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

FORM 10-Q

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

For the quarterly period ended March 31, 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: 001-38822

KALEIDO BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**47-3048279**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
65 Hayden Avenue, Lexington, MA	**02421**
(Address of principal executive offices)	(Zip Code)

(617) 674-9000
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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, a smaller reporting company, or an emerging growth company. See 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 ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☐
	Emerging growth company ☒

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 registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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	**KLDO**	**NASDAQ Global Select Market**

As of April 30, 2019, there were 29,807,703 shares of registrant's common shares outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plan, objectives of management and expected market growth are forward-looking statements. You can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "seeks," "approximately," "predicts," "intends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include but are not limited to those described under "Risk Factors" and include, among other things:

- the success, cost and timing of our product development activities and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to advance any product candidate into or successfully complete any clinical trial;
- our ability or the potential to successfully manufacture our product candidates for clinical trials or for commercial use, if approved;
- the potential for our identified research priorities to advance our technologies;
- our ability to maintain regulatory approval, if obtained, of any of our current or future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- the ability to license additional intellectual property relating to our product candidates and to comply with our existing license agreements;
- our ability to commercialize our products in light of the intellectual property rights of others;
- the success of competing therapies that are or become available;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the impact of laws and regulations; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

All of our forward-looking statements are as of the date of this Quarterly Report on Form 10-Q only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report on Form 10-Q or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and

adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report on Form 10-Q, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report on Form 10-Q that modify or impact any of the forward-looking statements contained in this Quarterly Report on Form 10-Q will be deemed to modify or supersede such statements in this Quarterly Report on Form 10-Q.

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets (Unaudited)
(in thousands, except share and per share data)

	As of	
	March 31 2019	December 31 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 121,340	$ 76,086
Prepaid expenses and other current assets	2,643	152
Due from related party	—	5
Total current assets	123,983	76,243
Property and equipment, net	5,103	4,693
Restricted cash	2,182	2,180
Deferred issuance costs	—	2,209
Total assets	$ 131,268	$ 85,325
Liabilities, Redeemable Convertible Preferred Stock and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,575	$ 3,442
Accrued expenses and other current liabilities	5,274	7,859
Total current liabilities	8,849	11,301
Long term debt, net of unamortized debt discount	14,844	14,831
Restricted shares repurchase liability	394	720
Other liabilities	45	278
Warrant liability	—	1,213
Total liabilities	24,132	28,343
Redeemable convertible preferred stock, $0.001 par value, no shares and 37,171,832 shares authorized; no shares and 37,034,802 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively; liquidation preference of $153,541 at December 31, 2018	—	153,226
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Preferred shares, $0.001 par value, 10,000,000 and no shares authorized; no shares issued or outstanding at March 31, 2019 and December 31, 2018, respectively	—	—
Common shares, $0.001 par value, 150,000,000 and 66,000,000 shares authorized; 29,759,249 and 6,115,535 shares issued; 29,579,468 and 5,786,911 shares outstanding at March 31, 2019 and December 31, 2018, respectively	30	6
Additional paid-in capital	233,553	9,978
Accumulated deficit	(126,447)	(106,228)
Total shareholders' equity (deficit)	107,136	(96,244)
Total liabilities, redeemable convertible preferred stock and shareholders' equity (deficit)	$ 131,268	$ 85,325

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

KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations (Unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 15,182	$ 7,546
General and administrative	5,433	2,670
Total operating expenses	20,615	10,216
Loss from operations	(20,615)	(10,216)
Other (expense) income:		
Interest income	407	70
Interest expense	(258)	(249)
Change in fair value of warrant liability	252	(350)
Other expense	(5)	(15)
Total other expense, net	396	(544)
Net loss	$ (20,219)	$ (10,760)
Net loss per share attributable to common shareholders—basic and diluted	$ (1.56)	$ (2.27)
Weighted-average common shares outstanding used in net loss per share attributable to common shareholders—basic and diluted	12,963,994	4,743,824

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

KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Stockholders' Equity (Deficit) (Unaudited)
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at January 1, 2019	37,034,802	$153,226	5,786,911	$ 6	$ 9,978	$ (106,228)	$ (96,244)
Conversion of redeemable convertible preferred stock into common stock	(37,034,802)	(153,226)	18,517,386	19	153,207	—	153,226
Conversion of preferred stock warrant to common stock warrant upon closing of initial public offering	—	—	—	—	871	—	871
Issuance of common stock, net of issuance costs of $8,411	—	—	5,000,000	5	66,584	—	66,589
Exercise of common stock warrant	—	—	51,015	—	—	—	—
Exercise of stock options	—	—	75,313	—	60	—	60
Stock-based compensation	—	—	—	—	2,528	—	2,528
Vesting of restricted shares	—	—	148,843	—	325	—	325
Net loss	—	—	—	—	—	(20,219)	(20,219)
Balance at March 31, 2019	—	$ —	29,579,468	$ 30	$ 233,553	$ (126,447)	$ 107,136

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at January 1, 2018	26,927,398	$ 52,494	4,711,963	$ 5	$ 800	$ (44,484)	$ (43,679)
Issuance of Series C convertible preferred stock (net of issuance costs of $168)	7,116,414	70,925	—	—	—	—	—
Exercise of stock options	—	—	9,944	—	2	—	2
Stock-based compensation	—	—	—	—	234	—	234
Vesting of restricted shares	—	—	72,656	—	158	—	158
Net loss	—	—	—	—	—	(10,760)	(10,760)
Balance at March 31, 2018	34,043,812	$123,419	4,794,563	$ 5	$ 1,194	$ (55,244)	$ (54,045)

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

KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows (Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2019	**2018**
Operating activities:		
Net loss	$ (20,219)	$ (10,760)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	293	156
Equity-based compensation	2,528	234
Non-cash interest expense	12	21
Change in fair value of warrant liability	(252)	350
Changes in:		
Prepaid expenses and other assets	(2,486)	(249)
Accounts payable	(129)	777
Accrued expense and other liabilities	(2,543)	13
Net cash used in operating activities	(22,796)	(9,458)
Investing activities:		
Purchase of property and equipment	(1,126)	(278)
Net cash and restricted cash used in investing activities	(1,126)	(278)
Financing activities:		
Proceeds from preferred stock financing, net of issuance costs	—	70,925
Proceeds from exercise of stock options	60	2
Payments related to capital lease	(25)	(26)
Issuance of common stock, net of issuance costs	69,443	—
Settlement of derivative liability	(300)	—
Net cash provided by financing activities	69,178	70,901
Net increase in cash, cash equivalents, and restricted cash	45,256	61,165
Cash, cash equivalents, and restricted cash, beginning of period	78,266	28,677
Cash, cash equivalents, and restricted cash, end of period	$ 123,522	$ 89,842
Supplemental cash flow information		
Interest paid	$ 245	$ 228
Supplemental disclosure of non-cash investing and financing activities		
Vesting of restricted stock	$ 325	$ 158
Reclassification of warrants to additional paid-in capital	$ 871	$ —
Conversion of preferred stock to common stock upon closing of the initial public offering	$ 153,226	$ —
Initial public offering costs incurred but unpaid at period end	$ 1,039	$ —
Purchase of property and equipment in accounts payable and accrued expenses	$ 181	$ 367

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

KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements (Unaudited)
(Amounts in thousands, except share and per share amounts)

1. Nature of the Business and Basis of Presentation

Kaleido Biosciences, Inc. and its wholly owned subsidiaries, Cadena Bio, Inc. and Kaleido Biosciences Securities Corporation (collectively referred to as the "Company") is a clinical-stage healthcare company that was incorporated in Delaware on January 27, 2015 and has a principal place of business in Lexington, Massachusetts. The Company was formed to use its differentiated, chemistry-driven approach to leverage the potential of the microbiome organ to treat disease and improve human health.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, successful development of technology, obtaining additional funding, protection of proprietary technology, compliance with government regulations, risks of failure of preclinical studies (including *ex-vivo* assays), non-IND human clinical studies and clinical trials, the need to obtain marketing approval for its drug candidates and its consumer products, fluctuations in operating results, economic pressure impacting therapeutic pricing, dependence on key personnel, risks associated with changes in technologies, development by competitors of technological innovations and the ability to supply sufficient amounts of Microbiome Metabolic Therapies ("MMTs") at an acceptable quality level.

On March 4, 2019, the Company completed its initial public offering (the "IPO"), pursuant to which it issued and sold 5,000,000 shares of common stock. The aggregate net proceeds received by the Company from the IPO were $69,750, after deducting underwriting discounts and commissions, but before deducting offering costs payable by the Company, which are estimated to be $3,161, as of March 31, 2019. Upon the closing of the IPO, all outstanding shares of convertible preferred stock converted into 18,517,386 shares of common stock (see Note 9).

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. Since inception, the Company has financed its operations through private placements of its equity securities, borrowings of long-term debt and most recently, through a public offering. As of March 31, 2019, the Company had an accumulated deficit of $126,447. The Company expects to continue to generate operating losses in the foreseeable future. As of the issuance date of the consolidated financial statements, the Company expects that its cash and cash equivalents, including net proceeds it received from the completion of the IPO, will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of the interim consolidated financial statements.

2. Summary of Significant Accounting Policies

Unaudited interim financial information

The consolidated financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Prospectus that forms a part of the Company's Registration Statement on Form S-1 (File No. 333-229204), which was filed with the SEC pursuant to Rule 424(b)(4) on March 1, 2019 (the "Prospectus").

All intercompany transactions and balances of the subsidiary have been eliminated in consolidation. In the opinion of management, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair representation of the results for the reported interim periods.

Use of Estimates

The preparation of the consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in the Prospectus. There have been no material changes to the significant accounting policies during the period ended March 31, 2019.

Accounting Pronouncements Issued and Not Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"), which applies to all leases and will require lessees to record most leases on the balance sheet but recognize expense in a manner similar to the current standard. The Company will use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. The Company is currently evaluating whether to early-adopt ASU 2016-02 and ASU No. 2018-11 and evaluating the impact that the adoption of ASU 2016-02 and ASU No. 2016-02 will have on its consolidated financial statements. The Company expects to recognize a significant lease obligation and right to use asset upon adoption.

3. Fair Value Measurements

The following tables set forth by level, within the fair value hierarchy, the assets and liabilities carried at fair value on a recurring basis:

	Fair Value Measurements as of March 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds included within cash and cash equivalents	$ 116,548	—	—	$ 116,548
Total	$ 116,548	—	—	116,548

	Fair Value Measurements as of December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds included within cash and cash equivalents	$ 74,145	—	—	$ 74,145
Total	$ 74,145	—	—	$ 74,145
Liabilities:				
Warrant liability	$ —	—	1,213	$ 1,213
Derivative liability	—	—	210	$ 210
	$ —	—	1,423	$ 1,423

The fair value of money market funds was measured by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy.

The preferred stock warrant liability consisted of the fair value of warrants to purchase Series A and Series B convertible preferred stock (see Note 7) and was based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The Company's valuation of the preferred stock warrants utilized the Black-Scholes option-pricing model, which incorporates assumptions and estimates to value the preferred stock warrants. The Company assesses these assumptions and estimates on a quarterly basis as additional information impacting the assumptions was obtained. Changes in the fair value of the preferred stock warrants are recognized as other income (expense) in the consolidated statements of operations.

The quantitative elements associated with the Company's Level 3 inputs that impact the fair value measurement of the preferred stock warrant liability include the fair value per share of the underlying Series A and Series B convertible preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The most significant assumption in the Black-Scholes option-pricing model that impacts the fair value of the preferred stock warrants is the fair value of the Company's convertible preferred stock as of each re-measurement date. The Company determines the fair value per share of the underlying preferred stock by taking into consideration its most recent sales of its convertible preferred stock as well as additional factors that the Company deems relevant. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly-traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company has estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared dividends.

Upon the closing of the IPO, the warrants for the purchase of preferred stock automatically became warrants for the purchase of common stock and the Company reclassified the carrying value of the warrants from a non-current liability to additional paid-in capital in its consolidated balance sheet.

The fair value of the derivative liability recognized in connection with the contingent success fee associated with the amended term loan agreement (see Note 6) was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability was determined using the probability-weighted expected return method ("PWERM"), which considered as inputs the probability of occurrence of an event (as defined), the expected timing of a liquidity event, the amount of the success fee and a risk-adjusted discount rate. As of December 31, 2018, the assumed probability of occurrence of the event that was most probable of triggering the payment was 70%, the expected timing of such an event was estimated to be less than one year, the amount of the success fee was $300 and the discount rate was assessed to be 0%. As of March 4, 2019, the closing date of the IPO, the assumed probability of occurrence of the event that was most probable of triggering the payment increased to 100% and the discount rate was assessed to be 0%. Based on these inputs, the Company determined that the fair value of the derivative liability was $210 as of December 31, 2018 and $300 as of March 4, 2019. Upon completion of the IPO, the success fee of $300 was paid in March 2019.

The following table provides a roll-forward of the aggregate fair values of the Company's preferred stock warrants for which fair value was determined by Level 3 inputs (in thousands):

	Warrant Liability	Derivative Liability
Fair value at January 1, 2019	1,213	210
Change in fair value through the exercise date	(342)	90
Reclassification to additional paid-in-capital in connection with IPO	(871)	—
Settlement of derivative instrument	—	(300)
Fair value at March 31, 2019	—	—

There were no transfers among the Level 1, Level 2, or Level 3 categories in the periods presented.

