UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

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: 001-40227

FINCH THERAPEUTICS GROUP, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-3433558**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
200 Inner Belt Road, Suite 400 Somerville, Massachusetts	**02143**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 229-6499

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

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

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

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

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

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

As of August 3, 2021, there were 47,449,147 outstanding shares of the registrant's common stock, par value $0.001 per share.

FINCH THERAPEUTICS, INC.
FORM 10-Q
For the quarterly period ended June 30, 2021

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will” or “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and related preparatory work and the period during which the results of the trials will become available, as well as our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to obtain regulatory approval of CP101 and any of our current and future product candidates that we develop;
- our ability to identify and develop additional product candidates;
- our ability to advance product candidates into, and successfully complete, preclinical studies and clinical trials;
- business disruptions affecting the initiation, patient enrollment, development and operation of our clinical trials, including a public health emergency, such as the ongoing COVID-19 pandemic;
- our expectations regarding the potential market size and the rate and degree of market acceptance for any product candidates that we develop;
- the effects of competition with respect to CP101 or any of our other current or future product candidates, as well as innovations by current and future competitors in our industry;
- our ability to fund our working capital requirements;
- our intellectual property position, including the scope of protection we are able to establish, maintain and enforce for intellectual property rights covering our product candidates;
- our financial performance and our ability to effectively manage our anticipated growth;
- our ability to obtain additional funding for our operations; and
- other risks and uncertainties, including those listed under the section titled “Risk Factors.”

These forward-looking statements are based on our management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management’s beliefs and assumptions and are not guarantees of future performance or development. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under “Risk Factors” and elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read the section titled “Risk Factors” set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the

forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

You should read this Quarterly Report on Form 10-Q, completely and with the understanding that our actual future results may be materially different from what we expect. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to new information, actual results or changes in our expectations, except as required by law. We qualify all of our forward-looking statements by these cautionary statements.

SPECIAL NOTE REGARDING COMPANY REFERENCES

Unless the context otherwise requires, references in this Quarterly Report on Form 10-Q to "FTG," the "Company," "we," "us" and "our" refer to Finch Therapeutics Group, Inc. and its subsidiaries.

SPECIAL NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

RISK FACTORS SUMMARY

The following is a summary of the principal risks that could adversely affect our business, financial condition, operating results, cash flows or stock price. Discussion of the risks listed below, and other risks that we face, are discussed in the section titled “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

- We face substantial competition which may result in others developing or commercializing drugs before or more successfully than us, particularly since we are aware of a number of companies focused on developing microbiome therapeutics in various indications, including three competitors that have a product candidate being evaluated in clinical trials for recurrent CDI.
- Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.
- We have a limited operating history, have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.
- We will require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our product development programs or other operations.
- We believe our current cash and cash equivalents will be sufficient to fund our business only for a limited amount of time, and if we are not able to raise additional funds, we may be unable to continue as a going concern.
- We are heavily dependent on the success of our product candidates, which are in clinical development. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- Our product candidates are based on microbiome therapeutics, which is an unproven approach to therapeutic intervention.
- Our product candidates may be associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, or prevent marketing approval.
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities.
- We rely on third-party donors of biological material to manufacture certain product candidates such as CP101, and if we do not obtain an adequate supply of acceptable material from those qualified donors, the clinical and commercial supply of these product candidates may be adversely impacted.
- We operate our own manufacturing facility for certain product candidates, which requires significant resources and we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.
- We have never commercialized a product candidate and may experience delays or unexpected difficulties in obtaining regulatory approval for our current or future product candidates for our initial or potential additional indications.
- We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved.
- If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.
- We identified a material weakness in our internal control over financial reporting. If we are not able to remediate the material weakness or if we otherwise fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial statements in a timely manner, which may adversely affect our business, investor confidence in our company and the market value of our common stock.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

FINCH THERAPEUTICS GROUP, INC.
Condensed Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share data)

	JUNE 30, 2021	DECEMBER 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 168,136	$ 99,710
Accounts receivable	2,245	1,034
Due from related party	5	61
Prepaid expenses and other current assets	6,617	5,359
Total current assets	177,003	106,164
Property and equipment, net	18,327	7,004
In-process research and development	32,900	32,900
Goodwill	18,057	18,057
Deferred initial public offering costs	—	1,013
Other assets	4,041	200
TOTAL ASSETS	$ 250,328	$ 165,338
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 1,719	$ 2,621
Accrued expenses and other current liabilities	5,222	5,228
Due to related party	8	266
Deferred revenue, current portion	2,575	3,371
Total current liabilities	9,524	11,486
Deferred tax liability	3,461	3,461
Deferred revenue, net of current portion	8,235	10,260
Loan payable	—	1,808
Deferred rent	724	766
Other liabilities	191	221
Total liabilities	22,135	28,002
COMMITMENTS AND CONTINGENCIES (Note 8)		
Series A redeemable convertible preferred stock, $0.001 par value; no shares authorized, issued or outstanding as of June 30, 2021; 167,496,750 shares authorized and 11,596,280 shares issued and outstanding as of December 31, 2020;	—	53,593
Series B redeemable convertible preferred stock, $0.001 par value; no shares authorized, issued or outstanding as of June 30, 2021; 74,620,739 shares authorized and 5,166,203 shares issued and outstanding as of December 31, 2020	—	36,336
Series C redeemable convertible preferred stock, $0.001 par value; no shares authorized, issued or outstanding as of June 30, 2021; 109,604,994 shares authorized and 7,588,254 shares issued and outstanding as of December 31, 2020	—	53,221
Series D redeemable convertible preferred stock, $0.001 par value; no shares authorized, issued or outstanding as of June 30, 2021; 99,705,359 shares authorized and 6,902,872 shares issued and outstanding as of December 31, 2020	—	89,904
STOCKHOLDERS' EQUITY (DEFICIT):		
Common stock, $0.001 par value; 200,000,000 and 598,232,153 shares authorized as of June 30, 2021 and December 31, 2020, respectively; 47,425,752 and 8,391,793 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	47	8
Additional paid-in capital	360,131	7,109
Accumulated deficit	(131,985)	(102,835)
Total stockholders' equity (deficit)	228,193	(95,718)
TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 250,328	$ 165,338

See notes to unaudited condensed consolidated financial statements.

FINCH THERAPEUTICS GROUP, INC.
Condensed Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share data)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2021	2020	2021	2020
REVENUE:				
Collaboration revenue	$ 2,830	$ 2,237	$ 6,383	$ 3,849
Royalties revenue from related party	—	112	—	292
Total revenue	2,830	2,349	6,383	4,141
OPERATING EXPENSES:				
Research and development	(13,964)	(8,135)	(26,939)	(15,532)
General and administrative	(5,882)	(2,574)	(10,433)	(4,832)
Total operating expenses	(19,846)	(10,709)	(37,372)	(20,364)
Net loss from operations	(17,016)	(8,360)	(30,989)	(16,223)
OTHER INCOME (EXPENSE), NET:				
Gain on extinguishment of PPP Loan	1,827	—	1,827	—
Interest income	7	21	6	112
Other income (expense), net	13	80	6	(49)
Total other income (expense), net	1,847	101	1,839	63
Loss before income taxes	(15,169)	(8,259)	(29,150)	(16,160)
Income tax provision	—	—	—	—
Net loss	$ (15,169)	$ (8,259)	$ (29,150)	$ (16,160)
Net loss attributable to common stockholders—basic and diluted (Note 14)	$ (15,169)	$ (8,259)	$ (29,150)	$ (16,160)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.32)	$ (1.02)	$ (0.95)	$ (2.03)
Weighted-average common stock outstanding—basic and diluted	47,379,887	8,069,304	30,798,698	7,968,267

See notes to unaudited condensed consolidated financial statements.

FINCH THERAPEUTICS GROUP, INC.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited, in thousands, except share and per share data)

	REDEEMABLE CONVERTIBLE PREFERRED STOCK												
	$0.001 PAR VALUE SERIES A		$0.001 PAR VALUE SERIES B		$0.001 PAR VALUE SERIES C		$0.001 PAR VALUE SERIES D		COMMON STOCK $0.001 PAR VALUE		ADDITIONAL PAID-IN	ACCUMULATED	TOTAL STOCKHOLDERS'
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	DEFICIT	DEFICIT
BALANCE, January 1, 2020	11,596,280	$ 53,593	5,166,203	$ 36,336	7,588,254	$ 53,221	—	$ —	7,778,552	8	$ 3,951	$ (63,494)	$ (59,535)
Exercise of common stock options	—	—	—	—	—	—	—	—	14,826	—	15	—	15
Vesting of restricted stock	—	—	—	—	—	—	—	—	183,744	—	3	—	3
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	75	—	75
Net loss	—	—	—	—	—	—	—	—	—	—	—	(7,901)	(7,901)
BALANCE, March 31, 2020	11,596,280	$ 53,593	5,166,203	$ 36,336	7,588,254	$ 53,221	—	$ —	7,977,122	$ 8	$ 4,044	$ (71,395)	$ (67,343)
Exercise of common stock options	—	—	—	—	—	—	—	—	15,447	—	4	—	4
Vesting of restricted stock	—	—	—	—	—	—	—	—	181,810	—	3	—	3
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	85	—	85
Net loss	—	—	—	—	—	—	—	—	—	—	—	(8,259)	(8,259)
BALANCE, June 30, 2020	11,596,280	$ 53,593	5,166,203	$ 36,336	7,588,254	$ 53,221	—	$ —	8,174,379	$ 8	$ 4,136	$ (79,654)	$ (75,510)

	REDEEMABLE CONVERTIBLE PREFERRED STOCK												
	$0.001 PAR VALUE SERIES A		$0.001 PAR VALUE SERIES B		$0.001 PAR VALUE SERIES C		$0.001 PAR VALUE SERIES D		COMMON STOCK $0.001 PAR VALUE		ADDITIONAL PAID-IN	ACCUMULATED	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	DEFICIT	(DEFICIT)
BALANCE, January 1, 2021	11,596,280	$ 53,593	5,166,203	$ 36,336	7,588,254	$ 53,221	6,902,872	$ 89,904	8,391,793	$ 8	$ 7,109	$ (102,835)	$ (95,718)
Conversion of redeemable convertible preferred stock into common stock upon initial public offering	(11,596,280)	(53,593)	(5,166,203)	(36,336)	(7,588,254)	(53,221)	(6,902,872)	(89,904)	31,253,609	31	233,022	-	233,053
Initial public offering, net of underwriting discounts, commissions and net of offering costs of $11,786	—	—	—	—	—	—	—	—	7,500,000	8	115,706	-	115,714
Exercise of common stock options	—	—	—	—	—	—	—	—	81,901	-	54	-	54
Stock-based compensation	—	—	—	—	—	—	—	—	—	-	335	-	335
Net loss	—	—	—	—	—	—	—	—	—	-	-	(13,981)	(13,981)
BALANCE, March 31, 2021	—	$ —	—	$ —	—	$ —	—	$ —	47,227,303	$ 47	$ 356,226	$ (116,816)	$ 239,457
Underwriters' exercise of overallotment option, net of underwriting discounts, commissions and initial public offering costs of $276	—	—	—	—	—	—	—	—	192,877	-	3,003	-	3,003
Exercise of common stock options	—	—	—	—	—	—	—	—	6,793	-	7	-	7
Shares repurchased for cashless exercise	—	—	—	—	—	—	—	—	(1,221)	-	(10)	-	(10)
Stock-based compensation	—	—	—	—	—	—	—	—	—	-	905	-	905
Net loss	—	—	—	—	—	—	—	—	—	-	-	(15,169)	(15,169)
BALANCE, June 30, 2021	—	$ —	—	$ —	—	$ —	—	$ —	47,425,752	$ 47	$ 360,131	$ (131,985)	$ 228,193

See notes to unaudited condensed consolidated financial statements.

