinones* case (described above). The complaint seeks, among other things, monetary damages, interest, attorneys' fees and costs. On September 27, 2022, this lawsuit was stayed pending final resolution of the *Quinones* case. This matter was voluntarily dismissed by the plaintiff on October 17, 2023.

16. Sublease

On July 8, 2022, the Company entered into a Sublease Agreement with a sublessee to sublease approximately 30,040 rentable square feet of the Company's office space in Lexington, MA for a two-year term. The base sublease rent per month for the first and second year of the sublease is \$197 and \$203, respectively. In addition to base rent, the sublessee will pay 49% of operating costs and taxes payable under the Company's lease for the Lexington, MA office space. On August 11, 2023 the Company entered into a Sublease Termination Agreement with the sublessee, pursuant to which the parties agreed to terminate the Sublease Agreement on January 31, 2024. The Company is not subject to any payments or costs as a result of the termination.

Since commencement, the Company has accounted for the Lexington, MA office space as an operating lease. In accordance with ASC 842, the Company concluded the sublease is also an operating lease. The Company recognized sublease income of \$580 and \$1,766 for the three and nine months ended September 30, 2023. The below table shows the expected future sublease income as of September 30, 2023.

	Years Ending December 31,	Sublease Income
2023		574
2024		191
Total future sublease income		765

17. Restructuring

On February 13, 2023, the Company announced the topline results for the Phase 2b study of FX-322 (FX-322-208) which failed to achieve its primary efficacy endpoint of an improvement in speech perception. As a result, the Company also announced that it would be discontinuing the FX-322 and FX-345 hearing development programs and focusing resources on its remyelination in MS development program. This restructuring resulted in a 55% reduction in the Company's workforce.

In the nine months ended September 30, 2023, the Company incurred \$4,329 in restructuring-related expenses. The total restructuring charges consist of accelerated depreciation expense of \$360, accelerated hearing program expense of \$129, and severance and other benefit-related costs of \$3,840.

During the nine months ended September 30, 2023, the following restructuring-related charges were included in the Consolidated Statement of Operations:

	Severance and other benefit-related costs	Accelerated depreciation charges	Accelerated hearing program charges	Total
Research and development	\$ 2,138	\$ 360	\$ 129	\$ 2,627
General and administrative	1,702	—	—	1,702
Total	\$ 3,840	\$ 360	\$ 129	\$ 4,329

At September 30, 2023, the liability for the restructuring is classified as current and included in accrued expenses in the Consolidated Balance Sheets.

	Accelerated hearing program charges	Severance and other benefit-related costs	Total
Liability balance as of December 31, 2022	\$ -	\$ -	\$ -
Net charges	6	916	922
Liability balance as of September 30, 2023	\$ 6	\$ 916	\$ 922

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and with our Annual Report on Form 10-K for the year ended December 31, 2022, or the 2022 Annual Report, including the audited consolidated financial statements and notes thereto contained in our 2022 Annual Report. Some of the information contained in this discussion and analysis contains forward-looking statements that involve risks and uncertainties. You should review the section titled “Risk factors” in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described below.

Overview

Our business has focused on developing therapeutics that activate a person’s innate regenerative potential through our proprietary progenitor cell activation, or PCA, approach. We first applied our PCA approach for the restoration of the cochlea, with a focus on treating sensorineural hearing loss, or SNHL. Beginning in 2019, we ran five clinical studies of FX-322 aimed at understanding safety as well as severities and etiologies that FX-322 might treat and the appropriate dose regime. In 2021, we commenced our sixth study, or the FX-322-208 study, and introduced a second hearing program, FX 345, which we believed might expand the opportunity to treat different types of SNHL. In February 2023, we announced that the FX-322-208 study failed to achieve its primary endpoint of an improvement in speech perception. We decided to discontinue the FX-322 development program and, given the similarities between the mechanisms of FX-322 and FX 345, decided to discontinue the FX-345 development program as well. Following this decision, we decided to focus our efforts on developing a product candidate designed to activate oligodendrocyte precursor cells with the goal of inducing remyelination and functional recovery for individuals living with multiple sclerosis, or the MS Program, and to explore strategic alternatives for the MS Program, including the sale of the MS Program. On July 14, 2023, we and Korro Bio entered into the Merger Agreement.

