

**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, 2019

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)
19 Presidential Way, 2nd Floor
Woburn, MA
(Address of principal executive offices)

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

01801
(Zip Code)

Registrant's telephone number, including area code: (866) 389-1970

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 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 October 31, 2019, the registrant had 30,784,936 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 our future results of operations and financial position, business strategy, product candidates, clinical development plans and expectations, prospective products, product approvals, research and development costs, timing and likelihood of success, and plans and objectives of management for future operations and results, 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, the following:

- the initiation, timing, progress and results of our preclinical and clinical trials and research and development of programs, including our ongoing Phase 2a clinical trial for FX-322 and our program to develop a product candidate for the treatment of multiple sclerosis, or MS;
- our ability to continue to develop our progenitor cell activation, or PCA, platform and identify additional product candidates;
- our ability to successfully complete clinical trials of any product candidate and obtain regulatory approval for it;
- the timing or likelihood of regulatory filings and approvals, including our planned filing of an investigational new drug application for our MS product candidate;
- the commercialization, marketing and manufacture of any product candidate, if approved;
- the pricing and reimbursement of any product candidate, if approved;
- the rate and degree of market acceptance and clinical utility of any products for which we receive regulatory approval;
- the implementation of our strategic plans for our business, product candidates, and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, PCA platform, and technology;
- estimates of our expenses, future revenues, capital requirements, and our needs for additional financing;
- our ability to maintain and establish collaborations, including our License and Collaboration Agreement with Astellas Pharma Inc.;
- our financial performance and the sufficiency of our financial resources; and
- developments relating to our competitors and our industry, including the impact of government regulation.

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)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 142,274	\$ 42,189
Short-term marketable securities	23,047	—
Prepaid expenses and other current assets	1,400	748
Total current assets	166,721	42,937
Property and equipment, net	1,566	1,511
Deferred financing costs	2,461	—
Other assets	101	100
Total assets	\$ 170,849	\$ 44,548
Liabilities, Convertible Preferred Stock, Non-Controlling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 3,574	\$ 1,863
Royalty payable	16,000	—
Accrued expenses	3,100	1,749
Current portion of deferred revenue	49,362	—
Other current liabilities	168	161
Total current liabilities	72,204	3,773
Deferred revenue - net of current portion	6,400	—
Long-term liabilities	222	349
Total liabilities	78,826	4,122
Series C convertible preferred stock, \$0.001 par value; 39,493,348 shares authorized at September 30, 2019: 39,492,960 shares issued and outstanding at September 30, 2019; no shares authorized, issued or outstanding at December 31, 2018	62,701	—
Series B convertible preferred stock, \$0.001 par value; 44,319,839 shares authorized at September 30, 2019 and December 31, 2018; 42,145,996 and 41,857,005 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	38,490	38,224
Series B-1 convertible preferred stock, \$0.001 par value; 10,000 shares authorized, issued and outstanding at September 30, 2019 and December 31, 2018	9	9
Series A convertible preferred stock, \$0.001 par value; 64,891,735 shares authorized at September 30, 2019 and December 31, 2018; 62,528,507 shares issued and outstanding at September 30, 2019 and December 31, 2018	46,694	46,694
Series A-1 convertible preferred stock, \$0.001 par value; 10,000 shares authorized, issued and outstanding at September 30, 2019 and December 31, 2018	8	8
Non-controlling interest	3,773	3,773
Stockholders' equity (deficit):		
Common stock, \$0.001 par value; 100,000,000 and 165,000,000 shares authorized at September 30, 2019 and December 31, 2018, respectively; 2,382,309 and 2,084,710 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	2	2
Additional paid-in capital	3,585	804
Accumulated other comprehensive income	116	—
Accumulated deficit	(63,355)	(49,088)
Total stockholders' deficit	(59,652)	(48,282)
Total liabilities, convertible preferred stock, non-controlling interest and stockholders' deficit	\$ 170,849	\$ 44,548

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

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,	
	2019	2018	2019	2018
Revenue	\$ 24,238	\$ —	\$ 24,238	\$ —
Operating expenses:				
Royalty	16,000	—	16,000	—
Research and development	5,221	3,550	12,588	8,959
General and administrative	4,269	1,507	9,837	4,660
Total operating expenses	<u>25,490</u>	<u>5,057</u>	<u>38,425</u>	<u>13,619</u>
Loss from operations	(1,252)	(5,057)	(14,187)	(13,619)
Interest income	624	—	842	—
Interest expense	—	(63)	—	(95)
Realized gain on investments	62	—	88	—
Foreign exchange gain (loss)	(9)	(16)	4	(7)
Net loss	(575)	(5,136)	(13,253)	(13,721)
Cumulative Series C convertible preferred stock dividends	(1,014)	—	(1,014)	—
Net loss attributable to common stockholders	\$ (1,589)	\$ (5,136)	\$ (14,267)	\$ (13,721)
Net loss per share attributable to common stockholders-basic and diluted	\$ (0.73)	\$ (3.26)	\$ (7.17)	\$ (9.29)
Weighted average shares outstanding-basic and diluted	<u>2,163,289</u>	<u>1,575,728</u>	<u>1,990,106</u>	<u>1,476,678</u>

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

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

	Three Months Ended September 30,		Nine Month Ended September 30,	
	2019	2018	2019	2018
Net loss	\$ (575)	\$ (5,136)	\$ (13,253)	\$ (13,721)
Other comprehensive gain (loss):				
Unrealized gain (loss) on marketable securities	(34)	—	116	—
Total comprehensive gain (loss)	(34)	—	116	—
Comprehensive loss	\$ (609)	\$ (5,136)	\$ (13,137)	\$ (13,721)

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

Frequency Therapeutics, Inc.

Consolidated Statement of Convertible Preferred Stock, Non-controlling Interest and Stockholders' Deficit (in thousands, except share and per share amounts) (unaudited)

	Series C convertible preferred shares issued	Series C convertible preferred value	Series B convertible preferred shares issued	Series B convertible preferred value	Series B-1 convertible preferred shares issued	Series B-1 convertible preferred value	Series A convertible preferred shares issued	Series A convertible preferred value	Series A-1 convertible preferred shares issued	Series A-1 convertible preferred value	Non-controlling interest	Common shares issued	Common par value	Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' deficit
Balance, December 31, 2018	—	\$ —	41,857,005	\$ 38,224	10,000	\$ 9	62,528,507	\$ 46,694	10,000	\$ 8	\$ 3,773	2,084,710	\$ 2	\$ 804	—	\$ (49,088)	\$ (48,282)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	2,456	—	—	2,456
Issuance of common stock upon exercise of options	—	—	—	—	—	—	—	—	—	—	—	297,599	—	325	—	—	325
Issuance of Series B convertible preferred stock	—	—	288,991	266	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock	39,492,960	61,687	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Accretion of Series C preferred dividend	—	1,014	—	—	—	—	—	—	—	—	—	—	—	—	—	(1,014)	(1,014)
Accumulated other	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Comprehensive income	—	—	—	—	—	—	—	—	—	—	—	—	—	—	116	—	116
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(13,253)	(13,253)
Balance, September 30, 2019	39,492,960	\$ 62,701	42,145,996	\$ 38,490	10,000	\$ 9	62,528,507	\$ 46,694	10,000	\$ 8	\$ 3,773	2,382,309	\$ 2	\$ 3,585	116	\$ (63,355)	\$ (59,652)
Balance, June 30, 2019	—	—	42,145,996	\$ 38,490	10,000	\$ 9	62,528,507	\$ 46,694	10,000	\$ 8	\$ 3,773	2,304,268	\$ 2	\$ 2,499	150	\$ (61,766)	\$ (59,115)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	925	—	—	925
Issuance of common stock upon exercise of options	—	—	—	—	—	—	—	—	—	—	—	78,041	—	161	—	—	161
Issuance of Series C convertible preferred stock	39,492,960	61,687	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Accretion of Series C preferred dividend	—	1,014	—	—	—	—	—	—	—	—	—	—	—	—	—	(1,014)	(1,014)
Accumulated other	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Comprehensive income	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(34)	—	(34)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(575)	(575)
Balance, September 30, 2019	39,492,960	\$ 62,701	42,145,996	\$ 38,490	10,000	\$ 9	62,528,507	\$ 46,694	10,000	\$ 8	\$ 3,773	2,382,309	\$ 2	\$ 3,585	116	\$ (63,355)	\$ (59,652)

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

Frequency Therapeutics, Inc.

Consolidated Statement of Convertible Preferred Stock, Non-controlling Interest and Stockholders' Deficit – (continued) (in thousands, except share and per share amounts) (unaudited)

	Series A convertible preferred shares issued	Series A convertible preferred value	Non-controlling interest	Common shares issued	Common par value	Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' deficit
Balance, December 31, 2017	62,528,507	\$ 46,694	\$ —	1,954,235	\$ 2	\$ 276	—	\$ (29,920)	\$ (29,642)
Stock-based compensation expense	—	—	—	—	—	267	—	—	267
Issuance of common stock upon exercise of options	—	—	—	113,402	—	70	—	—	70
Non-controlling interest	—	—	1,772	—	—	—	—	—	—
Accumulated other Comprehensive income	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(13,721)	(13,721)
Balance, September 30, 2018	62,528,507	\$ 46,694	\$ 1,772	2,067,637	\$ 2	\$ 613	—	\$ (43,641)	\$ (43,026)
	Series A convertible preferred shares issued	Series A convertible preferred value	Non-controlling interest	Common shares issued	Common par value	Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' deficit
Balance, June 30, 2018	62,528,507	\$ 46,694	\$ 1,772	2,016,966	\$ 2	\$ 480	—	\$ (38,505)	\$ (38,023)
Stock-based compensation expense	—	—	—	—	—	102	—	—	102
Issuance of common stock upon exercise of options	—	—	—	50,671	—	31	—	—	31
Issuance of Series C convertible preferred stock	—	—	—	—	—	—	—	—	—
Accretion of Series C preferred dividend	—	—	—	—	—	—	—	—	—
Accumulated other Comprehensive income	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(5,136)	(5,136)
Balance, September 30, 2018	62,528,507	\$ 46,694	\$ 1,772	2,067,637	\$ 2	\$ 613	—	\$ (43,641)	\$ (43,026)

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

Frequency Therapeutics, Inc.

Consolidated Statements of Cash Flows (in thousands) (unaudited)

	Nine Months Ended, September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (13,253)	\$ (13,721)
Adjustments to reconcile net loss to net cash provided in operating activities:		
Stock based compensation	2,456	267
Depreciation expense	588	444
Deferred lease incentives	(120)	(121)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(652)	(629)
Deferred financing costs and other assets	(1)	3
Accounts payable	1,711	1,107
Royalty payable	16,000	—
Deferred revenue	55,762	—
Accrued expenses and other current liabilities	1,467	345
Net cash provided by (used in) operating activities	<u>63,958</u>	<u>(12,305)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(643)	(197)
Redemption of available for sale securities	245,771	—
Purchase of available for sale securities	(268,818)	—
Net cash used in investing activities	<u>(23,690)</u>	<u>(197)</u>
Cash flows from financing activities:		
Proceeds from sale of non-controlling interest	—	1,772
Proceeds from notes payable	—	5,000
Proceeds from issuance of Series B convertible preferred stock	266	—
Proceeds from issuance of Series C convertible preferred stock, net of issuance costs	61,687	—
Proceeds from issuance of common stock	325	70
Deferred financing costs	(2,461)	—
Net cash provided by financing activities	<u>59,817</u>	<u>6,842</u>
Net increase (decrease) in cash and cash equivalents	100,085	(5,660)
Cash and cash equivalents at beginning of period	42,189	17,937
Cash and cash equivalents at end of period	<u>\$ 142,274</u>	<u>\$ 12,277</u>
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 71	\$ —
Dividend on Series C convertible preferred stock	\$ 1,014	\$ —

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

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 and its majority owned subsidiary, Frequency Therapeutics Japan KK (Frequency Japan) (the Company), headquartered in Woburn, Massachusetts, was incorporated in November 2014 as a Delaware corporation. The Company is a clinical-stage biotechnology company focused on harnessing the body's innate biology to repair or reverse damage caused by a broad range of degenerative diseases.

On September 20, 2019, the Company effected a 1-for-6.7355 reverse stock split of its common stock. The par value of the common stock was not adjusted as a result of the reverse stock split and the authorized capital was amended to 100,000,000 shares of common stock and 148,724,922 shares of \$0.001 par value preferred stock (the Preferred Stock). The reverse stock split resulted in an adjustment to the Series A Preferred Stock (Series A Preferred), Series B Preferred Stock (Series B Preferred) and Series C Preferred Stock (Series C Preferred) conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying unaudited consolidated financial statements and notes to the unaudited consolidated financial statements give retroactive effect to the reverse stock split for all periods presented. Shares of common stock underlying outstanding stock options were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the appropriate securities agreements.

In October 2019, the Company completed the initial public offering of its common stock (the "IPO"). In the IPO, the Company issued and sold 6,325,000 shares of its common stock at a price to the public of \$14.00 per share, inclusive of the underwriters exercise in part of their over-allotment option. The Company received approximately \$79.2 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses. In connection with the IPO, on October 7, 2019 all Preferred Stock and the preferred stock of Frequency Japan converted into 22,077,629 shares of common stock and all outstanding shares of Series A-1 and B-1 Preferred were forfeited. The consolidated financial statements, including share and per share amounts, do not give effect to the IPO or the related conversion of securities into shares of common stock.

Uncertainties

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

Liquidity and capital resources

The Company has funded its operations primarily with proceeds from the sale of its capital stock, convertible notes and amounts received under a collaboration agreement. The Company has incurred recurring losses since its inception. In addition, as of September 30, 2019, the Company had an accumulated deficit of \$63.4 million. 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 along with the proceeds from the IPO will be sufficient to fund planned operations for at least 12 months from the date the financial statements were available to be issued.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies

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 PTY, LTD and Frequency Therapeutics Securities Corporation and its majority owned subsidiary Frequency Japan. All intercompany transactions and balances have been eliminated.

Unaudited interim financial information

The accompanying consolidated balance sheet as of September 30, 2019, the consolidated statements of operations, for the three and nine months ended September 30, 2019 and 2018 and the consolidated statements of convertible preferred stock, non-controlling interest and stockholders' deficit and cash flows for the nine months ended September 30, 2019 and 2018 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, 2019, the results of its operations for the three and nine months ended September 30, 2019 and 2018, and cash flows for the nine months ended September 30, 2019 and 2018. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2019 and 2018 are also unaudited. The results for the nine months ended September 30, 2019 are not necessarily indicative of results to be expected for the year ending December 31, 2019, any other interim periods, or any future year or period. The consolidated balance sheet as of December 31, 2018 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, 2018 included in the Company's final prospectus dated October 2, 2019 for the IPO filed with the SEC on October 4, 2019 pursuant to Rule 424(b)(4) relating to our Registration Statement on Form S-1 (File No. 333-233652).

Use of estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of revenues and expenses during the reporting period. On an ongoing basis, the Company's management evaluates its estimates, which include but are not limited to management's judgments of revenue, accrued expenses, fair value of common stock, valuation of share-based awards and income taxes. Actual results could differ from those estimates.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company has utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation (the Practice Aid), to estimate the fair value of its common stock. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

Comprehensive income (loss)

Components of comprehensive income or loss, including net income or loss, are reported in the financial statements in the period in which they are recognized. Other comprehensive income or loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss) are reported net of any related tax effect to arrive at comprehensive income (loss). Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. The Company's comprehensive loss includes its net loss and unrealized gain on marketable securities.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker, the Company's chief executive officer, views the Company's operations and manages its business as a single operating segment, which is the business of discovering and developing small molecule drugs that activate progenitor cells within the body to create healthy tissue.

Foreign currency

All periods presented are reported in US dollars. The functional currency for entities outside the United States is the US dollar. Realized and unrealized gains and losses from foreign currency transactions are reflected in the consolidated statements of operations as other expense. During the three and nine months ended September 30, 2019, the Company recorded (\$9) and \$4 of foreign currency exchange gains (losses), respectively. During the three and nine months ended September 30, 2018, the Company recorded (\$16) and (\$7) of foreign currency exchange losses, respectively.

Cash and cash equivalents

The Company considers all highly liquid investments with an original maturity of ninety days or less at acquisition to be cash equivalents which are stated at fair market value. Cash and cash equivalents at December 31, 2018 consists of cash held in banks. Cash and cash equivalents at September 30, 2019 consists of cash held in banks and money market funds.