FINCH THERAPEUTICS GROUP, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited, in thousands)

	SIX MONTHS ENDED JUNE 30,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (29,150)	$ (16,160)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	985	369
Stock-based compensation expense	1,240	166
Gain on extinguishment of PPP Loan	(1,808)	—
(Gain) loss on sale of property and equipment	(28)	13
Changes in operating assets and liabilities:		
Accounts receivable	(1,211)	427
Due from related party	56	2,442
Prepaid expenses and other current assets	(1,258)	(2,082)
Other non-current assets	(3,824)	—
Accounts payable	(1,467)	491
Accrued expenses and other current liabilities	572	(1,627)
Due to related party	(258)	(200)
Deferred revenue	(2,821)	1,697
Deferred rent	(24)	331
Net cash used in operating activities	(38,996)	(14,133)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(11,617)	(270)
Proceeds from sale of property and equipment	62	—
Net cash used in investing activities	(11,555)	(270)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from initial public offering, net of underwriting discounts, commissions and offering costs	118,575	—
Proceeds from underwriters' exercise of overallotment option, net of underwriting discounts and commissions and initial public offering costs	3,049	—
Principal payments on capital lease obligation	(21)	(28)
Proceeds from exercise of stock options, net	51	19
Proceeds from PPP Loan	—	1,808
Payment of deferred offering costs	(2,659)	—
Net cash provided by financing activities	118,995	1,799
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	68,444	(12,604)
Cash, cash equivalents and restricted cash at beginning of period	99,908	42,396
Cash, cash equivalents and restricted cash at end of period	$ 168,352	$ 29,792
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 5	$ 4
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment in accounts payable and accrued liabilities	$ 724	$ 9
Conversion of redeemable convertible preferred stock into common stock	$ 233,053	$ —
Forgiveness of PPP Loan	$ 1,808	$ —

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

	SIX MONTHS ENDED JUNE 30,	
	2021	2020
Cash and cash equivalents	$ 168,136	$ 29,592
Restricted cash	216	200
Total cash, cash equivalents and restricted cash	$ 168,352	$ 29,792

See notes to unaudited condensed consolidated financial statements.

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Finch Therapeutics Group, Inc. (the "Company" or "FTG") was incorporated in 2017 as a Delaware corporation. The Company was formed as a result of a merger and recapitalization of Finch Therapeutics, Inc. ("Finch") and Crestovo Holdings LLC ("Crestovo") in September 2017 (the "Merger"), in which the former owners of Finch and Crestovo were issued equivalent stakes in the newly formed company, FTG. Crestovo was renamed Finch Therapeutics Holdings LLC in November 2020 ("Finch Holdings"). Finch and Finch Holdings are both wholly-owned subsidiaries of FTG.

The Company is a clinical-stage microbiome therapeutics company leveraging its Human-First Discovery® platform to develop a novel class of orally administered biological drugs. It is developing novel therapeutics designed to deliver missing microbes and their clinically relevant biochemical functions to correct dysbiosis and the diseases that emerge from it. The Company's Human-First Discovery platform uses reverse translation to identify diseases of dysbiosis and to design microbiome therapeutics that address them. Its lead product candidate, CP101, delivers a complete microbiome and is being developed initially for the treatment of patients with recurrent *Clostridioides difficile* infection, or CDI.

Initial Public Offering

On March 18, 2021, the Company completed its initial public offering ("IPO") in which the Company issued and sold 7,500,000 shares of its common stock at a public offering price of $17.00 per share, for aggregate gross proceeds of $127.5 million. The net proceeds from the IPO were $115.7 million after deducting underwriting discounts and commissions of $8.9 million and offering costs of $2.9 million. On April 20, 2021, the Company issued 192,877 additional shares of common stock, pursuant to the underwriters' partial exercise of their overallotment option, at a public offering price of $17.00 per share for aggregate gross proceeds of $3.3 million and net proceeds of $3.0 million after deducting underwriting discounts, commissions and offering costs.

In connection with the IPO, the Company's board of directors (the "Board") and stockholders approved an amended and restated certificate of incorporation to, among other things, effect a one-for-14.444 reverse stock split of the Company's issued and outstanding shares of common stock and redeemable convertible preferred stock, as well as to effect a proportional adjustment to the existing conversion ratios for the Company's redeemable convertible preferred stock. The reverse stock split was effected on March 12, 2021. Accordingly, all share and per share amounts of common stock for all periods presented in the accompanying unaudited interim condensed consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect this reverse stock split and adjustment of preferred stock conversion ratios. Upon the closing of the IPO, all of the then-outstanding shares of redeemable convertible preferred stock automatically converted into 31,253,609 shares of common stock at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding.

COVID-19 Impact

The extent of the impact of the COVID-19 pandemic on the Company's business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak, including with respect to variants of the virus, and its impact on clinical trial enrollment, trial sites, contract research organizations, contract manufacturing organizations, and other third parties with whom the Company does business, as well as its impact on regulatory authorities and its key scientific and management personnel. While the Company is experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, the Company's business, financial condition and results of operations ultimately could be materially adversely affected. The Company continues to closely monitor the COVID-19 pandemic as it evolves its business continuity plans, clinical development plans and response strategy.

At this time, it is unknown how long the adverse conditions associated with the COVID-19 pandemic will last and what the complete financial effect will be to the Company.

Liquidity and Capital Resources

Management believes that the Company's existing cash and cash equivalents, together with the net proceeds from the IPO, will allow the Company to continue its operations for at least the next 12 months from the date these financial statements are issued and therefore the conditions raising substantial doubt raised in prior periods have been alleviated. In the absence of a significant source of recurring

revenue, the continued viability of the Company beyond that point is dependent on its ability to continue to raise additional capital to finance its operations. If the Company is unable to obtain additional funding, the Company may be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared by the Company in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP") and, pursuant to the rules and regulations of Article 10 of Regulation S-X of the Securities Act published by the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes the disclosures are adequate. These unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the year ended December 31, 2020 included in the Company's final prospectus dated March 18, 2021, filed with the SEC on March 22, 2021 pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Prospectus").

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments which are necessary for a fair presentation of the Company's condensed consolidated balance sheets as of June 30, 2021 and December 31, 2020, condensed consolidated statements of operations for the three and six months ended June 30, 2021 and 2020, condensed consolidated statements of stockholders' equity (deficit) for the three and six months ended June 30, 2021 and 2020, and condensed consolidated cash flows for the six months ended June 30, 2021 and 2020. Such adjustments are of a normal and recurring nature. The results of operations for the six months ended June 30, 2021 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2021.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Significant Accounting Policies

The significant accounting policies and estimates used in preparation of the unaudited interim consolidated financial statements are described in the Company's audited consolidated financial statements as of and for the year ended December 31, 2020 and the notes thereto, which are included in the Prospectus. Except as detailed below, there have been no material changes to the Company's significant accounting policies during the six months ended June 30, 2021.

Deferred Initial Public Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity issuances as deferred initial public offering costs until such equity issuances are consummated. After consummation of the equity issuance, these costs are recorded as a reduction in the capitalized amount associated with the equity issuance. Should the equity issuance be abandoned, the deferred initial public offering costs will be expensed immediately as a charge to operating expenses in the consolidated statement of operations and comprehensive loss. On March 18, 2021, the Company completed the IPO; accordingly, the Company recognized the deferred initial public offering costs of approximately $2.9 million as a reduction from gross proceeds associated with the IPO through additional paid-in capital in the accompanying condensed consolidated balance sheet. On April 20, 2021, the Company issued 192,877 additional shares of common stock, pursuant to the underwriters' partial exercise of their overallotment option, the Company recognized offering costs of less than $0.1 million as a reduction from gross proceeds associated with the overallotment through additional paid-in capital in the accompanying condensed consolidated balance sheet. Accordingly, there were no deferred offering costs as of June 30, 2021. Deferred offering costs on the accompanying condensed consolidated balance sheet as of December 31, 2020 were $1.0 million.

Recently Issued Accounting Pronouncements

There have been no new accounting pronouncements or changes to accounting pronouncements that could be expected to materially impact the Company's unaudited condensed consolidated financial statements during the six months ended June 30, 2021, as compared to the recent accounting pronouncements described in Note 2 of the Company's audited financial statements as of and for the year ended December 31, 2020, which are included in the Prospectus.

3. FAIR VALUE MEASUREMENTS

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values (in thousands):

DESCRIPTION	JUNE 30, 2021	QUOTED PRICES IN ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 3)
Asset				
Money market funds	$ 167,134	$ 167,134	$ —	$ —
Total financial assets	$ 167,134	$ 167,134	$ —	$ —

DESCRIPTION	DECEMBER 31, 2020	QUOTED PRICES IN ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 3)
Asset				
Money market funds	$ 98,677	$ 98,677	$ —	$ —
Total financial assets	$ 98,677	$ 98,677	$ —	$ —

There were no transfers between fair value levels during the six months ended June 30, 2021 and the year ended December 31, 2020. The carrying values of accounts receivable, prepaid expenses, other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following as of June 30, 2021 and December 31, 2020 (in thousands):

	JUNE 30, 2021	DECEMBER 31, 2020
Lab equipment	$ 3,417	$ 2,363
Office furniture and fixtures	537	537
Leasehold improvements	2,143	2,143
Construction work-in-progress	9,921	2,635
Software	4,852	1,150
Computer equipment	367	205
Total	21,237	$ 9,033
Less: Accumulated depreciation	(2,910)	(2,029)
Property and equipment, net	$ 18,327	$ 7,004

Depreciation expense was $1.0 million and $0.4 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, the Company held $4.8 million of software and $0.2 million of lab equipment that were purchased from OpenBiome (See Note 12). As of December 31, 2020, the Company held $1.2 million of software that was purchased from a related party.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following as of June 30, 2021 and December 31, 2020 (in thousands):

	JUNE 30, 2021	DECEMBER 31, 2020
Accrued research and development	$ 725	$ 81
Accrued legal and professional fees	965	711
Accrued compensation and benefits	2,730	3,532
Accrued other	802	904
Total accrued expenses and other current liabilities	$ 5,222	$ 5,228

6. REVENUE

Takeda Pharmaceutical Company Limited

In January 2017, the Company entered into an agreement (the "Takeda Agreement") with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda"), pursuant to which the Company granted Takeda a worldwide, exclusive license, with the right to grant sublicenses, under certain of its patents, patent applications and know-how to develop the Company's microbiome therapeutic candidate FIN-524 for the prevention, diagnosis, theragnosis or treatment of diseases in humans. The Company subsequently amended and restated the Takeda Agreement in October 2019 to provide for the Company to allocate certain resources towards determining the feasibility of developing a second microbiome therapeutic candidate, FIN-525.

Under the terms of the Takeda Agreement, the Company has agreed to design FIN-524, a product candidate optimized for ulcerative colitis, for Takeda based on selection criteria within a product-specific development plan. The Company also agreed to conduct a feasibility study to potentially further develop FIN-525, a product candidate optimized for the treatment of Crohn's disease. Takeda can determine whether to initiate a full product-specific development plan for FIN-525 following its review of the data from the Company's feasibility study.

The Company assessed this arrangement in accordance with Accounting Standards Codification ("ASC") *Topic 606, Revenue from Contracts with Customers* ("ASC 606") and concluded that the contract counterparty, Takeda, is a customer. In accordance with the Company's ASC 606 assessment, the Takeda Agreement was determined to contain a single combined performance obligation.

The Company received an upfront payment from Takeda of $10.0 million in the year ended December 31, 2017 in exchange for the exclusive license of the Company's intellectual property. The Company has included the upfront payment and the estimable reimbursable research and development ("R&D") costs in the transaction price and is recognizing revenue associated with it over the period it expects to perform R&D services. All of the components of the combined performance obligation are recognized using the same measure of progress.

Takeda reimburses the Company for certain research and development costs under the Takeda Agreement on a quarterly basis, which are agreed upon by both parties through their participation on the joint steering committee and joint development committee and included in the transaction price and recognized according to the cost input method, as they are deemed to represent estimable variable consideration that is not expected to result in a significant reversal of revenue. The Company recorded accounts receivable of $2.2 million and $1.0 million on its condensed consolidated balance sheets as of June 30, 2021 and December 31, 2020, respectively. As of June 30, 2021, the Company recorded deferred revenue of $10.8 million ($2.6 million of which is classified as current) related to the Takeda Agreement, which represents the portion of the combined performance obligation that is considered partially unsatisfied as of June 30, 2021. As of December 31, 2020, the Company recorded deferred revenue of $13.6 million related to the Takeda Agreement. Deferred revenue will be recognized over the period the Company will perform research and development services, through the end of Phase 1 clinical trials.