Financial Instruments Not Recorded at Fair Value – The carrying value of cash, cash equivalents, restricted cash, accounts payable and accrued expenses that are reported on the consolidated balance sheets approximate their fair value due to the short-term nature of these assets and liabilities. The carrying value of the long-term debt approximates fair value as evidenced by the recent amendment to the term loan agreement.

4. Property and Equipment, net

Property and equipment consist of the following:

	As of	
	March 31, 2019	December 31, 2018
Laboratory equipment	$ 3,503	$ 3,226
Office and computer equipment	1,376	1,337
Leasehold improvements	653	653
Construction in process	1,085	698
Property and equipment – at cost	6,617	5,914
Less accumulated depreciation and amortization	(1,514)	(1,221)
Property and equipment – net	$ 5,103	$ 4,693

Depreciation and amortization expense for the three months ended March 31, 2019 and 2018 was $293 and $156, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	As of	
	March 31, 2019	December 31, 2018
Payroll and benefits	$ 1,213	$ 3,297
Consulting service	467	243
Legal service	180	90
Research and development	2,389	3,718
Capital lease payable – short term	88	91
Other	937	420
	$ 5,274	$ 7,859

6. Debt Financing

The Company is party to a loan and security agreement, as amended (the "2015 Credit Facility"), under which the Company has borrowed an aggregate of $15,000. Borrowings under the 2015 Credit Facility bear interest at an annual rate equal to the lender's prime rate plus 1.00%, subject to a floor of 5.75%, and are repayable in monthly interest-only payments through April 2020 and in equal monthly payments of principal plus accrued interest from May 2020 until the maturity date in April 2022. As of March 31, 2019, the interest rate applicable to borrowings under the 2015 Credit Facility was 6.50%.

Borrowings under the 2015 Credit Facility are collateralized by substantially all of the Company's personal property, other than its intellectual property. There are no financial covenants associated with the 2015 Credit Facility; however, the Company is subject to certain affirmative and negative covenants restricting the Company's activities, including limitations on dispositions, mergers or acquisitions; encumbering its intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the 2015 Credit Facility are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the Company's business, operations or financial or other condition.

The scheduled principal maturity of the long-term debt is $5,000 in 2020, $7,500 in 2021 and $2,500 in 2022.

As part of an amendment to the 2015 Credit Facility in June 2018, a success fee of $300 was required in the event of a liquidation event, including an IPO. The success fee represented an embedded derivative which the Company bifurcated from the debt arrangement and carried at fair value. In March 2019, the Company completed its IPO and paid the success fee of $300.

7. Warrant Liability

In 2015, the Company issued warrants to purchase up to 85,617 shares of Series A Preferred Stock in connection with the 2015 Credit Facility (see Note 6). The warrants were exercisable at a price of $0.73 per share and had a contractual term of ten years from issuance.

In October 2017, the Company issued warrants to purchase up to 51,413 shares of Series B Preferred Stock in connection with an amendment to the 2015 Credit Facility (see Note 6). The warrants were exercisable at a price of $3.89 per share and had a contractual term of ten years from issuance.

The Company remeasured the fair value of the liability for these preferred stock warrants at each reporting date and recorded any adjustments as other income (expense). The warrants outstanding at each reporting date were remeasured using the Black-Scholes option-pricing model (see Note 3), and the resulting change in fair value was recorded in other income (expense) in the Company's consolidated statements of operations.

Upon the closing of the IPO in March 2019, the Company's outstanding warrants to purchase Series A Preferred Stock and Series B Preferred Stock automatically became warrants to purchase an aggregate of 68,514 shares of common stock. In March 2019, the holders of such warrants completed a cashless exercise of the warrants, resulting in the Company's issuance of 51,015 shares of common stock.

8. Commitments and contingencies

Facilities Leases

Lexington, MA Lease

In March 2018, the Company entered into a non-cancelable ten-year lease agreement for laboratory and office space in Lexington, Massachusetts. In March 2019, the Company exercised its option to lease additional premises (the "Expansion Premises") comprised of 54,468 square feet of space (the entire second floor of the building). Under the terms of the option, the Company will not gain access to the additional space until December 1, 2019 at the earliest.

Rent expense for the three months ended March 31, 2019 and 2018 totaled $1,024 and $245, respectively. Future minimum lease payments under the non-cancelable operating leases consisted of the following as of March 31, 2019:

Year Ending December 31,		
2019	$	2,794
2020		5,757
2021		5,922
2022		6,100
2023		6,283
Thereafter		37,155
	$	64,011

9. Common stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

Upon the closing of the IPO in March 2019, all of the shares of the Company's outstanding convertible preferred stock automatically converted into 18,517,386 shares of common stock.

In March 2019, the Company filed a restated certificate of incorporation in the State of Delaware, which, among other things, restated the number of shares of all classes of stock that the Company has authority to issue to 160,000,000 shares, consisting of (i) 150,000,000 shares of common stock, $0.001 par value per share, and (ii) 10,000,000 shares of preferred stock, $0.001 par value per share. The shares of preferred stock are currently undesignated.

10. Stock-based compensation

2015 Stock Incentive Plan

The Company's 2015 Stock Incentive Plan (the "2015 Plan") provided for the Company to sell or issue incentive stock options or nonqualified stock options, restricted stock, and other equity awards to employees, directors and consultants of the Company. The 2015 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions were determined at the discretion of the board of directors, or its committee if so delegated.

The total number of shares of common stock that could have been issued under the 2015 Plan was 8,395,974 shares, of which 10,558 shares remained available for future issuance prior to the effectiveness of the Company's 2019 Stock Option and Incentive Plan (the "2019 Plan"). Upon effectiveness of the 2019 Plan, the remaining shares available under the 2015 Plan ceased to be available for issuance and no future issuances will be made under the 2015 Plan. The shares of common stock underlying outstanding awards under the 2015 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added to the shares of common stock available for issuance under the 2019 Plan.

2019 Stock Option and Incentive Plan

The 2019 Plan was adopted by the Company's board of directors on January 23, 2019, and approved by stockholders on February 19, 2019, and became effective on February 27, 2019. The 2019 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, directors and consultants. The number of shares initially reserved for issuance under the 2019 Plan is 2,168,976, which shall be cumulatively increased on January 1, 2020 and each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's board of directors or compensation committee of the board of directors.

2019 Employee Stock Purchase Plan

The 2019 Employee Stock Purchase Plan (the "2019 ESPP") was adopted by the Company's board of directors on January 23, 2019, and adopted by stockholders on February 19, 2019, and became effective on February 27, 2019. The 2019 ESPP has not been implemented as of March 31, 2019. A total of 180,748 shares of common stock were reserved for issuance under this plan. In addition, the number of shares of common stock that may be issued under the ESPP will automatically increase on January 1, 2020, and each January 1 thereafter, by the lesser of (i) 542,244 shares of common stock, (ii) 1% of the number of shares of the

Company's common stock outstanding on the immediately preceding December 31 or (iii) such lesser number of shares as determined by the administrator of the 2019 ESPP.

Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The assumptions that the Company used to determine the grant-date fair value of options granted to employees, non-employees, and directors were as follows:

	Three Months Ended March 31,
	2019
Expected volatility	66.1%-71.1%
Risk-free interest rate	2.27%-2.54%
Expected term (in years)	6.00-6.25
Expected dividend yield	0%

The Company did not grant options during the three months ended March 31, 2018.

Stock Options Activity

A summary of the Company's stock option activity and related information is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2019	6,686,267	$ 7.50	9.2	68,167
Granted	351,500	14.90		
Exercised	(75,313)	0.75		
Canceled	(24,748)	7.13		
Outstanding as of March 31, 2019	6,937,706	$ 7.95	9.0	47,698
Options exercisable as of March 31, 2019	677,605	$ 2.05	7.9	8,433
Options vested or expected to vest- March 31, 2019	6,937,706	$ 7.95	9.0	47,698

The weighted-average grant date fair value of the options granted during the three months ended March 31, 2019 was $9.35 per share. As of March 31, 2019 there was $31,575 of unrecognized compensation expense, which the Company expects to recognize over the weighted-average remaining term of 3.16 years.

Restricted Common Stock

During the year ended December 31, 2017, the Company signed agreements with seven employees to early exercise stock options covering 1,295,699 shares to convert such options to restricted common stock prior to the vesting of the underlying shares of common stock. The vesting conditions did not change. The consideration received due to the early exercises from the seven employees was recorded as a restricted share repurchase liability. As of March 31, 2019 and December 31, 2018, the outstanding balance of the restricted share repurchase liability was $394 and $720, respectively.

The following table summarizes the Company's restricted common stock activity for the period ended March 31, 2019:

	Number of Restricted Shares	Weighted-Average Grant Date Fair Value
Issued and unvested as of January 1, 2019	328,624	$ 2.19
Vested	(148,843)	
Issued and unvested as of March 31, 2019	179,781	$ 2.19

Stock- Based Compensation Expense

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations:

	Three Months Ended March 31,	
	2019	2018
Research and development	$ 873	$ 86
General and administrative	1,655	148
	$ 2,528	$ 234

11. Net Loss per Share

Basic and diluted net loss per common share is determined by dividing net loss by the weighted-average common shares outstanding during the period. The Company has computed diluted net loss per common share after giving consideration to all potentially dilutive common shares, including options to purchase common stock, restricted common stock, convertible preferred stock and warrants to purchase convertible preferred stock, outstanding during the period determined using the if-converted and treasury stock methods, except where the effect of including such securities would be anti-dilutive. Because the Company has reported net losses since inception, these potential common shares have been anti-dilutive and therefore basic and diluted net loss per share have been equivalent.

The following table presents securities that have been excluded from the computations of diluted weighted-average shares outstanding as they would be anti-dilutive:

	As of March 31,	
	2019	2018
Options to purchase common stock	6,937,706	2,765,623
Unvested restricted common stock	179,781	1,214,762
Convertible redeemable preferred stock (as converted to common stock)	—	17,021,894
Warrant to purchase redeemable convertible preferred stock (as converted to common stock)	—	68,514
	7,117,487	21,070,793

12. Related Party Transactions

The Company receives professional services from its principal investor, Flagship Pioneering, from time to time as needed. The Company reported general and administrative expense totaling $8 and $62 related to these services for the three months ended March 31, 2019 and 2018, respectively.

13. Subsequent Events

As of May 2, 2019, the Company is not aware of any events that have occurred that have a material effect on the financial statements.

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

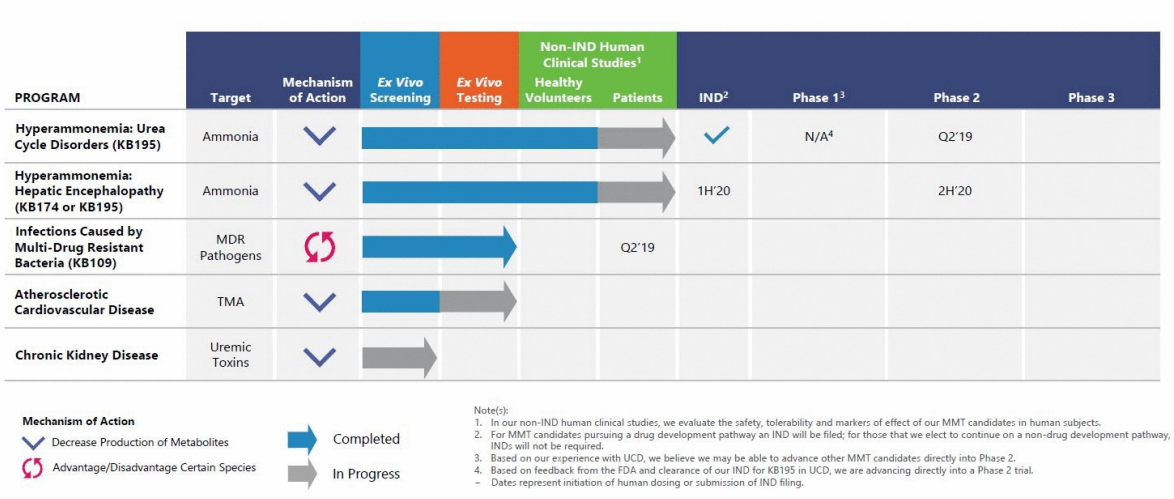
The following discussion and analysis of our financial condition and results of operations should be read in conjunction with (i) our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our final prospectus for our initial public offering filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, with the Securities and Exchange Commission, or SEC, on March 1, 2019.

*Investors and others should note that we announce material financial information to our investors using our investor relations website (*https://investors.kaleido.com/*), SEC filings, press releases, public conference calls and webcasts. We use these channels as well as social media to communicate with the public about our company, our business, our product candidates and other matters. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on the social media channels listed on our investor relations website.*

Overview

We are a clinical-stage healthcare company with a differentiated, chemistry-driven approach focused on leveraging the potential of the microbiome organ to treat disease and improve human health. We have built a human-centric proprietary product platform for discovery and development that we believe will enable the rapid advancement of a broad portfolio of novel product candidates into non-IND human clinical studies under regulations supporting research with food. Our product candidates are Microbiome Metabolic Therapies, or MMTs, which are designed to modulate the metabolic output and profile of the microbiome by driving the function and distribution of the organ's existing microbes. We have an industrialized approach to the discovery and development of MMTs, and our initial MMTs are targeted glycans. Each targeted glycan is an ensemble of complex carbohydrates that is intended to modulate microbial metabolism to drive a specific biological response. We believe our MMTs have the potential to be novel treatments across a variety of diseases and conditions.