On April 8, 2022, we announced a reduction in force of approximately 30% of our workforce to better align the workforce with the near-term needs of the business and focus more of our capital resources on research and development programs for hearing and remyelination in MS. On February 13, 2023, in connection with the discontinuation of the hearing program, we announced a restructuring of our business including a downsizing of personnel by approximately 55%. On May 31, 2023, we announced a reduction in force of approximately 55% of our workforce to better align our workforce with the needs of our business.

On August 11, 2023, we entered into a lease termination agreement with our landlord to terminate the lease for our Lexington, MA office on January 31, 2024. Also on August 11, 2023, we entered into a sublease termination agreement with our sublessee to terminate the sublease of our Lexington, MA office on January 31, 2024. We are not subject to any payments or costs pursuant to the lease or sublease termination agreements.

Since formation in 2014, we have devoted substantially all our resources to developing our PCA approach, conducting research and development activities, including product candidate development, recruiting skilled personnel, establishing our intellectual property portfolio, and providing general and administrative support for these operations. We have financed our operations primarily through private and public securities financings, a term loan, and amounts received under a collaboration agreement.

Since inception, we have incurred significant operating losses and have not generated any revenue from the sale of products. Our net losses were \$11.6 million, \$42.0 million and \$81.6 million for the three and nine months ended September 30, 2023 and year ended December 31, 2022, respectively. As of September 30, 2023, we had an accumulated deficit of \$303.6 million.

Our operating expenses discussed in this section reflect our development programs around FX-322, FX-345, the MS Program and contemplated future programs, as well as our operations as a public company. Following the Merger, the business of Korro Bio will be the business of the combined company, and we do not expect any further development of our product candidates or programs.

License and collaboration agreements

Astellas Pharma Inc.

In July 2019, we entered into a license and collaboration agreement, or the Astellas Agreement with Astellas Pharma, Inc., or Astellas, under which we granted Astellas an exclusive, royalty-bearing, sub-licensable, nontransferable license to certain patent rights to research, develop, manufacture, have manufactured, use, seek, and secure regulatory approval for, commercialize, offer for sale, sell, have sold and import, and otherwise exploit licensed products containing both a GSK-3 inhibitor and an HDAC inhibitor, including our product candidate FX-322, outside of the United States. On April 14, 2023, the Astellas Agreement was terminated. We are not subject to any payments or costs as a result of this termination.

Massachusetts Institute of Technology

In December 2016, we entered into an Exclusive Patent License Agreement, or the MIT License, with the Massachusetts Institute of Technology, or MIT, under which we received an exclusive, worldwide, royalty-bearing license to certain patent rights to develop, make, have made, use, sell, offer to sell, lease, and import products and to develop and perform processes that incorporate the licensed technology for the treatment of disease, including but not limited to the prevention and remediation of hearing loss. We were required to pay certain annual license maintenance fees ranging from \$30 thousand to \$0.1 million to MIT under the MIT License. On July 6, 2023, the MIT License Agreement was terminated. We are not subject to any payments or costs as a result of this termination.

Massachusetts Eye and Ear (Formerly Massachusetts Eye and Ear Infirmary)

In February 2019, we entered into a Non-Exclusive Patent License Agreement, or the MEE License, with the Massachusetts Eye and Ear, or MEE, under which we received a non-exclusive, non-sub-licensable, worldwide, royalty-bearing license to certain patent rights to develop, make, have made, use, sell, offer to sell, lease, and import products, and to develop and perform processes that incorporate the licensed technology for the treatment or prevention of hearing loss. We were obligated to pay certain annual license maintenance fees between \$5 thousand and \$7.5 thousand per each MEE patent family case number included in the licensed MEE patent rights under the MEE License. On April 4, 2023, the MEE License was terminated. We are not subject to any payments or costs as a result of this termination.

The Scripps Research Institute (California Institute for Biomedical Research)

In September 2018, we entered into a license agreement, or the CALIBR License, with the California Institute for Biomedical Research, or CALIBR, a division of Scripps, under which we received an exclusive, worldwide, royalty-bearing license to certain patent rights to make, have made, use, sell, offer to sell, and import products that incorporate licensed technology for the treatment of MS. On April 28, 2023, the CALIBR License was terminated. We are not subject to any payments or costs as a result of this termination.