The Takeda Agreement contains various milestone payments associated with development and commercialization efforts that provide for a maximum available amount of $180.0 million should all of the milestones be achieved. These milestones are constrained until the Company determines it is probable that the cumulative revenue related to the milestones will not be reversed, at which point the Company adds the consideration to the transaction price and recognizes the milestone revenue over the remaining performance period, according to the measure of progress, with a catch-up in the period it becomes probable that a significant reversal of revenue will not occur. As of June 30, 2021, the Company has earned and received $4.0 million in milestone payments.

The Company recognized revenue related to the Takeda Agreement of $6.4 million and $3.9 million in the six months ended June 30, 2021 and 2020, respectively, which is included under collaboration revenue in the condensed consolidated statements of operations.

Under the Takeda Agreement, Takeda is obligated to pay the Company mid-to-high single digit royalties based on annual aggregate net sales of the licensed products, on a product-by-product basis, subject to certain restrictions. The Company did not receive any payments or record any revenues related to sales-based royalties under the Takeda Agreement in the six months ended June 30, 2021 and June 30, 2020.

OpenBiome

The Company and OpenBiome entered into an Asset Purchase and License Agreement ("APL Agreement") in February 2019 that was effective through November 2020. Under the APL Agreement, the Company licensed certain intellectual property and sold certain fecal microbiota transplantation, or FMT, materials and equipment to OpenBiome (see Note 8).

The Company earned $0 and $0.3 million in royalty revenue related to the APL Agreement in the six months ended June 30, 2021 and 2020, respectively, which is recorded as royalties revenue from related party on the Company's condensed consolidated statements of operations.

On November 19, 2020, the Company entered into the license agreement ("LMIC Agreement") with OpenBiome, pursuant to which the Company granted OpenBiome a non-exclusive license, with the right to grant sublicenses, under certain patents, patent applications, and know-how that are reasonably necessary or useful for the exploitation of products manufactured directly from donor-sourced stool without the use of culturing or replication, or certain natural products ("OpenBiome Royalty Products"). The license granted excludes a license under the Company's intellectual property to exploit a lyophilized natural product (such as CP101) where processed stool is lyophilized. The Company owns all improvements and modifications made to the licensed intellectual property throughout the term of the LMIC Agreement, while OpenBiome is responsible for all manufacturing efforts and all expenses associated with these efforts.

The LMIC Agreement was entered into separately from the OpenBiome Agreement (See Note 12) and the license granted under the LMIC Agreement is unrelated to those assets acquired. The only consideration provided to the Company under the LMIC Agreement is in the form of future royalties on net sales of OpenBiome Royalty Products. The Company is entitled to receive tiered royalties on net sales of certain products, ranging from mid single digit to low second decile digits on a product-by-product and country-by-country basis. In the event that OpenBiome is required to pay a royalty to a third party to obtain rights under patents owned or controlled by such third party that are necessary for the exercise of its rights under the Company's intellectual property pursuant to the LMIC Agreement, then OpenBiome shall have the right to deduct a portion of the amount of the royalty due to the third party against the royalties that are due from OpenBiome to the Company. The Company has not earned any of these royalty payments as of June 30, 2021.

The LMIC Agreement will continue in perpetuity until the last royalty is earned under the LMIC Agreement unless otherwise terminated by either party. OpenBiome has the right to terminate the LMIC Agreement for convenience upon 90 days' specified prior written notice to the Company. Either party may terminate the LMIC Agreement in the event of an uncured material breach by the other party of the LMIC Agreement.

The Company did not recognize any revenue related to the LMIC Agreement for the six months ended June 30, 2021 and 2020, as there are currently no marketable OpenBiome Royalty Products.

7. INCOME TAXES

During the six months ended June 30, 2021 and the year ended December 31, 2020, the Company recorded a full valuation allowance on federal and state deferred tax assets since management does not forecast the Company to be in a profitable position in the near future. There were no material changes in the Company's tax position in the six months ended June 30, 2021 as compared to the year ended December 31, 2020.

8. COMMITMENTS AND CONTINGENCIES

Operating lease commitments

200 Inner Belt Rd

In December 2015, the Company entered into a 10-year lease agreement ("Inner Belt Road Lease") for approximately 25,785 square feet of space for its primary office and laboratory space in Somerville, Massachusetts. The Inner Belt Road Lease provided for a two-month rent holiday in the first year of the lease and rent abatements for the first two years of the lease. The monthly rental payments under the Inner Belt Road Lease, which include base rent charges of $0.1 million, are subject to periodic rent increases through September 2026.

In July 2016, the Company entered into a 10-year sublease agreement to share its leased space under the Inner Belt Road Lease with OpenBiome, a related party, as sub-tenant. The sublease with OpenBiome is coterminous with the Inner Belt Road Lease and provides for an allocation, based on OpenBiome's proportionate share, of base rent and other expenses under the Inner Belt Road Lease, which is subject to change each year based on current headcount and space used. OpenBiome's proportionate share is reassessed on a quarterly basis over the term of the sublease.

In January 2017, the Company amended the Inner Belt Road Lease to lease an additional 10,500 square feet of space for its primary office and laboratory space in Somerville, Massachusetts. The term of the Inner Belt Road Lease and the sublease with OpenBiome were not affected as a result of the amendment, although OpenBiome does occupy some of this additional space. The amendment to the Inner Belt Road Lease provided for leasehold improvement incentives of approximately $0.4 million related to the additional office and laboratory space. The rental payments for the additional space under the amended Inner Belt Road Lease, which include base rent charges of approximately $33,000 per month, are subject to periodic rent increases through September 2026. OpenBiome did not occupy any of the Company's premises between August 2018 and February 2019, and resumed occupancy and rental payments to the Company beginning in February 2019 when the APL Agreement was executed (see Note 12). In November 2020, pursuant to the OpenBiome Agreement, the Company and OpenBiome amended the terms of the sublease to provide for a reduction in the size of the subleased premises upon the closing of the OpenBiome Agreement (see Note 12), which occurred on March 1, 2021.

The Company recognizes rent expense, inclusive of a reduction to reflect the impact of lease incentives, under the Inner Belt Road Lease on a straight-line basis over the respective lease term and records deferred rent for rent expense incurred but not yet paid. The Company recognizes rent income under the sublease to OpenBiome on a straight-line basis over the sublease term and records prepaid rent for rent income received but not yet earned in due from related party on its condensed consolidated balance sheets. Gross rent expense under the Inner Belt Road Lease was $0.6 million for each of the six months ended June 30, 2021 and 2020. Gross rent income under the sublease to OpenBiome for each of the six months ended June 30, 2021 and 2020 was $0.1 million and $0.2 million, respectively, and is presented as an offset to rent expense on the condensed consolidated statements of operations.

Cherry Street

On March 1, 2021, the Company assumed a lease agreement (the "Cherry Street Lease") in conjunction with the closing of the OpenBiome Agreement. The Company's rent expense under the Cherry Street Lease for the six months ended June 30, 2021 and 2020 was approximately $33,000 and $0, respectively.

Concord Street

On June 9, 2021, the Company entered into a lease agreement (the "Concord Street Lease"). The Company's rent expense under the Concord Street Lease for the six months ended June 30, 2021 and 2020 was approximately $32,400 and $0, respectively.

A summary of the Company's future minimum lease payments required under non-cancellable lease agreements as of June 30, 2021 is as follows (in thousands):

2021	$	924
2022		1,552
2023		1,440
2024		1,460
2025		1,496
Thereafter		1,115
	$	7,987

Legal Contingencies

Legal claims may arise from time to time in the normal course of business. There are no such claims as of June 30, 2021 that will have a material effect on the Company's accompanying condensed consolidated financial statements.

License Payments

The Company enters into contracts in the normal course of business with contract research organizations and other third parties for preclinical studies, clinical studies, and testing and manufacturing services. Most contracts do not contain minimum purchase commitments and are cancelable by the Company upon prior written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers up to one year after the date of

cancellation. Under these agreements, in exchange for access to intellectual property the Company may be obligated to provide future minimum royalty payments and milestone payments related to regulatory approvals and sales-based events. The Company entered into the OpenBiome Agreement in November 2020 (see Note 12) and the closing of the OpenBiome Agreement occurred on March 1, 2021. Under the terms of the OpenBiome Agreement, the Company is required to make certain milestone and royalty payments to OpenBiome in conjunction with the license and purchase of certain intellectual property related to the underlying CMC process used to manufacture materials for its clinical trials. The OpenBiome Agreement also effectively terminated the APL Agreement and Material Access License Agreement (the "MAL Agreement") obligations.

Under the APL Agreement entered into in 2019 that was effective through November 2020, the Company was obligated to make certain contingent payments for milestones and royalties to OpenBiome, subject to the occurrence of specific underlying criteria that were dependent on regulatory approvals and sales-based events. The Company was obligated to make regulatory milestone payments to OpenBiome aggregating up to $2.5 million upon the achievement of regulatory approvals, and sales-based milestone payments of up to $23.3 million in sales-based milestone payments upon the achievement of certain net sales criteria. The Company paid $0.1 million to OpenBiome associated with milestones in 2020. The APL Agreement was terminated in November 2020 upon the execution of the OpenBiome Agreement (see Note 12).

Under the MAL Agreement, the Company was also obligated to pay to OpenBiome, a low single digit royalty on net sales of certain cultured products and a high single digit percentage of certain sublicensing revenue (including royalties) of licensed cultured products. These royalties were calculated on a product-by-product and country-by-country basis. The Company paid $0.2 million to OpenBiome under the MAL Agreement in 2020 related to royalty payments. During the year ended December 31, 2020, the Company recorded an additional $0.3 million owed to OpenBiome under the MAL Agreement, of which $0.1 million remained due as of December 31, 2020. The MAL Agreement was terminated in November 2020 upon the execution of the OpenBiome Agreement (see Note 12).

PPP Loan

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted to, amongst other provisions, provide emergency assistance for individuals, families and businesses affected by the COVID-19 pandemic. The CARES Act includes a Paycheck Protection Program ("PPP") administered through the Small Business Association ("SBA"). Under the PPP, beginning April 3, 2020, small businesses and other entities and individuals could apply for loans from existing SBA lenders and other approved regulated lenders that enroll in the program, subject to numerous limitations and eligibility criteria.

In April 2020, the Company issued a promissory note to Silicon Valley Bank, pursuant to which it received loan proceeds of $1.8 million (the "PPP Loan") provided under the PPP established under the CARES Act and guaranteed by the U.S. Small Business Administration ("SBA"). On May 8, 2021, the Company received notice from the SBA that the entirely of the PPP Loan was forgiven. Accordingly, the Company is no longer required to repay the $1.8 million in principal and approximately $19,000 in accrued interest borrowed under the PPP Loan. Gain on extinguishment of the PPP Loan is recorded in the condensed consolidated statements of operations for the six months ended June 30, 2021.

9. REDEEMABLE CONVERTIBLE PREFERRED STOCK

Upon the completion of the IPO, all 31,253,609 shares of outstanding preferred stock automatically converted into 31,253,609 shares of common stock. As of June 30, 2021, there were no shares of preferred stock outstanding.

10. STOCKHOLDERS' EQUITY

On February 24, 2021, the Board and the Company's stockholders approved the Company's amended and restated certificate of incorporation, which became effective immediately prior to the closing of the IPO on March 18, 2021. The certificate authorizes the issuance of up to 200,000,000 shares of $0.001 par value common stock and up to 10,000,000 shares of $0.001 par value undesignated preferred stock. The Board may designate the rights, preferences, privileges, and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference, and number of shares constituting any series or the designation of any series. The issuance of preferred stock could have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying or preventing a change in control. As of June 30, 2021, no shares of preferred stock were outstanding.

In conjunction with the IPO, the Company issued and sold 7,500,000 shares of common stock at a public offering price of $17.00 per share, for aggregate net proceeds of $115.7 million after deducting underwriting discounts and commissions and initial public offering costs. In connection with the IPO, all then outstanding shares of preferred stock were converted into 31,253,609 shares of common stock.

On April 20, 2021, the Company issued 192,877 additional shares of common stock, pursuant to the underwriters' partial exercise of their overallotment option, at a public offering price of $17.00 per share for aggregate gross proceeds of $3.3 million and net proceeds of $3.0 million after deducting underwriters' discounts, commissions and offering costs.