Short-term marketable debt securities

Short-term marketable securities represent holdings of available-for-sale marketable debt securities in accordance with the Company's investment policy. Short-term marketable investments mature within one-year from the balance sheet date. Investments in marketable securities are recorded at fair value, with any unrealized gains and losses reported within accumulated other comprehensive income as a separate component of stockholders' equity (deficit) until realized or until a determination is made that an other-than-temporary decline in market value has occurred. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion, together with interest on securities, are included in interest income on the Company's consolidated statements of operations. The cost of marketable securities sold is determined based on the specific identification method and any realized gains or losses on the sale of investments are reflected as a component of other income (expense).

Short – term marketable securities at September 30, 2019 consist of investments in U.S. Treasury Securities.

Concentration of credit risk and off-balance sheet risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. The Company maintains its cash and cash equivalents at several accredited financial institutions, in amounts that exceed federally insured limits. Marketable securities consist of U.S. Treasury securities with maturities of less than twelve months. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which its money market accounts are maintained.

The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

Significant suppliers

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including preclinical and clinical testing. In particular, the Company relies and expects to continue to rely on a single manufacturer of its product candidates for use in clinical trials. The Company would be adversely affected by a significant interruption in the supply of product for use in clinical programs.

Fair value measurements

Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability between market participants at measurement dates. ASC Topic 820, *Fair Value Measurement* (ASC 820), establishes a three-level valuation hierarchy for instruments measured at fair value. The hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The hierarchy defines three levels of valuation inputs, of which the first two are considered observable and the last is considered unobservable:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.
- Level 3 Unobservable inputs developed using estimates or assumptions developed by the Company, which reflect those that a market participant would use in pricing the asset or liability.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying values of other current assets, accounts payable, and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Impairment of long-lived assets

The Company continually evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. The Company did not recognize any impairment losses for the nine months ended September 30, 2019 and 2018.

Research and development costs and accruals

Research and development expenses include salaries and benefits, materials and supplies, preclinical and clinical trial expenses, stock-based compensation expense, depreciation of equipment, contract services and other outside expenses. The Company has entered into various research and development-related contracts with research institutions, contract research organizations, contract manufacturers and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. Costs of certain development activities, such as manufacturing, pre-clinical and clinical trial expenses, are recognized based on an evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. Costs incurred in obtaining technology licenses are charged to research and development expenses as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed as a charge to operating expenses. As of September 30, 2019, \$2,461 of deferred offering costs were included in the accompanying consolidated balance sheet related to the IPO. There were no deferred offering costs at December 31, 2018.

Patent costs

The Company expenses patent application and related legal costs as incurred and classifies such costs as general and administrative expenses in the accompanying consolidated statements of operations.

Stock-based compensation

The Company accounts for its stock-based compensation in accordance with ASC Topic 718, *Compensation—Stock Compensation* (ASC 718). ASC 718 requires all share-based payments to employees and directors to be recognized as expense in the consolidated statements of operations and comprehensive loss based on their grant date fair values. The Company adopted FASB Accounting Standards Update (ASU) 2016-09 which identifies areas for simplification of several areas of share-based payment transactions. The Company retroactively applied the mark to market approach on vesting to non-employee grants and the impact on the consolidated financial statements was not material. Going forward, the Company will treat non-employee grants the same as employee grants. The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. The Company believes the fair value of the stock options granted to non-employees is more reliably determinable than the fair value of the services provided.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for the Company's common stock prior to the IPO and a lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No.107, Share-Based Payment, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the contractual term of the share-based payment as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

There are significant judgments and estimates inherent in the determination of the fair value of the Company's common stock. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to its common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale.

The Company expenses the fair value of its share-based compensation awards to employees and non-employees on a straight-line basis over the requisite service period, which is generally the vesting period.

Non-controlling interest

The Company accounts for shares of preferred stock issued in Frequency Japan as a non-controlling interest in the temporary equity section of the consolidated balance sheets. The value ascribed to the non-controlling interest is the liquidation preference of the preferred stock in Frequency Japan as the holders of such shares do not share in any profits or losses of the subsidiary.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

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, 2019 and 2018 since all potential shares of common stock instruments are anti-dilutive as a result of the loss for such periods.

The Company's Preferred Stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods where the Company reports a net loss attributable to common stockholders, diluted net loss per share is the same as basic net loss per share, since dilutive shares of common stock are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the three and nine months ended September 30, 2019 and 2018.

Collaborative arrangements

The Company analyzes its collaborative arrangements to assess whether they are within the scope of ASC 808, Collaborative Arrangements ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship (e.g., a licensing arrangement) where the contracted party has obtained goods or services that are an output of the Company's ordinary activities in exchange for a consideration and therefore within the scope of Topic 606. For those elements of the arrangement that are accounted for pursuant to Topic 606, including those to which Topic 606 is applied by analogy, the Company applies the five-step model described in the Company's revenue recognition policy. For elements of collaborative arrangements that are accounted for pursuant to ASC 808, an appropriate and rational recognition method is determined and applied consistently. Reimbursements from the counter-party that are the result of a collaborative relationship with the counter-party, instead of a customer relationship, such as co-development or clinical activities, are recorded as a reduction to research and development expense as the services are performed. Similarly, amounts that are owed to a collaboration partner related to the co-development clinical activities are recognized as research and development expense.

The Company enters into out-licensing agreements that are within the scope of Topic 606. The terms of such out-license agreements include licenses to functional intellectual property (IP), given the functionality of the intellectual property is not expected to change substantially as a result of the licensor's ongoing activities. Such arrangements typically include payment of one or more of the following: non-refundable up-front license fees; reimbursement of certain costs; development and regulatory milestone payments and milestone payments based on the level of sales; and royalties on net sales of licensed products.

The Company considers the economic and regulatory characteristics of the licensed IP, research, development, manufacturing and commercialization capabilities of the licensee and the availability of the associated expertise in the general marketplace to determine if it has standalone value at the inception of the licensing arrangement, which would make the license distinct. In addition, the Company considers whether the licensee can benefit from a promise for its intended purpose without the receipt of any additional good or services promised in the contract, whether the value of the license is dependent on the remaining goods and services, whether there are other vendors that could provide the remaining promise, and whether the license is separately identifiable from the remaining good and services. For licenses that are combined with other goods and services, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

Revenue is allocated to the licensed IP on a relative standalone selling price basis and, for functional IP, is recognized at a point when the licensed IP is made available for the customer's use and benefit, which generally occurs at the inception of the arrangement. However, in cases, where the functionality of the IP is expected to substantively change as a result of activities of the Company that do not transfer additional promised goods or services, or in cases, where there is an expectation that the Company will undertake activities to change the standalone functionality of the IP and the customer is contractually or practically required to use the latest version of the IP, revenue for the license to functional IP is recognized over time.

Development and regulatory milestone fees, which are a type of variable consideration, are recognized as revenue to the extent that it is probable that a significant reversal will not occur. The Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

The Company has entered into a collaboration arrangement with Astellas Pharma Inc. ("Astellas"), as further described in Note 13 of notes to unaudited consolidated financial statements.

Revenue recognition

The Company accounts for contracts with customers in accordance with Accounting Standards Codification ("ASC"), Topic 606, Revenue from Contracts with Customers ("Topic 606"), including all amendments thereto. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as collaborative arrangements and leases. The Company's disclosure within the below sections or elsewhere within these unaudited consolidated financial statements reflects the Company's accounting policies in compliance with this new standard.

Under Topic 606, an entity recognizes revenue when or as its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To recognize revenue for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies its performance obligations. The Company only applies the five-step model to contracts when it is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and identifies as a performance obligation each promise to transfer to the customer either (a) a good or service (or bundle of goods and services) that is distinct, or (b) a series of distinct goods and services that are substantially the same and have been the same pattern of transfer to the customer.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner (the "customer" in this type of arrangement) and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. For each arrangement that results in revenues, the Company identifies all performance obligations, which may include, for example, a license to IP and know-how, research and development activities, and/or manufacturing services.

In addition to any upfront payment, if the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the estimated variable consideration in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or of the licensee such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

For contracts that include sales-based royalties (including milestone payments based on the level of sales) promised in the exchange for licenses of intellectual property, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestone payments at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied. In determining the transaction price, the Company adjusts the promised amount of consideration for the effects of the time value of money if the timing of payments provides the Company or the Company's customer with a significant benefit of financing the transfer of goods and services. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. The Company assesses each of its revenue generating arrangements in order to determine whether a significant financing component exists. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time. For performance obligations satisfied over time, the Company measures progress toward completion of its performance obligations using an input method based on the Company's efforts and inputs to satisfy its performance obligations relative to total expected inputs to the satisfaction of that performance obligation.

Amounts received from a customer prior to revenue recognition are recorded as deferred revenue. Amounts received from a customer that are expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying unaudited consolidated balance sheets. Amounts received from a customer that are not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Recently issued accounting pronouncements

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 considered to be an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (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. We have elected to avail ourselves of this extended transition period and, as a result, we 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 February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), as amended by various subsequently issued ASUs. The standard requires lessees to recognize an operating lease with a term greater than one year on their balance sheets as a right-of-use asset and corresponding lease liability, measured at the present value of the lease payments. Lessees are required to classify leases as either finance or operating leases. If the lease is effectively a financed purchase by the lessee, it is classified as a financing lease, otherwise it is classified as an operating lease. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. In July 2018, the FASB also issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements* ("ASU 2018-11"), which permits entities to continue applying legacy guidance in ASC 840, *Leases*, including its disclosure requirements, in the comparative periods presented in the year that the entity adopts the new leasing standard. The new standard will be effective for the Company on January 1, 2021. The Company will apply the transition method permitted by ASU 2018-11. The Company is currently evaluating the effect that adoption of the standard is expected to have on the Company's consolidated financial statements and related disclosures. The Company expects to take advantage of certain available expedients by electing the transition package of practical expedients permitted within ASU 2016-02, which allows the Company to not reassess previous accounting conclusions around whether arrangements are, or contain, leases, the classification of leases, and the treatment of initial direct costs. The Company also expects to make an accounting policy election to exclude leases with an initial term of twelve months or less from the balance sheet.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

3. Fair value measurements

The Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy at September 30, 2019 are summarized as follows:

	Fair Value Hierarchy	Amortization Cost	Unrealized Gain	Fair Market Value
Money market funds	Level 1	\$ 141,101	\$ —	\$ 141,101
U.S. Government treasury securities	Level 1	22,931	116	23,047
		<u>\$ 164,032</u>	<u>\$ 116</u>	<u>\$ 164,148</u>

The Company had no financial assets subject to fair value reporting requirements at December 31, 2018.

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

4. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following:

	September 30, 2019	December 31, 2018
Grants receivable	\$ 408	\$ 161
Research and development expenses	685	428
Other	307	159
Total	<u>\$ 1,400</u>	<u>\$ 748</u>

5. Property and equipment

Property and equipment consisted of the following:

	September 30, 2019	December 31, 2018
Lab equipment	\$ 1,689	\$ 1,109
Computer equipment	12	12
Furniture and office equipment	240	204
Leasehold improvements	1,414	1,406
Construction in progress	52	33
Total	3,407	2,764
Accumulated depreciation	(1,841)	(1,253)
Property and equipment, net	<u>\$ 1,566</u>	<u>\$ 1,511</u>

Depreciation expense for the three months ended September 30, 2019 and 2018 was \$215 and \$148, respectively. Depreciation expense for the nine months ended September 30, 2019 and 2018 was \$588 and \$444, respectively.

6. Accrued expenses

Accrued expenses consisted of the following:

	September 30, 2019	December 31, 2018
Payroll and employee related expenses	\$ 1,960	\$ 1,034
Professional fees	980	322
Third-party research and development expenses	160	393
Total	<u>\$ 3,100</u>	<u>\$ 1,749</u>

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

7. Convertible preferred stock

As of September 30, 2019, the Company had authorized 148,724,922 shares of Preferred Stock and has designated 64,891,735 shares as Series A Preferred, 10,000 shares as Series A-1 Preferred Stock (Series A-1 Preferred), 44,319,839 shares as Series B Preferred, 10,000 shares as Series B-1 Preferred Stock (Series B-1 Preferred) and 39,493,348 shares as Series C Preferred. Since the Preferred Stock was redeemable upon a liquidation event, which was not considered to be within the Company's control, it has been classified in temporary equity on the accompanying unaudited consolidated balance sheets. The carrying value of the Preferred Stock is the proceeds received less issuance costs. All shares of Series A, B and C Preferred Stock were converted into common stock in conjunction with the IPO. Shares of Series A-1 and B-1 Preferred were forfeited in conjunction with the IPO.

As of September 30, 2019, Preferred Stock consisted of the following (in thousands, except share amounts):

	Designated	Issued and Outstanding	Carrying Value	Liquidation Preference
Series A preferred stock	64,891,735	62,528,507	\$ 46,694	\$ 46,897
Series A-1 preferred stock	10,000	10,000	8	8
Series B preferred stock	44,319,839	42,145,996	38,490	38,793
Series B-1 preferred stock	10,000	10,000	9	9
Series C preferred stock	39,493,348	39,492,960	62,701	61,999
	148,724,922	144,187,463	\$ 147,902	\$ 147,706

Issuances of preferred stock

In January and February 2019, the Company issued 288,991 shares of Series B Preferred for net proceeds of \$266.

On July 17, 2019, the Company issued 39,492,960 shares of Series C Preferred for net proceeds of \$61,687. The rights and preferences of the Series C Preferred were similar to the Preferred Stock with the exception that the Series C Preferred has a cumulative 8% dividend, was senior in liquidation to the Series A Preferred, Series B Preferred and common stock and was automatically convertible into Common Stock upon the closing of a firm commitment underwritten public offering meeting certain minimum criteria. The Company has evaluated the rights, preferences and privileges of the Series C Preferred and has concluded that there are no freestanding derivative investments or any embedded derivatives requiring bifurcation.

8. Non-controlling interest

In 2018, the Company issued shares of preferred stock in its subsidiary, Frequency Japan, to a Japanese investor. The Company has consolidated Frequency Japan in the consolidated unaudited financial statements and has recorded the proceeds received for the sale of the preferred stock in Frequency Japan as a non-controlling interest in the temporary equity section of the unaudited consolidated balance sheets. The liquidation preference of the shares of preferred stock equals the purchase price of such shares.

The Frequency Japan preferred stock held by such investor was convertible, at the option of the holder, into 673,605 shares of Company common stock, adjustable for certain dilutive events, upon an initial public offering of Company common stock, a Company liquidation or upon a 70% vote of the holders of the Preferred Stock. The preferred shares also have a liquidation preference equal to the amount paid for the shares. The Company had the option to acquire the preferred shares of Frequency Japan under certain circumstances and the holder of such preferred shares had the right to require the Company to purchase such shares under certain circumstances, primarily a merger or liquidation.

In connection with this sale of the preferred stock in Frequency Japan, FT-FJ Investment, LLC (FT-FJ), a Delaware limited liability company controlled by the Company, purchased 10,000 shares of the Company's Series A-1 Preferred and 10,000 shares of the Company's Series B-1 Preferred. FT-FJ also granted to the Japanese investor an irrevocable proxy to vote the shares of Series A-1 and Series B-1 Preferred held by FT-FJ. Each share of Series A-1 Preferred had 236 times the voting power of one share of common stock and each share of Series B-1 Preferred has 217 times the voting power of one share of common stock.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

On August 20, 2019, the Company, Frequency Japan, the Japanese investor, and FT-FJ entered into an agreement pursuant to which, contingent upon the closing of the initial public offering of the Company's common stock: (i) the Japanese investor agreed to convert its shares of preferred stock held in Frequency Japan and to terminate its proxy over the shares of Series A-1 and B-1 Preferred Stock held by FT-FJ and (ii) FT-FJ agreed to forfeit its shares of Series A-1 and Series B-1 Preferred Stock. The shares were converted into common stock and the Series A-1 and B-1 preferred stock were forfeited in conjunction with the IPO.

9. Common stock

On September 20, 2019, the Company effected a 1-for-6.7355 reverse stock split of its common stock. The par value of the common stock was not adjusted as a result of the reverse stock split and the authorized capital was amended to 100,000,000 shares of common stock and 148,724,922 shares of \$0.001 par value preferred stock. The reverse stock split resulted in an adjustment to the Series A Preferred, Series B Preferred and Series C Preferred conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying unaudited consolidated financial statements and notes to the unaudited consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

The Company had authorized 100,000,000 shares of \$0.001 par value common stock of which 2,382,309 were issued and outstanding as of September 30, 2019. Common shares are voting, and dividends may be paid when, as and if declared by the Board of Directors, subject to the limitations and preferences of the Preferred Stock.