Components of our results of operations

Research and development expenses

Research and development expenses presented in this section consist primarily of costs related to activities largely focused on hearing restoration and MS. These expenses include the following:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including contract research organizations, or CROs, and other third parties that conduct preclinical research and development activities and clinical trials on our behalf;
- costs to manufacture our clinical trial material for use in our preclinical studies and clinical trials;
- costs of outside consultants, including their fees and related travel expenses;
- costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- option and license payments made to third parties, including MIT, CALIBR, and MEE for intellectual property used in research and development activities; and
- facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and other operating costs if specifically, identifiable to research activities.

We track external research and development costs, including the cost of services, outsourced research and development, clinical trials, contract manufacturing, laboratory equipment and maintenance, and certain other development costs, by product candidate when the costs are specifically identifiable to a product candidate. Internal and external costs associated with infrastructure resources, other research and development costs, facility-related costs, and depreciation and amortization that are not identifiable to a specific product candidate are included in the platform development, early-stage research, and unallocated expenses category.

In connection with the Merger, we are focusing on pursuing strategic alternatives for our MS Program and expect research & development expenses incurred for the remainder of 2023 to relate to this initiative.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, business development, and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; investor and public relations costs; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities, and other operating costs that are not specifically attributable to research and development activities.

Interest income

Interest income consists of interest earned on cash equivalents and marketable securities.

Interest expense

Interest expense consists of interest paid on our term loan.

Other income, net

Other income, net consists of amortization expense and accretion income on investments as well as sublease income.

Income taxes

Our total provision is based on the United States statutory rate of 21%, increased by state taxes and reduced by a full valuation allowance on our deferred tax assets. The income tax expense for the three and nine months ended September 30, 2023 and 2022 represents state taxes on interest income earned by our subsidiary, Frequency Therapeutics Securities Corporation, a Massachusetts Securities Corporation.

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, we have recorded a valuation allowance against our deferred tax assets at December 31, 2022 because we have determined that it is more likely than not that we will not recognize the benefits of our federal and state deferred tax assets primarily due to our cumulative loss position and, as a result, a valuation allowance has been established.

Since our inception in 2014, we have generated cumulative federal and state net operating loss and research and development credit carryforwards for which we have not recorded any net tax benefit due to uncertainty around utilizing these tax attributes within their respective carryforward periods.

Results of operations

Comparison of three months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		
	2023	2022	Increase (Decrease)
	(in thousands)		
Operating expenses:			
Research and development	\$ 2,560	\$ 11,715	\$ (9,155)
General and administrative	10,105	8,560	1,545
Total operating expenses	12,665	20,275	(7,610)
Loss from operations	(12,665)	(20,275)	7,610
Interest income	448	351	97
Interest expense	-	(263)	263
Other income, net	596	617	(21)
Loss before income taxes	(11,621)	(19,570)	7,949
Income tax	7	23	(16)
Net loss	\$ (11,614)	\$ (19,547)	\$ 7,933

Research and development expenses

	Three Months Ended September 30,		
	2023	2022	Increase (Decrease)
	(in thousands)		
Direct research and development expenses by therapeutic area and product candidate:			
FX-322	\$ —	\$ 2,922	\$ (2,922)
FX-345	—	1,011	(1,011)
Multiple Sclerosis	175	1,128	(953)
Platform development, early-stage research and unallocated expenses:			
Employee-related costs	1,607	4,431	(2,824)
Laboratory supplies	2	49	(47)
Outsourced research and development	7	67	(60)
Facility-related costs	615	1,523	(908)
Depreciation and amortization	119	392	(273)
Other research and development costs	35	192	(157)
Platform development, early-stage research and unallocated expenses total	2,385	6,654	(4,269)
Total research and development expenses	\$ 2,560	\$ 11,715	\$ (9,155)

There were no costs incurred related to FX-322 for the three months ended September 30, 2023 as the program was discontinued in the first quarter of 2023 and all remaining expense was accelerated at that time. The \$3.0 million of costs related to FX-322 incurred for the three months ended September 30, 2022 consisted primarily of \$2.7 million of clinical costs associated with trials, including the Phase 2b clinical trial (FX-322-208), and \$0.1 million of drug development and manufacturing costs.