Each share of common stock entitles the holder to one vote, together with the holders of preferred stock, on all matters submitted to the stockholders for a vote. Common stockholders are also entitled to receive dividends. As of June 30, 2021, no cash dividends have been declared or paid.

The Company has issued restricted stock to founders, employees and consultants. All restricted stock was fully vested and all expense related to these shares was recognized prior to 2020.

As of June 30, 2021 and December 31, 2020, the Company has reserved the following shares of common stock for potential conversion of outstanding preferred stock, the vesting of restricted stock and exercise of stock options and common stock warrants:

	JUNE 30, 2021	DECEMBER 31, 2020
Redeemable convertible preferred stock	-	31,253,609
Options to purchase common stock	2,965,264	1,053,874
Common stock warrants	19,346	19,346
	2,984,610	32,326,829

11. STOCK-BASED COMPENSATION

2017 Equity Incentive Plan

The Company adopted the 2017 Equity Incentive Plan (the "2017 Plan") in February 2017 for the issuance of stock options and other stock-based awards to employees, consultants, officers and directors. As of June 30, 2021, there were no shares available for future issuance since all shares in the 2017 Plan ceased to be available upon the effective date of the 2021 Equity Incentive Plan. There were 698,601 shares of common stock available for future grants under the Plan as of December 31, 2020.

2021 Equity Incentive Plan

In March 2021, the Board adopted, and the stockholders approved, the 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan became effective on the date of the underwriting agreement related to the IPO and no further grants will be made under the 2017 Plan.

The 2021 Plan provides for the grant of incentive stock options, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of the Company's affiliates.

Initially, the maximum number of shares of the Company's common stock that may be issued under the 2021 Plan will not exceed 5,291,446 shares of common stock, which is the sum of (1) 4,700,000 new shares, plus (2) an additional number of shares equal to the number of shares of common stock subject to outstanding stock options or other stock awards granted under the 2017 Plan that, on or after the 2021 Plan became effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time. In addition, the number of shares of common stock reserved for issuance under our 2021 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2022 through January 1, 2031, in an amount equal to (i) 5.0% of the total number of shares of common stock outstanding on December 31 of the year before the date of each automatic increase, or (ii) a lesser number of shares determined by the Board prior to the applicable January 1. The maximum number of shares of common stock that may be issued on the exercise of incentive stock options under the 2021 Plan will be 14,100,000 shares. Shares subject to stock awards granted under the 2021 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares will not reduce the number of shares available for issuance under the 2021 Plan.

As of June 30, 2021, there were 1,735,240 shares of common stock issuable upon the exercise of outstanding options and there were 2,964,760 shares available for future issuance under the 2021 Plan.

2021 Employee Stock Purchase Plan

In March 2021, the Board adopted the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective on the date of the underwriting agreement related to the IPO. The 2021 ESPP is administered by the Board or by a committee appointed by the Board. The 2021 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 500,000 shares of common stock. As of June 30, 2021, no offering periods had commenced under the 2021 ESPP and no shares were available for issuance.

Stock Options

The following table summarizes the activity of the Company's stock options under the 2017 Plan and 2021 Plan for the six months ended June 30, 2021:

	SHARES	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (in years)	AGGREGATE INTRINSIC VALUE (in thousands)
Outstanding as of December 31, 2020	1,053,874	$ 1.51	7.49	$ 4,964
Granted	2,012,026	$ 14.97		
Exercised	(88,694)	$ 0.77		
Cancelled or forfeited	(10,104)	$ 3.41		
Expired	(1,838)	$ 1.73		
Outstanding as of June 30, 2021	2,965,264	$ 10.65	8.98	$ 12,515
Options exercisable as of December 31, 2020	652,549	$ 1.37	7.12	$ 3,205
Options exercisable as of June 30, 2021	681,216	$ 1.84	7.07	$ 8,333

As of June 30, 2021, there was approximately $19.6 million of unrecognized compensation expense related to the stock-based compensation arrangements granted under the 2021 Plan remaining to be recognized. The Company expects to recognize this cost over a weighted average period of 3.09 years.

Stock-Based Compensation Expense

Total stock-based compensation expense recorded as research and development and general and administrative expenses, respectively, for employees, directors and non-employees for the periods presented is as follows (in thousands):

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2021	2020	2021	2020
Research and development	$ 238	$ 63	$ 404	$ 115
General and administrative	667	25	836	51
Total	$ 905	$ 88	$ 1,240	$ 166

12. RELATED PARTY TRANSACTIONS

OpenBiome Historical Agreements

Under Master Strategic Affiliation Agreement with OpenBiome (the "Strategic Agreement"), OpenBiome and the Company reimbursed one another for certain administrative expenses. The Company's Chief Executive Officer and a member of its board of

directors, is the spouse of the Executive Director and co-founder of OpenBiome, and certain of the OpenBiome directors are shareholders of the Company.

For the six months ended June 30, 2021 and 2020, the Company reimbursed OpenBiome $0.1 million and approximately $0.3 million, respectively, under the Strategic Agreement. Also under the Strategic Agreement, OpenBiome reimbursed the Company $0.1 million for the six months ended June 30, 2021 and 2020. The Company recorded less than $0.1 million due to OpenBiome and less than $0.1 million due from OpenBiome as of June 30, 2021 and December 31, 2020.

OpenBiome subleases office and lab space from the Company. The Company's rent income under the sublease was $0.1 million and $0.2 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021 and December 31, 2020, the Company had less than $0.1 million receivable from OpenBiome related to the sublease recorded as due from related party in the condensed consolidated balance sheets. This lease was amended as of March 1, 2021 (see Note 8).

The Company also earned a low single digit royalty on net sales of OpenBiome's FMT materials under the Quality System and Supply Agreement with OpenBiome (the "QSS Agreement"), which was partially terminated on February 1, 2019 and, ultimately, was fully terminated in November 2020 in connection with the Company's execution of the OpenBiome Agreement (see OpenBiome 2020 Agreements below), which closed on March 1, 2021.

OpenBiome 2020 Agreements

Clinical Supply and Services Agreement

On February 10, 2020, the Company entered into a Clinical Supply and Services Agreement ("CSA") with OpenBiome, the term of which is one year, as the CSA terminated upon closing of the OpenBiome Agreement. In accordance with the CSA, OpenBiome agreed to supply the Company with certain manufactured material and to provide additional support services to the Company. In consideration for these materials and services, the Company agreed to pay a monthly platform fee of $0.2 million, all direct employee overhead costs, and variable costs for consumables. Under a related payment agreement executed concurrently with the CSA, the Company paid a $0.5 million security deposit in the event of cost overruns under the CSA arrangement and approximately $1.6 million in prepaid fees. The $0.5 million security deposit was returned to the Company during the same period. The Company paid $1.1 million in total to OpenBiome under the CSA for the six months ended June 30, 2021, and $2.1 million for the six months ended June 30, 2020, including the security deposit that was returned. The Company recorded $0 and $0.2 million due to OpenBiome under the CSA as of June 30, 2021, and December 31, 2020, respectively, which is classified as due to related party in the Company's condensed consolidated balance sheets.

OpenBiome Purchase Agreement

On November 19, 2020, the Company entered into an asset purchase agreement (the "OpenBiome Agreement") with OpenBiome in order to obtain OpenBiome's CMC manufacturing process to enhance its current manufacturing capabilities for its lead program, CP101; the OpenBiome Agreement was fully executed and closed on March 1, 2021. Simultaneously with entering into the OpenBiome Agreement, the Company terminated the Strategic Agreement, the MAL Agreement, the QSS Agreement and the APL Agreement, as well as certain subject matter agreements. Upon closing of the OpenBiome Agreement on March 1, 2021, the CSA was also terminated and the Company will not incur any additional expense to be paid to OpenBiome. The Company also amended the Strategic Agreement as part of the OpenBiome Agreement ("A&R Strategic Agreement").

Pursuant to the OpenBiome Agreement, the Company acquired certain biological samples, software, and a non-exclusive license to OpenBiome's CMC technology upon signing in November 2020, and acquired certain biological samples, a commercial lease, contract services intellectual property and capital equipment upon the closing of the transaction in March 2021. The Company previously licensed the biological samples and OpenBiome's CMC technology under various historical agreements with OpenBiome which terminated upon signing of the OpenBiome Agreement. As such, the acquisition of the CMC technology license was a continuation of previously granted rights. The OpenBiome Agreement also releases, for a one-year period upon signing, a hiring restriction under the A&R Strategic Agreement (i.e. non-solicitation) such that the Company may hire, at its discretion, certain OpenBiome employees. The Company did not acquire any such employees as part of the transaction.

In connection with the OpenBiome Agreement, the Company paid $1.2 million for the acquisition of certain assets in November 2020, which was capitalized as property and equipment as software on the Company's consolidated balance sheet as of December 31, 2020, and paid $3.8 million upon the closing of the OpenBiome Agreement on March 1, 2021, for the remaining assets. The Company accounted for the OpenBiome Agreement as an asset acquisition, and capitalized $5.0 million of property and equipment on the condensed consolidated balance sheet as of March 31, 2021 for the acquired software and property and equipment. The Company did not assign any value to biological samples, contract services intellectual property, or the CMC technology license, as the Company did not acquire any additional rights that were not previously granted under the legacy agreements.

The Company is also required to pay certain milestones up to $26.0 million upon the occurrence of certain research and development events, regulatory approvals, and commercial sales, and low single digit royalties on net sales of products on a product-by-product and country-by-country basis, as well as a mid single digit royalties on sublicensing revenue related to such products.

The Company previously granted OpenBiome a royalty-bearing, non-exclusive license to its intellectual property under the APL Agreement, which terminated upon the signing of the OpenBiome Agreement. The Company will continue to earn royalties under the OpenBiome Agreement based on sales of FMT materials.

13. RETIREMENT PLAN

The Company has adopted a defined contribution plan intended to qualify under Section 401(k) of the Internal Revenue Code covering all eligible employees of the Company. All employees are eligible to become participants of the plan immediately upon hire. Each active employee may elect, voluntarily, to contribute a percentage of their compensation to the plan each year, subject to certain limitations. The Company reserves the right to make additional contributions to this plan. The Company made contributions to the plan of $0.4 million and $0.2 million in the six months ended June 30, 2021 and 2020, respectively.

14. LOSS PER SHARE

Basic and diluted loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding (in thousands, except share and per share data):

	FOR THE THREE MONTHS ENDED JUNE 30,		FOR THE SIX MONTHS ENDED JUNE 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (15,169)	$ (8,259)	$ (29,150)	$ (16,160)
Net loss attributable to common stockholders—basic and diluted	(15,169)	(8,259)	(29,150)	(16,160)
Denominator:				
Weighted-average common stock outstanding—basic and diluted	47,379,887	8,069,304	30,798,698	7,968,267
Net loss per share attributable to common stockholders—basic and diluted	$ (0.32)	$ (1.02)	$ (0.95)	$ (2.03)

The Company's potentially dilutive securities, which include preferred stock, restricted stock, stock options, and warrants, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders at June 30, 2021 and 2020 because including them would have had an anti-dilutive effect:

	SIX MONTHS ENDED JUNE 30,	
	2021	2020
Preferred stock	-	24,350,737
Options to purchase common stock	2,965,264	1,104,704
Common stock warrants	19,346	19,346
	2,984,610	25,474,787

15. SUBSEQUENT EVENTS

Hood Lease

On August 3, 2021 (the "Execution Date"), Finch entered into a lease (the "Hood Lease") with Hood Park LLC (the "Landlord"), pursuant to which Finch will lease approximately 61,139 square feet of office and laboratory space on the second floor of a building located at 100 Hood Park Drive, Charlestown, Massachusetts 02129 (the "Premises").

The term of the Hood Lease commenced on the Execution Date, and Finch will become responsible for paying rent under the Hood Lease on the earlier of (i) January 1, 2022 and (ii) the date Finch's work on the Premises is substantially completed and Finch has commenced business operations in the Premises (the "Rent Commencement Date").