The Company has reserved the following shares of common stock for future issuance as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Series A Preferred conversion	9,283,307	9,283,425
Conversion of Frequency Japan preferred stock	673,605	673,605
Series B Preferred conversion	6,257,256	6,214,387
Series C Preferred conversion	5,863,365	—
Stock options outstanding	4,787,897	2,089,334
Shares available for future grant under stock option plan	3,095,619	1,028,096
	<u>29,961,049</u>	<u>19,288,847</u>

10. Stock-based compensation

On November 13, 2014, the Company adopted the 2014 Stock Incentive Plan (2014 Plan). All of the Company's employees, officers, directors, and consultants are eligible to be granted options to purchase common shares and restricted stock under the terms of the 2014 Plan. The Company reserved an aggregate of 8,550,415 shares of common stock for issuance under the 2014 Plan. As of September 30, 2019, 3,095,619 shares of common stock were available for future grants under the 2014 Plan. These were canceled on the effective of the 2019 Plan.

On September 17, 2019, the Company's board of directors and on September 19, 2019, its stockholders approved and adopted the 2019 Incentive Award Plan (the "2019 Plan") which became effective on the day prior to the IPO. Under the 2019 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock or cash-based awards to individuals who are then employees, officers, directors or consultants of the Company, and employees and consultants of the Company's subsidiaries. A total of 3,100,000 shares of common stock were approved to be initially reserved for issuance under the 2019 Plan. The number of shares under the 2014 Plan subject to outstanding awards as of the effective date of the 2019 Plan that are subsequently canceled, forfeited or repurchased by the Company will be added to the shares reserved under the 2019 Plan. In addition, the number of shares of common stock available for issuance under the 2019 Plan will be automatically increased on the first day of each calendar year during the ten-year term of the 2019 Plan, beginning with January 1, 2020 and ending with January 1, 2029, by an amount equal to 4% 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. In October 2019, 1,162,661 options were granted under the 2019 Plan at \$14.00 per share.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

All stock option grants are non-statutory stock options except option grants to employees (including officers and directors) intended to qualify as incentive stock options under the Internal Revenue Code of 1986, as amended. Incentive stock options may not be granted at less than the fair market value of the Company's common stock on the date of grant, as determined in good faith by the Board of Directors at its sole discretion. Nonqualified stock options may be granted at an exercise price established by the Board of Directors at its sole discretion (which has not been less than fair market value on the date of grant) and the vesting periods may vary. Vesting periods are generally four years and are determined by the Board of Directors. Stock options become exercisable as they vest. Options granted under the 2014 Plan and the 2019 Plans expire no more than ten years from the date of grant.

Stock options

A summary of the stock option activity under the 2014 Plan for the nine months ended September 30, 2019 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	2,089,334	\$ 0.61	—	
Granted	3,015,381	4.17	—	
Exercised	(297,599)	1.09	—	
Forfeited	(19,219)	0.61	—	
Outstanding as of September 30, 2019	4,787,897	2.83	9.14	\$ 37,374
Options exercisable as of September 30, 2019	1,441,449	1.81	8.84	12,715
Options unvested as of September 30, 2019	3,346,448			24,659

Stock option valuation

The fair value of stock options granted during the nine months ended September 30, 2019 and 2018 under the 2014 Plan has been calculated on the date of grant using the following weighted average assumptions:

	September 30, 2019	September 30, 2018
Risk-free interest rate	2.0%	2.8%
Expected term (in years)	5.8	5.7
Expected volatility	80.0%	81.1%
Expected dividend yield	0.0%	0.0%

The aggregate intrinsic value of stock options exercised during the three and nine months ended September 30, 2019 was \$669 and \$2,842, respectively. The aggregate intrinsic value of stock options exercised during the three and nine months ended September 30, 2018 was \$2 and \$3, respectively. During the three and nine months ended September 30, 2019, 78,041 and 297,599 stock options, respectively, were exercised. During the three and the nine months ended September 30, 2018, 54,671 and 113,402 stock options, respectively, were exercised.

The weighted average grant date fair value of stock options granted during the three and nine months ended September 30, 2019 was \$5.66 per share and \$2.86 per share, respectively. The weighted average grant date fair value of stock options granted during the three and nine months ended September 30, 2018 was nil per share and \$0.42 per share, respectively.

The total grant date fair value of options vested during the three and nine months ended September 30, 2019 was \$997 and \$1,766, respectively. The total grant date fair value of options vested during the three and nine months ended September 30, 2018 was \$78 and \$182, respectively.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

Restricted common stock

The Company issued common stock to founders, employees and advisors which was subject to vesting over four years. If any of these individuals ceased to be employed or to provide services to the Company prior to vesting, the Company had the right to repurchase any unvested common stock at the price paid by the holder.

A summary of the status of restricted common stock as of September 30, 2019 is presented below:

	Number of Shares	Weighted Average Fair Value
Outstanding as of December 31, 2018	1,657,345	\$ 0.27
Granted	—	—
Issued	37,112	2.23
Forfeited	—	—
Repurchased	—	—
Outstanding as of September 30, 2019	1,694,457	0.31
Vested during period	226,519	0.42
Unvested as of September 30, 2019	156,202	0.55

Stock-based compensation

The total compensation cost recognized in the statements of operations associated with all stock-based compensation awards granted by the Company is as follows (in thousands):

	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
	2019	2018	2019	2018
Research and development	\$ 391	\$ 57	\$ 1,200	\$ 175
General and administrative	534	45	1,256	92
Total stock-based compensation expense	\$ 925	\$ 102	\$ 2,456	\$ 267

As of September 30, 2019, total unrecognized stock-based compensation expense relating to unvested stock options was \$6,325. This amount is expected to be recognized over a weighted-average period of 2.38 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 IPO. The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation. A total of 315,000 shares of common stock were approved to be initially reserved for issuance under the ESPP. In addition, 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. No shares were issued under the ESPP at September 30, 2019.

12. Income taxes

The company did not record an income tax benefit in its consolidated statement of operations for the nine months ended September 30, 2019 and 2018 as it is more likely than not that the Company will not recognize the federal and state deferred tax benefits generated by its losses. The Company had net deferred tax assets and liabilities of \$12,229 at December 31, 2018. The Company has provided a valuation allowance for the full amount of its net deferred tax assets and liabilities as of December 31, 2018 and September 30, 2019 as management has determined it is more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2018 or September 30, 2019.

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.

The Company has agreed to conduct Phase 2a clinical studies in the United States. Upon the completion thereof, the Company and Astellas have agreed to jointly develop the Astellas Licensed Products, including carrying out joint studies. Each party has agreed to use commercially reasonable efforts to carry out development activities assigned to it under an agreed-upon development plan. Astellas has agreed to use commercially reasonable efforts to obtain regulatory approval for at least one Astellas Licensed Product in sensorineural hearing loss and in age-related hearing loss, in each case, in one major Asian country and one major European country. The Company has agreed to use commercially reasonable efforts to obtain regulatory approval for at least one Astellas Licensed Product in the United States. Astellas has the sole right to commercialize the Astellas Licensed Products outside of the United States, and the Company has the sole right to commercialize the Astellas Licensed Products in the United States. Astellas has agreed to use commercially reasonable efforts to commercialize Astellas Licensed Products in a major Asian country and a major European country following receipt of regulatory approval in such countries.

The collaboration is governed by a joint steering committee ("JSC") established under the Astellas Agreement and shall be comprised of three representatives each from the Company and Astellas. The JSC shall oversee and coordinate the overall conduct of the development, manufacture and commercialization of the Astellas Licensed Products. All decisions of JSC shall be taken through a unanimous vote with each party's representatives collectively having one vote. Both the parties shall be responsible for carrying out the development and manufacturing activities in their defined territory in accordance with the plan as reviewed and approved in the JSC.

As consideration for the licensed rights under the Astellas Agreement, Astellas paid the Company an upfront payment of \$80.0 million, and agreed to pay potential development milestone payments up to \$230.0 million. If the Astellas Licensed Products are successfully commercialized, the Company would be eligible for up to \$315.0 million in potential commercial milestone payments and also tiered royalties at rates ranging from low- to mid-teen percentages. The parties shall 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.

The Astellas Agreement remains in effect until the expiration of all royalty obligations. Royalties are paid on a licensed product-by-licensed product and country-by-country basis until the latest of (i) the expiration of the last valid claim in the licensed patent rights with respect to such Astellas Licensed Product in such country or (ii) a set number of years from the first commercial sale of such Astellas Licensed Product in such country. Astellas may terminate the Astellas Agreement at will upon 60 days' written notice. Each party has the right to terminate the Astellas Agreement due to the other party's material breach if such breach remains uncured for 90 days (or 45 days in the case of nonpayment) or if the other party becomes bankrupt.

The Astellas Agreement is a collaborative agreement that is within the scope of ASC 808. The Company analyzed the joint research and development activities to assess whether they fall within the scope of ASC 808, and will reassess this throughout the life of the arrangement based on changes in the roles and responsibilities of the parties. Based on the terms of the arrangement as outlined above, both parties are deemed to be active participants in the collaboration. Both parties are performing research and development activities in their defined territory and will be performing joint clinical studies in accordance with the development plan and the study protocol approved by the JSC. Additionally, Astellas and the Company are exposed to significant risks and rewards dependent on the commercial success of any product candidates that may result from the collaboration. As such, the collaboration arrangement is deemed to be within the scope of ASC 808.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued)

(Amounts in thousands, except share and per share amounts)

The arrangement consists of two components; the license of IP and the research and development activities, including committee participation, to support the co-development and research plan. Under the provisions of ASC 808, the Company has determined that it will apply the guidance in ASC 606 to recognize the revenue related to the license since that component of the arrangement is more reflective of a vendor-customer relationship. The Company determined that the license and the related research and development services associated with the Phase 2a clinical study were not distinct from one another, as the license has limited value to Astellas without the performance of the research and development activities and the Phase 2a study is essential to the use of the license. As such, the Company determined that these activities should be accounted for as a single combined performance obligation.

Revenue associated with this single performance obligation is being recognized as the research and development work is performed, using an input method on the basis of research and development costs incurred to date relative to total research and development costs expected to be incurred. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. The Company determined that the period of performance of the research and development services began upon the signing of the Astellas Agreement and is expected to be completed into the fourth quarter of 2020, therefore the transaction price of \$80.0 million has been allocated to the single combined performance obligation and will be recognized over such period. The Company is required to pay MIT a royalty on sublicense revenues and as of September 30, 2019 has accrued \$16.0 million related to the \$80.0 million upfront payment received. The \$16.0 million royalty was expensed in the three months ended September 30, 2019.

The \$80.0 million upfront payment received from Astellas in July 2019 was initially recorded as deferred revenue and is being recognized as revenue according to the policy described above. In the quarter ended September 30, 2019, the company recorded \$24.2 million of revenue under the Astellas Agreement which included \$16.0 million related to the royalty payment to MIT and \$8.2 million based upon the application of the input method to the remaining \$64.0 million to be recognized over the estimated period to completion of the Phase 2a clinical trial for FX-322.

The potential development and regulatory milestone payments are fully constrained until the Company can conclude that achievement of the milestone is probable and that it is probable that recognition of revenue related to the milestone will not result in a significant reversal in the amount of cumulative revenue recognized when the uncertainty associated with the variable consideration is ultimately resolved and as such these have been excluded from the transaction price. As part of its evaluation of the constraint, the Company considers numerous factors, including the fact that achievement of the milestones is outside the control of the Company and contingent upon the future success of clinical trials, the licensee's efforts, and the receipt of regulatory approval. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to Astellas and therefore are recognized at the later of when the performance obligation is satisfied, or the related sales of licensed products occur. The Company re-evaluates the transaction price, including its estimated variable consideration included in the transaction price and all constrained amounts, at each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

The Astellas Agreement contains joint research and development activities that are not within the scope of ASC 606. The Company will recognize research and development expense related to the joint study costs for all the joint activities in future periods and reimbursements received from Astellas will be recognized as an offset to research and development expense on the consolidated statement of operations during the development period.

Frequency Therapeutics, Inc.

Notes to unaudited consolidated financial statements – (continued) (Amounts in thousands, except share and per share amounts)

14. Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

(in thousands, except share and per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss attributable to common stockholders	\$ (1,589)	\$ (5,136)	\$ (14,267)	\$ (13,721)
Denominator:				
Weighted-average shares of common stock outstanding-basic and diluted	2,163,289	1,575,728	1,990,106	1,476,678
Net loss per share attributed to common stockholders-basic and diluted	\$ (0.73)	\$ (3.26)	\$ (7.17)	\$ (9.29)

The weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Unvested Restricted Common Stock	156,202	409,099	156,202	409,099
Series C Preferred (as converted to common stock)	5,863,365	—	5,863,364	—
Series B Preferred (as converted to common stock)	9,257,256	—	6,257,256	—
Series A Preferred (as converted to common stock)	9,283,307	9,283,307	9,283,307	9,283,307
Conversion of Frequency Japan preferred stock	637,605	—	637,605	—
Outstanding stock options (as converted to common stock)	4,787,897	2,052,218	4,787,897	2,052,218
Total	29,985,632	11,744,624	26,985,631	11,744,624

15. Subsequent events

The Company has evaluated subsequent events for recognition and remeasurement purposes through November 15, 2019, the date that these interim unaudited consolidated financial statements were available to be issued and through November 18, 2019 for disclosure purposes. The identified subsequent events are discussed below:

In October 2019, the company completed the IPO, see discussion in Note 1.

In November 2019, the company signed a lease amendment for its Woburn, Massachusetts facility. The lease amendment increased the office space under lease by 7,550 square feet and extended the term of the lease for the facility to February 2025. The annual rent is approximately \$545.0 with a provision for an annual increase of 3%.

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 Form 10-Q. 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 Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described below.

Overview

We are a clinical-stage biotechnology company focused on harnessing the body's innate biology to potentially repair or reverse damage caused by a broad range of degenerative diseases. Our proprietary approach, called Progenitor Cell Activation, or PCA, uses combinations of small molecules to activate progenitor cells within the body to create functional tissue. Further, these progenitor cells, which are closely related to stem cells, are already resident in the targeted location in the body and programmed to develop and differentiate into specific cell types within an organ.

Our initial therapeutic focus is sensorineural hearing loss, or SNHL, which is the most prevalent type of hearing loss. We are developing FX-322 to treat the underlying cause of SNHL, which is the loss of hair cells. FX-322 is designed to regenerate hair cells through the activation of progenitor cells already present in the ear. In our Phase 1/2 clinical trial evaluating FX-322 in 23 patients with stable SNHL, we observed a statistically significant improvement in word recognition, a key measure of hearing function, and FX-322 was observed to be well-tolerated. We commenced a Phase 2a clinical trial of FX-322 in patients with SNHL in October 2019 and anticipate reporting top-line results from this trial in the second half of 2020. We are also working to identify a product candidate for the treatment of multiple sclerosis, or MS. This program focuses on activating progenitor cells in the central nervous system to repair the myelin sheath that protects nerves and may have the potential to reverse damage done by the disease. We intend to submit an investigational new drug application or, IND, to the U.S. Federal Drug Administration, or the FDA, for our MS product candidate in the second half of 2021.

In October 2019, we completed the initial public offering of our common stock, or the IPO. In the IPO, we issued and sold 6,325,000 shares of our common stock at a price to the public of \$14.00 per share, inclusive of the underwriters' exercise in part of their over-allotment option. We received approximately \$79.2 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses. In July 2019, we closed our Series C convertible preferred stock financing in which we issued and sold 39,492,960 shares of our Series C convertible preferred stock for aggregate gross proceeds of approximately \$62.0 million. In July 2019, we also entered into a License and Collaboration Agreement, or the Astellas Agreement, with Astellas Pharma, Inc., or Astellas, pursuant to which Astellas paid us an upfront payment of \$80.0 million.

Since our formation in 2014, we have devoted substantially all our resources to developing our PCA platform, 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 proceeds from the sale of convertible notes and of our convertible preferred stock, our IPO and the Astellas Agreement. To date, we have raised approximately \$316.5 million through a combination of convertible notes, convertible preferred stock financings, the upfront payment under the Astellas Agreement, grants and our IPO.

Since our formation, we have incurred significant operating losses and have not generated any revenue from the sale of products. Our ability to generate any product revenue or product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were \$20.2 million, \$19.2 million and \$13.3 million for the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, respectively. As of September 30, 2019, we had an accumulated deficit of \$63.4 million.