The human microbiome is generally a community of more than 30 trillion microbes, organisms that include bacteria, viruses, archaea and fungi, which reside on and inside the human body. By evolving together over thousands of years, microbes and humans have developed an intricate and mutually beneficial relationship. Given the profound impact that microbes have on human health, this highly complex microbial ecosystem has been referred to as a "newly discovered organ." There is a growing body of research that links a healthy microbiome with overall human health, while dysbiosis, or imbalance, in the microbiome has been correlated with numerous human conditions, including those that can cause significant morbidity and mortality. Some of these conditions include irritable bowel syndrome, Parkinson's disease, diabetes, metabolic syndrome, cancer, allergies and ulcerative colitis. The microbiome organ remains a largely untapped frontier in healthcare, and we believe that we are uniquely positioned to succeed in translating its promise into solutions for human health.



Since our inception in 2015, we have devoted substantially all of our resources to building our proprietary product platform, developing our pipeline of MMT candidates, building our intellectual property portfolio and process development and manufacturing function, business planning, raising capital and providing general and administrative support for these operations. To date, we have primarily financed our operations through public offering of our equity securities, private placement of our preferred shares and borrowings of long-term debt.

On March 4, 2019, we completed our initial public offering (the "IPO"), pursuant to which we issued and sold 5,000,000 shares of common stock. We received net proceeds of $69,750, after deducting underwriting discounts and commissions, but before deducting offering costs payable by us, which are estimated to be $3,161 as of March 31, 2019.

We have incurred significant net losses since inception and expect to continue to incur net operating losses for the foreseeable future. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- conduct preclinical studies, non-IND human clinical studies and clinical trials for our product candidates;
- advance the development of our product candidate pipeline;
- continue to discover and develop additional product candidates;
- continue to build out our proprietary product platform and to increase its throughput for the discovery and nomination of product candidates;
- develop, acquire or in-license other product candidates and technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- expand manufacturing capabilities, including in-house and third-party commercial manufacturing, through the purchase, renovation, customization and operation of a manufacturing facility and securing supply chain capacity sufficient to provide non-IND human clinical study and clinical trial materials and commercial quantities of any product candidates which we may commercialize;
- seek regulatory approvals for any product candidates for therapeutic indications that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval or identify alternate commercial pathways; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our transition to a public reporting company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for or identify alternate non-drug pathways for our product candidates. If we obtain regulatory approval for or otherwise commercialize any of our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution. Further, we expect to incur additional costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through equity or debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, 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 are able to generate 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 unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of March 31, 2019, we had $121,340 in cash and cash equivalents and an accumulated deficit of $126,447. We expect that our existing cash and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements and debt obligations through the next 12 months from the issuance date of the interim consolidated financial statements. See "-Liquidity and capital resources."

Financial Overview

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts for our current product candidates or additional product candidates that we may develop in the future are successful and can be commercialized, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Research and Development Expenses

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

- development and operation of our proprietary product platform;
- employee-related expenses, including salaries, related benefits and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants and contract research organizations, or CROs;
- the cost of laboratory supplies and acquiring, developing and manufacturing products for use in our preclinical studies, non-IND human clinical studies and clinical trials, including under agreements with third parties, such as consultants and contract manufacturing organizations, or CMOs;
- facilities, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance; and
- costs related to compliance with regulatory requirements.

We expense research and development costs as incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct external research and development expenses are tracked on a program-by-program basis and consist of costs that include fees, reimbursed materials and other costs paid to consultants, contractors, CMOs and CROs in connection with our preclinical and clinical development and manufacturing activities. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies and facilities expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple programs and our platform technology and, as such, are not separately classified.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of programs we decide to pursue and their regulatory paths to market;
- raising additional funds necessary to complete preclinical and clinical development of and commercialize our product candidates;
- the progress of the development efforts of parties with whom we have entered into and may enter into collaboration arrangements;
- our ability to maintain our current research and development programs and to establish new ones;
- our ability to maintain existing and establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities for any product candidates for therapeutic indications;

- the availability of specialty raw materials for use in production of our product candidates;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates is approved or commercialized on an alternate regulatory pathway;
- meeting demand in a timely fashion with sufficient supply at appropriate quality levels;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved if approval to market is required;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our product candidates, if commercialized, by patients, consumers, the medical community and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our therapies following commercialization.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval or commercialization for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance, corporate and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates and due to the increased costs of operating as a public company. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Other Income (Expense)

Interest income

Interest income consists of interest earned on our cash equivalents, which consist of money market funds. We expect our interest income to increase as we invest the cash received from the net proceeds from the IPO.

Interest expense

Interest expense consists of interest on outstanding borrowings under our loan and security agreement as well as amortization of debt discount and debt issuance costs.

Change in fair value of warrant liability

In connection with our original loan and security agreement in 2015 and subsequent amendment in 2017, we issued warrants to purchase shares of our convertible preferred stock. We classified these warrants as a liability on our consolidated balance sheet that we remeasured to fair value at each reporting date, and we recognized changes in the fair value of the warrant liability as a component of other income (expense), net in our consolidated statements of operations. Upon the closing of the IPO in March 2019, the convertible preferred stock warrants became exercisable for common stock and were concurrently exercised by the holders. As a result, the fair value of the warrant liability as of the conversion date was reclassified to additional paid-in capital.

Results of Operations

Comparison of Three Months Ended March 31, 2019 and 2018

The following table summarizes our results of operations for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,		
	2019	2018	Change
		(in thousands)	
Operating expenses:			
Research and development	$ 15,182	$ 7,546	7,636
General and administrative	5,433	2,670	2,763
Total operating expenses	20,615	10,216	10,399
Loss from operations	(20,615)	(10,216)	(10,399)
Other income (expense)			
Interest income	407	70	337
Interest expense	(258)	(249)	(9)
Change in fair value of warrant liability	252	(350)	602
Other expense	(5)	(15)	10
Total other expense, net	396	(544)	940
Net loss	$ (20,219)	$ (10,760)	(9,459)

Research and Development Expenses

	Three Months Ended March 31,		
	2019	2018	Change
		(in thousands)	
Direct research and development expense for KB195 program	$ 1,568	$ 1,616	(48)
Platform development, early-stage research and unallocated expenses:			
Personnel-related	6,125	3,551	2,574
Stock-based compensation expense	873	86	787
External manufacturing and research	3,528	1,052	2,476
Laboratory supplies and research materials	405	369	36
Professional and consulting fees	716	184	532
Facility-related and other	1,967	688	1,279
Total research and development expenses	$ 15,182	$ 7,546	$ 7,636

Research and development expenses were $15,182 for the three months ended March 31, 2019, compared to $7,546 for the three months ended March 31, 2018. The decrease in direct costs related to our KB195 program of $48 was primarily due to continued costs incurred with external CROs, external CMOs, and IND-enablement costs associated with our preclinical and clinical development activities of KB195 for hyperammonemia. The increase in personnel-related costs of $2,574 and stock-based compensation expense of $787 was due to increased headcount in our research and development function. The increase in external manufacturing and research costs of $2,476 was primarily due to an increase in production of study material used in preclinical studies, non-IND human clinical studies and clinical trials, as well as increased clinical CRO activities. The increase in professional and consulting fees of $532 was primarily due to higher consulting fees within our technical operations function and higher market research costs. The increase in facility-related and other expenses of $1,279 was primarily due to increased depreciation expense for our lab equipment and leasehold improvements and higher facility operating costs.

General and Administrative Expenses

	Three Months Ended March 31,		
	2019	2018	Change
		(in thousands)	
Personnel-related	$ 1,958	$ 1,407	$ 551
Stock-based compensation expense	1,655	148	1,507
Professional and consulting fees	1,026	842	184
Facility-related and other	794	273	521
Total general and administrative expenses	$ 5,433	$ 2,670	$ 2,763

General and administrative expenses for the three months ended March 31, 2019 were $5,433, compared to $2,670 for the three months ended March 31, 2018. The increase in personnel-related costs of $551 was primarily due to the hiring of key executives in 2018, including our Chief Operating and Financial Officer, as well as additional personnel in our general and administrative functions as we continued to expand our operations to support the organization. The increase in stock-based compensation expense of $1,507 was primarily due to the modification of the vesting provision of stock options granted to certain executives. The increase in professional and consulting fees of $184 was primarily due to legal costs incurred in connection with maintaining and registering worldwide patents and an increase in public relations costs . The increase in facility-related and other expenses of $521 was primarily due to increased facility operating costs that were attributed to general and administrative functions.

Interest Income

Interest income for the three months ended March 31, 2019 was $407 due to interest earned on invested cash balances.

Interest expense

Interest expense for the three months ended March 31, 2019 was $258, compared to $249 for the three months ended March 31, 2018. The increase in interest expense was due to interest incurred on additional borrowings in October 2017 pursuant to the fourth amendment to our original term loan.

Change in fair value of warrant liability

The change in the fair value of our preferred stock warrant liability was due to the increase in the value of our preferred stock prior to the warrant becoming a warrant for common stock upon the closing of our IPO.

Other expense

Other expense for the three months ended March 31, 2019 was primarily due to the to the increase in fair value of the derivative liability related to the success fee included in our loan agreement.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. To date, we have primarily financed our operations through public offering of our equity securities, private placement of our preferred shares and borrowings of long-term debt. As of March 31, 2019, $15,000 remained outstanding and no amounts were available for borrowing under the loan and security agreement. As of March 31, 2019, we had cash and cash equivalents of $121,340. In March 2019, we completed our IPO, pursuant to which we issued and sold 5,000,000 shares of common stock. We received aggregate net proceeds of $69,750, after deducting underwriting discounts and commissions, but before deducting offering costs payable by us, which are estimated to be $3,161.

Cash Flows

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

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (22,796)	$ (9,458)
Net cash used in investing activities	(1,126)	(278)
Net cash provided by financing activities	69,178	70,901
Net increase in cash, cash equivalents and restricted cash	$ 45,256	$ 61,165

Net Cash Used in Operating Activities

During the three months ended March 31, 2019, operating activities used $22,796 of cash, due to our net loss of $20,219, partially offset by non-cash charges of $2,581 and net cash used by changes in our operating assets and liabilities of $5,158. Net cash provided by changes in our operating assets and liabilities primarily consisted of a $2,486 decrease in prepaid expenses and other assets and a $2,543 decrease in accrued expenses and other liabilities.

During the three months ended March 31, 2018, operating activities used $9,458 of cash, due to our net loss of $10,760, partially offset by non-cash charges of $761 and net cash provided by changes in our operating assets and liabilities of $541. Net cash provided by changes in our operating assets and liabilities primarily consisted of a $777 increase in accounts payable and a $249 decrease in prepaid expenses and other assets.

Changes in prepaid expenses and other current assets, accounts payable and accrued expenses and other liabilities were generally due to growth in our business, the advancement of our research programs and the timing of vendor invoices and payments.

Net Cash Used in Investing Activities

During the three months ended March 31, 2019 and 2018, net cash used in investing activities was $1,126 and $278, respectively, due to purchases of property and equipment.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2019, net cash provided by financing activities was $69,178, consisting primarily of proceeds from our IPO in March 2019, partially offset by $307 in the payment of IPO costs and $300 in the settlement of our derivative liability.

During the three months ended March 31, 2018, net cash provided by financing activities was $70,901, consisting primarily of $70,925 in proceeds from the sale of our preferred stock.

Loan and security agreement

As of March 31, 2019, we had borrowed an aggregate of $15,000 under a loan and security agreement and no amounts remained available for borrowing.

In June 2018, we entered into an amendment to the loan and security agreement. As of December 31, 2018, outstanding borrowings of $15,000 bear interest at a rate equal to the greater of (i) 1.00% above the Prime Rate in effect or (ii) 5.25%, which is payable monthly. As of March 31, 2019, the interest rate in effect was 6.50%. Any principal outstanding is payable in 24 equal monthly installments plus any accrued interest, beginning on May 13, 2020. We may prepay all, but not less than all of the term loan at any time. All balances once repaid may not be borrowed again and the term loan matures on April 13, 2022. As part of the June 2018 amendment, in the event of a liquidation event, including an initial public offering, we will be required to pay a success fee of $300.

The borrowings under the amended loan and security agreement are secured by a lien on all of our assets except intellectual property. The loan and security agreement contains customary representations, warranties and covenants by us, including negative covenants restricting our activities, such as disposing of our business or certain assets, changing our business, management, ownership or business locations, incurring additional debt or liens or making payments on other debt, making certain investments and declaring dividends, acquiring or merging with another entity, engaging in transactions with affiliates or encumbering intellectual property. The obligations under the loan and security agreement are subject to acceleration upon occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical and clinical development activities of our product candidates. In addition, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the commencement, enrollment or results of the planned non-IND human clinical studies or clinical trials of our product candidates or any future non-IND human clinical studies or clinical trials we may conduct, or changes in the development status of our product candidates;
- the timing and outcome of regulatory review of our product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- developments concerning our CMOs;
- our ability to obtain materials and to produce adequate current good manufacturing practice compliant product supply for any approved or commercialized product or inability to do so at acceptable prices;
- our ability to establish and maintain collaborations, if needed;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we obtain marketing approval or identify an alternate regulatory pathway to market;
- the legal patent costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates; and
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder.

We believe that our existing cash and cash equivalents, will enable us to fund our operating expenses, capital expenditure requirements and debt service obligations through the second half of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could 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 restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

In March 2019, we exercised our option to lease additional premises (the “Expansion Premises”) comprised of 54,468 square feet of space (the entire second floor of the building) in its primary building in Lexington, MA. Under the terms of the option, we will not gain access to the additional space until December 1, 2019 at the earliest (see Note 8).

Off-Balance Sheet Arrangements

As of March 31, 2019, we did not have any off-balance sheet arrangements as defined under applicable SEC rules.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes to our critical accounting policies from those described in the Prospectus.