The initial term of the Hood Lease will be for a period commencing on the Execution Date and expiring on the date that is ten years from the Rent Commencement Date, unless earlier terminated. The Hood Lease also provides Finch with an option to extend the Lease for one additional five-year term. Finch's annual base rent for the Premises will start at approximately $4.5 million, commencing on the Rent Commencement Date and will increase on each anniversary of the Rent Commencement Date by approximately 2.8% per annum, up to a maximum annual base rent during the initial term of approximately $5.8 million. The Hood Lease provides for a tenant improvement allowance of approximately $14.8 million for the cost of Finch's work on the Premises.

Finch is required to post a customary letter of credit in the amount of approximately $2.3 million, subject to decrease on a set schedule, as a security deposit pursuant to the Hood Lease.

Takeda Amendment

On August 9, 2021, Finch and Takeda Development Center Americas, Inc., a wholly owned subsidiary of Takeda, entered into an amendment (the "Amendment") to the Takeda Agreement.

Under the terms of the Takeda Agreement, among other things, Finch and Takeda agreed to jointly develop the microbiome therapeutic candidate FIN-524, with Finch primarily responsible for early-stage development and manufacturing activities. Pursuant to the Amendment, Finch and Takeda will transition primary responsibility for such development and manufacturing activities from Finch to Takeda in accordance with a transition plan, and Takeda will assume sole responsibility for regulatory matters with respect to FIN-524. Finch will have the right to provide input with respect to the design of the first Phase 1 and Phase 2 clinical trials of FIN-524 in ulcerative colitis in the United States. Further, Finch will remain responsible for certain development activities designated in the FIN-524 development plan, for which Finch will continue to receive reimbursement from Takeda.

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

You should read the following discussion and analysis of our financial condition and results of operations together with (1) our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and (2) the audited consolidated financial statements and the related notes and management's discussion and analysis of financial condition and results of operations for the fiscal year ended December 31, 2020 included in our final prospectus for our initial public offering, or IPO, dated March 18, 2021, filed with the Securities and Exchange Commission, or SEC, pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, on March 22, 2021, which we refer to as the Prospectus.

Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section titled "Risk Factors" set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements." You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

Overview

We are a clinical-stage microbiome therapeutics company leveraging our Human-First Discovery platform to develop a novel class of orally administered biological drugs. The microbiome consists of trillions of microbes that live symbiotically in and on every human and are essential to our health. When key microbes are lost, the resulting dysbiosis can increase susceptibility to immune disorders, infections, neurological conditions, cancer and other serious diseases. We are developing novel therapeutics designed to deliver missing microbes and their clinically relevant biochemical functions to correct dysbiosis and the diseases that emerge from it. Our Human-First Discovery platform uses reverse translation to identify diseases of dysbiosis and to design microbiome therapeutics that address them. Our lead product candidate, CP101, delivers a complete microbiome and is being developed initially for the treatment of patients with recurrent Clostridioides difficile infection, or CDI. In June 2020, we reported positive topline data from our first of two pivotal trials in recurrent CDI. We have completed several key trial start-up activities, including the receipt of central IRB approval, for our Phase 3 clinical trial, which we refer to as PRISM4, which will be our second pivotal trial of CP101 for recurrent CDI. We anticipate that topline data from PRISM4 will be available in the first half of 2023. Although we need to generate additional data confirming safety and efficacy to support regulatory approval of CP101 for the treatment of recurrent CDI, we believe data from our pivotal, Phase 2 clinical trial with CP101 validates our platform, positioning us to initiate new clinical trials in chronic hepatitis B virus, or HBV, and autism spectrum disorder, or ASD, over the next 15 months. We have decided to expand our planned Phase 1b clinical trial of CP101 in chronic HBV, which we refer to as RECLAIM, from two cohorts to four cohorts and we anticipate initiating RECLAIM in early 2022, with an initial safety readout expected in the first half of 2022 and topline data from multiple cohorts available in the second half of 2022. Further, we anticipate initiating our Phase 1b clinical trial of FIN-211 in ASD in the second half of 2021, with topline data expected to be available in the second half of 2022. We believe that our differentiated platform, rich pipeline and the broad therapeutic potential of this new field of medicine position us to transform care for a wide range of unmet medical needs.

Since our inception, we have focused primarily on developing and progressing our product candidates through clinical development, organizing and staffing our company, research and development activities, establishing and protecting our intellectual property portfolio including for our Human-First Discovery platform, and raising capital. We do not have any product candidates approved for sale and have not generated any revenue from product sales. Since our inception, we have funded our operations primarily with proceeds from the IPO, the sale of convertible preferred stock and from collaboration revenue.

On March 12, 2021, we effected a 1-for-14.444 reverse stock split of our issued and outstanding shares of common stock and redeemable convertible preferred stock, as well as effected a proportional adjustment to the existing conversion ratios for our redeemable convertible preferred stock. All historical share and per share information shown herein and in our unaudited condensed financial statements and related notes have been retroactively adjusted to give effect to the reverse stock split.

On March 18, 2021, we completed an IPO in which we issued and sold 7,500,000 shares of our common stock at a public offering price of $17.00 per share, resulting in aggregate gross proceeds of $127.5 million. On April 20, 2021, we issued and sold 192,877 additional shares of common stock, pursuant to the underwriters' partial exercise of their overallotment option, at a public offering price of $17.00 per share, for aggregate gross proceeds of $3.3 million. Inclusive of the underwriters' option to purchase additional shares, we received approximately $118.8 million in net proceeds from the IPO after deducting underwriting discounts and

commissions and offering costs. Upon completion of the IPO, all 31,253,609 shares of outstanding redeemable convertible preferred stock automatically converted into 31,253,609 shares of common stock.

Since our inception, we have incurred significant operating losses. Our net losses were $29.2 million and $16.2 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of $132.0 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future if and as we:

- continue the research and development of our product candidates;
- initiate clinical trials for, or additional preclinical development of, our product candidates;
- further develop and refine the manufacturing processes for our product candidates;
- seek regulatory and marketing authorizations for any of our product candidates that successfully complete development;
- seek to identify and validate additional product candidates;
- acquire or license other product candidates, technologies or biological materials;
- make milestone, royalty or other payments under any current or future license agreements;
- obtain, maintain, protect and enforce our intellectual property portfolio;
- seek to attract and retain new and existing skilled personnel;
- create additional infrastructure to support our operations as a public company and incur increased legal, accounting, investor relations and other expenses; and
- experience delays or encounter issues with any of the above.

We will not generate any revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution.

As a result, we will need substantial additional funding to support our operating activities as we advance our product candidates through clinical development, seek regulatory approval and prepare for and, if any of our product candidates are approved, proceed to commercialization. Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all.

If we are unable to obtain funding, we will be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

We expect that our existing cash and cash equivalents of $168.1 million as of June 30, 2021 will enable us to fund our operating expenses and capital expenditure requirements into mid-2023. 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. See “—Liquidity and Capital Resources.”

COVID-19 Business Update

In response to the ongoing global COVID-19 pandemic, we established a cross-functional task force and have implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on our employees and our business, including our clinical trials. We have taken measures to secure our research and development activities, while work in laboratories and facilities has been organized to reduce risk of COVID-19 transmission. The extent of the impact of the COVID-19 pandemic on our business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak, including with respect to variants of the virus, and its impact on our clinical trial enrollment, trial sites, contract research organizations, or CROs, contract manufacturing organizations, and other third parties with

whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. While we are experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition and results of operations ultimately could be materially adversely affected. We continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans, clinical development plans and response strategy.

Components of Our Results of Operations

Revenue

We have no products approved for commercial sale. We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of licensed products for the foreseeable future. Our revenue to date has been generated primarily through collaboration and license agreements. We recognize revenue over our expected performance period under each agreement. We expect that our revenue for the next several years will be derived primarily from our current collaboration agreement and any additional collaborations that we may enter into in the future, and any collaboration revenue we generate will fluctuate from period to period as a result of the timing and amount of milestones and other payments. To date, we have not received any royalties under our collaboration agreement with Takeda Pharmaceutical Company Limited, or Takeda. However, during the six months ended June 30, 2020, we received royalties in the aggregate of $0.3 million pursuant to our 2019 Asset Purchase and License Agreement, or APL Agreement, with OpenBiome. The APL Agreement was terminated in November 2020, and we received no royalties thereafter.

Collaboration and License Agreement with Takeda

In January 2017, we entered into a research collaboration and exclusive license agreement, or the Takeda Agreement, with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda, pursuant to which we granted Takeda a worldwide, exclusive license, with the right to grant sublicenses, under certain of our patents, patent applications and know-how to develop, have developed, manufacture, have manufactured, make, have made, use, have used, offer for sale, sell, have sold, commercialize, have commercialized and import our microbiome therapeutic candidate FIN-524 for the prevention, diagnosis, theragnosis or treatment of diseases in humans. We subsequently amended and restated the Takeda Agreement in October 2019 to provide a similar worldwide, exclusive license to a second microbiome therapeutic candidate, FIN-525.

In connection with entry into the Takeda Agreement, we received a one-time, upfront payment from Takeda in the amount of $10.0 million. Additionally, we received $4.0 million in the aggregate for the achievement of certain development milestones for FIN-524 therapeutic products and are entitled to receive up to $176.0 million in the aggregate, for the achievement of specified development, regulatory and commercial sale milestones for FIN-524 therapeutic products. We are entitled to receive up to $177.7 million in the aggregate, for the achievement of specified development, regulatory and commercial sale milestones for FIN-525 therapeutic products, subject, to certain specified reductions based upon the nature of the FIN-525 product and certain additional milestones to be negotiated by the parties. We are also entitled to receive up to $10.0 million for the first diagnostic product for each of FIN-524 and FIN-525, subject to certain reductions in the event that Takeda uses a third party to develop such diagnostic products. Revenue under the Takeda Agreement is recognized as our research and development services are provided and is recorded as collaboration revenue on our consolidated statement of operations. In August 2021, we amended the Takeda Agreement to transition primary responsibility for early-stage development and manufacturing activities with respect to FIN-524 from us to Takeda in accordance with a transition plan, as further described in Note 15 to our condensed consolidated financial statements.

Agreements with OpenBiome

We have historically collaborated with OpenBiome under several agreements related to, among other things, the license of various technology and intellectual property rights, and the supply of certain materials, as further described below.

In February 2017, we entered into the Quality System and Supply Agreement, or QSS Agreement, with OpenBiome, which was subsequently amended in September 2017 and was partially terminated in February 2019. Under the QSS Agreement, OpenBiome granted us an exclusive license, eligible for sublicense, of certain OpenBiome technology and intellectual property. Additionally, we acquired certain assets of OpenBiome for use in manufacturing and supplying product. The QSS Agreement allowed us to use the licensed OpenBiome technology and intellectual property for our own research and development efforts in exchange for up to $27.5 million in milestone payments associated with development and commercialization efforts. We were responsible for providing support to OpenBiome related to manufacturing product, produced to OpenBiome’s specifications, which has been included as service revenue in our consolidated statements of operations. Revenue under the QSS Agreement was recorded as either contract manufacturing revenue or royalty revenue in our consolidated statements of operations.

On November 19, 2020, we entered into the LMIC License Agreement, or the LMIC Agreement, with OpenBiome, pursuant to which we granted OpenBiome a non-exclusive royalty-bearing license, with the right to grant sublicenses, under certain patents, patent

applications, and know-how that are reasonably necessary or useful for the exploitation of products manufactured directly from stool from a stool donor source without the use of culturing or replication, or certain natural products. The license granted excludes a license under our intellectual property to exploit a lyophilized Natural Product (such as CP101) where processed stool is lyophilized. The only consideration provided to us under the LMIC Agreement is in the form of future royalties on net sales of these products, which are not currently commercially viable. We are entitled to receive tiered royalties on net sales of certain products, ranging from mid-single digit to low second decile digits on a product-by-product and country-by-country basis. We did not recognize any revenue related to the LMIC Agreement for the six months ended June 30, 2021 and 2020, as there are currently no products available for sale.