There were no costs incurred related to FX-345 for the three months ended September 30, 2023 as the program was discontinued in the first quarter of 2023 and all remaining expense was accelerated at that time. The \$1.0 million of costs related to FX-345 incurred for the three months ended September 30, 2022 consisted primarily of \$0.6 million of clinical costs associated with the Phase 1b trial and \$0.4 million of drug development and manufacturing costs.

The \$0.2 million of costs related to the MS development program incurred for the three months ended September 30, 2023 consisted primarily of clinical and regulatory costs. The \$1.1 million of costs related to the MS development program incurred for the three months ended September 30, 2022 consisted primarily of \$0.8 million of chemistry and compound characterization costs and \$0.2 million of drug development costs.

The \$2.4 million of platform development, early-stage research and unallocated expenses incurred for the three months ended September 30, 2023, consisted primarily of \$1.6 million in employee-related costs, including \$0.8 million of stock-based compensation expense, and \$0.6 million in facility-related costs. The decrease in platform development, early-stage research and unallocated expenses of \$4.3 million during the three months ended September 30, 2023, compared to the three months ended September 30, 2022, is primarily attributable to a decrease of \$2.8 million in employee-related costs, including salary, bonus, and stock-based compensation costs, as a result of the reductions in force implemented in April 2022 and February 2023, as well as a \$0.9 million decrease in facility-related costs due to a combination of reduced headcount and the initiation of cost sharing with our sublessee in connection with our sublease.

General and administrative expenses

The \$10.1 million of general and administrative expenses for the three months ended September 30, 2023 consisted primarily of \$2.9 million in employee-related costs, including \$2.2 million of stock-based compensation, \$1.5 million in facility-related costs, \$5.4 million in professional services costs, and \$0.3 million in depreciation expense. General and administrative expenses increased by \$1.5 million from the three months ended September 30, 2022 due primarily to an increase in professional service fees, particularly legal fees.

Interest income

Interest income was \$0.4 million for the three months ended September 30, 2023 and 2022.

Interest expense

There was no interest expense for the three months ended September 30, 2023 compared to interest expense of \$0.3 million for the three months ended September 30, 2022. The decrease is due to the loan prepayment in April 2023.

Other income, net

Other income, net was \$0.6 million for the three months ended September 30, 2023 and 2022.

Income tax

Income tax benefit was \$7 thousand for the three months ended September 30, 2023 as compared to income tax benefit of \$23 thousand for the three months ended September 30, 2022.

Results of operations

Comparison of nine months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		Increase (Decrease)
	2023	2022	
	(in thousands)		
Operating expenses:			
Research and development	\$ 18,509	\$ 38,769	\$ (20,260)
General and administrative	26,498	26,037	461
Total operating expenses	45,007	64,806	(19,799)
Loss from operations	(45,007)	(64,806)	19,799
Interest income	1,317	871	446
Interest expense	(284)	(649)	365
Other income, net	2,043	357	1,686
Loss before income taxes	(41,931)	(64,227)	22,296
Income tax	(22)	9	(31)
Net loss	\$ (41,953)	\$ (64,218)	\$ 22,265

Research and development expenses

	Nine Months Ended September 30,		Increase (Decrease)
	2023	2022	
	(in thousands)		
Direct research and development expenses by therapeutic area and product candidate:			
FX-322	\$ 1,081	\$ 8,583	\$ (7,502)
FX-345	647	3,493	(2,846)
Multiple Sclerosis	2,956	3,194	(238)
Platform development, early-stage research and unallocated expenses:			
Employee-related costs	9,206	15,834	(6,628)
Laboratory supplies	74	223	(149)
Outsourced research and development	73	620	(547)
Facility-related costs	3,151	4,934	(1,783)
Depreciation and amortization	1,079	1,233	(154)
Other research and development costs	242	655	(413)
Platform development, early-stage research and unallocated expenses total	13,825	23,499	(9,674)
Total research and development expenses	\$ 18,509	\$ 38,769	\$ (20,260)

The \$1.1 million of costs related to FX-322 incurred for the nine months ended September 30, 2023 consisted of clinical costs associated with the Phase 2b clinical trial (FX-322-208) which concluded in the first quarter 2023. The \$8.6 million of costs related to FX-322 incurred for the nine months ended September 30, 2022 consisted primarily of \$7.8 million of clinical costs associated with clinical trials, including the Phase 2b clinical trial (FX-322-208), and \$0.5 million of drug development and manufacturing costs.