Recent Accounting Pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to the consolidated financial statements for a discussion of recent accounting pronouncements.

Item 3. Qualitative and Quantitative Disclosures about Market Risk

Interest rate risk

As of March 31, 2019, we had cash and cash equivalents of $121,340, which consisted of cash and money market funds. Interest income is impacted by changes in the general level of interest rates; however, an immediate 10% change in interest rates would not have a material effect on the fair value of our cash equivalents.

As of March 31, 2019, we had $15,000 of borrowings outstanding under the loan and security agreement. Commencing in June 2018, outstanding borrowings bear interest at a variable rate equal to the greater of (i) 1.00% above the Prime Rate in effect or (ii) 5.25%. An immediate 10% change in the Prime Rate would not have had a material impact on our debt-related obligations, financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. We do not hedge any foreign currency risks.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2019 and 2018.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submits under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. 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. Based on the evaluation of our disclosure controls and procedures as of March 31, 2019, our Principal Executive Officer and Principal Financial Officer 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 currently a party to any material legal proceedings.

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our consolidated financial statements and the related notes and "Management's discussion and analysis of financial condition and results of operations," and in our other filings with the Securities and Exchange Commission. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks related to our business, technology and industry

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are a clinical stage healthcare company with a limited operating history. Investment in product development in the healthcare industry, including of biopharmaceutical products, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. Our lead product candidates are currently in clinical development. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2015. For the year ended December 31, 2018 and the three months ended March 31, 2019, we reported net losses of $61,744 and $20,219, respectively. As of March 31, 2019, we had an accumulated deficit of $126,447. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. We anticipate that our expenses will increase substantially if, and as, we:

- Conduct preclinical studies, non-IND human clinical studies and clinical trials for our product candidates;
- further develop our proprietary product platform;
- continue to discover and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire or contract additional clinical, scientific, manufacturing and commercial personnel to support our product development and commercialization efforts;
- validate a manufacturing process and specifications for our product candidates;
- establish in-house manufacturing capabilities for research and non-IND human clinical studies;
- establish a commercial cGMP manufacturing source and secure supply chain capacity sufficient to provide preclinical study material, non-IND human clinical study material, clinical trial material and commercial quantities of any product candidates for which we may obtain regulatory approval;
- acquire or in-license other product candidates and technologies;
- seek various non-drug product pathways and drug regulatory authorizations;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval or identify an alternate regulatory pathway to market; and
- add operational, compliance, financial and management information systems and personnel to support our transition to a public company.

To become and remain profitable, we or any potential future collaborator must develop and eventually commercialize products with significant market potential at an adequate profit margin after cost of goods sold and other expenses. This will require us to be successful in a range of challenging activities, including completing preclinical studies, non-IND human clinical studies and clinical trials, obtaining marketing approval or identifying alternate regulatory pathways for product candidates, cGMP

manufacturing, marketing and selling products for which we may obtain marketing approval or successfully identify alternate regulatory pathways and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to conduct further research and development, preclinical studies, non-IND human clinical studies and clinical trials of our current and future programs, to validate the manufacturing process and establish specifications for our product candidates, to seek regulatory approvals for or identify alternate regulatory pathways to market for our product candidates and to launch and commercialize any products for which we receive regulatory approval or identify an alternate regulatory pathway to market, including potentially building our own commercial organization. As of March 31, 2019, we had $121,340 of cash and cash equivalents on hand. Based on our current operating plan, we believe that the net proceeds from the IPO, together with our existing cash and cash equivalents, will enable us to fund our operating expenses, capital expenditure requirements and debt service obligations through the second half of 2020. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of any of our current product candidates. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved 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 preclinical studies, non-IND human clinical studies and clinical trials for our product candidates and any need to conduct additional such studies as may be required by a regulator;
- the clinical development plans we establish for these product candidates;
- further development of our proprietary product platform and supporting infrastructure;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to initiate or conclude;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities;
- the effect of changes in regulation or policy relating to the development and commercialization of our product candidates by the FDA, the EMA, and other comparable foreign regulatory authorities;
- the costs of establishing, maintaining, and overseeing a quality system compliant with current good manufacturing practice requirements, or cGMPs, and a supply chain for the development and manufacture of our product candidates;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us, our product candidates or our proprietary product platform;
- the effect of competing technological and market developments;
- the cost and timing of establishing, expanding and scaling manufacturing capabilities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval or identify alternate regulatory pathways in regions where we choose to commercialize our products on our own.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible into or exchangeable for common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring or licensing intellectual property rights. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. 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 one or more of our products or product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We have a limited operating history, which may make it difficult to evaluate our technology and product development capabilities and predict our future performance.

We are early in our development efforts and we have not initiated therapeutic clinical trials for any of our product candidates for therapeutic indications. Similarly, we have not selected a product candidate to develop as a non-drug product such as a food or medical food. We were formed in 2015, have no products approved for commercial sale or marketed via other regulatory pathways (e.g., non-drug products) and have not generated any revenue from product sales. Our ability to generate product revenue or profits, which we do not expect will occur for many years, if ever, will depend on the successful development and eventual commercialization of our product candidates, which may never occur. We may never be able to develop or commercialize a marketable product.

Our current and future therapeutics programs and product candidates require additional discovery research, preclinical development, clinical development, regulatory approval in multiple jurisdictions or identification of alternate regulatory pathways to market, manufacturing validation, obtaining cGMP manufacturing supply, capacity and expertise, building of a commercial and distribution organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. Our non-therapeutic programs require additional discovery research, preclinical development and non-IND human clinical studies. In addition, our drug product candidates must be approved for marketing by the FDA or certain other health regulatory agencies, including the EMA, or we must secure alternate non-therapeutic regulatory pathways to market our non-therapeutic product candidates before we may commercialize any product in the respective jurisdictions.

Our limited operating history may make it difficult to evaluate our technology and industry and predict our future performance. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in evolving fields. If we do not address these risks successfully, our business will suffer. Similarly, we expect that our financial condition and operating results will fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our stockholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance.

In addition, as an early-stage company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown circumstances. As we advance our product candidates, we will need to transition from a company with a research focus to a company capable of supporting clinical development and, if successful, commercial activities. We may not be successful in such a transition.

Microbiome Metabolic Therapies, or MMTs, are a novel approach and negative perception of any product candidates that we develop could adversely affect our ability to conduct our business, obtain regulatory approvals or identify alternate regulatory pathways to market for such product candidates.

Microbiome therapies and therapy candidates in general, and our MMT candidates in particular, are a relatively new and novel approach. In the United States and the European Union, no products to date have been approved specifically demonstrating an impact on the microbiome as part of their therapeutic effect. MMTs and microbiome therapies in general may not be successfully developed or commercialized or gain the acceptance of the public or the medical community. Our success will depend upon

physicians who specialize in the treatment of diseases targeted by our product candidates that we pursue as drugs, prescribing potential treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Our access will also depend on consumer acceptance and adoption of our products that we commercialize. Adverse events in non-IND human clinical studies and clinical trials of our product candidates or in clinical trials by others developing similar products and the resulting publicity, as well as any other adverse events in the field of the microbiome, could result in a decrease in demand for any product that we may develop. In addition, responses by the U.S., state or foreign governments to negative public perception or ethical concerns may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval, identify alternate regulatory pathways to market or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop.

All of our initial product candidates, including those targeting urea cycle disorders, or UCD, and hepatic encephalopathy, or HE, will require significant additional preclinical and clinical development before we can seek regulatory approval for and launch a therapeutic product commercially.

Our business and future success depends on our ability to obtain regulatory approval of and then successfully launch and commercialize our initial product candidates, including those targeting UCD or HE. We have filed an Investigational New Drug Application, or IND with the US FDA, for our initial therapeutic product candidate, which has cleared and allows for the commencement of a Phase 2 clinical trial for therapeutic applications. Similar clinical trial applications are being filed in countries outside the US, including in Europe, as we include clinical sites in those countries. However, our clinical trials may experience preliminary complications in trial execution, such as complexities surrounding regulatory clearance of our clinical trial applications, the need for additional preclinical data to support allowance for those applications, the need for additional preclinical data to support authorization to proceed under those applications, trial design and establishing trial protocols, bioanalytical assay method development, dose level and regimen selection, patient recruitment and enrollment, quality and supply of clinical doses or safety issues.

Additionally, our planned Phase 2 clinical trial is intended to allow us to evaluate the efficacy of KB195 in reducing ammonia in UCD patients. In compliance with FDA regulations, the clinical trial will initially enroll only adults. We hope that the data from the trial will support the inclusion of pediatric patients as soon as possible, as UCD primarily affects pediatric patients. We expect this will also be acceptable to regulatory authorities outside of the US where we plan to conduct the trial. However, trials involving pediatric populations can be difficult to conduct, can be quite costly and, like other clinical trials, may not yield the anticipated results. In addition, pediatric studies can be difficult to recruit for and many sites are largely ill-equipped to manage pediatric subjects for the requisite daily time period to ensure adherence to the schedule of a clinical trial, which in turn can limit site availability, therein driving cost. Moreover, it may be challenging to ensure that pediatric or adolescent patients adhere to clinical trial protocols. Our inability to enroll a sufficient number of pediatric patients for our clinical trial could result in significant delays, could require us to abandon one or more clinical trials altogether, could impact our ability to raise additional capital and could delay or prevent our ability to obtain necessary regulatory approvals for any drug product candidate. In addition, because UCD primarily affects pediatric patients, if we are unable to obtain regulatory approval for KB195 for an indication including pediatric patients, the commercial prospects or viability for our product candidate could be materially harmed, even if we obtain regulatory approval for an indication including adult patients.

All of our initial product candidates are in the early stages of development and will require significant additional preclinical and clinical development, regulatory review and approval in multiple jurisdictions or identification of alternate non-therapeutic regulatory pathways, substantial investment, access to sufficient validated and cGMP compliant commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. In addition, because KB195 is our most advanced product candidate, if KB195 encounters safety, efficacy, supply or manufacturing problems, developmental delays, regulatory or commercialization issues or other problems, our development plans, including for other product candidates, and business would be significantly harmed.

The successful development of our product candidates is highly uncertain.

Successful development of product candidates is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical or non-IND, or their ex-US equivalent, human clinical study results may show our product candidates to be less effective than desired or to have harmful or problematic side effects or toxicities;

- clinical trial results may show our therapeutic product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to execute the non-IND, or their ex-US equivalent, human clinical studies or clinical trials caused by slow enrollment in non-IND human clinical studies and clinical trials, patients dropping out of clinical trials or volunteers dropping out of non-IND, or their ex-US equivalent, human clinical studies, length of time to achieve clinical trial endpoints, additional time requirements for data analysis, inability to validate the manufacturing process or to achieve cGMP compliance for our product candidates or inability to identify a suitable bioanalytical assay method agreeable to our regulators;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals for, including but not limited to, a new drug application, or NDA, delays in NDA preparation, a new dietary ingredient notification, discussions with the FDA, responding to an FDA request for additional preclinical or clinical data or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, manufacturing deficiencies or other factors that make our product candidates uneconomical; and
- proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

The length of time necessary to complete clinical trials and to submit an application for marketing approval of a drug product candidate for a final decision by a regulatory authority may be difficult to predict for our therapeutic product candidates, in large part because of their limited regulatory history.

Even if we are successful in obtaining market approval for drug products, commercial success of any approved therapeutic products will also depend in large part on marketing acceptance, the availability of insurance coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, and managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost-effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide adequate insurance coverage and reimbursement levels for any of our drug products once approved, market acceptance and commercial success would be reduced.

In addition, if any of our drug product candidates is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration. If approved, our drug products would be subject to restrictions on our products' labels and other conditions of regulatory approval that may limit our ability to market our products for therapeutic indications. We will also need to comply (and ensure that our third-party contractors comply) with current cGMPs and Good Clinical Practices, or GCPs, as we (and our third-party contractors) will be required to comply with cGMPs for products used in any clinical trials. In addition, we will need to comply with GCPs for any therapeutic indications we develop for approval and for any additional therapeutic indications we develop after approval of our first drug candidate. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a drug product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly and any failure to comply or other issues with our product candidates' post-approval could have a material adverse effect on our business, financial condition and results of operations.

Clinical development is a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.

To obtain the requisite regulatory approvals to commercialize any product candidates for therapeutic uses, we must demonstrate through extensive preclinical studies, non-IND, or their ex-US equivalent, human clinical studies and clinical trials that our product candidates are safe and effective in humans for their intended use. Clinical testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. We may be unable to establish clinical endpoints, dose levels and regimens or bioanalytical assay methods that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. The outcome of preclinical studies, non-IND, or their ex-US equivalent, human clinical studies and early clinical trials may not be predictive of the success of later preclinical studies, non-IND, or their ex-US equivalent, human clinical studies and clinical trials, and interim results of these studies or trials do not necessarily predict final results. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

Successful completion of clinical trials is a prerequisite to submitting an NDA to the FDA, a Marketing Authorization Application to the EMA, and similar marketing applications to comparable foreign regulatory authorities, for each product candidate for therapeutic indications and, consequently, the ultimate approval and commercial marketing of any product candidates for therapeutic indications. We do not know whether any of our clinical trials will begin or be completed on schedule, if at all.