On November 19, 2020, we entered into an asset purchase agreement with OpenBiome, or the OpenBiome Agreement, the effect of which was to terminate certain existing agreements with OpenBiome and internalize some of functions for which we have previously relied on OpenBiome. Pursuant to the OpenBiome Agreement, we acquired certain biological samples and obtained a license to certain OpenBiome technology and, upon closing of the transaction, which occurred March 1, 2021, we acquired certain additional assets, including biological samples, capital equipment and contracts. As of June 30, 2021, we have made payments of $5.0 million to OpenBiome related to the OpenBiome Agreement, which is the full amount agreed upon. We are also required to pay certain milestones up to $26.0 million upon the occurrence of certain research and development events, regulatory approvals, and commercial sales, and low single digit royalties on net sales of products on a product-by-product and country-by-country basis, as well as a mid single digit royalties on sublicensing revenue related to such products.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- upfront, milestone and maintenance fees incurred under license, acquisition and other third-party agreements;
- costs of laboratory supplies and acquiring, developing and manufacturing study materials;
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs; and
- costs of outside consultants, including their fees and related travel expenses engaged in research and development functions.

Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we initiate clinical trials for our product candidates and continue to discover and develop additional product candidates. If any of our product candidates enter into later stages of clinical development, they will 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. There are numerous factors associated with the successful commercialization of any product candidates we may develop in the future, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development program and plans.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services, 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 expect that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our continued research and development and potential commercialization of our product candidates and expand our corporate headquarters. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services, director and officer insurance costs, and investor and public relations costs.

Total Other Income (Expense), Net

Gain on Extinguishment of PPP Loan

Gain on extinguishment of PPP Loan relates to the PPP loan forgiveness.

Interest Income

Interest income primarily consists of interest earned on our cash and cash equivalents. Our interest income has not been significant due to low interest earned on cash balances related to our sweep account.

Other Income (Expense), net

Other income (expense), net consists of gains and losses on disposals of fixed asset as well as realized gains and losses on foreign exchange.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2020 (in thousands):

	THREE MONTHS ENDED JUNE 30,	
	2021	2020
REVENUE:		
Collaboration revenue	$ 2,830	$ 2,237
Royalties revenue from related party	-	112
Total revenue	2,830	2,349
OPERATING EXPENSES:		
Research and development	(13,964)	(8,135)
General and administrative	(5,882)	(2,574)
Total operating expenses	(19,846)	(10,709)
Net operating loss	(17,016)	(8,360)
OTHER INCOME:		
Gain on extinguishment of PPP Loan	1,827	-
Interest income	7	21
Other income	13	80
Total other income	1,847	101
Net loss	$ (15,169)	$ (8,259)

Revenue

Revenue of $2.8 million and $2.4 million for the three months ended June 30, 2021 and 2020, respectively, primarily consisted of collaboration revenue earned under the Takeda Agreement. Our collaboration revenue increased by $0.4 million in the three months ended June 30, 2021 compared to the three months ended June 30, 2020 primarily due to an increase in the overall percentage-of-completion of costs incurred under the Takeda Agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2021 and 2020 (in thousands):

	THREE MONTHS ENDED JUNE 30,		
	2021	2020	Increase (Decrease)
CDI (CP101)	$ 3,733	5,308	$ (1,575)
Inflammatory Bowel Diseases (FIN-524 and FIN-525)	2,098	1,978	120
Autism Spectrum Disorder (ASD) (FIN-211)	1,771	691	1,080
Hepatitis B (HBV) (CP101)	875	32	843
Platform	4,955	311	4,644
Unallocated	532	(185)	717
	$ 13,964	$ 8,135	$ 5,829

Research and development expenses for the three months ended June 30, 2021 were $14.0 million, compared to $8.1 million for the three months ended June 30, 2020. The increase of $5.8 million for the three months ended June 30, 2021 included a $4.6 million increase from manufacturing related expenses, personnel costs and early asset discovery work and a $1.9 million increase in expenses related to the expansion and development of the ASD and HBV programs. These increases were offset by a $1.6 million decrease in costs related to our CDI program due to a decrease in contract manufacturing costs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended June 30, 2021 and 2020 (in thousands):

	THREE MONTHS ENDED JUNE 30,		
	2021	2020	Increase (Decrease)
Personnel expenses (including stock-based compensation)	$ 2,989	1,517	$ 1,472
Facilities and supplies	48	127	(79)
Professional fees	1,587	702	885
Other expenses	1,258	228	1,030
	$ 5,882	$ 2,574	$ 3,308

General and administrative expenses were $5.9 million for the three months ended June 30, 2021, compared to $2.6 million for the three months ended June 30, 2020. The increase of $3.3 million for the three months ended June 30, 2021 was primarily due to a $1.5 million increase in personnel expenses, a $1.0 million increase in other expenses, and a $0.9 million increase in professional fees. The increase in personnel expenses is related to an increase in headcount to support our operational growth as well as an increase in stock-based compensation expense. The increase in other expenses was related to an increase in business insurance, and the increase in professional fees was related to our transition to a public company in March 2021.

Other Income

Total other income for the three months ended June 30, 2021 was $1.8 million, compared to $0.1 million for the three months ended June 30, 2020. The increase of $1.7 million for the three months ended June 30, 2021 was primarily due to the forgiveness of the PPP Loan of $1.8 million in May 2021.

Comparison of the Six Months Ended June 30, 2021 and 2020

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020 (in thousands):

	SIX MONTHS ENDED JUNE 30,	
	2021	2020
REVENUE:		
Collaboration revenue	$ 6,383	$ 3,849
Royalties revenue from related party	-	292
Total revenue	6,383	4,141
OPERATING EXPENSES:		
Research and development	(26,939)	(15,532)
General and administrative	(10,433)	(4,832)
Total operating expenses	(37,372)	(20,364)
Net operating loss	(30,989)	(16,223)
OTHER INCOME (EXPENSE), NET:		
Gain on extinguishment of PPP Loan	1,827	-
Interest income	6	112
Other income (expense), net	6	(49)
Total other income, net	1,839	63
Net loss	$ (29,150)	$ (16,160)

Revenue

Revenue of $6.4 million and $4.1 million for the six months ended June 30, 2021 and 2020, respectively, primarily consisted of collaboration revenue earned under the Takeda Agreement. Our collaboration revenue increased by $2.5 million in the six months ended June 30, 2021 compared to the six months ended June 30, 2020 primarily due to an increase in the overall percentage-of-completion of costs incurred under the Takeda Agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2021 and 2020 (in thousands):

	SIX MONTHS ENDED JUNE 30,		
	2021	2020	Increase (Decrease)
CDI (CP101)	$ 8,034	$ 9,690	$ (1,656)
Inflammatory Bowel Diseases (FIN-524 and FIN-525)	4,902	4,110	792
Autism Spectrum Disorder (ASD) (FIN-211)	3,230	1,182	2,048
Hepatitis B (HBV) (CP101)	1,451	32	1,419
Platform	8,465	492	7,973
Unallocated	857	26	831
	$ 26,939	$ 15,532	$ 11,407

Research and development expenses for the six months ended June 30, 2021 were $26.9 million, compared to $15.5 million for the six months ended June 30, 2020. The increase of $11.4 million for the six months ended June 30, 2021 included an $8.0 million increase from manufacturing related expenses, personnel costs and early discovery work, a $3.5 million increase in expenses related to the expansion and development of the ASD and HBV programs, and a $0.8 million increase in inflammatory bowel diseases, or IBD, program expenses. These increases were offset by a $1.7 million decrease in CDI from a decrease in contract manufacturing costs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the six months ended June 30, 2021 and 2020 (in thousands):

	SIX MONTHS ENDED JUNE 30,		
	2021	2020	Increase (Decrease)
Personnel expenses (including stock-based compensation)	$ 5,357	$ 3,018	$ 2,339
Facilities and supplies	137	390	(253)
Professional fees	3,411	1,015	2,396
Other expenses	1,528	409	1,119
	$ 10,433	$ 4,832	$ 5,601

General and administrative expenses were $10.4 million for the six months ended June 30, 2021, compared to $4.8 million for the six months ended June 30, 2020. The increase of $5.6 million for the six months ended June 30, 2021 was primarily due to a $2.4 million increase in professional fees, a $2.3 million increase in personnel expenses, and a $1.1 million increase in other expenses. The increase in professional fees was related to our transition to a public company in March 2021. The increase in personnel expenses is related to an increase in headcount to support our operational growth as well as an increase in stock-based compensation expense, and the increase in other expenses is related to business insurance.

Other Income, Net

Total other income, net for the six months ended June 30, 2021 was $1.8 million, compared to $0.1 million for the six months ended June 30, 2020. The increase of $1.8 million for the six months ended June 30, 2021 was primarily due to the forgiveness of the PPP Loan of $1.8 million.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not recognized any product revenue and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. We have funded our operations primarily through equity financings and from collaboration revenue. We have raised an aggregate of approximately $177.0 million from the sale of convertible preferred stock and $14.0 million in collaboration revenue from the upfront payment and milestone payments received under our collaboration agreement. In March 2021, we completed our IPO whereby we sold an aggregate of 7,500,000 shares of our common stock. In April 2021, we sold an additional 192,877 shares of our common stock, pursuant to the underwriters' partial exercise of their overallotment option, at a public offering price of $17.00 per share, for aggregate gross proceeds of $3.3 million. In aggregate, we received approximately $118.8 million in net proceeds related to our IPO after deducting $9.2 million of underwriting discounts and commissions and $2.9 million of offering expenses.

In April 2020, we received proceeds of $1.8 million from the PPP Loan. We have used the PPP Loan to retain current employees, maintain payroll and make lease and utility payments. On May 8, 2021, we received notice from the SBA that the entirety of the PPP Loan we received was forgiven. Accordingly, we are no longer required to repay the $1.8 million in principal and approximately $19,000 in accrued interest borrowed under the PPP Loan. Gain on extinguishment of the PPP Loan is recorded in the condensed consolidated statements of operations for the six months ended June 30, 2021.

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2021 and 2020 (in thousands):

	SIX MONTHS ENDED JUNE 30,	
	2021	2020
Net cash used in operating activities	$ (38,996)	$ (14,133)
Net cash used in investing activities	(11,555)	(270)
Net cash provided by financing activities	118,995	1,799
Net increase (decrease) in cash and cash equivalents, and restricted cash	$ 68,444	$ (12,604)

Operating Activities

During the six months ended June 30, 2020, cash used in operating activities was $14.1 million. This cash outflow was primarily related to our net loss. The outflow was also impacted by a net increase in our operating assets and liabilities of $1.5 million. This net increase includes a $2.4 million decrease in due from related party and a $1.7 million increase in deferred revenue related to our Takeda agreement. This increase was offset by an increase in prepaid expenses and other current assets of $2.1 million, and a decrease in accrued expenses and other current liabilities of $1.6 million. The cash outflow also included $0.4 million in non-cash depreciation and amortization expense for our fixed assets, including leasehold improvements and $0.2 million in stock-based compensation expense.

During the six months ended June 30, 2021, cash used in operating activities was $39.0 million. This cash outflow was primarily related to our net loss of $29.2 million. The outflow was also impacted by a net decrease in our operating assets and liabilities of $10.2 million. The net decrease includes a $3.8 million increase in other non-current assets, a $2.8 million decrease in deferred revenue related to our Takeda Agreement, a $1.5 million decrease in accounts payable, and a $1.2 million increase in accounts receivable. The cash outflow also included $0.4 million in non-cash activity.

Investing Activities

During the six months ended June 30, 2020 and 2021, we used $0.3 million and $11.6 million, respectively, of cash in investing activities. The $0.3 million used during the six months ended June 30, 2020 and $11.6 million used during the six months ended June 30, 2021 was related to the purchase of property and equipment. Purchases of property and equipment during the six months ended June 30, 2021 includes $3.9 million in purchases from a related party.

Financing Activities

During the six months ended June 30, 2020, net cash provided by financing activities was $1.8 million, primarily related to $1.8 million of proceeds received from the PPP Loan.

During the six months ended June 30, 2021, net cash provided by financing activities was $119.0 million, primarily related to $118.6 million of proceeds received from the IPO, net of underwriting discounts and commissions and $3.0 million of proceeds from the underwriters' exercise of their overallotment option, net of underwriting discounts and commissions. The proceeds are partially offset by $2.7 million of payments of issuance costs related to the IPO.