The \$0.6 million of costs related to FX-345 incurred for the nine months ended September 30, 2023 consisted of clinical trial costs associated with the planned Phase 1b trial (FX-345-101), which was discontinued in the first quarter of 2023. The \$3.5 million of costs related to FX-345 incurred for the nine months ended September 30, 2022 consisted primarily of \$2.4 million of drug development and manufacturing costs, \$0.5 million in clinical trial costs associated with the Phase 1b trial, and \$0.2 million in regulatory fees related to the investigational new drug filing.

The \$3.0 million of costs related to the MS development program incurred for the nine months ended September 30, 2023 consisted primarily of \$1.2 million of chemistry and compound characterization costs, \$0.6 million of drug development and manufacturing costs, \$0.2 million of clinical and regulatory costs, and \$0.8 million of preclinical safety costs. The \$3.2 million of costs related to the MS development program incurred for the nine months ended September 30, 2022 consisted primarily of \$1.9 million of chemistry and compound characterization costs, \$0.4 million of preclinical safety costs, and \$0.3 million of drug development and manufacturing costs.

The \$13.8 million of platform development, early-stage research and unallocated expenses incurred for the nine months ended September 30, 2023, consisted primarily of \$9.2 million in employee-related costs, including \$1.8 million of stock-based compensation expense, and \$3.2 million in facility-related costs. The decrease in platform development, early-stage research and unallocated expenses of \$9.7 million during the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022, is primarily attributable to a decrease of \$6.6 million in employee-related costs, including salary, bonus, and stock-based compensation costs, as a result of the reductions in force implemented in April 2022 and February 2023, as well as a \$1.8 million decrease in facility-related costs due to a combination of reduced headcount and the initiation of cost sharing with our sublessee in connection with our sublease.

General and administrative expenses

The \$26.5 million of general and administrative expenses for the nine months ended September 30, 2023 consisted primarily of \$12.4 million in employee-related costs, including \$7.5 million of stock-based compensation, \$4.3 million in facility-related costs, \$9.0 million in professional services costs, and \$0.8 million in depreciation expense. General and administrative expenses increased by \$0.5 million from the nine months ended September 30, 2022 due primarily to an increase in professional service fees, particularly legal fees, partially offset by decreases in employee-related costs as a result of the reductions in force implemented in April 2022 and February 2023.

Interest income

Interest income was \$1.3 million for the nine months ended September 30, 2023 compared to interest income of \$0.9 million for the nine months ended September 30, 2022. This increase is due to the changes in investment balances from the previous year.

Interest expense

Interest expense was \$0.3 million for the nine months ended September 30, 2023 compared to interest expense of \$0.6 million for the nine months ended September 30, 2022. The decrease is due to the loan prepayment in April 2023.

Other income, net

Other income, net was \$2.0 million for the nine months ended September 30, 2023 as compared to \$0.4 million for the nine months ended September 30, 2022. This increase is due to the sublease income generated in the nine months ended September 30, 2023.

Income tax

Income tax expense was \$22 thousand for the nine months ended September 30, 2023 as compared to income tax benefit of \$9 thousand for the nine months ended September 30, 2022.

Liquidity and capital resources

Since our inception, we have incurred significant operating losses. We do not currently have any approved products and have never generated any revenue from product sales. We have financed our operations primarily through proceeds from private and public securities financings, a term loan, and amounts received under a collaboration agreement. To date, we have raised approximately \$378.3 million, including from grants and option exercises. Our cash, cash equivalents and marketable securities totaled \$41.7 million as of September 30, 2023.

In December 2020, we entered into a Loan and Security Agreement with a commercial bank for a term loan with a principal balance of \$15.0 million. We made monthly interest only payments through November 30, 2022. On April 3, 2023, we prepaid the remaining \$11.7 million due under the term loan. We were not subject to any prepayment premium as the prepayment occurred after the second anniversary of the closing date.