We may experience delays in completing our preclinical studies and initiating or completing non-IND human clinical studies and clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future non-IND human clinical studies or clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials for therapeutic indications or the marketing of our products as non-drug products;
- regulators or institutional review boards (IRBs), or ethics committees (ECs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of any product candidates may fail to show safety, purity or potency, or produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of patients required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- we may need to add new or additional clinical trial sites;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- the cost of preclinical studies, non-IND, or their ex-US equivalent, human clinical studies and clinical trials of any product candidates may be more than we anticipate or more than our available financial resources;
- the supply or quality of our product candidates or other materials necessary to conduct non-IND human clinical studies and clinical trials of our product candidates may be insufficient or inadequate and may not achieve compliance with applicable cGMPs;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ECs to suspend or terminate non-IND, or their ex-US equivalent, human clinical studies and clinical trials, or reports may arise from preclinical or clinical testing of our product candidates that raise safety or efficacy concerns about our product candidates;
- preclinical studies, non-IND, or their ex-US equivalent, human clinical studies or clinical trials of our product candidates may produce negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; and
- the FDA or other regulatory authorities may disagree with the design, implementation or results of our non-IND, or ex-US equivalent,human clinical studies or clinical trials or require us to submit additional data such as long-term toxicology studies or impose other requirements before permitting us to initiate a clinical trial.

We could also encounter delays if a preclinical study, non-IND, or ex-US equivalent, human clinical study or clinical trial is suspended or terminated for any reason. A suspension or termination may be imposed 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 product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that 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 for therapeutic indications.

Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for our preclinical studies, non-IND, or ex-US equivalent, human clinical studies or clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our preclinical studies, non-IND, or ex-US equivalent, human clinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical studies, non-IND, or ex-US equivalent,human clinical studies or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our preclinical or future clinical development programs may harm our business, financial condition and prospects significantly.

Our planned clinical trials or those of our future collaborators may reveal significant adverse events not seen in our preclinical studies, non-IND, or ex-US equivalent, human clinical studies or other clinical trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products for therapeutic indications, we must demonstrate through lengthy, complex and expensive preclinical studies, non-IND, or ex-US equivalent, human clinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Preclinical and 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 preclinical or clinical trial process. The results of preclinical studies, non-IND, or ex-US equivalent, human clinical studies as well as early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such clinical trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. We believe that our product candidates for therapeutic indications will be well tolerated by participants in our clinical trials, but we are not certain that we will be able to dose trial participants at a high enough dose that will demonstrate efficacy without unacceptable safety risk. Our product candidates are expected to have limited systemic exposure after oral administration but if the product candidates we use in our clinical trials are absorbed by the body, participants may suffer adverse effects. There is also a concern that the microbiome could re-configure itself in such a way as to cause a limited time window of effectiveness and tolerability of our product candidates or unanticipated short or long-term effects.

Product candidates in later stages of clinical trials also may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the healthcare industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier clinical trials. Most product candidates that commence clinical trials are never approved as products for therapeutic indications and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our clinical trials or we may be required to significantly redesign or abandon trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities or an IRB or EC may suspend clinical trials of a product candidate at any time for various reasons, including a belief that patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the healthcare industry that initially showed therapeutic promise in early-stage clinical trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Positive results from early preclinical studies, non-IND, or ex-US equivalent, human clinical studies and clinical trials of our product candidates are not necessarily predictive of the results of later preclinical studies, non-IND, or ex-US equivalent, human clinical studies and any future clinical trials of our product candidates for therapeutic indications. If we cannot replicate the positive results from our earlier preclinical studies of our product candidates in our later preclinical studies and future non-IND, or ex-US equivalent, human clinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates

Any positive results from our preclinical studies, non-IND, or ex-US equivalent, human clinical studies and clinical trials of our product candidates may not necessarily be predictive of the results from required later preclinical studies, non-IND, or ex-US equivalent, human clinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any future non-IND, or ex-US equivalent, human clinical studies and clinical trials of our product candidates according to our

current development timeline, the positive results from such preclinical studies, non-IND, or ex-US equivalent, human clinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies, non IND, or ex-US equivalent, human clinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies, non-IND, or ex-US equivalent, human clinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies, non-IND, or ex-US equivalent, human clinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval.

If we encounter difficulties enrolling patients in our non-IND, or ex-US equivalent, human clinical studies or clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our non-IND, or ex-US equivalent, human clinical studies and clinical trials for a variety of reasons. The timely completion of non-IND, or ex-US equivalent, human clinical studies or 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 non-IND, or ex-US equivalent, human clinical study or clinical trial until its conclusion. The enrollment of patients depends on many factors, including:

- the severity of the disease or condition under investigation;
- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the study patient population required for analysis of the primary endpoint(s) of the non-IND human clinical study or clinical trial;
- the proximity of patients to trial sites;
- the design of the clinical study or trial;
- our ability to recruit investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the efforts to facilitate timely enrollment in clinical studies or trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and the risk that patients enrolled in non-IND, or ex-US equivalent, human clinical studies or clinical trials will drop out of the non-IND, or ex-US equivalent, human clinical studies or clinical trials before completion.

In addition, our clinical studies or trials will compete with other clinical studies or trials for product candidates 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 clinical studies or trials may instead opt to enroll in a study or trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical studies or trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Moreover, because our product candidates represent a departure from more commonly used methods for our targeted therapeutic areas, potential patients and their doctors may be inclined to use conventional therapies, rather than enroll patients in any future clinical study or trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical studies or trials, which could prevent completion of these clinical studies or trials and adversely affect our ability to advance the development of our product candidates.

Interim top-line and preliminary data from our non-IND, or ex-US equivalent human clinical studies or 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, once we commence conducting non-IND, or ex-US equivalent, human clinical studies or clinical trials, we may publish interim top-line or preliminary data from our non-IND, or ex-US equivalent, human clinical studies and clinical trials. Interim data from these non-IND, or ex-US equivalent, human clinical studies and clinical trials that we may complete are subject to the risk that one or more of the outcomes may materially change as preclinical studies complete, patient enrollment continues, and more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of biological waste or hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage or workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of testing our product candidates in non-IND human clinical studies and clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during non-IND human clinical studies, clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;
- damage to our reputation;
- withdrawal of non-IND human clinical study or clinical trial participants and patients and inability to enroll future participants or continue non-IND human clinical studies or clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and our resources;

- substantial monetary awards to participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate via any regulatory pathway; and
- decline in our share price.

We maintain clinical trial insurance. We review our clinical trial insurance policy annually and we believe that our coverage is currently adequate to cover any claims that may arise in connection with our non-IND human clinical studies or clinical trials. There is no guarantee that we will be able to obtain additional clinical trial insurance at an acceptable cost in the future, which could prevent or inhibit the ongoing development of our products.

Since we have not yet commenced marketing of any products, we do not yet hold product liability insurance for commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. If and when coverage is secured, our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

The market opportunities for our product candidates may be limited and our estimates of the incidence and prevalence of our target patient populations may be inaccurate.

Our projections of both the number of people who have the diseases we are targeting, as well as the subset of people with these diseases in a position to receive our therapies, if approved, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, input from key opinion leaders, patient foundations or secondary market research databases, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases or regulatory approvals may include limitations for use or contraindications that decrease the addressable patient population. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, we estimate that there are approximately 3,000 patients with UCD in the United States and over 500,000 patients that suffer from some form of HE in the United States, not all of whom have been diagnosed. Even if we obtain significant market share for our product candidates, because certain of the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

We are early in our development efforts and may not be successful in our efforts to use our proprietary product platform to build a pipeline of product candidates and develop marketable products.

We are developing our proprietary product platform to systematically direct functional outputs of the microbiome organ. However, our proprietary product platform has not yet, and may never lead to, FDA approved or commercialized products. We are developing our initial product candidates and additional product candidates that we intend to use in a number of areas of health and disease, including diabetes, obesity, cancer, neurology, autoimmunity and liver and kidney function. We may have problems applying our technologies to these other areas, and our product candidates may not demonstrate a comparable ability in treating disease as our initial product candidates. Even if we are successful in identifying additional product candidates, they may not be suitable for clinical development as a result of our inability to manufacture more complex proprietary compounds, limited efficacy, unacceptable safety profiles or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. The success of our product candidates will depend on several factors, including the following:

- completion of preclinical studies, non-IND, or ex-US equivalent, human clinical studies and clinical trials with positive results;
- receipt of marketing approvals from applicable regulatory authorities, if necessary;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing our own, commercial manufacturing capabilities;

- supplying sufficient quantities of our products at appropriate quality levels;
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- entering into new collaborations throughout the development process as appropriate, from preclinical studies through to commercialization;
- acceptance of our products, if and when approved, by patients, consumers, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved;
- protecting our rights in our intellectual property portfolio;
- operating without infringing or violating the valid and enforceable patents or other intellectual property of third parties;
- maintaining a continued acceptable safety profile of the products following approval or commercialization; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our products and technology.

If we do not successfully develop and commercialize product candidates based upon our platform approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

We face significant competition from other healthcare companies, and our operating results will suffer if we fail to compete effectively.

The healthcare industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or products that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, nutritional foods companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the healthcare industry may result in even more resources being concentrated amongst our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis microbiome therapies that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

We anticipate competing with the largest healthcare companies in the world, many of which have greater financial and human resources than we currently have. In addition to these fully integrated healthcare companies, we also compete with those companies whose products target the same indications as our product candidates. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations. Any treatments developed by our competitors could be superior to our product candidates. It is possible that these competitors will succeed in developing technologies that are more effective than our products or that would render our product candidates obsolete or noncompetitive. We anticipate that we will face increased competition in the future as additional companies enter our market and scientific developments surrounding other therapies targeted at the microbiome continue to accelerate.

In addition, we have identified several companies that are targeting the microbiome, such as Synlogic, Inc., Seres Therapeutics, Inc. and Evelo Biosciences, Inc.

Even if we obtain regulatory approval to market our product candidates or are successful in identifying alternate regulatory pathways to market for our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to

reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see "Business—Competition."

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

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

- efficacy, safety and potential advantages compared to alternative treatments;
- the labeled uses or limitations for use, including age limitations or contraindications, for our product candidates compared to alternative treatments;
- 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;
- public perception of new therapies and non-therapeutic nutritional products, including our MMTs;
- the strength of marketing and distribution support;
- the ability to offer our products, if approved, for sale at competitive prices;
- the ability to obtain sufficient third-party insurance coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As our research, development, manufacturing and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, compensating, integrating, maintaining and motivating additional employees;
- managing our internal research and development efforts effectively, including identification of clinical candidates, scaling our manufacturing process and navigating the clinical and FDA review process for our product candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain organizations, advisors and consultants to provide certain services, including many aspects of regulatory affairs, clinical management and manufacturing. There can be no assurance that the services of these organizations, advisors and consultants will continue to be available to us on a timely basis when needed or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our current operations are located in Massachusetts, and we or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are located in Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify and develop new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive healthcare industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including Michael Bonney, our Executive Chair, Alison Lawton, our Chief Executive Officer and President, Joshua Brumm, our Chief Operating Officer and Chief Financial Officer, and Katharine Knobil, M.D., our Chief Medical Officer and Head of Research and Development. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations in Massachusetts. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock and stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Employment of our key employees is at-will, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, contract manufacturing organizations, or CMOs, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. For our non-IND human clinical studies, we rely on third-party manufacturers for spray drying the MMT substance and filling sachets with the resulting spray-dried powder. For materials to be used in our clinical trials, we plan to rely on an external contract manufacturing organization for the entire manufacturing supply chain. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our internal computer systems, or those used by our CROs, CMOs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs, CMOs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical 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 confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Regulators globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the European Union adopted a new regulation governing data practices and privacy called the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR applies to any company that collects and uses personal data in connection with offering goods or services to individuals in the European Union or the monitoring of their behavior. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase the cost of providing our product candidates, if approved, or even prevent us from offering our product candidates, if approved, in certain jurisdictions.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, 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 a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act, or FCA. The 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. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. 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 FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit 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 by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- 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, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also 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 the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security 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; and
- GDPR and other ex-U.S. protections.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements

comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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 be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, 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, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

A variety of risks associated with testing and developing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates for therapeutic and other uses outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act, or FCPA, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

Additionally, we intend to contract with third parties to conduct some of our clinical trials outside the United States, which will subject us to additional risks and regulations. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We currently have no marketing and sales organization and have no experience in marketing products for therapeutic or other non-drug uses. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products for therapeutic or other uses. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other healthcare companies to recruit, hire, train and retain marketing and sales personnel.

In addition to establishing internal sales, marketing and distribution capabilities, we intend to optimistically pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of products which act on the microbiome, which may be difficult to predict.

The FDA, the EMA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products and product candidates, such as MMTs. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in non-IND, or ex-US equivalent, human clinical studies or clinical trials of MMT products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. Similarly, the EMA governs the development of MMTs as drugs in the European Union and member state regulatory bodies govern the development of MMTs under food regulations and may issue new guidelines concerning the development and marketing authorization for MMT products and require that we comply with these new guidelines. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected, delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

The Tax Cuts and Jobs Act, or the TCJA, significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal tax rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”). We continue to examine the impact this tax reform legislation may have on our business. We urge investors to consult with their legal and tax advisers regarding the implications of the TCJA on an investment in our common stock.

Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.