Funding Requirements

As of June 30, 2021, our cash and cash equivalents were $168.1 million. In April 2021, we sold an additional 192,877 shares of our common stock, pursuant to the underwriters' partial exercise of their overallotment option, at a public offering price of $17.00 per share, for aggregate gross proceeds of $3.3 million. We believe that our existing cash on hand will enable us to fund our operating expenses and capital expenditure requirements into mid-2023. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we expect.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. We expect that our expenses will increase substantially if and as we:

- continue the research and development of our product candidates;
- initiate clinical trials for, or additional preclinical development of, our product candidates;
- further develop and refine the manufacturing process for our product candidates;
- change or add manufacturers or suppliers of product candidate materials;
- seek regulatory and marketing authorizations for any of our product candidates that successfully complete development;
- seek to identify and validate additional product candidates;
- acquire or license other product candidates, technologies or biological materials;

- make milestone, royalty or other payments under any current or future license agreements;
- obtain, maintain, protect and enforce our intellectual property portfolio;
- seek to attract and retain new and existing skilled personnel;
- create additional infrastructure to support our operations as a public company, including the expansion of our corporate headquarters, and incur increased legal, accounting, investor relations and other expenses; and
- experience delays or encounter issues with any of the above.

Contractual Obligations and Commitments

During the six months ended June 30, 2021, there were no material changes to our contractual obligations and commitments from those described under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Prospectus.

Critical Accounting Policies and Significant Judgments and Estimates

Our unaudited interim condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our unaudited interim condensed 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 condensed 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. However, even though we believe we have used reasonable estimates and assumptions in preparing our interim condensed consolidated financial statements, the future effects of the COVID-19 pandemic on our results of operations, cash flows, and financial position are unclear. 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in our Prospectus.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Recently Issued Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements.

Emerging Growth Company Status and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. We expect to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company and, as a result, we will not adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenues of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of interest rate sensitivities.

Interest Rate Sensitivity

As of June 30, 2021 and December 31, 2020, we had cash and cash equivalents of $168.1 million and $99.7 million, respectively. Our exposure to interest rate sensitivity is impacted by changes in the underlying U.S. bank interest rates. Our surplus cash has been invested in money market fund accounts as well as interest-bearing savings accounts from time to time. We have not entered into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, which is predicated on capital preservation of investments with short-term maturities, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our portfolio, and therefore, we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

As of June 30, 2021 and December 31, 2020, we had no debt outstanding that is subject to interest rate variability. Therefore, we are not subject to interest rate risk related to debt.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act that are 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 recorded, processed, summarized and reported, within the time periods specified in the SEC’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 our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2021. Our disclosure controls and procedures are designed to ensure that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures, and is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms.

Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective due to the material weakness identified in fiscal year 2019 in our internal control over financial reporting process which included (1) an ineffective control environment, including a lack of sufficient accounting personnel and personnel with financial reporting expertise; (2) ineffective controls over cutoff, recording and classification of certain accounts, and the valuation and recognition of intangible assets acquired in a business combination that occurred in 2017; (3) ineffective risk assessment controls, including those policies and practices that would identify changes in our business practices, which could significantly impact our consolidated financial statements and system of internal controls; and (4) ineffective monitoring of controls related to the financial close and reporting process.

Remediation Plan

We are committed and are taking steps necessary to remediate the control deficiencies that constituted the above material weakness by implementing changes to our internal control over financial reporting. During the last quarter of 2020 and through June 30, 2021, we made the following enhancements to our control environment including the following:

- We added finance personnel to the organization to strengthen our internal accounting team to include a controller, assistant controller, and senior accountant.
- We engaged external accounting advisory consultants to provide additional depth and breadth in our technical accounting and financial reporting capabilities.

- With the support of internal control consultants, we are in the process of completing risk assessment activities and evaluating the design and implementation of internal controls to address relevant risk, including developing remediation plans for any design deficiencies in our system of internal controls,

- We implemented a financial close policy and monitoring program, including the formation of a Disclosure Committee comprised of members of our senior management team and representatives from our accounting and legal departments to review and approve SEC filings and investor communications, the results of which are discussed with the audit committee quarterly.

Our remediation activities are continuing through the remainder of 2021. In addition to the above activities, we expect to engage in additional activities including:

- Continue to engage internal control consultants to assist us with the remediation of any identified control design deficiencies, and to perform tests of our internal controls to evaluate the operating effectiveness of our system of internal controls.

- Hire additional qualified accounting personnel to further strengthen the accounting organization and continue to engage external accounting advisory consultants on an as-needed basis.

Changes in Internal Control Over Financial Reporting

Except for the remediation efforts of the previously identified material weakness as described above, there was no change in our internal control over financial reporting that occurred during the six months ended June 30, 2021 that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

As a result of the COVID-19 pandemic, certain employees began working remotely in March 2020. Notwithstanding these changes to the working environment, we have not identified any material changes in our internal control over financial reporting. We will continue to monitor and assess the COVID-19 situation to determine any potential impact on the design and operating effectiveness of our internal controls over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become subject to arbitration, litigation or claims arising in the ordinary course of business. We are not currently a party to any material arbitration or legal proceedings. The results of any future claims or proceedings cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and litigation costs, diversion of management resources, and other factors.

Item 1A. Risk Factors

Our business is subject to numerous risks. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Quarterly Report on Form 10-Q as well as our other public filings with the Securities and Exchange Commission, or the SEC. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects and cause the trading price of our common stock to decline.

Risks Related to Our Financial Position and Capital Needs

We have a limited operating history, 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 biopharmaceutical company with a limited operating history. Since our inception, we have focused primarily on developing and progressing our product candidates through clinical development, organizing and staffing our company, research

and development activities, establishing and protecting our intellectual property portfolio including for our Human-First Discovery platform, and raising capital. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have not yet demonstrated the ability to progress any product candidate through clinical trials, we have no products approved for commercial sale and we have not generated any revenue from product sales to date. 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. For the six months ended June 30, 2020 and 2021, we reported net losses of $16.2 million and $29.2 million, respectively. As of June 30, 2021, we had an accumulated deficit of $132.0 million. 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 lead therapeutic product candidate, CP101, for the treatment of recurrent Clostridioides difficile infection, or CDI, and any future product candidates we may develop.

We anticipate that our expenses will increase substantially if, and as, we:

- continue our ongoing and planned development of CP101 for the treatment of recurrent CDI, including our planned Phase 3 clinical trial of CP101;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future, including our earlier-stage programs such as our planned Phase 1 clinical trials of FIN-211 for the treatment of autism spectrum disorder, or ASD, and CP101 for the treatment of chronic hepatitis B virus, or HBV;
- develop, optimize and scale our manufacturing processes and capabilities, including constructing facilities to support the commercial scale production of CP101 and, in the future, our other drug candidates;
- establish and expand a donor program to support our clinical supply for trial and initial commercial needs;
- increase the amount of research and development activities to identify and develop product candidates using our proprietary discovery approach;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing, quality systems and commercialization efforts and our operations as a public company;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;
- invest in or in-license other technologies; and
- experience any delays or encounter any issues with any of the above, including, but not limited to, failed studies, complex results, manufacturing challenges, quality issues, safety issues or other regulatory challenges, or as a result of the ongoing COVID-19 pandemic.

To become and remain profitable, we, our collaborators and any potential future collaborators must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval 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 or large 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 substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our product development programs or other operations.

To date, we have primarily funded our operations through the IPO, private placements of equity securities and upfront and milestone payments received pursuant to our collaboration agreement with Millennium Pharmaceuticals, Inc., or Takeda. We expect to spend substantial amounts to advance our product candidates into clinical development and to complete the clinical development of, seek regulatory approvals for and commercialize our product candidates, if approved. We will require additional capital, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources to enable us to complete the development and potential commercialization of our product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs.

As of June 30, 2021, our cash and cash equivalents were $168.1 million. We believe that our existing cash on hand will enable us to fund our operating expenses and capital expenditure requirements into mid-2023. However, we will need to obtain substantial additional funding in connection with our continuing operations and planned activities. Our future capital requirements will depend on many factors, including:

- the timing, costs, progress and results of our planned clinical trials of CP101 and other product candidates;
- the progress of preclinical development and possible clinical trials of our current earlier-stage programs;
- the scope, progress, results and costs of our research programs and preclinical development of other product candidates that we may pursue;
- the development requirements of other product candidates that we may pursue;
- any possible delays or interruptions with our clinical trials, our receipt of services from our third-party service producers on whom we rely, our supply chain or other regulatory challenges, including those due to the COVID-19 pandemic or to other unforeseen global events;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the timing and amount of milestone and royalty payments that we are required to make or eligible to receive under our current or future licensing and collaboration agreements;
- the cost of establishing a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or the FDA, and any comparable foreign regulatory authority;
- the costs and timing of future commercialization activities, including product manufacturing and related quality systems implementation, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs associated with operating our commercial scale manufacturing facility;

- the cost of expanding, maintaining and enforcing our intellectual property portfolio, including filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the extent to which we partner our programs, acquire or in-license other product candidates and technologies or enter into additional strategic collaborations;
- the revenue, if any, received from commercial sales of CP101 and any future product candidates for which we receive marketing approval;
- the cost of equipment and physical infrastructure to support our research and development; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, CP101 and any future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether terminate our research and development programs or future commercialization efforts.

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

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish certain valuable rights to our intellectual property, 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 capital when needed, we may be required to delay, limit, reduce or terminate our clinical development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Risks Related to the Development of Our Product Candidates

We are heavily dependent on the success of our product candidates, which are in clinical development. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. We are early in our product candidate development efforts, as CP101 is our only product candidate to reach clinical development to date. Because CP101 is our lead product candidate, if CP101 encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be significantly harmed.

Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of CP101 and any future product candidates we develop, which may never occur. CP101 and any future product candidates we develop will require additional preclinical and clinical development, management of clinical, preclinical, manufacturing and quality activities, marketing approval in the United States and other jurisdictions for specific indications for use, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales. The success of our current and future product candidates will depend on several factors, including the following:

- successful and timely completion of clinical trials and preclinical studies for which the FDA or any comparable foreign regulatory authority agree with the design, endpoints or implementation;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting our planned clinical trials or future clinical trials;
- initiation and successful patient enrollment in, and completion of, additional clinical trials on a timely basis;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and effective as a treatment for our targeted indications or, in the case of an applicable product candidate that is regulated as a biological product, that the applicable product is safe, pure, and potent for our targeted indications;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing that meet current Good Manufacturing Practices, or cGMP, and other legal and regulatory requirements, if any of our product candidates are approved;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates, both in the United States and internationally;
- successfully scaling a sales and marketing organization and launching commercial sales of our product candidates, if approved;
- acceptance of our product candidates' benefits and uses, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of our product candidates following approval, including long-term safety;
- effectively competing with companies developing and commercializing other therapies in the indications that our product candidates target;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- enforcing and defending against intellectual property rights and claims.

Many of these risks are beyond our control, including the risks related to clinical development, the regulatory review process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive regulatory approval for, or successfully commercialize our current or future product candidates, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize CP101 or any future product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for our current and future product candidates, we may not be able to continue our operations.

Our product candidates are based on microbiome therapeutics, which is an unproven approach to therapeutic intervention.

All of our product candidates are based on microbiome therapy, a therapeutic approach that is designed to treat disease by restoring the function of a dysbiotic microbiome. We have not, nor to our knowledge, has any other company, received regulatory approval for a therapeutic based on this approach. We cannot be certain that our approach will lead to the development of approvable or marketable products. In addition, the efficacy potential of our microbiome therapeutics may vary based on indication and use in different patient populations including geographical areas. Finally, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of products based on microbiome therapeutics, which could result in a longer than expected regulatory review process or evolving FDA standards and guidance, increase our expected development costs and delay or prevent commercialization of our product candidates. Regulatory requirements governing microbiome therapies are still developing and may change in the future. Regulatory authorities and advisory groups, and the new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our current or future product candidates or lead to significant post-approval limitations or restrictions.

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 success 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 non-IND human clinical studies and clinical trials of others developing similar products or products that are perceived to be similar to ours, such as fecal microbiota transplant, or FMT, materials, as well as any other adverse findings that arise in connection with research and development in the microbiome field, could result in negative publicity and a decrease in demand for any product that we may develop. In addition, responses by the federal, 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.