We expect our operating expenses to increase substantially in connection with the expansion of our product development programs and capabilities. We will not generate revenue from product sales unless and until we successfully complete clinical development, obtain regulatory approval for, and successfully commercialize our product candidates, or until our collaborators do so, which could result in milestone payments or royalties to us. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution. In addition, we expect to continue to incur additional costs associated with operating as a public company.

As a result of these anticipated expenditures, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our cash needs through a combination of public or private equity or debt financings and other sources, which may include current and new collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We cannot be sure that we will ever generate sufficient revenue to achieve profitability.

Because of the numerous risks and uncertainties associated with the development of therapeutics, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we can generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be required to raise additional capital on terms that are unfavorable to us or we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

License and collaboration agreements

Astellas Pharma, Inc.

In July 2019, we entered into the Astellas Agreement with 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, or the Astellas licensed products, including our product candidate FX-322, outside of the United States. We and Astellas have agreed to jointly develop the Astellas licensed products, including carrying out joint studies. Each party has agreed to use commercially reasonable efforts to carry out development activities assigned to it under an agreed-upon development plan. Astellas has agreed to use commercially reasonable efforts to obtain regulatory approval for at least one Astellas licensed product in SNHL and in age-related hearing loss, in each case in one major Asian country and one major European country. We have agreed to use commercially reasonable efforts to obtain regulatory approval for at least one Astellas licensed product in the United States. Astellas has the sole right to commercialize the Astellas licensed products outside of the United States and we have the sole right to commercialize the Astellas licensed products in the United States. Astellas has agreed to use commercially reasonable efforts to commercialize Astellas licensed products in a major Asian country and a major European country following receipt of regulatory approval in such countries.

As consideration for the licensed rights under the Astellas Agreement, Astellas agreed to pay us an upfront payment of \$80.0 million, which we received in July 2019, and potential development milestone payments up to \$230.0 million. If the Astellas licensed products are successfully commercialized, we would be eligible for up to \$315.0 million in potential commercial milestone payments and also tiered royalties at rates ranging from low- to mid-teen percentages. Pursuant to our Exclusive Patent License Agreement, or the MIT License, with the Massachusetts Institute of Technology, or MIT, we are required to pay MIT a royalty on sublicense revenues and as of September 30, 2019, we have accrued \$16.0 million related to the \$80.0 million upfront payment received. The \$16.0 million royalty was expensed in the three months ended September 30, 2019. The \$80.0 million upfront payment received from Astellas in July 2019 has been recorded as deferred revenue and will be recognized as revenue, using the input method, over the period in which we will be conducting Phase 2a clinical trials for FX-322, which is estimated to be the period from execution of the Astellas Agreement into the fourth quarter of 2020. In the three months ended September 30, 2019, we recognized \$24.2 million of the \$80.0 million as revenue.

Massachusetts Institute of Technology

In December 2016, we entered into the MIT License, with 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, or the MIT licensed products, and to develop and perform processes, or the MIT licensed processes, which incorporate the licensed technology for the treatment of disease, including but not limited to the prevention and remediation of hearing loss. We are required to use diligent efforts to develop and commercialize the MIT licensed products or processes, and to make such products or processes reasonably available to the public. We are also subject to certain development obligations with regards to a first MIT licensed product. We have satisfied certain obligations related to preclinical studies and the filing of an IND for a first MIT licensed product with our development activities related to FX-322. Our future development obligations are: (i) to commence a Phase 2 clinical trial for such product within two years of the IND filing for such product, (ii) to commence a Phase 3 clinical trial for such product within five years of the IND filing for such product, (iii) to file a New Drug Application, or NDA, or equivalent with the FDA or comparable European regulatory agency for such product within nine years of the IND filing for such product, and (iv) to make a first commercial sale of such product within 11 years of the IND filing for such product. We also have certain development obligations with regards to a second MIT licensed product.

Upon entering into the MIT License, we paid a \$50 thousand license fee payment and issued shares of our common stock equal to 5% of our then-outstanding capital stock to MIT. We are required to pay certain annual license maintenance fees ranging from \$30 thousand to \$0.1 million per year prior to first commercial sale of a MIT licensed product and an annual license maintenance fee of \$0.2 million every year afterwards, which may be credited to running royalties during the same calendar year, if any. We are also required to make potential milestone payments in an aggregate amount of up to \$2.9 million on each MIT licensed product or process. In addition, we agreed to pay a low single-digit royalty on the MIT licensed products and processes and a low-twenties royalty on sub-license revenues.

Massachusetts Eye and Ear Infirmary

In February 2019, we entered into a Non-Exclusive Patent License Agreement, or the MEEI License, with the Massachusetts Eye and Ear Infirmary, or MEEI, 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, or the MEEI licensed products. We are obligated to use diligent efforts to develop and commercialize the MEEI licensed products. We are also subject to milestone timeline obligations to dose a first patient in a Phase II trial by December 31, 2020 and to dose a first patient in a Phase 3 trial by December 31, 2024.

Upon entering into the MEEI License, we made a \$20 thousand license fee payment. We are obligated to pay certain annual license maintenance fees between \$5 thousand and \$7.5 thousand per each MEEI patent family case number included in the licensed MEEI patent rights prior to first commercial sale of an MEEI licensed product. We are also obligated to pay a minimum annual royalty payment of \$15 thousand per each MEEI patent family case number included in the licensed MEEI patent rights after first commercial sale of an MEEI licensed product. We are also obligated to make milestone payments up to \$350 thousand on each product or process that incorporates the licensed patent rights. In addition, we have agreed to pay a low single-digit royalty on products and processes that incorporate the licensed patent rights.

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 the Scripps Research Institute, or 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, or the CALIBR licensed products, which incorporate licensed technology for the treatment of MS. We have agreed to use commercially reasonable efforts to develop, manufacture, and sell at least one CALIBR licensed product. We are also subject to certain milestone timeline obligations to: (i) submit an IND (or equivalent) for a CALIBR licensed product by the 30th month after the effective date of the CALIBR License, (ii) initiate a Phase 2 clinical trial (or equivalent) for a CALIBR licensed product by the fourth anniversary of the effective date of the CALIBR License, and (iii) initiate a Phase 3 clinical trial (or equivalent) for a CALIBR licensed product by the sixth anniversary of the effective date of the CALIBR License.

Upon entering into the CALIBR License, we made a \$1.0 million license fee payment, and are required to make milestone payments in an aggregate amount of up to \$26.0 million for each category of CALIBR licensed products. Category 1 is any CALIBR licensed products containing a compound that modulates any muscarinic receptor, and Category 2 is any CALIBR licensed products not included in Category 1 that could differentiate oligodendrocyte precursor cells from *in vitro* studies and/or are active in animal models relevant to MS. We are also required to pay a mid-single-digit royalty on CALIBR licensed products and a royalty on sub-license revenues ranging from a low-teen percentage to 50%.

The Scripps Research Institute

In September 2018, we entered into a Research Funding and Option Agreement, or the Scripps option agreement, with Scripps, under which we were granted an exclusive option to acquire an exclusive, sublicensable, worldwide license under certain intellectual property related to the treatment of MS. As consideration for the Scripps option agreement, we are required to make funding payments totaling \$0.7 million to Scripps to support its research activities. Scripps has agreed to use reasonable efforts to perform the research program pursuant to the Scripps option agreement.

Components of our results of operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the foreseeable future. In July 2019, we entered into the Astellas Agreement and received an upfront license fee payment of \$80.0 million. In accordance with ASC 606, we are recognizing the \$80.0 million as revenue over the period that research and development services and the Phase 2a clinical study for FX-322 are being provided using the input method. This is estimated to be the period from execution of the Astellas Agreement into the fourth quarter of 2020. In the three months ended September 30, 2019, we recognized \$24.2 million of the \$80.0 million upfront fee as revenue. This reflects revenue of \$16.0 million equal to the royalty expense under the MIT License as well as \$8.2 million from applying the input method to the remaining \$64.0 million of the upfront payment.

Royalty

We are required to pay royalties under the MIT License on the receipt of fees for the sublicense of the MIT intellectual property. We expensed the \$16.0 million royalty due MIT on the \$80.0 million license fee pursuant to the Astellas Agreement in the third quarter of 2019.

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and for the development of our product candidate, FX-322. These 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, Scripps, and MEEI, 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 expense research and development costs as incurred.

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 the table below.

The following table summarizes our research and development expenses by product candidate or development program for the three and nine month period ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Increase (Decrease)	Nine Months Ended September 30,		Increase (Decrease)
	2019	2018		2019	2018	
Direct research and development expenses by product candidate:						
FX-322 external development costs	\$ 1,574	\$ 639	\$ 935	\$ 3,190	\$ 1,711	\$ 1,479
Platform development, early-stage research and unallocated expenses:						
Employee-related costs	2,344	987	1,357	5,743	3,270	2,473
Laboratory supplies	138	75	63	294	232	62
Outsourced research and development	726	1,633	(907)	2,332	2,979	(647)
Facility-related costs	315	156	159	710	587	123
Depreciation and amortization	124	60	64	319	180	139
Total research and development expenses	\$ 5,221	\$ 3,550	\$ 1,671	\$ 12,588	\$ 8,959	\$ 3,629

We expect that our research and development expenses will continue to increase substantially for the foreseeable future and will comprise a larger percentage of our total expenses as we continue and complete our Phase 2a clinical trial and initiate additional clinical trials for FX-322 and continue to discover and develop additional product candidates. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to increased scale and duration.

We cannot determine with certainty the duration and costs of future clinical trials of FX-322 or any other product candidate we may develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. The duration, costs, and timing of clinical trials and development of FX-322 and any other product candidate we may develop will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials of FX-322, as well as of any future clinical trials of other product candidates and other research and development activities that we may conduct;
- the actual probability of success for our product candidates, including their safety and efficacy, early clinical data, competition, manufacturing capability, and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals;
- the progress of the development efforts of parties with whom we may enter into collaboration agreements;
- our ability to secure manufacturing supply through relationships with third parties;
- the commercialization of our product candidates, if and when approved;
- raising additional funds necessary to complete preclinical and clinical development of our product candidates; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate.

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; 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.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support our continued research activities and development of product candidates. We also expect to continue to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with the requirements of The Nasdaq Stock Market and the SEC; director and officer insurance costs; and investor and public relations costs.

Interest income

Interest income consists of interest earned on cash equivalents and short-term investments.

Interest expense

Interest expense consists of interest paid on convertible notes payable which were converted in our Series B convertible preferred stock financing in 2018.

Realized gain on investments

Realized gain on investments represents the gain realized on our marketable securities in the three and nine months ended September 30, 2019.

Loss on extinguishment of debt

In 2018, we issued notes payable, which were convertible at a 5% discount to the price of shares issued in a qualified financing. In October 2018, the notes payable converted into Series B convertible preferred stock at a 5% discount to the price of the Series B convertible preferred stock, which we recorded as a \$0.3 million loss on extinguishment of debt.

Foreign exchange gain (loss)

Foreign exchange gain (loss) represents the gain or loss recorded as a result of remeasuring the financial statements of our foreign subsidiaries.

Income taxes

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.

As of December 31, 2018, we had federal net operating loss carryforwards, or NOLs, of approximately \$39.3 million and Massachusetts state NOLs of approximately \$31.7 million which may be available to offset future taxable income. Our federal NOLs include \$22.4 million available to reduce future taxable income through 2037 and approximately \$16.9 million of NOLs that do not expire and are available to reduce future taxable income indefinitely. The state NOLs are available to offset future taxable income through 2038. As of December 31, 2018, we also had federal and Massachusetts research and development tax credit carryforwards of \$0.7 million and \$0.4 million, respectively, which are available to offset federal and state tax liabilities through 2038 and 2033, respectively.

Realization of future tax benefits is dependent on many factors, including our ability to generate taxable income within the NOL period. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as provided under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, as well as under similar state provisions. These ownership changes may limit the amount of NOLs that can be utilized annually to offset future taxable income. In general, an ownership change, as defined under Section 382 of the Code, or Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. We have completed several financings and have conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception and have determined that an ownership change did occur in March 2017. Accordingly, utilization of \$12.4 million of the federal NOLs that were incurred prior to March 2017 (pre-ownership change) is limited under Section 382. After the Section 382 limitations, we may utilize approximately \$10.8 million of our pre-ownership change NOLs based upon an annual usage of approximately \$1.6 million for each of the next five years after the ownership change and approximately \$0.2 million for each of the 15 years thereafter. The remaining pre-ownership change NOLs of approximately \$1.6 million were written off due to expiration under limitation. The limitation has been determined by first multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate. These NOLs may be subject to further annual limitations under Section 382 in the event of future changes in ownership.

In December 2017, the Tax Cuts and Jobs Act was signed into U.S. law. The Tax Cuts and Jobs Act included a number of changes to the tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from a top marginal tax rate of 35% to a flat rate of 21%, which went into effect on January 1, 2018, as well as a limitation of the deduction for NOLs to 80% of annual taxable income, and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely). The federal tax rate change resulted in a reduction in the gross amount of our deferred tax assets and liabilities recorded as of December 31, 2017, and a corresponding reduction in our valuation allowance. As a result, no income tax expense or benefit was recognized as of the enactment date of the Tax Cuts and Jobs Act.

Results of operations

Comparison of three months ended September 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Increase (Decrease)
	2019	2018	
Revenue	\$ 24,238	\$ —	\$ 24,238
Operating expenses:			
Royalty	16,000	—	16,000
Research and development	5,221	3,550	1,671
General and administrative	4,269	1,507	2,762
Total operating expenses	25,490	5,057	20,433
Loss from operations	(1,252)	(5,057)	3,805
Interest income	624	—	624
Interest expense	—	(63)	63
Realized gain on investments	62	—	62
Foreign exchange gain (loss)	(9)	(16)	7
Net loss	\$ (575)	\$ (5,136)	\$ 4,561

Revenue

We had no revenue for the three months ended September 30, 2018. In July 2019, we entered into the Astellas Agreement and received an upfront license fee payment of \$80.0 million. In accordance with ASC 606, we are recognizing the \$80.0 million as revenue over the period that research and development services and the Phase 2a clinical study for FX-322 are being provided using the input method. In the three months ended September 30, 2019, we recognized \$24.2 million of the \$80.0 million as revenue. This reflects revenue of \$16.0 million equal to the royalty expense under the MIT License as well as \$8.2 million from applying the input method to the remaining \$64.0 million of the upfront payment.

Royalty

We are required to pay royalties under the MIT License on the receipt of fees for the sublicense of the MIT intellectual property. In the three months ended September 30, 2019, we expensed the \$16.0 million royalty due MIT on the \$80.0 million upfront license fee received from Astellas.

Research and development expenses

	Three Months Ended September 30,		Increase (Decrease)
	2019	2018	
Direct research and development expenses by product candidate:			
FX-322 external development costs	\$ 1,574	\$ 639	\$ 935
Platform development, early-stage research and unallocated expenses:			
Employee-related costs	2,344	987	1,357
Laboratory supplies	138	75	63
Outsourced research and development	726	1,633	(907)
Facility-related costs	315	156	159
Depreciation and amortization	124	60	64
Total research and development expenses	\$ 5,221	\$ 3,550	\$ 1,671

Research and development expenses for the three months ended September 30, 2019 were \$5.2 million, compared to \$3.5 million for the three months ended September 30, 2018. The increase of \$1.7 million was primarily due to an increase of \$0.9 million in FX-322 external research and development expenses and an increase of \$0.8 million in platform development, early-stage research and unallocated expenses. The \$1.6 million of FX-322 external development costs incurred for the three months ended September 30, 2019 consisted primarily of approximately \$1.1 million of clinical development costs for the Phase 2a clinical trial, including manufacturing costs for FX-322 to be used in clinical trials, and approximately \$0.2 million of outside consulting costs. The \$0.6 million of FX-322 external development costs incurred in the three months ended September 30, 2018 consisted primarily of approximately \$0.2 million of preclinical costs for safety testing and consulting, and approximately \$0.4 million related to conducting the Phase 1 clinical trial. FX-322 external development costs for the three months ended September 30, 2019 are presented net of approximately \$0.2 million in research and development tax credits received from the Australian government related to our Phase 1 clinical trial conducted in Australia.

Platform development, early-stage research and unallocated expenses were \$3.6 million for the three months ended September 30, 2019, compared to \$2.9 million for the three months ended September 30, 2018. The increase of \$0.7 million was primarily due to \$1.4 million of increased employee-related costs associated with increased headcount to support our preclinical and clinical development of FX-322 and research on our PCA platform development and \$.3 of increased facility and supply costs. The increase in employee-related costs includes an increase of \$0.3 million in compensation related to stock options. The \$0.7 increase in the 2019 period is net of a \$1.0 million expense in the three months ended September 30, 2018 for the upfront license fee to Scripps for the MS program.