As of December 31, 2018, the Company had net operating loss (NOL) carryforwards for U.S. federal and state tax purposes of $90.7 million and $88.6 million, respectively. NOLs for U.S. federal and state tax purposes generated before 2018 of $38.8 million and $37.7 million, respectively, will begin expiring in varying amounts in 2035 unless utilized. NOLs for U.S. federal and state tax purposes generated in 2018 of $51.8 million and $50.9 million, respectively, will be carried forward indefinitely but may be used to offset up to 80% of our taxable income in each future taxable year. As of December 31, 2018, we also had U.S.

federal and state research and development tax credit carryforwards of $3.0 million and $1.5 million respectively, both of which expire at various dates through 2038. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future taxable income or tax liabilities, respectively. In addition, in general, under Sections 382 and 383 of the Code, and corresponding provisions of state law, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards or tax credits, or NOLs or credits, to offset future taxable income or taxes. 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. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above under "Risk Factors—Risks Related to Our Business, Technology and Industry," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOLs or credits that are subject to limitation by Sections 382 and 383 of the Code. The reduction of the corporate tax rate under the TCJA caused a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, NOLs generated after December 31, 2017 will not be subject to expiration.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

As of March 31, 2019, we had cash and cash equivalents of approximately $121.3 million. While we are not aware of any downgrades, material losses or other significant deterioration in the fair value of our cash equivalents since March 31, 2019, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Risks related to government regulation

We are very early in our development efforts. All of our product candidates will require significant additional preclinical and clinical development before we seek regulatory approval of our therapeutic product candidates or identify alternate regulatory pathways to market for our non-therapeutic products and launch a product commercially. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and we have invested substantially all of our efforts and financial resources in the identification and early clinical development of MMT candidates, including the development of our initial product candidates. To date, we have not elected a product candidate to develop and market as a conventional food or medical food and may never do so. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies, non-IND, or ex-US equivalent, human clinical studies and, where applicable, clinical trials;

- clearance of INDs, or ex-US equivalent, for our planned clinical trials or future clinical trials for therapeutic indications;
- successful enrollment in, and completion of, non-IND, or ex-US equivalent, human clinical studies and clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for therapeutic product candidates;
- establishing cGMP-compliant clinical supply and commercial manufacturing operations or making arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- supplying sufficient quantities of our products at appropriate quality levels;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- launching commercial sales of our product candidates, if and when approved or allowed for marketing, whether alone or in collaboration with others;
- acceptance of our therapeutic product candidates, if and when approved, by patients, the medical community and third-party payors or any non-therapeutic product by consumers;
- effectively competing with other therapies;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- enforcing and defending intellectual property rights and claims;
- the marketing of our products; and
- maintaining a continued acceptable safety profile of the product candidates following approval or commercialization.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals or identify alternate regulatory pathways to market for our product candidates, we may not be able to continue our operations.

Regulatory requirements for development of our MMT candidates as drugs and non-drugs are uncertain and evolving. Changes in these laws, including our ability to conduct non-IND, or ex-US equivalent, human clinical studies, or the current interpretation or application of these laws would have a significant adverse impact on our ability to develop and commercialize our products.

In the United States, under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance that is reasonably expected to become a component of food is considered to be a food additive, and therefore subject to FDA premarket review and approval, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use. We have determined that our initial product candidates are safe for non-IND human clinical studies, based on initial safety assessments conducted by third-party qualified experts and because they are related to a class of compounds that is Generally Recognized as Safe, or GRAS, based on their history of safe human exposure, when utilized for particular uses as food substances. As a result, we believe we may use our product candidates to conduct non-IND human clinical studies in order to evaluate safety, tolerability and biomarkers for non-drug applications in advance of deciding whether or not to file an IND.

The FDA may determine that our MMT candidates are not governed by food regulations and therefore may classify any product candidates as being ineligible for use in non-IND human clinical studies without an IND.

The FDA may determine that our product candidates cannot be marketed as conventional foods or medical foods. The FDA may not agree the products meet the medical food definition or the agency may take the position that we failed to satisfy the premarket authorization requirements for GRAS ingredients or new dietary ingredients. Moreover, if we choose to study a product under an IND before the product candidate has been marketed as a food, the first to market provisions of Section 301(ll) could prevent us from marketing the product as a food if we are unable to secure FDA approval as a new drug. Any delay in the regulatory consultation process, or a determination that any of our drug or food product candidates do not meet the regulatory requirements of the FDA, including any applicable GRAS requirements, could cause a delay in the commercialization of our product candidates, which may lead to reduced acceptance by the public or others.

The FDA may determine that the only pathway for conducting non-IND human clinical studies is under an IND. Any such determination could prevent our reliance on existing regulatory frameworks to conduct non-IND human clinical studies for other product candidates and could significantly increase the cost of and delay the commercialization of our product candidates for therapeutic applications. If the FDA were to disagree with our determination that we may conduct non-IND human clinical

studies in advance of filing an IND, they could ask us to halt any clinical trials we have commenced. Should we choose to commercialize our food products, whether as conventional foods or medical foods, and if the FDA determines our product candidates fall outside the food regulations, the agency could ask us to withdraw any products we have commercialized as foods or non-drug products from the market. In addition, if new safety issues are raised by non-IND human clinical studies in advance of deciding whether to file an IND that suggest safety concerns for all of our product candidates, then FDA could ask us to modify approved labeling for or withdraw from the market any previously approved products for therapeutic uses or products being commercialized for other non-drug uses. A decision by the FDA that we cannot conduct non-IND human clinical studies in advance of filing an IND would significantly impact our current business model and we may incur significant expense and operational difficulties.

Changes in the legal and regulatory environment could limit our future business activities, increase our operating or regulatory costs, reduce demand for our product candidates or result in litigation.

The conduct of our business, including the development, testing, production, storage, distribution, sale, display, advertising, marketing, labeling, health and safety practices, and possible regulatory classification and approval (where necessary) use of many of our product candidates, are subject to various laws and regulations administered by federal, state and local governmental agencies in the United States, as well as to laws and regulations administered by government entities and agencies outside the United States in markets in which our products candidates and components thereof (such as packaging) may be manufactured or sold.

These laws and regulations and interpretations thereof may change, sometimes dramatically, as a result of a variety of factors, including political, economic or social events. Such changes may include changes in:

- food and drug laws (including FDA regulations);
- laws related to product candidate labeling;
- advertising and marketing laws and practices;
- laws and programs restricting the sale and advertising of certain of product candidates;
- laws and programs aimed at regulating, restricting or eliminating ingredients present in certain of our product candidates;
- increased regulatory scrutiny of, and increased litigation involving, product claims and concerns regarding the actual or possible effects or side effects of ingredients in, or attributes of, certain of our product candidates; and
- state and federal consumer protection and disclosure laws.

New laws, regulations or governmental policy and their related interpretations, or changes in any of the foregoing, may alter the environment in which we do business and, therefore, may impact our operating results or increase our costs or liabilities.

Inadequate funding for the FDA, the SEC and other US and non US government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, 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 the SEC and other government agencies on which our operations may rely, including those 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 and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government 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. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may rely on academic and private non-academic institutions to conduct investigator-sponsored non-IND human clinical studies or trials of our product candidates. Any failure by the investigator-sponsor to meet its obligations with respect to the

clinical development of our product candidates may delay or impair our ability to obtain regulatory approval or commercialize for other product candidates.

We may rely on academic and private non-academic institutions to conduct and sponsor clinical studies or trials relating to our product candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored studies or trials as providing adequate support for future clinical trials, whether controlled by us or independent investigators, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored studies or trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored studies or trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored studies or trials. If we are unable to confirm or replicate the results from the investigator-sponsored studies or trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored studies or trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

Additionally, the FDA or non-U.S. regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored studies or trials or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored studies or trials. If so, the FDA or other non-U.S. regulatory authorities may require us to obtain and submit additional preclinical, manufacturing or clinical data before we may initiate our planned clinical trials and/or may not accept such additional data as adequate to initiate our planned clinical trials. In addition, it could limit or prevent our ability to commercialize product candidates for non-therapeutic uses.

Obtaining and maintaining regulatory approval of our product candidates for therapeutic indications or the ability to commercialize our product candidates through an alternate regulatory pathway in one jurisdiction does not mean that we will be successful in obtaining regulatory approval or identifying a similar alternate regulatory pathway for our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval for therapeutic indications or identifying an alternate regulatory pathway for our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval or identify a similar alternate regulatory pathway in any other jurisdiction, while a failure or delay in obtaining regulatory approval or an alternate regulatory in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate for therapeutic indications, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies, non-IND human clinical studies and clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Preclinical and clinical development is uncertain. Our preclinical programs, non-IND, or non- US equivalent, human clinical studies and clinical trials may experience delays or may never advance to the next stage of development, which would adversely affect our ability to obtain regulatory approvals or identify alternate regulatory pathways to commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

Our product candidates are in preclinical stages, and their risk of failure is high. To proceed with our development plans and ultimately commercialization, we may be required to conduct preclinical, non-IND, or non-US equivalent, human clinical studies or clinical trials. For therapeutic applications, the FDA or non-US regulatory authorities may require additional extensive preclinical studies. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs, including the design, dose level,

and dose regimen, or if the outcome of our preclinical testing and studies will ultimately support the further development of our clinical programs for therapeutic indications. As a result, we cannot be sure that we will be able to submit INDs or similar applications on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates for therapeutic indications, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization for therapeutic indications, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates for therapeutic indications, we must obtain marketing approval. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We, as a company, have no experience in filing and supporting the applications necessary to gain regulatory approvals for therapeutic indications and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy.

Securing regulatory approval for therapeutic indications also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals for therapeutic indications, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, NDA or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, including study population, dose level, dose regimen, and bioanalytical assay methods, 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 drug candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials 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, non-IND, or non-US equivalent, human clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve 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 FDA or foreign regulatory approval processes and are commercialized. The 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.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval for therapeutic indications may be significantly impacted.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval for therapeutic indications. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited therapeutic indications than we request, may include limitations for use or contraindications that limit the suitable patient population, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or 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 scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or non-IND, or non-US equivalent, human clinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical studies or trials and could result in a more restrictive clinical label or the delay or denial of regulatory approval by the FDA or other regulatory authorities for our product candidates for therapeutic indications. Results of our clinical studies or trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our clinical studies or trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Additionally, our regulators could require significant modifications or amendments to ongoing clinical studies or trials that limit the available study population or lead to withdrawal of participation by already enrolled subjects. Any treatment-related side effects could affect patient recruitment or the ability of enrolled patients to complete the study or trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, clinical studies or trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval for therapeutic indications and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

Breakthrough Therapy Designation, Fast Track Designation or Rare Pediatric Disease Designation by the FDA, and equivalents granted by other regulatory authorities, even if granted for any of our product candidates developed for therapeutic indications, may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in any jurisdication.

We may seek a Breakthrough Therapy Designation for some of our product candidates. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy 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 therapies 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. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek Fast Track Designation for some of our product candidates for therapeutic indications. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation; we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. 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 Rare Pediatric Disease Designation and conditional designation of our marketing application as a "rare pediatric disease product application" for some of our product candidates for therapeutic indications, which, if granted, could qualify us to receive a Rare Pediatric Priority Review Voucher. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation; we cannot assure you that the FDA would decide to grant it and determination whether to issue such a voucher is made by FDA only at the time of its review and approval of a marketing application. A Rare Pediatric Priority Review Voucher can be redeemed to receive a priority review of a subsequent marketing application for a different product.

We may seek priority review designation for one or more of our product candidates for therapeutic indications, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may fail to obtain and maintain orphan drug designations from the FDA or the EMA for our current and future therapeutic product candidates, as applicable.

Our strategy includes filing for orphan drug designation where available for our product candidates for therapeutic indications that are eligible. In the United States, under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or

biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the orphan-designated disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations.

In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the European Union, orphan drug designation entitles a party to financial incentives such as reductions of fees or fee waivers. In addition, ten years of market exclusivity is granted following drug product approval, meaning that another application for marketing authorization of a later similar medicinal product for the same indication will generally not be approved in the European Union. This period may be reduced to six years if the orphan designation criteria are no longer met, including where it is shown that the product is not sufficiently profitable to justify maintenance of market exclusivity. The market exclusivity period is extended by two additional years for an orphan-designated condition when the results of specific studies are reflected in the summary of product characteristics (SmPC) addressing the pediatric population and completed in accordance with a fully compliant pediatric investigation plan (PIP).

Even if we receive regulatory approval of any product candidates for therapeutic indications, we will be subject to ongoing regulatory compliance obligations and continued regulatory review, which may result in significant additional expense. Additionally, any of our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved for therapeutic indications, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, advertising, promotion, sampling, record-keeping, export, import, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

The regulatory authorities have significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks

related to the use of a drug. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled enforcement letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label or other regulatory marketing pathway. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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. For example, certain policies of the current administration may impact our business and industry. Namely, the current 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. It is difficult to predict how these executive actions, including any executive orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, 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.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance requirements, can also result in significant financial penalties.

Healthcare insurance coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably.

The success of our product candidates, if approved for therapeutic indications, depends on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to the treatment of the diseases they target, we cannot be sure that coverage and reimbursement will be available for, or accurately

estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage, and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates may have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. 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.

Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Middle Class Tax Relief and Job Creation Act of 2012 required that the Centers for Medicare & Medicaid Services, the agency responsible for administering the Medicare program, or CMS, reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain pharmaceutical products or additional pricing pressures.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad 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 our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

Healthcare insurance often does not cover foods or medical foods administered outside of the hospital setting. This may impact our products if we decide to commercialize them as medical food, which is required to be administered under medical supervision.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, or the ACA, was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the current administration to repeal or replace certain aspects of the ACA.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

European Union drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our therapeutic products in the European member states.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of pharmaceutical products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including the European Economic Area, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically,

products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

European data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

The collection and use of personal health data in the European Union is governed by the provisions of the Data Protection Directive, and as of May 2018 the GDPR. These directives impose several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent

registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Risks related to our intellectual property

If we are unable to obtain and maintain patent protection for any product candidates we develop or for our proprietary product platform, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates, proprietary product platform and other technologies we may develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad relating to our product candidates and proprietary product platform, as well as other technologies that are important to our business. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. We have filed or intend to file patent applications on these aspects of our technology and our product candidates; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our technology and product candidates and each of these provisional patent applications is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office, or the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions of matter relating to our product candidates and proprietary product platform, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indications, physicians may prescribe these products “off-label” for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our product candidates and proprietary product platform could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If any of our owned patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned patents. With respect to our patent portfolio, as of December 31, 2018, our patent portfolio consisted of eight issued U.S. patents, two issued European patents, 12 issued patents in other jurisdictions, including Argentina, Australia, Canada, China, Colombia, Hong Kong, Indonesia, Mexico, New Zealand and South Africa, six pending PCT applications, 103 pending non-provisional applications (U.S., EP, and other jurisdictions), and 12 pending U.S. provisional applications, which include claims directed to compositions, methods of use, and manufacturing processes. With respect to owned intellectual property, we cannot predict whether the patent applications we 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 or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents and 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 in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such

agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, 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 at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our owned or pending patent applications, or that we were the first to file for patent protection of such inventions.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.

The patent position of healthcare companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our owned pending and future patent applications may not result in patents being issued which protect our product candidates, proprietary product platform technology, or other technologies or which effectively prevent others from commercializing competitive technologies and product candidates.

No consistent policy regarding the scope of claims allowable in patents in the biotechnology field has emerged in the United States. The patent situation outside of the United States is even more uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. With respect to company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our products and the methods used to manufacture those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our patented product candidates and practicing our proprietary technology. Our issued patent and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or limit the length of the term of patent protection that we may have for our product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Moreover, 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 patent applications we own issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and patents that we own may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party preissuance submission of prior art to the USPTO or to foreign patent authorities or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned patent rights, allow third parties to commercialize our product candidates, proprietary product platform technologies or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our owned patents and patent applications. Such challenges may result in loss of patent rights, loss

of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, 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 product candidates, proprietary product platform and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may in the future co-own patent rights relating to future product candidates and our proprietary product platform with third parties. We may need the cooperation of any such co-owners of our patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our rights to develop and commercialize our product candidates and proprietary product platform may be subject, in part, to the terms and conditions of future licenses granted to us by others.

We may rely upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our product candidates and proprietary product platform. Patent rights that we in-license in the future may be subject to a reservation of rights by one or more third parties. As a result, any such third parties may have certain rights to such intellectual property.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution and maintenance, and we may not have the right to control the enforcement, and defense of patents and patent applications covering the technology that we license from third parties. We cannot be certain that our in-licensed patent applications (and any patents issuing therefrom) that are controlled by our licensors will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents rights, or lose rights to those patent applications (or any patents issuing therefrom), the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our product candidates and proprietary product platform technologies that are subject of such licensed rights could be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. Moreover, we cannot be certain that such activities by our potential future licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. In addition, even where we may have the right to control patent prosecution of patents and patent applications that we may license to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our potential future licensees, licensors and their counsel that took place prior to the date of assumption of control over patent prosecution.

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

Filing, prosecuting and defending patents on our product candidates, proprietary product platform technologies and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. 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, 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. 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 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.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law 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 the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. 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 America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other 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. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to our product candidates, proprietary product platform or other technologies.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned patent applications and the enforcement or defense of our owned 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 existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Issued patents covering our product candidates, and any patents that may issue covering our proprietary product platform technologies and other technologies, could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we or any of our third-party licensees, such as Midori Animal Health, which holds an exclusive license to certain of our patents in the field of non-human animal health, initiated legal proceedings against a third party to enforce a patent covering our product candidates, proprietary product platform technologies or other technologies, the defendant could counterclaim that such patent is 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 raise claims challenging the validity or enforceability of our owned patents 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). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our product candidates, proprietary product platform technologies, or other technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates, proprietary product platform or other technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

If we do not obtain patent term extension and/or data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent 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 extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories 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 applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates, proprietary product platform or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our owned patent rights, trade secrets or other intellectual property. If we 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, proprietary product platform and other technologies. 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.

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 our product candidates, proprietary product platform and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We expect our trade secrets and know-how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We currently, and may continue in the future continue to, rely on third parties to assist us in developing and manufacturing our product candidates. Accordingly, we must, at times, share know-how and trade secrets, including those related to our proprietary product platform, with them. We may in the future also enter into research and development collaborations with third parties that

may require us to share know-how and trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our know-how, trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements, and including in our vendor and service agreements terms protecting our confidential information, know-how and trade secrets, with parties who have access to such information, such as our employees, 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 as well as train our employees not to bring or use proprietary information or technology from former employers to us or in their work, and we remind former employees when they leave their employment of their confidentiality obligations. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Despite our efforts, any of the aforementioned parties may breach the agreements and disclose our proprietary information, including our trade secrets, or there may be a lapses or failures in our physical and electronic security systems which lead to our proprietary information being disclosed, and we may not be able to obtain adequate remedies in the event of any such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of our scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. 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 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 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.

We rely on our proprietary product platform to identify microbiome therapies. Our competitive position could be materially harmed if our competitors develop a similar platform and develop rival product candidates.

We rely on know-how, inventions and other proprietary information, to strengthen our competitive position. We consider know-how to be our primary intellectual property with respect to our proprietary product platform. Our clinical trials allow us to collect clinical data, which we use as a feedback loop to make improvements to our proprietary product platform. In particular, we anticipate that, with respect to this proprietary product platform, this data may over time be disseminated within the industry through independent development, the publication of journal articles describing the method, and the movement of skilled personnel.

We cannot rule out that our competitors may have or obtain the knowledge necessary to analyze and characterize similar data to our known data for the purpose of identifying and developing products that could compete with any of our product candidates. Our competitors may also have significantly greater financial, product development, technical, and human resources and access to date. Further, our competitors may have significantly greater experience in using translational science methods to identify and develop product candidates.

We may not be able to prohibit our competitors from using technology or methods that are the same as or similar to our proprietary product platform to develop their own product candidates. If our competitors develop associated therapies, our ability to develop and market a promising product or product candidate may diminish substantially, which could have a material adverse effect on our business, financial condition, prospects and results of operations.

We may not be successful in obtaining, through acquisitions, in-licenses or otherwise, necessary rights to our product candidates, proprietary product platform technologies or other technologies.

We currently have rights to certain intellectual property, through licenses from third parties, to develop our product candidates and proprietary product platform technologies. Some healthcare companies and academic institutions are competing with us in the field of microbiome therapies and may have patents and have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. We may also require licenses from third parties for certain technologies that we may evaluating for use with our current or future product candidates. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for our current or future product candidates and our proprietary product platform at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual

property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all.

In the event that we try to obtain rights to required third party intellectual property rights, and are ultimately unsuccessful, 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 product candidates or continue to utilize our existing proprietary product platform technology, which could harm our business, financial condition, results of operations, and prospects significantly.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other healthcare companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals 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. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that 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 condition, results of operations, and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the development and commercialization of our product candidates, proprietary product platform and other technologies.

The field of developing therapeutics that target the microbiome is competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our owned, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to glycan technologies and in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates, proprietary product platform technologies and other technologies may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates, proprietary product platform technologies and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, proprietary product platform and other technologies might assert are infringed by our current or future product candidates, proprietary product platform or other technologies, including claims to compositions, formulations, methods

of manufacture or methods of use or treatment that cover our product candidates, proprietary product platform or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates, proprietary product platform or other technologies, could be found to be infringed by our product candidates, proprietary product platform or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates, proprietary product platform or other technologies may infringe. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our proprietary product platform technologies, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our product candidates, proprietary product platform or other technologies infringes upon these patents. In the event that any third party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our product candidates, proprietary product platform or other technologies. In this case, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates, proprietary product platform, or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing product candidates, proprietary product platform, or other technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, proprietary product platform, or other technologies, which could harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe our patents, or we may be required to defend against claims of infringement. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable, the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §27I)(1), or may refuse to stop the other party from using the technology at issue on the grounds that our owned patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned patents at risk of being invalidated or interpreted narrowly. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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.

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 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 more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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 or 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 partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, 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 trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

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:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we may own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own now or in the future;
- we, or our current or future licensors or 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 intellectual property rights;
- it is possible that our current or future pending owned patent applications 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 or other third parties;
- our competitors or other third parties 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 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.

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

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. 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. 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 but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims 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 biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent 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 and 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 rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks related to our reliance on third parties

We will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We will depend upon third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medicinal institutions, CROs, strategic partners and others. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We will rely heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable 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 suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials for therapeutic indications must be conducted with drug product produced under cGMP requirements and may require a large number of patients.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval or commercialization process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our future clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced 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 other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

We expect to rely on third parties to manufacture our clinical supply of product candidates, and we intend to rely on third parties to produce and process our products, if approved.

We currently rely on outside vendors to supply raw materials and other important components, such as the heterogenous catalyst and chromatographic resins used to purify crude MMT candidates. We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. We will make changes as we work to optimize the manufacturing process for our product candidates, and we cannot be sure that even minor changes in the process will result in therapies that are safe and effective.

The facilities used to manufacture our product candidates must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit a marketing application to the FDA or other foreign regulatory agencies. Additionally, any facilities used for the manufacture of product candidates commercialized for non-therapeutic uses will be subject to inspection by the FDA and foreign regulatory authorities. We do not currently control all aspects of the manufacturing process of, and are currently largely dependent on, our contract manufacturing partners for compliance with regulatory requirements, known as cGMP requirements, for manufacture of our product candidates. If and when our manufacturing facility becomes operational, we will be responsible for compliance with cGMP requirements. If we or our contract manufacturers cannot successfully manufacture in conformance with our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we and they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities with respect to the manufacture of our product candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

For more information, see “Risk Factors—Risks Related to Manufacturing and Supply” below.

If our sole contract manufacturing organization for materials to be used in our clinical trials fails to supply us with the necessary materials, we may be unable to complete our clinical trials on a timely basis, if at all.

In 2018, we entered into a services agreement with a subsidiary of Thermo Fisher Scientific, or Thermo Fisher, to handle the manufacturing supply chain from drug substance synthesis through labeling and packaging for our planned clinical trials. If Thermo Fisher is unable or unwilling to provide us with sufficient quantities of applicable MMT candidates to meet our demands or fails to meet our standards of quality or other specification or to achieve drug cGMP compliance, we may not be able to locate any alternative suppliers or enter into commercially reasonable agreements with substitute suppliers in a timely manner or at all.

Third-party relationships are important to our business. If we are unable to maintain our collaborations, enter into new relationships or if these relationships are not successful, our business could be adversely affected.

We have limited capabilities for product development and do not yet have any capability for sales, marketing or distribution. Accordingly, we enter into relationships with other companies to provide us with important technologies, and we may receive additional technologies and funding under these and other collaborations in the future. Relationships we enter into, may pose a number of risks, including the following:

- third parties have, and future third-party collaborators may have, significant discretion in determining the efforts and resources that they will apply;
- current and future third parties may not perform their obligations as expected;

- current and future third parties may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the third parties' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- third parties may delay non-IND human clinical studies or clinical trials, provide insufficient funding for a non-IND human clinical study or clinical trial program, stop a non-IND human clinical study or clinical trial or abandon a product candidate, repeat or conduct non-IND human clinical studies or new clinical trials or require a new formulation of a product candidate for clinical testing;
- current and future third parties could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the third parties believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our current or future third parties as competitive with their own product candidates or products, which may cause such third parties to cease to devote resources to the commercialization of our product candidates;
- current and future third parties may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- current and future third parties with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with current or future third parties, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- current and future third parties may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- current and future third parties may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a current or future third parties of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- current and future relationships may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our relationships do not result in the successful discovery, development and commercialization of products or if one of our third parties terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our technology and product candidates could be delayed and we may need additional resources to develop product candidates and our technology. All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report on Form 10-Q also apply to the activities of our therapeutic collaborators.

Additionally, if any of our current or future third parties terminate its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

Relationships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable third parties on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into relationships or do not

have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected.

Risks related to manufacturing and supply

Our MMT product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Our product candidates require certain specialty raw materials, some of which we obtain from small companies with limited resources and experience to support a commercial product. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We do not currently have contracts in place with all of the suppliers that we may need at any point in time, and if needed, may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

Our product candidates require specialized manufacturing capabilities. If we or any of our third-party manufacturers encounter difficulties in manufacturing our product candidates, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The manufacturing process used to produce our product candidates has not yet been validated for commercial production. Our cGMP manufacturing process development and scale-up is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates.

Our manufacturing process may be susceptible to manufacturing issues associated with interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, production at such manufacturing facilities may be interrupted for an extended period of time to investigate and remedy the contamination. Further, as product candidates are developed through preclinical to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

Although we continue to refine our manufacturing process for our MMT product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of reagents and/or raw materials. We ultimately may not be successful in transferring our production system from our contract manufacturer to any manufacturing facilities we establish ourselves, or our contract manufacturer may not have the necessary capabilities to complete the implementation and development process. If we are unable to adequately validate or scale-up the manufacturing process for our product candidates with our current manufacturer, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply, and it is not certain we will be able to come to agreement on terms acceptable to us. As a result, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

The manufacturing process for any products that we may develop for therapeutic indications is subject to the FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates for therapeutic indications, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of

our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition, and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design, or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

We may depend on third parties for clinical and commercial supplies, including, in some instances, a single supplier.