In December 2021, we entered into an Equity Distribution Agreement with Oppenheimer & Co. Inc., or Oppenheimer, to sell shares of our common stock, having an aggregate offering price of up to \$125.0 million, from time to time, through an “at the market” equity offering program under which Oppenheimer will act as sales agent and/or principal, or the ATM Program. During the year ended December 31, 2022, we sold 12,767 shares of common stock under the ATM Program for net proceeds of approximately \$50 thousand and paid \$2 thousand to Oppenheimer in sales agent fees. No shares of common stock have been sold under the ATM Program in 2023. On September 26, 2023, the ATM Program was terminated.

On April 8, 2022, we announced a reduction in force of approximately 30% of our workforce to better align our workforce with the needs of our business and focus more of our capital resources on our research and development programs. The total costs related to this reduction in force are approximately \$1.0 million in research and development expense and \$0.2 million in general and administrative expense, primarily related to severance costs and related expenses.

On February 13, 2023, in connection with the discontinuation of the FX-322 and FX-345 hearing programs, we announced a restructuring that included downsizing personnel by approximately 55%. These changes are expected to preserve capital, ensuring that we are appropriately resourced to complete a first clinical trial of our MS development program. The total costs related to this restructuring are approximately \$4.3 million, of which \$3.8 million is related to severance costs and related expenses, \$0.4 million is related to accelerated depreciation, and \$0.1 million is related to accelerated hearing program costs.

On May 31, 2023, we announced a reduction in force of approximately 55% of our workforce. This reduction in force was to better align our workforce with the needs of our business. The total costs related to this reduction in force are approximately \$1.1 million in research and development expense and \$22 thousand in general and administrative expense, primarily related to severance costs and related expenses.

On July 14, 2023, we entered into the Merger Agreement. Following the Merger, the business of Korro Bio will be the business of the combined company, and we do not expect any further development of our product candidates or programs.

Cash flows

The following table summarizes our sources and uses of cash for the periods presented:

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	\$ (27,358)	\$ (42,618)
Net cash provided by investing activities	31,528	6,573
Net cash (used in) provided by financing activities	(14,133)	256
Decrease in cash and cash equivalents	<u>\$ (9,963)</u>	<u>\$ (35,789)</u>

Cash flows for the nine months ended September 30, 2023

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2023 was \$27.4 million, consisting of a net loss of \$42.0 million. In addition, we had non-cash charges of \$12.8 million for depreciation, stock-based compensation expense, non-cash lease expense, and non-cash gain on investments. Net cash used in operating activities was also impacted by changes in operating assets and liabilities, including a \$4.0 million decrease prepaid expenses and other current assets, a

\$2.8 million decrease in accounts payable, and a \$1.6 million decrease in lease liabilities, partially offset by a \$2.2 million increase in accrued expenses.

The decrease in net cash used in operating activities for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily due to a \$22.3 million decrease in net loss. This decrease was partially offset by a \$6.2 million decrease in stock based compensation expense and various changes in operating assets and liabilities year over year.

Investing activities

Net cash provided by investing activities for the nine months ended September 30, 2023 was \$31.5 million, which was primarily attributable to \$33.5 million in redemptions of marketable securities, partially offset by \$2.0 million purchases of marketable securities.

The increase in net cash provided by investing activities for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily due to a \$45.0 million decrease in the purchase of marketable securities partially offset by a \$19.9 million decrease in redemptions of marketable securities.

Financing activities

Net cash used in financing activities for the nine months ended September 30, 2023 was \$14.1 million, primarily attributable to term loan repayments. This represents an increase in net cash used in financing activities when compared to the nine months ended September 30, 2022 as no such repayments were made in nine months ended September 30, 2022.

Cash flows for the nine months ended September 30, 2022

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2022 was \$42.6 million, consisting of a net loss of \$64.2 million as we incurred expenses associated with our FX-322 program, FX-345 program, MS program, platform development and early-stage research, and general and administrative expenses. In addition, we had non-cash charges of \$19.7 million for depreciation, stock-based compensation expense, non-cash lease expense, and non-cash interest expense. Net cash used in operating activities was also impacted by a net \$4.5 million decrease in operating assets and liabilities, including a \$3.2 million decrease in prepaid expenses and other current assets, a \$1.4 million decrease in lease liabilities, and a \$0.4 million decrease in accrued expenses, partially offset by a \$0.5 million increase in accounts payable.