General and administrative expenses

General and administrative expenses were \$4.3 million for the three months ended September 30, 2019, compared to \$1.5 million for the three months ended September 30, 2018. General and administrative expenses increased by \$2.8 million due to increased business development activities, increases in the infrastructure necessary to manage research and development and fundraising activities, an increase of \$0.9 million in audit, tax and consulting fees, \$0.2 million in legal and patent filing fees incurred to file and defend intellectual property and \$1.7 million in employee-related costs as we increased our general and administrative headcount to manage our growth, including an increase of \$0.5 in compensation related to stock options.

Interest income

Interest income was \$0.6 million for the three months ended September 30, 2019 due to an increase in cash equivalents and short-term investments. We did not have interest income in the three months ended September 30, 2018.

Interest expense

Interest expense was \$63 thousand for the three months ended September 30, 2018. This represents interest on convertible notes payable issued in 2018 and converted into Series B convertible preferred stock in 2018. We did not incur interest expenses in the three months ended September 30, 2019.

Realized gain on investments

Realized gain on investments was \$62 thousand for the three months ended September 30, 2019 due to our purchasing short-term marketable securities in 2019. We held no investments in the three months ended September 30, 2018.

Foreign exchange gain (loss)

Foreign exchange loss was \$9 thousand for the three months ended September 30, 2019, compared to a foreign exchange loss of \$16 thousand for the three months ended September 30, 2018. The decrease of \$7 thousand was due to differences in foreign exchange remeasurement of the financial statements of our foreign subsidiaries.

Comparison of nine months ended September 30, 2019 and 2018

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,		Increase (Decrease)
	2019	2018	
Revenue	\$ 24,238	\$ —	\$ 24,238
Operating expenses:			
Royalty	16,000	—	16,000
Research and development	12,588	8,959	3,629
General and administrative	9,837	4,660	5,177
Total operating expenses	38,425	13,619	24,806
Loss from operations	(14,187)	(13,619)	(568)
Interest income	842	—	842
Interest expense	—	(95)	95
Realized gain on investments	88	—	88
Foreign exchange gain (loss)	4	(7)	11
Net loss	\$ (13,253)	\$ (13,721)	\$ 468

Revenue

We had no revenue for the nine months ended September 30, 2018. In July 2019, we entered into the Astellas Agreement and received an upfront license fee payment of \$80.0 million. In accordance with ASC 606, we are recognizing the \$80.0 million as revenue over the period that research and development services and the Phase 2a clinical study for FX-322 are being provided using the input method. This is estimated to be into the fourth quarter of 2020. In the nine months ended September 30, 2019, we recognized \$24.2 million of the \$80.0 million as revenue. This reflects revenue of \$16.0 million equal to the royalty expense under the MIT License as well as \$8.2 million applying the input method to the remaining \$64.0 million of the upfront payment.

Royalty Expense

We are required to pay royalties under the MIT License on the receipt of fees for the sublicense of the MIT intellectual property. In the nine months ended September 30, 2019, we expensed the \$16.0 million royalty due MIT on the \$80.0 million upfront license fee received from Astellas.

Research and development expenses

	Nine Months Ended September 30,		Increase (Decrease)
	2019	2018	
Direct research and development expenses by product candidate:			
FX-322 external development costs	\$ 3,190	\$ 1,711	\$ 1,479
Platform development, early-stage research and unallocated expenses:			
Employee-related costs	5,743	3,270	2,473
Laboratory supplies	294	232	62
Outsourced research and development	2,332	2,979	(647)
Facility-related costs	710	587	123
Depreciation and amortization	319	180	139
Total research and development expenses	\$ 12,588	\$ 8,959	\$ 3,629

Research and development expenses for the nine months ended September 30, 2019 were \$12.6 million, compared to \$9.0 million for the nine months ended September 30, 2018. The increase of \$3.6 million was primarily due to an increase of \$1.5 million in FX-322 external research and development expenses and an increase of \$2.1 million in platform development, early-stage research and unallocated expenses. The \$3.2 million of FX-322 external development costs incurred for the nine months ended September 30, 2019 consisted primarily of approximately \$1.9 million of clinical development costs for the Phase 1 and 2a clinical trials of FX-322, including manufacturing costs for FX-322 to be used in clinical trials, and approximately \$0.6 million of outside consulting costs. The \$1.7 million of FX-322 external development costs incurred in the nine months ended September 30, 2018 consisted primarily of approximately \$0.2 million of preclinical costs for safety testing and consulting, and approximately \$0.9 million related to conducting the Phase 1 clinical trial. FX-322 external development costs for the nine months ended September 30, 2018 are presented net of approximately \$0.2 million in research and development tax credits received from the Australian government related to our Phase 1 clinical trial conducted in Australia.

Platform development, early-stage research and unallocated expenses were \$9.4 million for the nine months ended September 30, 2019, compared to \$7.2 million for the nine months ended September 30, 2018. The increase of \$2.2 million was primarily due to a \$0.4 million increase in outsourced research and development spending on our development programs, excluding our FX-322 program, and \$2.5 million of increased employee-related costs associated with increased headcount to support our preclinical and clinical development of FX-322 and research on our PCA platform development. The increase in employee-related costs includes an increase of \$1.0 million in compensation related to stock options. Platform development, early-stage research and unallocated expenses in the nine months ended September 30, 2018 includes an expense of \$1.0 million for the upfront license fee to Scripps for the MS program.

General and administrative expenses

General and administrative expenses were \$9.8 million for the nine months ended September 30, 2019, compared to \$4.7 million for the nine months ended September 30, 2018. General and administrative expenses increased by \$5.1 million due to increased business development activities, increases in the infrastructure necessary to manage research and development and fundraising activities, an increase of \$1.3 million in audit, tax and consulting fees, \$0.8 million in legal and patent filing fees incurred to file and defend intellectual property, \$0.2 million in corporate legal fees and \$2.0 million in employee-related costs as we increased our general and administrative headcount to manage our growth, including an increase of \$1.1 million in compensation related to stock options.

Interest income

Interest income was \$0.8 million for the nine months ended September 30, 2019 due to an increase in cash equivalents and short-term investments. We did not have interest income in the nine months ended September 30, 2018.

Interest expense

Interest expense was \$95 thousand for the nine months ended September 30, 2018. This represents interest on convertible notes payable issued in 2018 and converted into Series B convertible preferred stock in 2018. We did not incur interest expenses in the nine months ended September 30, 2019.

Realized gain on investments

Realized gain on investments was \$88 thousand for the nine months ended September 30, 2019 due to our purchasing short-term marketable securities in 2019. We held no investments in the nine months ended September 30, 2018.

Foreign exchange gain (loss)

Foreign exchange gain was \$4 thousand for the nine months ended September 30, 2019, compared to a foreign exchange loss of \$7 thousand for the nine months ended September 30, 2018. The decrease of \$11 thousand was due to differences in foreign exchange remeasurement of the financial statements of our foreign subsidiaries.

Liquidity and capital resources

Since our inception, we have incurred significant operating losses. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect that our research and development and general and administrative costs will continue to increase, including in connection with conducting preclinical studies and clinical trials for our product candidates, contracting with contract manufacturing organizations, or CMOs, to support preclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations particularly as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

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 the sale of our convertible notes, convertible preferred stock, our IPO and the Astellas Agreement. To date, we have raised approximately \$316.5 million through a combination of convertible notes, convertible preferred stock, the upfront payment under the Astellas Agreement, grants and our IPO. Our cash, cash equivalents and short-term investments totaled \$165.3 million as of September 30, 2019. In October 2019, we completed an IPO of our common stock and issued and sold 6,325,000 shares of common stock at a public offering of \$14.00 per share, inclusive of the exercise in part by the underwriters of their option to purchase additional shares, resulting in net proceeds of \$79.2 million after deducting underwriting discounts and commissions and offering expenses. We had no indebtedness as of September 30, 2019. In July 2019, we closed our Series C convertible preferred stock financing, in which we issued 39,492,960 shares of our Series C convertible preferred stock, for aggregate gross proceeds of approximately \$62.0 million. In connection with our receipt of the upfront payment of \$80.0 million under the Astellas Agreement, we are obligated to pay \$16.0 million to MIT under the MIT License in satisfaction of a royalty owed to MIT upon receipt of such upfront payment.

Cash flows

The following table summarizes our cash flows for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
Net cash provided by (used in) operating activities	\$ 63,958	\$ (12,305)
Net cash used in investing activities	(23,690)	(197)
Net cash provided by financing activities	59,817	6,842
Increase (decrease) in cash and cash equivalents	\$ 100,085	\$ (5,660)

Cash flows for the nine months ended September 30, 2019 and 2018

Operating activities

Net cash provided by operating activities for the nine months ended September 30, 2019 was \$64.0 million, primarily consisting of a net loss of \$13.3 million as we incurred expenses associated with our FX-322 program, platform development and early-stage research, and general and administrative expenses. In addition, we had non-cash charges of \$3.0 million for depreciation, stock-based compensation expense and deferred lease incentives. Net cash provided by operating activities was also impacted by a net \$71.8 million change in operating assets and liabilities, including an increase of \$55.8 million in deferred revenue, \$16.0 million in royalty payable, \$1.7 million in accounts payable and \$1.4 million in accrued expenses, which were partially offset by an increase of \$3.1 million in grants receivable, prepaid expenses and other assets.

Net cash used in operating activities for the nine months ended September 30, 2018 was \$12.3 million, primarily consisting of a net loss of \$13.7 million as we incurred expenses associated with our FX-322 program, platform development and early-stage research, and general and administrative expenses. In addition, we had non-cash charges of \$0.6 million for depreciation, stock-based compensation expense and deferred lease incentives. Net cash used in operating activities was also impacted by a net \$0.8 million change in operating assets and liabilities, including an increase of \$1.1 million in accounts payable, and an increase of \$0.3 million in accrued expenses, which were partially offset by an increase of \$0.6 million in grants receivable, prepaid expenses and other current assets.

Investing activities

Net cash used in investing activities for the nine months ended September 30, 2019 was \$23.7 million, which was attributable to \$0.6 million of purchases of property and equipment and \$23.0 million of net purchases of marketable securities.

Net cash used in investing activities for the nine months ended September 30, 2018 was \$0.2 million, which was attributable to purchases of property and equipment.

Financing activities

Net cash provided by financing activities for the nine months ended September 30, 2019 was \$59.8 million, consisting of net proceeds from the issuance of our Series C and Series B convertible preferred stock of \$62.0 million and \$0.3 million of proceeds from the exercise of stock options.

Net cash provided by financing activities for the nine months ended September 30, 2018 was \$6.8 million, consisting of \$5.0 million in proceeds received upon the issuance of convertible notes payable and \$70 thousand of proceeds from the exercise of stock options. We also issued shares of preferred stock in Frequency Therapeutics Japan KK, our majority-owned subsidiary, for proceeds of \$1.8 million, which has been recorded as a liability.

Funding requirements

Our operating expenses increased substantially in the nine months ended September 30, 2019, and are expected to increase substantially in the future in connection with our ongoing activities, particularly as we advance FX-322 through clinical trials and as we research and develop additional product candidates including preclinical activities, studies for INDs applications, and initiation of human clinical trials. In addition, we expect to continue to incur additional general and administrative costs associated with operating as a public company.

Specifically, our costs and expenses will increase as we:

- advance the clinical development of FX-322;
- pursue the preclinical and clinical development of other product candidates using our PCA platform, including our program for the treatment of MS;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional personnel in research, manufacturing, and regulatory and clinical development, as well as management personnel; and
- expand our operational, financial, and management systems and increase personnel, including personnel to support our operations as a public company.

As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Based on our current operating plan, we believe that the net proceeds from our IPO of \$79.2 million, together with our existing cash, cash equivalents, and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements into 2022. We have based this estimate on assumptions that may prove to be incorrect, and we could utilize our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with the research, development, and commercialization of therapeutics, it is difficult to estimate with certainty the amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the progress, costs, and results of our clinical development and clinical trials for FX-322;
- the progress, costs, and results of our additional research and preclinical development programs, including our program for the treatment of MS;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and comparable foreign regulatory authorities, if applicable, for our product candidates;
- the costs and timing of internal process development, manufacturing activities, and clinical trial management associated with FX-322 and other product candidates we advance through preclinical and clinical development;

- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results, and costs of any product candidates that we may derive from our PCA platform or any other product candidates we may develop alone or with collaborators;
- the extent to which we in-license or acquire rights to other products, product candidates, or technologies;
- additions or departures of key scientific or management personnel;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and protecting our intellectual property rights, and defending against any intellectual property-related claims; and
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution for any product candidates for which we or our collaborators obtain marketing approval.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our cash needs through a combination of public or private equity or debt financings and other sources, which may include current and new collaborations with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through other sources, such as collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, product development, and research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

There have been no material changes from the contractual commitments and obligations previously disclosed in our final prospectus, dated October 2, 2019, filed with the SEC on October 4, 2019 pursuant to Rule 424(b) relating to our Registration Statement on Form S-1 (File No. 333-233652):

	Payments Due by Period				
	Total	Less Than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 years
Operating lease obligation(1)	\$ 2,740	\$ 505	\$ 1,716	\$ 249	\$ —

(1) In November 2019, the company signed a lease amendment for its Woburn, Massachusetts facility. The lease amendment increased the office space under the lease by 7550 square feet and extended the term of the lease for the facility to February 2025. The annual rent is approximately \$545.0 with provisions for an annual increase of 3%.

We have not included future milestone payments under our collaboration and license agreements in the table above since the payment obligations under these agreements are contingent upon future events, such as the achievement of specified product development milestones or generating product sales, and we are unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. We are also required to spend certain minimum amounts on research and development of licensed products or processes under the MIT License, and may have certain funding obligations under the Scripps option agreement, which are not included in the table above.

We also enter into contracts in the normal course of business with CROs, CMOs, universities, and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the table above as the amount and timing of such payments are not known.

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 three months ended September 30, 2019, there were no material changes to our critical accounting policies from those described in our final prospectus dated October 2, 2019 for our IPO filed with the SEC on October 4, 2019 pursuant to Rule 424(b)(4) relating to our Registration Statement on Form S-1 (File No. 333-233652).

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 Form 10-Q.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

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.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. Our interest-earning assets consist of cash, cash equivalents and short-term investments, which are denominated in U.S. dollars. We had cash, cash equivalents and short-term investments of \$165.3 million, or 96.7% of our total assets, at September 30, 2019. Interest income earned on these assets was \$0.8 million for the nine months ended September 30, 2019. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. Such interest-earning instruments carry a degree of interest rate risk; however, a change by 10% in interest rates would not have a material impact on our financial position or results of operations. We had no debt outstanding as of September 30, 2019.

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.

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 of September 30, 2019. Based on the evaluation of our disclosure controls and procedures as of September 30, 2019, our Chief Executive Officer and Vice President of Finance and Operations concluded that, as of such date, 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.

We are not subject to any material legal proceedings.

Item 1A. Risk Factors.

Our future operating results could differ materially from the results described in this Quarterly Report on Form 10-Q due to the risks and uncertainties described below. You should consider carefully the following information about risks below in evaluating our business. If any of the following risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. In these circumstances, the market price of our common stock would likely decline. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See "Forward Looking Statements" for a discussion of some of the forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those factors discussed below.

Risks related to our financial position and need for additional capital

We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability. If we are unable to achieve or sustain profitability, the market value of our common stock will likely decline.

We are a clinical-stage biotechnology company with a limited operating history. As a result, we are not profitable and have incurred significant losses since our formation. We had net losses of \$20.2 million, \$19.2 million and \$13.3 million for the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, respectively. As of September 30, 2019, we had an accumulated deficit of \$63.4 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. We have not commercialized any products and have never generated revenue from the commercialization of any product. To date, we have devoted most of our financial resources to licensing technologies and research and development, including our preclinical platform development activities and clinical trials.