We may depend on third-party suppliers for clinical and commercial supplies, including the active ingredients which are used in our product candidates. These supplies may not always be available to us at the standards we require or on terms acceptable to us, or at all, and we may not be able to locate alternative suppliers in a timely manner, or at all. If we are unable to obtain necessary clinical or commercial supplies, our manufacturing operations and clinical trials and the clinical trials of our collaborators may be delayed or disrupted, and our business and prospects may be materially and adversely affected as a result.

We may rely on a sole supplier for certain of our supplies. If this sole supplier is unable to supply to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all.

We have limited experience manufacturing our drug product candidates for purposes of clinical trials for therapeutic indications or for non-therapeutic clinical studies or trials or the marketing of our products as non-drug products and at commercial scale, and if we decide to establish our own manufacturing facility for our drug product candidates, we cannot assure you that we can manufacture our drug product candidates in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

We may establish a manufacturing facility for our product candidates for production as investigational new drugs for purposes of clinical trials for therapeutic indications or for the production of non-drug product candidates at a commercial scale. We have limited experience in cGMP compliant manufacturing of our drug product candidates for purposes of clinical trials in therapeutic indications or at a commercial scale. We similarly have limited experience in complying with the manufacturing requirements for non-drug applications for our products at a commercial scale. In the future, we may develop our manufacturing capacity in part by expanding our current facility or building additional facilities. This activity will require substantial additional funds and we would need to hire and train a significant number of qualified employees to staff these facilities. We may not be able to develop cGMP-compliant manufacturing facilities that are adequate to produce materials for additional later-stage clinical trials or commercial use.

The equipment and facilities employed in the manufacture of pharmaceuticals and foods (including medical foods) are subject to stringent qualification requirements by regulatory agencies, including validation of facility, equipment, systems, processes and analytics. We may be subject to lengthy delays and expense in conducting validation studies, if we can meet the requirements at all.

MMTs are complex and difficult to manufacture. We could experience production problems that may impact our ability to manufacture certain MMT product candidates, if at all, and result in delays in our development or otherwise adversely affect our business.

The manufacturing process we anticipate using to produce our MMT product candidates is highly complex and may be subject to variation or production difficulties. Issues with any of our manufacturing processes could result in insufficient yield, product deficiencies or manufacturing failures that result in adverse patient reactions, lot failures and insufficient inventory.

Many factors could also cause production interruptions, including raw materials shortages, raw material failures, growth media failures, equipment malfunctions, facility contamination, labor problems, natural disasters, disruption in utility services, terrorist activities or acts of god beyond our control. We also may encounter problems in hiring and retaining the experienced specialized personnel needed to operate our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing processes could make us a less attractive collaborator for academic research institutions and other parties, which could limit our access to additional attractive development programs, result in delays in our clinical development and materially harm our business.

Risks related to our common stock

An active trading market for our common stock may not be sustained

Our shares of common stock began trading on The NASDAQ Global Select Market on February 28, 2019. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. Since our common stock began trading on The Nasdaq Global Select Market on February 28, 2019, our stock price has traded at prices as low as $12.50 per share and as high as $16.00 per share through April 30, 2019. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- the commencement, enrollment or results of our ongoing and planned non-IND human clinical studies and clinical trials of our product candidates or any future non-IND human clinical studies or clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- adverse results from or delays in non-IND human clinical studies or clinical trials of our product candidates, including as a result of clinical holds, safety events, enrollment difficulties, or study protocol amendments;
- our decision to initiate a non-IND human clinical study or clinical trial, not to initiate a non-IND human clinical study or clinical trial or to terminate an existing non-IND human clinical study or clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates for therapeutic indications or to proceed on alternate regulatory pathways to market for our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals or marketing of dietary non-drug products or food products;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services by our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or microbiome therapies in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;

- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- adoption of new accounting standards;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for healthcare companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. You may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our 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. In addition, our ability to pay cash dividends is currently restricted by the terms of our credit facility with Pacific Western Bank, and future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of their stock.

Our principal stockholders and management own a significant percentage of our stock and may be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and their affiliates beneficially hold, in the aggregate, over 50% of our outstanding voting stock. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this Quarterly Report on Form 10-Q and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following 2019, the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO; (b) in which we have total annual gross revenue of at least $1.07 billion; or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th; and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may 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 stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we may adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. This may make comparison of our financial statements with the financial statements of another public company that is not an emerging growth company, or an emerging growth company that has opted out of using the extended transition period, difficult or impossible because of the potential differences in accounting standards used.

We will incur significant 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.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which will require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale entered into during our IPO lapse, the trading price of our common stock could decline. Only the shares of common stock sold in the IPO by us are currently freely tradable without restriction in the public market.

The lock-up agreements that we entered into with our directors, officers and substantially all of our stockholders in connection with the IPO will expire 180 days from the date of the IPO, subject to earlier release of all or a portion of the shares subject to such agreements by the representatives of the underwriters in their sole discretion. After the lock-up agreements expire, based upon the number of shares of common stock, on an as-converted basis, outstanding as of March 31, 2019, up to an additional 24,632,921 shares of common stock will be eligible for sale in the public market. Approximately 63.1% of these additional shares are held by directors, executive officers and other affiliates and will be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity compensation plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, 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. Additionally, the number of shares of our common stock reserved for issuance under our 2019 Stock Option and Incentive Plan will automatically increase on January 1, 2020 and each January 1 thereafter by 4% of the number of shares of common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by our compensation committee. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution.

The holders of 22,058,869 shares of our common stock as of March 31, 2019 are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements 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 have broad discretion in the use of our existing cash, cash equivalents and marketable securities and may not use them effectively.

Our management will have broad discretion in the application of our existing cash, cash equivalents and marketable securities, and you will not have the opportunity as part of your investment decision to assess whether such proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of our existing cash, cash equivalents and marketable securities, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash, cash equivalents and marketable securities in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. We may invest in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash, cash equivalents or marketable securities in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees, directors and non-employee consultants based on the fair value of the award on either the grant date or service completion date, and we recognize the cost as an expense over the recipient's service period. Because the variables that we use as a basis for valuing stock-based awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- our ability to enroll patients in non-IND, and non-US equivalent, human clinical studies or clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical trials for our current product candidates and any other future product candidates or competing product candidates;
- competition from existing and potential future products that compete with our current product candidates and any other future product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;

- any delays in regulatory review or approval or commercialization of our current product candidates or any other future product candidates;
- the level of demand for our current product candidates and any other future product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future products that compete with our current product candidates and any other future product candidates;
- our ability to commercialize our current product candidates and any other future product candidates inside and outside of the United States, either independently or working with third parties;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated by-laws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chair of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any by-laws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated by-laws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire.

Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2020. When we lose our status as an "emerging growth company," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to implement additional financial and management controls, reporting systems and procedures and may need to hire additional accounting and finance staff.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able

to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Covenants and events of default in our debt instruments could limit our ability to undertake certain types of transactions and adversely affect our liquidity.

Our current debt financing agreements contain, and our future debt financing agreements may contain covenants and events of default that may limit our financial flexibility and ability to undertake certain types of transactions. Typically, these covenants would restrict our business activities, including restrictions on:

- creating liens;
- engaging in mergers, consolidations and sales of assets;
- incurring additional indebtedness;
- providing guarantees;
- engaging in different businesses;
- making investments;
- making certain dividend, debt and other restricted payments;
- engaging in certain transactions with affiliates; and
- entering into certain contractual obligations.

Our ability to comply with these expected covenants may depend on factors outside our control. We cannot assure you that we will be able to satisfy these covenants. If we fail to satisfy the covenants established in these facilities or an event of default occurs under the applicable debt agreement, the maturity of the debt instruments could be accelerated, or we could be prohibited from future borrowing. If our obligations under the debt instruments are accelerated and we do not have sufficient cash on hand to pay all amounts due, we could be required to sell assets, to refinance all or a portion of our indebtedness or to obtain additional financing through equity or debt financings. Refinancing may not be possible and additional financing may not be available on commercially acceptable terms, or at all. If we cannot obtain such financing, we would need to curtail our planned operations.

Our amended and restated by-laws designate 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.

Pursuant to our amended and restated by-laws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or by-laws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or by-laws; or (5) any action asserting a claim governed by the internal affairs doctrine. The forum selection clause in our amended and restated by-laws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Alternatively, if a court were to find the choice of forum provision contained in our restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

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

Set forth below is information regarding shares of equity securities sold, and options granted, by us during the three months ended March 31, 2019 that were not registered under the Securities Act.

Recent Sales of Unregistered Equity Securities

On March 4, 2019, upon the closing of our IPO all 37,034,802 shares of our then-outstanding convertible preferred stock automatically converted into 18,517,386 shares of common stock. The issuance of such common shares was exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) of the Securities Act, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. No underwriters were involved in this issuance of shares.

On March 4, 2019, we issued an aggregate of 51,015 shares of common stock, or the Warrant Shares, to PacWest Bancorp upon the cashless exercise of their warrants to purchase an aggregate of 68,514 shares of preferred stock that converted into warrants to purchase shares of common stock, each of which occurred concurrently with the closing of the IPO. The aggregate exercise price of the Warrant Shares was approximately $0.3 million, representing a weighted average exercise price per share of $3.83. The sale and issuance of the Warrant Shares were not registered under the Securities Act or any state securities laws. We have relied on the exemption from the registration requirements of the Securities Act by virtue of Section 4(a)(2) thereof and the rules and regulations promulgated thereunder relating to a transaction not involving any public offering to a single accredited investor and Rule 506(c) of Regulation D thereof. No underwriters were involved in this issuance of shares.

During the period between January 1, 2019 and March 7, 2019, we issued to certain of our employees and advisors, options to purchase an aggregate of 284,000 shares of our common stock at an exercise price of $15.00 per share. We deemed these issuances to be exempt from registration under the Securities Act either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit.

Use of Proceeds from Initial Public Offering

On March 4, 2019, we completed the IPO of our common stock pursuant to which we issued and sold 5,000,000 shares of our common stock at a price to the public of $15.00 per share.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333- 229204), which was declared effective by the SEC on February 27, 2019. Goldman Sachs & Co. LLC, J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, and Canaccord Genuity LLC acted as joint book-running managers of our IPO.

We received aggregate gross proceeds from our IPO of $75.0 million, or aggregate net proceeds of $66.6 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

As of March 31, 2019, we have used $6.7 million of the net proceeds from the IPO, consisting of $6.5 million used in operations and $0.2 million for the purchase of other property, plant, and equipment. There has been no material change in our planned use of the net proceeds from the IPO as described in the Prospectus.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits

Exhibit No.	Exhibit Index
3.1	Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K (File No. 001-38822) filed on March 4, 2019
3.2	Amended and Restated By-laws (Incorporated by reference to Exhibit 3.2 to the Registrant's From 3.2 to the Registrant's Form 8-K (File No. 001-38822) filed on March 4, 2019
4.1	Specimen Stock Certificate evidencing shares of common stock (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-229204) filed on February 19, 2019
10.1#	2019 Stock Option and Incentive Plan and forms of award agreements thereunder (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-229204) filed on February 19, 2019
10.2#	Senior Executive Cash Incentive Bonus Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-229204) filed on January 11, 2019
10.3#	2019 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-229204) filed on February 19, 2019
10.4#	Employment Agreement between the Registrant and Michael Bonney, dated January 24, 2019 (Incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-229204) filed on February 19, 2019
10.5#	Employment Agreement between the Registrant and Alison Lawton, dated January 24, 2019 (Incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-229204) filed on February 19, 2019
10.6#	Employment Agreement between the Registrant and Joshua Brumm, dated January 24, 2019 (Incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-229204) filed on February 19, 2019
10.7#	Employment Agreement between the Registrant and Katharine Knobil, M.D., dated January 24, 2019 (Incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-229204) filed on February 19, 2019
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1†	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.
† This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.
# Indicates a management contract or any compensatory plan, contract or arrangement.

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.

KALEIDO BIOSCIENCES, INC.

Date: May 2, 2019

By: /s/ Alison Lawton

Alison Lawton
Chief Executive Officer, President and Director
(Principal Executive Officer)

Date: May 2, 2019

By: /s/ Joshua Brumm

Joshua Brumm
Chief Operating Officer and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Alison Lawton, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Kaleido Biosciences, 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    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.

5. The registrant's other certifying officer 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: May 2, 2019

By: /s/ Alison Lawton
Alison Lawton
Chief Executive Officer, President and Director
(Principal Executive Officer)

Exhibit 31.2

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Joshua Brumm, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Kaleido Biosciences, 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    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.

5. The registrant's other certifying officer 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: May 2, 2019

By: /s/ Joshua Brumm
Joshua Brumm
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
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 on Form 10-Q of Kaleido Biosciences, Inc. for the quarterly period ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Alison Lawton, as Chief Executive Officer, President and Director of Kaleido Biosciences, Inc., hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of her knowledge the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Kaleido Biosciences, Inc.

Date: May 2, 2019

By: /s/ Alison Lawton
Alison Lawton
Chief Executive Officer, President and Director
(Principal Executive Officer)

In connection with the Quarterly Report on Form 10-Q of Kaleido Biosciences, Inc. for the quarterly period ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Joshua Brumm, as Chief Operating Officer and Chief Financial Officer of Kaleido Biosciences, Inc., hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Kaleido Biosciences, Inc.

Date: May 2, 2019

By: /s/ Joshua Brumm
Joshua Brumm
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)