Investing activities

Net cash provided by investing activities for the nine months ended September 30, 2022 was \$6.6 million, which was attributable to \$53.4 million in redemptions of marketable securities and \$18 thousand sales of property and equipment, partially offset by \$46.9 million purchases of marketable securities.

Financing activities

Net cash provided by financing activities for the nine months ended September 30, 2022 was primarily attributable to \$0.3 million in proceeds from the issuance of common stock and the sale of shares of common stock under the Employee Stock Purchase Plan.

Funding requirements

Following the Merger, the business of Korro Bio will be the business of the combined company, and we do not expect any further development of our product candidates or programs that would require additional funding. The funding requirements of the combined company will reflect the funding requirements for the development of Korro Bio's product candidates and programs. A discussion of Korro Bio's funding requirements can be found in the section titled "Korro Bio Management's Discussion and Analysis of Financial Condition and Results of Operations—Funding Requirements" in the prospectus filed pursuant to Rule 424(b)(3) of the Securities Act with the Securities and Exchange Commission on September 29, 2023.

Critical accounting policies and use of estimates

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make

estimates and assumptions that affect the reported amounts of assets and liabilities, 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.

Our significant accounting policies are described in more detail in the notes to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. During the nine months ended September 30, 2023, there were no material changes to our critical accounting policies from those described in our Annual Report on Form 10-K filed with the SEC on March 10, 2023.

Recent accounting pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations, or cash flows is disclosed in Note 2 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Emerging growth company status

The Jumpstart Our Business Startups Act of 2012 permits an “emerging growth company,” such as us, to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to take advantage of this extended transition period.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

This item is not required as we are currently considered a small reporting company.

Item 4. Controls and Procedures.**Limitations on Effectiveness of Controls and Procedures**

Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Vice President of Finance and Operations (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2023. Based on that evaluation, our Chief Executive Officer and Vice President of Finance and Operations concluded that, as of September 30, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

See Note 15, “Commitments and contingencies – Legal Contingencies”, for more information.

Item 1A. Risk Factors.

Except as set forth below, the risk factors set forth under the caption “Risk Factors” in our [prospectus filed pursuant to Rule 424\(b\)\(3\) of the Securities Act](#) with the SEC on September 29, 2023 (File No. 333-273490) are incorporated by reference in this section.

Risks related to Frequency’s financial position and need for additional capital

Frequency has incurred significant losses since inception and anticipates that Frequency will continue to incur losses for the foreseeable future. Frequency is not currently profitable, and Frequency may never achieve or sustain profitability. If Frequency is unable to achieve or sustain profitability, the market value of Frequency common stock will likely decline.

Frequency is a preclinical-stage biotechnology company with a limited operating history. As a result, Frequency is not profitable and has incurred significant losses since the formation. Frequency had net losses of \$11.6 million, \$42.0 million and \$81.6 million for the three and nine months ended September 30, 2023 and year ended December 31, 2022, respectively. As of September 30, 2023, Frequency had an accumulated deficit of \$303.6 million. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to gain regulatory approval and become commercially viable. Frequency has not commercialized any products and has never generated revenue from the commercialization of any product. To date, Frequency has devoted most of its financial resources to licensing technologies and research and development, including its preclinical platform development activities and clinical trials.

Frequency expects to incur significant additional operating losses to advance any product candidate, including a potential therapeutic candidate for MS, through clinical development, clinical trials, regulatory approval and commercialization. The costs of advancing product candidates into each clinical phase tend to increase substantially over the duration of the clinical development process. Therefore, the total costs to advance any product candidate to marketing approval in even a single jurisdiction are substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, Frequency is unable to accurately predict the timing or amount of increased expenses or when, or if, Frequency will be able to begin generating revenue from the commercialization of any product candidates or achieve or maintain profitability. Frequency’s expenses will also increase substantially if Frequency:

- develops and commences clinical trials for any product candidate, including for its MS Program;
- expands its development programs based on its PCA approach;
- further develops its PCA approach;
- seeks regulatory approvals for any other product candidates;
- secures a commercial manufacturing source and supply chain capacity sufficient to produce commercial quantities of any product candidate for which Frequency obtains regulatory approval;
- establishes a sales, marketing and distribution infrastructure to commercialize any product candidates, if approved;
- maintains, expands, and protects its intellectual property portfolio; and
- acquires or in-licenses other product candidates or technologies.