We expect to incur significant additional operating losses for the next several years, at least, as we advance FX-322 and any other product candidate through clinical development, complete clinical trials, seek regulatory approval and commercialize FX-322 or any other product candidate, if approved. 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, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of any product candidates or achieve or maintain profitability. Our expenses will also increase substantially if and as we:

- continue our Phase 2a trial of FX-322 in sensorineural hearing loss, or SNHL;
- expand our development programs based on our progenitor cell activation, or PCA, platform, including our program for a treatment for multiple sclerosis, or MS, and develop other product candidates;
- continue to develop our PCA platform;
- seek regulatory approvals for FX-322 and any other product candidates;
- expand the target indications and patient population for FX-322;
- secure a commercial manufacturing source and supply chain capacity sufficient to produce commercial quantities of any product candidate for which we obtain regulatory approval;
- establish a sales, marketing and distribution infrastructure to commercialize FX-322 for the treatment of SNHL, if approved, and for any other product candidates for which we may obtain marketing approval;

- maintain, expand, and protect our intellectual property portfolio;
- hire additional clinical, scientific, and commercial personnel;
- add operational, financial, and management personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support operations as a public company; and
- acquire or in-license other product candidates or technologies.

Furthermore, our 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, we expect 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 our stockholders’ equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are 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, we will not achieve profitability. Even if we successfully commercialize FX-322, we may continue to incur substantial research and development and other expenses to identify and develop other product candidates. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the value of our common stock will be materially adversely affected.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of FX-322 and additional product candidates.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and, if approved, commercialize FX-322. These expenditures will include costs related to the Phase 2a trial of FX-322 for the treatment of SNHL, and, if the Phase 2a trial is supportive, a planned Phase 2b trial of FX-322, and any additional trials we conduct to support the development of FX-322. In addition, we are obligated to make milestone and royalty payments in connection with the sale of resulting products and licensing revenues under our license agreements with Massachusetts Institute of Technology, or MIT, and the Scripps Research Institute, or Scripps. We also expect to spend substantial amounts to identify and develop new product candidates based on our PCA platform.

We will require additional capital to enable us to develop additional product candidates based on our PCA platform, which we may acquire through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts.

Based upon our current operating plan, we believe that our existing cash and cash equivalents, including the net proceeds from our IPO of \$79.2 million, and short-term investments will enable us to fund our operating expenses and capital expenditure requirements into 2022. This estimate and our expectation regarding the sufficiency of our current financial resources to advance the clinical development of FX-322 and any other product candidates are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, or our clinical trials, including our Phase 2a trial of FX-322 for the treatment of SNHL, may be more expensive, time consuming or difficult to design or implement than we currently anticipate. Changing circumstances, including any unanticipated expenses, could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length of time and scope of activities associated with successful development of FX-322 or any product candidate we may develop is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our clinical trials through all phases of development, including the Phase 2a trial for FX-322 and the development of any other product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or the FDA, and other comparable foreign regulatory authorities, including any additional clinical trials required by the FDA or other comparable foreign regulatory authorities;

- the willingness of the FDA and other comparable foreign regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned clinical trials and preclinical studies, as the basis for review and approval of FX-322 and any other product candidates;
- the cost of filing, prosecuting, defending, and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the costs of operating as a public company;
- the cost of making royalty, milestone or other payments under current and any future in-license agreements;
- the extent to which we in-license or acquire other product candidates or technologies;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates, if approved;
- our ability to maintain our collaboration with Astellas Pharma Inc., or Astellas on favorable terms and establish new collaborations; and
- the initiation, progress, and timing of our commercialization of FX-322, if approved, or any other product candidate.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of FX-322 or any other product candidate, or potentially discontinue operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenues, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, our existing stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. In addition, debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. Furthermore, any capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to advance research programs, product development activities or product candidates. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We were established and began operations in 2014. Our operations to date have been limited to financing and staffing our company, licensing technologies, developing our PCA platform, developing and conducting preclinical and clinical studies of FX-322 for the treatment of SNHL, and developing a pipeline of preclinical and research programs, including our program for the treatment of MS. We have not yet demonstrated the ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We will eventually need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition and, as a result, our business may be adversely affected.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, the results of any particular quarterly or annual period are not necessarily indicative of future operating performance.

Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2018, we had net operating loss carryforwards, or NOLs, of \$39.3 million for federal income tax purposes and \$31.7 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our NOLs begin to expire in various amounts in 2036, provided that NOLs generated after December 31, 2017 will not be subject to expiration. As of December 31, 2018, we also had federal and state research and development and other tax credit carryforwards of approximately \$0.7 million and \$0.4 million, respectively, available to reduce future tax liabilities. Our tax credit carryforwards expire at various dates through 2038. These NOLs and tax credit carryforwards could expire unused, to the extent subject to expiration, and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs and tax credit carryforwards to offset future taxable income. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We believe we have experienced an ownership change in the past, and may experience ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. If we undergo another ownership change, our ability to use our NOLs and tax credit carryforwards could be further limited. For these reasons, we may not be able to use a material portion of our NOLs or tax credit carryforwards, even if we attain profitability. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets. The reduction of the corporate tax rate under the Tax Cuts and Jobs Act of 2017, or TCJA, from 35% to 21% may cause a reduction in the economic benefit of our NOLs and other deferred tax assets available to us. Furthermore, under the TCJA, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond will only be able to offset 80% of taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

Risks related to development, clinical testing, manufacturing, and regulatory approval

We are heavily dependent on the success of FX-322, our lead product candidate, which is still under clinical development, and if FX-322 does not receive regulatory approval or is not successfully commercialized, our business will be materially adversely harmed.

To date, we have invested a significant portion of our efforts and financial resources in the development of FX-322 for the treatment of SNHL. Our future success is substantially dependent on our ability to successfully complete clinical development for, obtain regulatory approval for, and successfully commercialize FX-322, which may never occur. We currently have no products that are approved for commercial sale and may never be able to develop a marketable product. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to FX-322, which will require additional clinical development, management of clinical and manufacturing activities, regulatory approval, establishing commercial scale manufacturing, and significant sales, marketing, and distribution efforts before we can generate any revenues from any commercial sales. We cannot be certain that we will be able to successfully complete any of these activities or that, even if it receives regulatory approval, FX-322 will be as effective as anticipated at treating SNHL.

The research, testing, manufacturing, labeling, approval, sale, packaging, marketing, and distribution of drug products are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries. We are not permitted to market FX-322 in the United States until we receive approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries until our collaborator, Astellas, receives the requisite approval from such countries. We have not submitted an NDA to the FDA and Astellas has not submitted comparable applications to other regulatory authorities for FX-322. We or Astellas may not be in a position to do so for several years, if ever. If we or Astellas are unable to obtain the necessary regulatory approval for FX-322 in a particular country, we or Astellas will not be able to commercialize FX-322 for the treatment of SNHL in that country. As a result, our financial position will be materially adversely affected and we may not be able to generate sufficient revenue to continue our business.

We utilize our PCA platform to develop product candidates that are designed to activate progenitor cells, which is a new approach to therapeutic intervention and, as a result, successful development, approval, and commercialization of our product candidates, including FX-322, is uncertain.

We utilize our PCA platform to develop product candidates, including FX-322, for the treatment of SNHL. Our PCA platform is designed to identify pathways to activate progenitor cells already present in the body to treat conditions or diseases through cellular regeneration. We have not, nor to our knowledge has any other company, received regulatory approval utilizing this mechanism of cellular regeneration. Given the novelty of our approach, we could encounter a longer than expected regulatory review process, increased development costs, or unexpected delays in, or even prevention of, the regulatory approval and commercialization of our product candidates, and we cannot be certain that our approach will lead to the development of any approvable or marketable products. For example, the FDA-approved treatment options available for patients with SNHL are hearing aids and cochlear implants. Unlike FX-322, which is a therapeutic that targets the underlying biology of SNHL, these treatment options are medical devices that are designed to target the symptoms of SNHL. As a result, these treatment options are not directly comparable to FX-322, and FDA requirements for marketing authorization of these treatment options may not be relevant for FX-322. While we are developing what we believe are appropriate measurements of efficacy for FX-322, we cannot be certain that the FDA will agree with our measurements or that they will be sufficient for approval. If we were to encounter any of the foregoing, our business and financial prospects could be materially harmed.

Clinical trials are expensive, time consuming, and difficult to design and implement, and involve an uncertain outcome. The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and any product candidates we develop may not be further developed or have favorable results in later studies or trials. Clinical trial failure may result from a multitude of factors, including, but not limited to, flaws in study design, dose selection, placebo effect, patient enrollment criteria, selection of patients based on patient misrepresentations, and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the pharmaceutical industry have suffered setbacks in the advancement of their drug candidates into later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding favorable results in earlier preclinical studies or clinical trials. Based upon negative or inconclusive results or a need for additional information, we may decide, or regulatory authorities may require us, to conduct additional clinical trials or preclinical studies.

We may experience delays in initiating and completing any clinical trials that we intend to conduct, and we do not know whether our clinical trials will begin on time, need to be redesigned, enroll patients on time, or be completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory approval to commence a trial;
- reaching an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining Institutional Review Board, or IRB, approval at each site within the United States, or Independent Ethics Committee, or IEC, approval at sites outside the United States;
- recruiting suitable patients to participate in a trial in a timely manner and in sufficient numbers;
- having patients complete a trial or return for post-treatment follow-up;
- imposition of a clinical hold by regulatory authorities, including as a result of unforeseen safety issues or side effects or failure of trial sites or investigators to adhere to regulatory requirements or follow trial protocols;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- addressing patient safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of a product candidate for use in clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the FDA or other regulatory authorities, or recommended for termination by a Data and Safety Monitoring Board, or DSMB, for such trial. Such authorities may impose a suspension or termination or recommend an alteration due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial.

Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in the section titled “—Risks related to our dependence on third parties.”

Our lead product candidate, FX-322, is still in development and will require the successful completion of one, and possibly more, Phase 3 trials before we are prepared to submit an NDA for regulatory approval by the FDA. We cannot predict with any certainty if or when we might complete the development of FX-322 and submit an NDA for regulatory approval by the FDA of FX-322 or whether any such NDA will be approved by the FDA.

If we experience delays in the commencement or completion of any clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of any product candidate we develop could be harmed, and our ability to generate revenues may be delayed. In addition, any delays in our clinical trials could increase our costs, slow the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may materially harm our business, financial condition, and results of operations. In addition, many of the factors that may cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of a clinical trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of a product candidate.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for FX-322 or any other product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that we will never obtain regulatory approval for any product candidate. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA from the FDA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authority, that such product candidates are safe and effective for their intended uses. In addition, data obtained from preclinical trials and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit, or prevent development efforts, clinical trials, or marketing approval. Furthermore, as more competing drug candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other comparable regulatory authorities.

The FDA or any foreign regulatory authority can delay, limit, or deny approval of FX-322 or any other product candidates that we develop or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates, or other products containing an active ingredient in our product candidates;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials;
- the FDA's or the applicable foreign regulatory authority's disagreement regarding the formulation, the labeling, and/or the specifications of our product candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations, and prospects.

In addition, the FDA or the applicable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable foreign regulatory authority may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing circumstances could materially harm the commercial prospects for our product candidates and our business.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials.

Patient enrollment and retention in clinical trials depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the nature of the trial protocol;
- the existing body of safety and efficacy data with respect to the product candidate;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or medical devices that may be approved for the indications we are investigating;
- competing clinical trials being conducted by other companies or institutions;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates and medical devices that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Furthermore, any negative results we may report in clinical trials of any product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs or program delays, which could have a harmful effect on our ability to develop a product candidate or could render further development impossible.

Results of preclinical studies, clinical trials, or analyses may not be indicative of results that may be obtained in later trials.

The results of preclinical studies, clinical trials, or analyses of the results from such trials, including our prospective and *post hoc* analyses of the data from the Phase 1/2 trial of FX-322 for the treatment of SNHL, may not be predictive of the results of later clinical trials. Product candidates in later clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and prior clinical trials or having shown promising results based on analyses of data from earlier trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding earlier promising results. In addition, conclusions based on promising data from analyses of clinical results, such as the prospective and *post hoc* analysis of results from our Phase 1/2 clinical trial of FX-322 for the treatment of SNHL, may be shown to be incorrect in subsequent clinical trials that have pre-specified endpoints or may not be considered adequate by regulatory authorities. Even if we complete later clinical trials as planned, we cannot be certain that their results will support the safety and efficacy requirements sufficient to obtain regulatory approval, and, as a result, our clinical development plans may be materially harmed.

Interim and preliminary "top-line" data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim or preliminary "top-line" data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. In addition, we may report interim or preliminary analyses of only certain endpoints rather than all endpoints. Furthermore, the information we choose to publicly disclose regarding a particular study or clinical trial is based on more extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to disclose. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities, or otherwise regarding a particular drug, drug candidate, or our business. Others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of particular programs, the approvability or commercialization of the particular product candidates, and our business in general. As a result, interim and preliminary data and analyses should be viewed with caution. Adverse differences between preliminary or interim data and final data or changes in what is material information regarding the results from a particular study or clinical trial could significantly harm our clinical development and business prospects and cause volatility in the price of our common stock.

Any product candidate that we develop or the administration thereof, may cause serious adverse events or undesirable side effects, which may halt their clinical development, delay or prevent marketing approval, or, if approved, require them to be taken off the market, include safety warnings, or otherwise limit their sales.

Serious adverse events or undesirable side effects caused by any product candidate we develop could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects. To date, subjects treated with FX-322 have experienced adverse events that include ear discomfort and ear pain that are considered to be associated with the intratympanic injection procedure.

If unacceptable side effects arise in the development of any product candidate, we, the FDA, or the IRBs or IECs at the institutions in which our studies are conducted, or the DSMB, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may have to train medical personnel regarding the proper administration protocol for our product candidates and to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Additionally, if FX-322 or any other product candidate we develop receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw, or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require us to recall a product or we may decide to initiate a voluntary recall of a product;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or contraindication;
- additional restrictions may be imposed on the marketing of the product or the manufacturing processes for the product or any component thereof;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to conduct post-market studies or agree to post marketing commitments;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, the choice of which may prove to be wrong and adversely affect our business.

Although we intend to explore additional product candidates based on our PCA platform, we may fail to identify viable new product candidates for clinical development for several reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to develop additional product candidates based on our PCA platform require substantial technical, financial, and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications or product candidates, yet fail to yield results for clinical development for several reasons, including:

- the research methodology used may not be successful in identifying potential indications or product candidates;
- potential product candidates may, after further study, be shown to have harmful or unexpected adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify, and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that could have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. For example, we may encounter delays in the process of selecting a product candidate for the treatment of MS and we may not achieve the time line we currently anticipate for submitting an IND. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

The market opportunities for FX-322, if approved, may be smaller than we anticipate and, as a result, our commercial opportunity may be limited.

We expect to initially seek approval of FX-322 for the treatment of SNHL. Our projections of the number of eligible patients are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, patient foundations, and market research, and may prove to be incorrect. Further, new sources may reveal a change in the estimated number of eligible patients, and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates may be limited. For example, even if we obtain FDA approval for FX-322, it may be approved for a target population that is more limited than what we currently anticipate. Even if we obtain significant market share for any product candidate, if approved, if the potential target populations are smaller, we may never achieve profitability without obtaining marketing approval for additional indications.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any product candidate.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of our product candidates. We believe our approach of activating progenitor cells to treat conditions or diseases through cellular regeneration is novel and, as a result, the process for, and the outcome of, FDA approval is especially uncertain. If the FDA does not accept or approve our NDAs for our product candidates, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that we submit may be delayed, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

Even if we obtain FDA approval for a product candidate in the United States, we or our collaborators may never obtain approval for or commercialize the product candidate in any other jurisdiction, which would limit our ability to realize its full market potential.

In order to market any product in a particular jurisdiction, we or our collaborators must establish and comply with numerous and varying regulatory requirements regarding safety and efficacy on a country-by-country basis. Approval by the FDA in the United States does not ensure approval by comparable regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our or our collaborators' ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and we will be unable to realize the full market potential of any product we develop.

Even if we obtain regulatory approval for any product candidate, we will still face extensive and ongoing regulatory requirements and obligations, which may result in significant additional expense, and any product candidates, if approved, may face future development and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, and advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and Good Clinical Practice, or GCP, and requirements for any clinical trials that we conduct post-approval.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, including a requirement to implement a REMS. If a product candidate receives marketing approval, the accompanying label may limit the approved indicated use of the product, which could limit sales of the product. The FDA may also require costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of prescription drugs, may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers, or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls or market withdrawals of products;

- fines, restitution, or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions, consent decrees, or the imposition of civil or criminal penalties.

Further, the FDA's policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of a product candidate. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects, and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. The policies of the FDA and of other comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of a product candidate. For example, certain policies of the current presidential administration may impact our business and industry. Namely, the current presidential administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. These executive actions and other policies of the current administration may impact the FDA's ability to exercise its regulatory authority, though the extent to which they will impact the development of FX-322 or any other product candidates we develop is unknown. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition, and results of operations. Furthermore, noncompliance by us or any collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, may also result in significant financial penalties, which would adversely affect our business.