Furthermore, Frequency’s ability to successfully develop, commercialize and license any product candidates and generate product revenue is subject to substantial additional risks and uncertainties, as described under “Risks related to development, clinical testing, manufacturing, and regulatory approval” and “Risks related to commercialization.” As a result, Frequency expects to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on Frequency’s stockholders’ equity and working capital. The amount of its future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenues. If Frequency is unable to develop and commercialize one or more product candidates, either alone or through collaborations, or if revenues from any product that receives marketing approval are insufficient, Frequency will not

achieve profitability. Even if Frequency successfully commercializes any product candidates, Frequency may continue to incur substantial research and development and other expenses to identify and develop other product candidates. Even if Frequency does achieve profitability, Frequency may not be able to sustain profitability or meet outside expectations for its profitability. If Frequency is unable to achieve or sustain profitability or to meet outside expectations for its profitability, the value of Frequency common stock will be materially adversely affected.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities.

In October 2019, we completed our IPO and issued and sold 6,325,000 shares of our common stock (including 325,000 shares of our common stock in connection with the full exercise of the underwriters' option to purchase additional shares) at a price to the public of \$14.00 per share. We received approximately \$79.7 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus, dated October 2, 2019, filed with the SEC pursuant to Rule 424(b) relating to our registration statement on Form S-1 on October 4, 2019.

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

- a) Not applicable.
- b) Not applicable.
- c) We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
2.1 [^]	Agreement and Plan of Merger, dated July 14, 2023, by and among Frequency Therapeutics, Inc., Frequency Merger Sub, Inc., and Korro Bio, Inc.	8-K	001-39062	2.1	7/14/23	
3.1	Restated Certificate of Incorporation of Frequency Therapeutics, Inc.	8-K	001-39062	3.1	10/7/19	
3.2	Amended and Restated Bylaws of Frequency Therapeutics, Inc.	8-K	001-39062	3.1	9/23/20	
4.1	Second Amended and Restated Investors' Rights Agreement, dated as of July 17, 2019	S-1	333-233652	4.2	9/6/19	
10.1	Form of Support Agreement by and between Frequency Therapeutics, Inc. and certain stockholders of Korro Bio, Inc.	8-K	001-39062	10.1	7/14/23	
10.2	Form of Support Agreement by and between Korro Bio, Inc. and certain stockholders of Frequency Therapeutics, Inc.	8-K	001-39062	10.1	7/14/23	
10.3	Form of Lock-Up Agreement by and between Korro Bio, Inc. and directors, officers and certain stockholders of Korro Bio, Inc.	8-K	001-39062	10.1	7/14/23	
10.4	Form of Lock-Up Agreement by and between Korro Bio, Inc. and directors and officers of Frequency Therapeutics, Inc.	8-K	001-39062	10.1	7/14/23	
10.5	Form of CVR Agreement.	8-K	001-39062	10.1	7/14/23	
10.6	Separation Agreement, dated as of July 28, 2023, by and between Frequency Therapeutics, Inc. and Christopher Loose	8-K	001-39062	10.1	7/31/23	
31.1	Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a) / 15d-14(a) Certification of Vice President of Finance and Operations					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Vice President of Finance and Operations					**

101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	***
101.SCH	Inline XBRL Taxonomy Extension Schema Document	***
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	***
101.DEF	Inline XBRL Extension Definition Linkbase Document	***
101.LAB	Inline XBRL Taxonomy Label Linkbase Document	***
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	***
104	The cover page for the Company’s Quarterly Report on Form 10-Q has been formatted in Inline XBRL and contained in Exhibit 101.	***

* Filed herewith

** Furnished herewith

*** Submitted electronically herewith

^ Registrant has omitted schedules and exhibits pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

FREQUENCY THERAPEUTICS, INC.

Date: November 2, 2023

By: _____
/s/ David L. Lucchino
David L. Lucchino
President and Chief Executive Officer
(principal executive officer)

Date: November 2, 2023

By: _____
/s/ Richard Mitrano
Richard Mitrano
Vice President, Finance and Operations
(principal financial officer and principal accounting officer)