We may seek Fast Track designation by the FDA for our product candidates, but we might not receive such a designation and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

In October 2019, FX-322 received Fast Track designation by the FDA. If a drug is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, a drug sponsor may qualify for FDA Fast Track designation. Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. The FDA has broad discretion whether to grant Fast Track designation, and we may not receive such a designation for all of the product candidates for which we may request it. Moreover, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

We may seek a Breakthrough Therapy designation for our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek a Breakthrough Therapy designation for FX-322 if future results support such designation or other product candidates we may develop. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that a product candidate meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such a designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate qualifies as a Breakthrough Therapy, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of any product candidate we may develop in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize a product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased market demand for any product; and
- loss of revenue.

The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any product candidate, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operation and business, including preventing or limiting the commercialization of any product candidates we develop.

Risks related to commercialization

We face significant competition from biotechnology, pharmaceutical, and medical device companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology, pharmaceutical, and medical device industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain marketing approval for new products on a cost-effective basis and to market them successfully. If a product candidate we develop is approved, we will face intense competition from a variety of businesses, including large, fully-integrated pharmaceutical companies, specialty pharmaceutical companies, and early-stage companies, particularly if the early-stage company has a collaborative arrangement with a large and established company. We are aware of several companies developing products to treat SNHL through the regeneration of hair cells, and we also anticipate that new companies will enter the SNHL market in the future. If we successfully develop and, if approved, commercialize FX-322 for the treatment of SNHL, it may compete, or potentially be used in conjunction, with currently marketed devices, including the hearing aids and cochlear implants currently available and the next generation of improved hearing aids and cochlear implants, and any new therapies that may become available in the future.

Competition could render any product candidate we develop obsolete, less competitive, or uneconomical. Our competitors may, among other things:

- have significantly greater name recognition and financial, manufacturing, marketing, product development, technical, and human resources than we do, with mergers and acquisitions in the biotechnology, pharmaceutical, and medical device industries resulting in even more resources being concentrated in our competitors;

- more effectively recruit and retain qualified scientific and management personnel;
- more effectively establish clinical trial sites and patient registration;
- develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe side effects;
- obtain quicker regulatory approval;
- better protect their patents and intellectual property or acquire technologies that are complementary to, or necessary for, our programs;
- implement more effective approaches to sales, marketing, pricing, coverage, and reimbursement; or
- form more advantageous strategic alliances or collaborations.

If we are not able to effectively compete for any of the foregoing reasons, our business will be materially harmed.

The successful commercialization of any product candidate we develop will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our or our collaborators' ability to market those products and decrease our or our collaborators' ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers, and other third-party payors are essential for most patients to be able to afford prescription medications. Our ability to achieve acceptable levels of coverage and reimbursement for products or procedures using our products by governmental authorities, private health insurers and other organizations will influence our ability to successfully commercialize any product candidates we develop. Obtaining adequate coverage and reimbursement for any product candidate we develop that is administered under the supervision of a physician, which is what we anticipate for FX-322, may be particularly difficult because of the higher prices associated with such products. In addition, we believe that FX-322 is a novel approach to treating hearing loss and, as a result, availability of coverage and reimbursement by payors is highly uncertain. A decision by a third-party payor not to cover or separately reimburse for our products or procedures using our products could reduce physician utilization of our products once approved. Assuming we obtain coverage for our product candidates or procedures using our products by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product we commercialize, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and the current presidential administration and Congress have introduced several proposals related to drug pricing. Many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar, or a less expensive therapy is available. Although there are currently no FDA approved drugs for the treatment of SNHL, it is possible that a third-party payor may consider FX-322 as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy, pricing of existing drugs may limit the amount we will be able to charge for any product we commercialize. Payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize a satisfactory return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates. Additionally, our ability to obtain a satisfactory financial return depends on what, if any, proposals related to drug pricing may be implemented and, if implemented, when they might take effect.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor, and one third-party payor's decision to cover a particular product does not ensure that other payors will also provide similar coverage. Additionally, the process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the price of such product or establishing the reimbursement rate that the payor will pay for the product once coverage is approved. As a result, the determination of coverage and reimbursement is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Moreover, increasing efforts by governmental and third-party payors in the United States to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for any product we commercialize. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations, and additional legislative, administrative, or regulatory changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

We or our collaborators may also be subject to extensive governmental price controls and other market regulations outside of the United States, and we believe the increasing emphasis on cost-containment initiatives in other countries have and will continue to put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we or our collaborators are able to charge for products we or our collaborators commercialize. Accordingly, in markets outside the United States, the reimbursement for products we or our collaborators commercialize may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Even if a product candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors, or others in the medical community necessary for commercial success.

If a product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved, will depend on several factors, including, but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of our product candidates, if approved, to generate substantially all our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales and marketing capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing any product candidate we develop, if approved.

In order to market and successfully commercialize any product candidate we develop, if approved, we must build our sales and marketing capabilities or enter into collaborations with third parties for these services. We currently have no sales, marketing or distribution capabilities and as a company have no experience in marketing products. We intend to directly market and commercialize FX-322 for the treatment of SNHL, if approved, in the United States by developing our own sales and marketing force, targeting ear, nose, and throat doctors and audiologists. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, train, retain, and appropriately incentivize a sufficient number of qualified individuals, generate sufficient sales leads and provide our sales and marketing team with adequate access to physicians who may prescribe our product, effectively manage a geographically dispersed sales and marketing team, and other unforeseen costs and expenses. Any failure or delay in the development of a product candidate that affects the expected timing of commercialization of the product candidate or results in the failure of the product candidate to be commercialized could result in us having prematurely or unnecessarily incurred costly commercialization expenses. Our investment would be lost if we are unable to retain or reposition our sales and marketing personnel.

We may also enter into collaborations for the sales and marketing of our product candidates, if approved. To the extent that we depend on collaborators for sales and marketing activities, any revenues we receive will depend upon the success of those collaborators' sales and marketing teams and the collaborators' prioritization of our product and compliance with applicable regulatory requirements, and there can be no assurance that the collaborators' efforts will be successful. For example, under the License and Collaboration Agreement with Astellas, or the Astellas Agreement, we will depend on Astellas to sell and market FX-322 for the treatment of SNHL, if approved, outside of the United States, and we can have no assurance that it will be successful in its efforts or devote sufficient resources to the sale and marketing of FX-322.

If we are unable to build our own sales and marketing team or enter into a collaboration for the commercialization of product candidates we develop, if approved, we may be forced to delay the commercialization of our product candidates or reduce the scope of our sales or marketing activities, which would have an adverse effect on our business, operating results and prospects.

A variety of risks associated with operating internationally could materially adversely affect our business.

Our business strategy includes potentially expanding internationally if any of our product candidates receive regulatory approval. Doing business internationally involves several risks, including, but not limited to:

- multiple, conflicting, and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, economic sanctions laws and regulations, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;
- certain expenses, including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, its books and records provisions, or its anti-bribery provisions, as well as other applicable laws and regulations prohibiting bribery and corruption.

Any of these factors could significantly harm any future international expansion and operations and, consequently, our results of operations.

Risks related to our dependence on third parties

The Astellas Agreement is important to our business. If we or Astellas fail to adequately perform under the Astellas Agreement, or if we or Astellas terminate the Astellas Agreement, the development and commercialization of FX-322 for SNHL outside the United States would be materially delayed and our business would be adversely affected.

Under the Astellas Agreement, Astellas is responsible for the development and commercialization of FX-322 outside of the United States and we are responsible for development and commercialization in the United States. We and Astellas are jointly responsible for conducting global clinical studies and coordinating commercial launch activities. We have received an upfront payment from Astellas of \$80.0 million and we may also receive up to an additional \$545.0 million based on development and commercial milestones, as well as double-digit royalties on any future product sales in the licensed territory.

Termination of the Astellas Agreement could cause significant delays in our development and commercialization efforts for FX-322 for the treatment of SNHL outside of the United States. If the Astellas Agreement is terminated, we would need to expand our internal capabilities or enter into another agreement to compensate for the loss in funding and clinical development support from Astellas. Any suitable alternative agreement would take considerable time to negotiate and could also be on less favorable terms to us. Whether or not we identify another suitable collaborator, we may need to seek additional financing to continue the development of FX-322, or we may be forced to discontinue development of FX-322, either of which could have a material adverse effect on our business.

We intend to continue to collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in establishing and maintaining collaborations, which may significantly limit our ability to successfully develop and commercialize our other product candidates, if at all.

We have entered into the Astellas Agreement for the development and commercialization of FX-322 for the treatment of SNHL outside the United States and may seek collaborations for the development and commercialization of other product candidates. The process of establishing and maintaining collaborative relationships is difficult, time-consuming, and involves significant uncertainty, such as:

- a collaborator may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale, or downsizing;
- a collaborator may seek to renegotiate or terminate its relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaborator may cease development in therapeutic areas which are the subject of our collaboration;
- a collaborator may not devote sufficient capital or resources towards our product candidates, or may fail to comply with applicable regulatory requirements;
- a collaborator may change the success criteria for a product candidate, thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaborator will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaborator could develop a product that competes, either directly or indirectly, with our product candidate;
- a collaborator with commercialization obligations may not commit sufficient financial resources or personnel to the marketing, distribution, or sale of a product;
- a collaborator with manufacturing responsibilities may encounter regulatory, resource, or quality issues and be unable to meet demand requirements;
- a collaborator may terminate a strategic alliance;
- a dispute may arise between us and a collaborator concerning the research, development, or commercialization of a product candidate resulting in a delay in milestones or royalty payments or termination of the relationship and possibly resulting in costly litigation or arbitration, which may divert management's attention and resources; and
- a collaborator may use our products or technology in such a way as to invite litigation from a third party.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing, or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborations on acceptable terms or to successfully transition away from terminated collaborations, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense, or find alternative sources of capital, which would have a material adverse impact on our clinical development plans and business.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization of our product candidates, could engage in misconduct, including intentional, reckless, or negligent conduct or unauthorized activities that violate applicable laws, rules, and regulations including: the laws and regulations of the FDA or other similar regulatory requirements of other authorities, including those laws that require the reporting of true, complete, and accurate information to such authorities; manufacturing standards; data privacy, security, fraud and abuse, and other healthcare laws and regulations; or laws that require the reporting of true, complete, and accurate financial information and data. Specifically, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these or other laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us or them and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

We currently rely on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of FX-322 and intend to rely on CMOs for the production of commercial supply of FX-322, if approved, and for clinical and commercial supply of our future product candidates, as well as to supply raw materials necessary to produce our product candidates. Our dependence on CMOs may impair the development of our product candidates and may impair their commercialization, which would adversely impact our business and financial position.

We do not own facilities for manufacturing FX-322 or any product candidate. Instead, we rely on and expect to continue to rely on CMOs for the supply of cGMP grade clinical trial materials of FX-322 and any product candidates we develop and, in future, for commercial quantities. Reliance on CMOs may expose us to more risk than if we were to manufacture our product candidates ourselves. If any CMO we engage is unable to provide sufficient supply of any product candidate we develop, we may be unable to arrange for an alternative supply or to do so on commercially reasonable terms or in a timely manner, which could delay any clinical trials, the commercial launch of our product candidates, if approved, or, regarding any commercial supply, result in a shortage in supply that could negatively impact our revenues. For example, we are substantially dependent on the CMO that supplies us with the proprietary glycogen synthase kinase 3, or GSK3, inhibitor that is a key component of FX-322 and the CMO that lyophilizes FX-322 into a powder. While there are other CMOs who are able to supply the GSK3 inhibitor or lyophilize FX-322, manufacture of the GSK3 inhibitor and the lyophilization process require proprietary knowledge or specialized capabilities that only a limited number of CMOs have. As a result, transitioning to a new CMO for either the supply of the GSK3 inhibitor or to conduct the lyophilization process would be particularly time consuming and costly. We have not engaged any other CMOs as back-up for the manufacture and supply of FX-322. As a result, if any of the CMOs involved in the manufacture and supply of FX-322 experience a delay or disruption, we may not have sufficient quantities of FX-322 for our planned activities and may not be able to transition to a new CMO in a timely or cost-effective manner, or at all, which would negatively impact our ability to develop and potentially commercialize FX-322.

The facilities used to manufacture our product candidates must be inspected by the FDA and comparable foreign regulatory authorities. While we provide oversight of manufacturing activities, we do not and will not control the execution of manufacturing activities by, and are or will be dependent on, our CMOs for compliance with cGMP requirements for the manufacture of our product candidates. As a result, we are subject to the risk that our product candidates may have manufacturing defects that we have limited ability to prevent. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. While we have engaged independent auditors to assess the compliance with the protocol that we co-developed with our CMOs regarding the manufacturing process for FX-322, in general, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance, and qualified personnel, and we were not involved in developing our CMOs' policies and procedures.

If the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved. In addition, any failure to achieve and maintain compliance with laws, regulations, and standards related to manufacturing could subject us to risks, including the risk that we may have to suspend the manufacture of our product candidates, that obtained approvals could be revoked, and that the FDA or another governmental regulatory authority may take enforcement actions, including untitled letters, warning letters, seizures, injunctions, or product recalls. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed.

We contract for the supply of the active pharmaceutical ingredient, or API, and other raw material necessary to produce FX-322 and we may contract in the future for the supply of API and other raw material for any other product candidate we develop. Supplies of API or other raw material could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable time frame, at an acceptable cost, or at all. In addition, a disruption in the supply of API or other raw material could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues. Growth in the costs and expenses of API or other raw material may also impair our ability to cost-effectively manufacture our product candidates. In addition, there may be a limited number of suppliers for API or other raw material that we may use to manufacture our product candidates, and we cannot be certain that we will be able to engage such suppliers in a timely manner or at all. If we are unable to do so, clinical development of our product candidates, commercialization for any approved product, or our business could be adversely affected.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved.

We intend to rely on third parties to conduct, supervise, and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.

We rely, and will continue to rely, on CROs, CRO-contracted vendors, and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including our Phase 2a trial of FX-322 for the treatment of SNHL. Our reliance on CROs for clinical development activities limits our control over these activities and we were not involved in developing our CRO's policies and procedures, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards.

We and our CROs will be required to comply with the Good Laboratory Practice requirements for our preclinical studies and GCP requirements for our clinical trials, which are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators, and clinical trial sites. If we or our CROs fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Accordingly, if our CROs fail to comply with these requirements, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we do not control whether they devote sufficient time and resources to our clinical trials. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with any CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition, and prospects.

Risks related to healthcare laws and other legal compliance matters

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes, and additional proposed changes, to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of health care. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the biotechnology and pharmaceutical industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted, or injected;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial challenges to certain aspects of the ACA, and we expect there will be additional challenges to the ACA in the future. For example, in December 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was modified as part of the TCJA, the remaining provisions of the ACA are invalid as well. While the current presidential administration, Department of Health and Human Services, and CMS have indicated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, or other efforts to repeal and amend some or all aspects of the ACA will impact the law. Additionally, the current presidential administration will likely continue to seek to modify, repeal, use executive actions to change the implementation of or otherwise invalidate all or certain provisions of the ACA. This includes enactment of the TCJA which, among other things, modified penalties for not complying with the ACA's individual mandate to carry health insurance. The extent to which any such changes may impact our business or financial condition is uncertain.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our potential customers and accordingly, our financial operations.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been administrative efforts, Congressional inquiries and proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for drugs. For example, the current presidential administration's fiscal year 2019 budget proposal contains further drug price control measures which could be implemented in future legislation or through rulemakings or administrative or executive actions. These measures include, for example, allowing some states to negotiate drug prices under Medicaid and eliminating cost sharing for generic drugs for low-income patients. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U.S. federal healthcare reform measures will be implemented in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These reforms could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, customers, and others will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand;
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, or FCA, which, among other things, impose criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. A claim includes “any request or demand” for money or property presented to the federal government. In addition, pharmaceutical manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, specified requirements relating to privacy, security and breaches of individually identifiable health information by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information. HITECH created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA, as amended by HITECH, and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- the U.S. federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical

supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by certain physicians and their immediate family members;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- similar healthcare laws and regulations in the European Union, or EU, and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information, such as, where applicable, the General Data Protection Regulation, or GDPR, which imposes obligations and restrictions on the collection, use, and disclosure of personal data relating to individuals located in the EU and the European Economic Area, or EEA, (including health data); and
- laws and regulations prohibiting bribery and corruption such as the FCPA, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with healthcare providers, some of whom receive stock or stock options as compensation for their services, could be subject to challenge under one or more of such laws. Ensuring that our current and future internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to actions including the imposition of civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements, or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Any clinical trial programs, marketing, or research collaborations in the European Economic Area will subject us to the GDPR.

The GDPR applies to companies established in the EEA, as well as to companies that are not established in the EEA and which collect and use personal data in relation to (i) offering goods or services to, or (ii) monitoring the behavior of, individuals located in the EEA. If we conduct clinical trial programs in the EEA (whether the trials are conducted directly by us or through a clinical vendor or collaborator), or enter into research collaborations involving the monitoring of individuals in the EEA, or market our products to individuals in the EEA, we will be subject to the GDPR. The GDPR puts in place stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data (or reliance on another appropriate legal basis), the provision of robust and detailed disclosures to individuals about how personal data is collected and processed (in a

concise, intelligible and easily accessible form), a comprehensive individual data rights regime (including access, erasure, objection, restriction, rectification and portability), maintaining a record of data processing, data export restrictions governing transfers of data from the EEA, short timelines for data breach notifications to be given to data protection regulators or supervisory authorities (and in certain cases, affected individuals) of significant data breaches, and limitations on retention of information. The GDPR also puts in place increased requirements pertaining to health data and other special categories of personal data, as well as a definition of pseudonymized (i.e., key-coded) data. Further, the GDPR provides that EEA member states may establish their own laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use, and share such data and/or could cause our costs to increase. In addition, there are certain obligations if we contract third-party processors in connection with the processing of personal data. If our or our collaborators' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data, or fines of up to 20 million Euros or up to 4% of our total worldwide annual revenue of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, including class-action type litigation, negative publicity, reputational harm and a potential loss of business and goodwill.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

Risks related to our intellectual property

If we are unable to obtain, maintain, enforce and protect patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others, or may license from others, particularly patents, in the United States and other countries with respect to any proprietary technology and product candidates we develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technologies and product candidates that are important to our business and by in-licensing intellectual property related to such technologies and product candidates. If we are unable to obtain or maintain patent protection with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, defend, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain, enforce, and defend the patents, covering technology that we license from third parties. Therefore, these in-licensed patents, and applications may not be prepared, filed, prosecuted, maintained, defended, and enforced in a manner consistent with the best interests of our business.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the scope of patent protection outside of the United States is uncertain and laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. In

addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability, and commercial value of our owned and in-licensed patent rights are uncertain. Moreover, our owned and in-licensed pending and future patent applications may not result in patents being issued which protect our technology and product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend, and enforce our patent rights, narrow the scope of our patent protection and, more generally, could affect the value or narrow the scope of our patent rights.

Moreover, we or our licensors may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, *inter partes* review, post-grant review, or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our competitors may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar or identical to any of our technology and product candidates.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Additionally, if we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, or delay or prohibit the further development or commercialization of, one or more product candidates that rely on such agreements.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for any product candidates we may develop, our business may be materially harmed.

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. In addition, only one patent applicable to an approved drug may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations, and prospects could be materially harmed.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a United States patent covering any of our product candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO, of a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement, or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution, and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

Although we or our licensors are not currently involved in any litigation, we may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our licensors' issued patents or other intellectual property. As a result, we or our licensors may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable.

An adverse result in any such proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly, and could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed patents do not cover such technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations, and prospects.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs, and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third party intellectual property is invalid or that our activities and product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the discovery, use or manufacture of the product candidates that we may identify or related to our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the product candidates that we may develop may be found to infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the product candidates that we may develop, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could also be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right and could be forced to indemnify our customers or collaborators. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals, and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service, outside firms, and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are party to license and funding agreements that impose, and we may enter into additional licensing and funding arrangements with third parties that may impose, diligence, development, and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Under our existing licensing and funding agreements, we are obligated to pay royalties on net product sales of product candidates or related technologies to the extent they are covered by the agreements. If we fail to comply with such obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements or require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we in-license. If other third parties have ownership rights to patents and/or patent applications we in-license, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect, to the same extent or at all, inventions that constitute new methods of treatment.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets, or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, or we have wrongfully used or disclosed alleged trade secrets of their current or former employers, or claims asserting we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered and unregistered trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trade names or trademarks that incorporate variations of our unregistered trade names or trademarks. Over the long term, if we are unable to successfully register our trade names and trademarks and establish name recognition based on our trade names and trademarks, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trade names and trademarks may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our owned and in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;

- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks related to our employees, managing our growth and our operations

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

We are highly dependent on the expertise of David L. Lucchino, our President and Chief Executive Officer, as well as the other principal members of our management, scientific, and clinical teams. Although we have employment agreements, offer letters or consulting agreements with our executive officers, these agreements do not prevent them from terminating their services at any time.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous biotechnology and pharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by other companies or organizations and may have commitments that limit their availability. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities or acquire new facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may engage in transactions that could disrupt our business, cause dilution to our shareholders or reduce our financial resources.

In the future, we may enter into transactions to acquire or in-license rights to product candidates, products or technologies, or to acquire other businesses. If we do identify suitable candidates, we may not be able to enter into such transactions on favorable terms, or at all. Any such acquisitions or in-licenses may not strengthen our competitive position, and these transactions may be viewed negatively by analysts, investors, customers, or other third parties with whom we have relationships. We may decide to incur debt in connection with an acquisition, or in-license or issue our common stock or other equity securities as consideration for the acquisition, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the sellers of the acquired business. In addition, we may not be able to successfully integrate the acquired personnel, technologies, and operations into our existing business in an effective, timely, and nondisruptive manner. Such transactions may also divert management attention from day-to-day responsibilities, increase our expenses, and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or in-licenses or the effect that any such transactions might have on our operating results.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural and manmade disasters (including hurricanes), terrorism, war, and telecommunication and electrical failures. While we do not believe that we have experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our or their operations, it could result in delays and/or material disruptions of our research and development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing, or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we currently rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, and the development of our product candidates could be delayed.

Our proprietary or confidential information may be lost or we may suffer security breaches.

The U.S. federal and various state and foreign governments have enacted or proposed requirements regarding the collection, distribution, use, security and storage of personally identifiable information and other data relating to individuals. In the ordinary course of our business, we and third parties with which we have relationships will continue to collect and store sensitive data, including clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our and our collaborators' security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, breaches due to employee error, technical vulnerabilities, malfeasance, or other disruptions. A number of proposed and enacted federal, state and international laws and regulations obligate companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by third parties, including collaborators, vendors, contractors, or other organizations with which we have formed strategic relationships. Although, to our knowledge, neither we nor any such third parties have experienced any material security breach, and even though we may have contractual protections with such third parties, any such breach could compromise our or their networks and the information stored therein could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure, notifications, follow-up actions related to such a security breach or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and significant costs, including regulatory penalties, fines, and legal expenses, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation, and cause a loss of confidence in us and our or such third parties' ability to conduct clinical trials, which could adversely affect our reputation and delay the clinical development of our product candidates.

Risks related to our common stock

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.

The market price of our common stock is likely to be highly volatile and may be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this section titled "Risk factors" and elsewhere in this prospectus, these factors include:

- any delay in the enrollment or ultimate completion of our Phase 2a trial of FX-322 for the treatment of SNHL;
- the results of the Phase 2a trial of FX-322 for the treatment of SNHL or clinical trials of our competitors for the same indication;
- our ability to develop additional product candidates based on our PCA platform, including MS;
- any delay in submitting a regulatory filing and any adverse development or perceived adverse development with respect to the regulatory review of such filing;
- failure to successfully develop and commercialize FX-322 for the treatment of SNHL or any future product candidate;
- inability to obtain additional funding;
- regulatory or legal developments in the United States and other countries applicable to our PCA platform or any product candidate;

- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- adverse developments concerning our CMOs or CROs;
- inability to obtain adequate product supply for our other product candidates, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- our ability to effectively manage our growth;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of companies similar to us;
- market conditions in the biotechnology and pharmaceutical sectors, and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- the termination of a collaboration agreement, licensing agreement or other strategic arrangement, or the inability to establish additional collaboration arrangements that we need on favorable terms, or at all;
- significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our product candidates and PCA platform;
- additions or departures of key scientific or management personnel;
- sales of our common stock by us or our shareholders in the future;
- trading volume of our common stock; and
- general economic, industry and market conditions.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory, and market conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Our directors, executive officers and shareholders affiliated with our directors and executive officers own a significant percentage of our common stock and, if they choose to act together, will be able to exert significant influence over matters subject to shareholder approval.

Our directors, executive officers, and shareholders affiliated with our directors and executive officers exert significant influence on us. As of October 31, 2019, these holders beneficially own approximately 17.1% of the voting power of our outstanding common stock. As a result, these holders, acting together, have significant influence over all matters that require approval of our stockholders, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transactions. The interests of these holders may not always coincide with our corporate interests or the interests of other shareholders, and they may act in a manner with which our shareholders may not agree or that may not be in the best interests of our other shareholders.

If securities or industry analysts issue an adverse or misleading opinion regarding our common stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be the sole source of gain on an investment in our common stock for the foreseeable future.

Sales of a substantial number of shares of our common stock, or the perception that substantial sales might occur, could cause the price of our common stock to fall.

Sales of a substantial number of shares of our common stock, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. The shares of common stock that were sold in the initial public offering of our common stock are freely transferable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act, except for any shares acquired by our affiliates, as defined in Rule 144 under the Securities Act. The remaining shares of our common stock that are outstanding are restricted as a result of securities laws, lock-up agreements or other contractual restrictions that restrict, subject to certain exceptions, transfers for 180 days after the date of our initial public offering. We or certain of the underwriters of our initial public offering may release certain stockholders from the lock-up agreements or other contractual restrictions prior to the end of the 180-day period. In addition, there are shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity incentive plans and may become eligible for future sale subject to vesting, the lock-up agreements, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Based on the shares of capital stock outstanding as of September 30, 2019, after giving effect to the conversion of shares of convertible preferred stock into 22,079,913 shares of common stock and our initial public offering, the holders of shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements and other contractual restrictions described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we no longer qualify as an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur previously. The Sarbanes-Oxley Act of 2002, or SOX, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC, and other applicable securities rules and regulations impose various requirements on U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. In addition, these rules and regulations are often subject to varying interpretations, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of SOX, or Section 404, as a public company, we will be required to furnish a report by our senior management on our internal control over financial reporting, and our independent registered public accounting firm will be required to provide an attestation report on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to provide the attestation report. To ensure compliance with Section 404, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction on the price of our common stock in the market due to a loss of confidence in the reliability of our financial statements. Furthermore, if we are unable to conclude that our internal control over financial reporting is effective, our investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline.

We are an “emerging growth company” and a “smaller reporting company” and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and a “smaller reporting company” as defined under the rules promulgated under the Securities Act. As an emerging growth company and a smaller reporting company we may follow reduced disclosure requirements and do not have to make all of the disclosures that public companies that are not emerging growth companies or smaller reporting companies do. We will remain an emerging growth company until the earlier of (a) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (b) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (c) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (d) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC, which means the market value of our voting and non-voting common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404;
- an exemption from compliance with the requirement of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on the financial statements;
- progressively adding to the number of years of audited financial statements required to be included in our periodic reports; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, stockholder approval of any golden parachute payments not previously approved, and having to disclose the ratio of the compensation of our chief executive officer to the median compensation of our employees. In addition, 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. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards; and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than \$250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than \$100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than \$700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of Section 404, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We may choose to take advantage of some, but not all, of the available exemptions for emerging growth companies and smaller reporting companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our shares price may be more volatile.

Provisions in our restated certificate of incorporation and our amended and restated bylaws or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control of our company that our shareholders may consider favorable, including transactions in which our shareholders might otherwise receive a premium for their shares.

Our restated certificate of incorporation and our amended and restated bylaws include certain anti-takeover provisions, including those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents shareholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president, or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a shareholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our restated certificate of incorporation, or our amended and restated bylaws, (4) any action to interpret, apply, enforce, or determine the validity of our restated certificate of incorporation or our amended and restated bylaws, or (5) any action asserting a claim governed by the internal affairs doctrine. Under our restated certificate of incorporation, this exclusive forum provision will not apply

to claims which are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended, or the rules and regulations thereunder. This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition, or results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

In July 2019, we issued and sold an aggregate of 39,492,960 shares of our Series C convertible preferred stock to investors in a private placement to private investors for aggregate gross proceeds of approximately \$62 million. These securities were issued under Section 4(a)(2) of the Securities Act and Rule 506 in transactions not involving a public offering.

From July 2019 to September 2019 we issued an aggregate of 78,089 shares of our common stock as a result of the exercise of outstanding options for aggregate gross proceeds of approximately \$0.2 million. These securities were issued under Section 4(a)(2) of the Securities Act and Rule 701 in transactions not involving a public offering.

In October 2019, we issued and sold 6,000,000 shares of our common stock in an initial public offering, or IPO, at a public offering price of \$14.00 per share and on October 31, 2019 we issued and sold an additional 325,000 shares of our common stock pursuant to the exercise in part by the underwriters of their over-allotment option to purchase additional shares at the same public offering price.

The offer and sale of all the shares in IPO, inclusive of the underwriters' exercise in part of their over-allotment option, were registered under the Securities Act pursuant to a registration statement on Form S-1 (Reg. No. 333-233652), as amended, which was declared effective by the Securities and Exchange Commission, or the SEC on October 2, 2019. J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC and Cowen and Company, LLC acted as joint book-running managers for the offering. The initial public offering commenced on September 23, 2019 and terminated upon the closing of the sale of shares to the underwriters pursuant to the underwriters' exercise in part of their over-allotment option on October 31, 2019. Upon completion of the IPO, inclusive of the underwriters' exercise in part of their over-allotment option, we received approximately \$79.2 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by us of approximately \$9.3 million. No payments for any expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

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.

None

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
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	3.2	10/1/19	
4.1	Form of Specimen Common Stock Certificate	S-1/A	333-233652	4.1	9/23/19	
4.2	Second Amended and Restated Investors' Rights Agreement, dated as of July 17, 2019	S-1	333-233652	4.2	9/6/19	
10.1	2019 Incentive Award Plan and form of option agreements thereunder	S-1/A	333-233652	10.2	9/23/19	
10.2	Non-Employee Director Compensation Program	S-1/A	333-233652	10.3	9/23/19	
10.4	Form of Indemnification Agreement for Directors and Officers	S-1/A	333-233652	10.5	9/23/19	
10.5	Lease Agreement, effective as of August 1, 2019 between the University of Connecticut and Frequency Therapeutics, Inc.	S-1/A	333-233652	10.6.2	9/23/19	
10.6	Second Amended and Restated Executive Employment Agreement, dated as of September 20, 2019, between David L. Lucchino and Frequency Therapeutics, Inc.	S-1/A	333-233652	10.7	9/23/19	
10.7	Amended and Restated Employment Agreement, dated as of September 20, 2019, between Christopher R. Loose and Frequency Therapeutics, Inc.	S-1/A	333-233652	10.8	9/23/19	
10.8	Employment Agreement, dated as of September 19, 2019, between Carl P. LeBel and Frequency Therapeutics, Inc.	S-1/A	333-233652	10.9	9/23/19	
10.9	License and Collaboration Agreement, dated as of July 16, 2019, between Astellas Pharma, Inc. and Frequency Therapeutics, Inc.	S-1	333-233652	10.12	9/6/19	
10.10	2019 Employee Stock Purchase Plan	S-1/A	333-233652	10.13	9/23/19	
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 Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
101.INS	XBRL Instance Document					***
101.SCH	XBRL Taxonomy Extension Schema Document					***
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					***
101.DEF	XBRL Extension Definition Linkbase Document					***
101.LAB	XBRL Taxonomy Label Linkbase Document					***
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					***

* Filed herewith
 ** Furnished herewith
 *** Submitted electronically herewith

SIGNATURES

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

Company Name

Date: November 18, 2019

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

Date: November 18, 2019

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

CERTIFICATIONS

I, David L. Lucchino, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Frequency Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [OMITTED];
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 18, 2019

By:

/s/ David L. Lucchino

David L. Lucchino
President and Chief Executive Officer
(principal executive officer)

CERTIFICATIONS

I, Richard Mitrano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Frequency Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [OMITTED];
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 18, 2019

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

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Frequency Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David L. Lucchino, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 18, 2019

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

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Frequency Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard Mitrano, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 18, 2019

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