Our microbiome therapeutics platform relies on third parties for biological materials, including human stool. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these biological materials could materially adversely affect our business. For example, if any supplied biological materials are contaminated with pathogens or disease organisms, we would not be able to use such biological materials. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. While we screen for a broad set of pathogens as a part of our manufacturing process, the donated human stool may contain organisms of which we are not aware and that could have an adverse effect on the safety of our product candidates and on the outcomes of our preclinical studies or clinical trials. Improper storage of these materials, by us or any third-party suppliers, may require us to destroy some of our raw materials or products which could create supply shortages, interruptions or other delays or require identification and contracting of additional third-party suppliers which we may not be able to do in a timely manner or on favorable terms.

Our relationship with OpenBiome may adversely affect our ability to develop our product candidates and subject us to increased liability.

The Microbiome Health Research Institute, Inc., or OpenBiome, is a non-profit organization that was co-founded in 2012 by our Chief Executive Officer and member of our board of directors, Mark Smith, Ph.D. OpenBiome operates a stool bank and manufactures, sells, and distributes fecal microbiota transplant products, or OpenBiome FMT Materials, for clinical research and for use in treating CDI not responding to standard therapy under its interpretation of the FDA's policy of enforcement discretion. In July 2013, the FDA issued guidance stating that it intended to exercise a policy of enforcement discretion regarding the IND regulatory requirements for the use of FMT used to treat CDI not responding to standard therapies, provided that the treating physician obtains appropriate informed consent from the patient or his or her legally authorized representative. We have historically had a close relationship with OpenBiome and are currently and have previously been party to several agreements with OpenBiome related to, among other things, the license of various technology and intellectual property rights. In addition, Carolyn Edelstein, the Executive Director and co-founder of OpenBiome, is married to Dr. Smith. Although we believe our agreements with OpenBiome have been negotiated at an

arms-length basis, there may be a perception that the terms of any such agreements have not been fairly negotiated, which could increase regulatory scrutiny, adversely impact our reputation or otherwise impair our ability to operate effectively.

In 2016, we entered into a Master Strategic Affiliation Agreement with OpenBiome, or the Strategic Agreement, pursuant to which, among other things, we manufactured OpenBiome FMT Materials to specifications defined by OpenBiome for distribution and sale by OpenBiome through February 2019. These OpenBiome FMT Materials have been and may continue to be distributed and sold by OpenBiome, and administered to patients. The FDA may not agree with OpenBiome's interpretation or application of the FDA's enforcement discretion policy to its product distribution. We terminated the Strategic Agreement in 2020 as part of signing an asset purchase agreement, or the OpenBiome Agreement, and license agreement with OpenBiome, pursuant to which we acquired certain biological materials, equipment, and other assets, and cross-licensing certain intellectual property. The OpenBiome Agreement also retained certain existing intellectual property and biological materials licenses from the Master Strategic Affiliation Agreement into a stand-alone agreement. Although we are indemnified for causes of action relating to the distribution and sale of the OpenBiome FMT Materials, we may nonetheless become parties to potential product liability claims that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products such as OpenBiome FMT Materials.

Moreover, the availability of OpenBiome FMT Materials under the FDA's policy of enforcement discretion, and for use in clinical research, may negatively prejudice and slow enrollment of clinical trials sponsored by us or our collaborators that are directed at the same or similar disease or condition, such as CDI. Additionally, while CP101 is an orally administered biologic consisting of a complete microbiome and a distinct product from OpenBiome FMT Materials, with additional testing, manufacturing and control steps, it is possible that the FDA and others might perceive CP101 or any of our other product candidates as similar owing to their common raw material. The FDA has issued two safety alerts since 2019 related to the use of FMT treatment, including in March 2020 after OpenBiome reported occurrences of enteropathogenic E. coli and shigatoxin-producing E. coli in FMT recipients. This and similar adverse safety events associated with OpenBiome FMT Materials or other similar products manufactured or supplied by other third-party stool banks, physicians or others may cause the FDA to perceive CP101 as unsafe and bring increased regulatory scrutiny to our clinical and manufacturing operations more broadly, lead to decreased confidence by patients and physicians in our product candidates, and result in reduced demand for any product that we may develop.

OpenBiome has also supplied us with biological materials derived from human stool, which we intend to use as raw materials, subject to additional testing, screening and processing, in the manufacture of our product candidates, such as CP101, for use in our planned clinical trials. During the time we engaged OpenBiome to supply us with such human stool material, OpenBiome received a clinical hold from the FDA with respect to the need for new screening measures to mitigate the risk of transmission of SARS-CoV-2 from donor to recipient of its OpenBiome FMT materials, and the need for additional information regarding OpenBiome's quality systems. This clinical hold was removed in January 2021. Although the OpenBiome clinical hold did not preclude us from receiving OpenBiome-supplied biological materials for our manufacturing activities, given that some materials were received while OpenBiome was under clinical hold, we may not be able to use these materials for such purposes if we determine they fail to meet our quality standards, or if the FDA or other parties perceive such materials to be unsafe. For example, the FDA or other regulatory agencies may determine that they should not be used for the same reasons underlying the clinical hold, or different reasons. In addition, while we intend to test these materials to ensure they meet our quality standards, we plan to use an assay to screen for COVID-19 that has not been reviewed or approved by the FDA on behalf of Finch. If we are unable to use the biological materials we have received from OpenBiome, or are delayed in our use of those materials, our planned clinical trials could be significantly delayed and adversely affected. In addition, we may not be able to recoup the costs associated with acquiring these biological materials from OpenBiome.

In connection with the closing of the transactions contemplated by the OpenBiome Agreement, we acquired certain capital equipment and assumed the contracts with certain service providers to which OpenBiome was a party. We may encounter difficulties assimilating or integrating the personnel, technologies and equipment contemplated by the OpenBiome Agreement. This transaction may also disrupt our business and require management attention that would otherwise be available for development of our existing business. If the resulting benefits from the consummation of the transactions contemplated by the OpenBiome Agreement fail to meet our expectations, our business, results of operations and financial condition may be harmed. In addition, although the OpenBiome Agreement is structured to exclude the assumption of any liabilities of OpenBiome, we may be subject to unknown liabilities with respect to the assets we have acquired or contracts we have assumed.

Clinical trials are difficult to design and implement, and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of CP101 or any future product candidates.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We cannot guarantee that any of our ongoing and planned clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, even if these trials are initiated or conducted on a timely basis, issues may arise that could result in the suspension or termination of such clinical trials.

Although we have completed the topline readout in connection with PRISM3, our Phase 2 clinical trial of CP101, we may experience delays in our ongoing clinical trials or preclinical studies and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or in sufficient numbers, have sufficient drug supply for our product candidates on a timely basis or be completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing, and our ongoing and future clinical trials may not be successful. We also may experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize CP101 or any future product candidates, including:

- delays in or failure to obtain regulatory authorizations to commence clinical trials;
- delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical trials; for example, we plan to have further discussions with the FDA regarding the size and make-up of the safety database for CP101 which could result in the need for additional studies or delays in our development timelines;
- delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in or failure to obtain institutional review board, or IRB, approval at each site;
- delays in or failure to recruit a sufficient number of suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delays in adding new clinical trial sites;
- failure to manufacture sufficient quantities of our product candidates at the required quality for use in clinical trials in a timely manner, including the failure to acquire sufficient starting material from third-party donors;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or safety or tolerability concerns that could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- failure to perform clinical trials in accordance with the FDA's or any other regulatory authority's good clinical practices, or GCP, requirements, or regulatory guidelines in other countries;
- changes in regulatory requirements, policies and guidelines;
- failure of our third-party research contractors to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- delays in establishing the appropriate dosage levels in clinical trials;
- the quality or stability of our product candidates falling below acceptable standards; and
- business interruptions resulting from geo-political actions, including war and terrorism, an outbreak of a contagious disease, such as the COVID-19 pandemic, or natural disasters including earthquakes, typhoons, floods and fires.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing preclinical studies and clinical trials, as applicable. We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or comparable foreign regulatory authorities, or recommended for suspension or termination by the Data Safety Monitoring Board for such trial. 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 comparable foreign 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. Further, the FDA or comparable foreign 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 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 clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant 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 clinical development programs may harm our business, financial condition and results of operations significantly.

Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.

Our business and operations may be adversely affected by the effects of the ongoing COVID-19 global pandemic, which has resulted in various restrictions aimed at containing the virus, including public health directives and orders that, among other things and for various periods of time, directed individuals to shelter in place, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings and events, and ordered cessation of non-essential travel. Future remote work policies and similar government orders or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity and may disrupt our ongoing research and development activities and our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Further, such orders also may impact the availability or cost of materials, which would disrupt our supply chain and manufacturing efforts and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities.

In connection with the COVID-19 pandemic, we experienced a slowdown to enrollment in our PRISM-EXT clinical trial. We may experience additional COVID-19 related disruptions in the future that could severely impact our clinical trials, including:

- delays, difficulties or a suspension in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- interruptions in our ability to manufacture and deliver drug supply for trials, including related to a lack of human donors for stool due, in part, to the fact that qualified donors may be hesitant to visit a donor center, or related to the failure of third-party manufacturers and suppliers to timely provide such supply;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruption of key clinical trial activities, such as clinical trial site monitoring, and the ability or willingness of subjects to travel to trial sites due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the manufacture and testing of our products and the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in certain affected geographies.

Known or unanticipated impacts of the COVID-19 pandemic may have a material adverse effect on our business. While the ultimate economic impact brought by, and the duration of, the COVID-19 pandemic are difficult to assess or predict, the pandemic has resulted, and could further result, in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the COVID-19 pandemic could materially affect our business and the value of our common stock.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this Quarterly Report on Form 10-Q, such as the ultimate geographic spread of the disease, the duration of the outbreak, the impact of emerging variants, the duration and effect of business disruptions and the short- and long-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease, and the effectiveness and acceptance of vaccines. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

The demand for vaccines for COVID-19, which are being granted Emergency Use Authorization by the FDA, and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. Moreover, since the Office of Vaccines Research and Review at FDA, which is responsible for review and approval of microbiome product candidates, is responsible for the review of COVID-19 vaccines, responses from FDA may be delayed.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, including CP101 and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our investigational drug products are safe and effective for use in each targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency. Prior to obtaining approval to commercialize CP101 and any future product candidates in the United States or abroad, we, our collaborators or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. For example, we plan to have further discussions with the FDA regarding the size and make-up of the safety database for CP101 which could result in the need for additional studies or delays in our development timelines.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do. More trials could be required before we submit our product candidates for approval, especially for indications such as ASD, for which clinical endpoints are not well-established, or chronic HBV, for which we may propose new biomarkers as evidence of efficacy. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in clinical trials. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of CP101 and any future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

The results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Initial success in third-party studies or our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later-stage trials.

The results of nonclinical and preclinical studies and clinical trials may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, we have relied on third-party clinical research in order to inform certain aspects of our own clinical trials and preclinical studies. We have not independently verified the accuracy, safety or other results of such third-party studies, and we may be unable to replicate the results from such third-party studies. For example, insights gained from the use of FMT materials, including FMT clinical data, may not be predictive of our clinical trials, particularly given that the dosage form and potency, delivery mechanisms and manufacturing process vary significantly.

Accordingly, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the biotechnology and pharmaceutical 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 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 and clinical trials nonetheless failed to obtain FDA approval. Additionally, product used in small early-stage studies may be from a limited number of donors, and it is possible that efficacy might be linked to the microbial community found in a specific donor or a limited set of donors, such that the results might not apply for a broader group of donors with varying microbial compositions. Any such setbacks in our clinical development could have a material adverse effect on our business, financial condition and results of operations.

Additionally, some of the clinical trials we conduct may include open-label trials conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved product or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Given that we plan to in the future conduct open-label clinical trials, the results from these clinical trials may not be predictive of future clinical trial results with these or other product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Our product candidates may be associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, or prevent marketing approval. If such side effects are identified during the development of our product candidates or following approval we may suspend or abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. While we have observed no treatment-related serious adverse events, or SAEs, to date in clinical trials of our lead product candidate CP101, the results from future preclinical studies and clinical trials of our other product candidates may identify safety concerns or other undesirable properties of our product candidates. Additionally, if we expand our product development for current or future product candidates into new patient populations or disease areas, side effects or adverse events not seen by our product candidates in earlier clinical research could emerge.

The results of our planned clinical trials of CP101 and future clinical trials of our other product candidates may show that our product candidates cause undesirable or unacceptable side effects or even death. In such an event, our 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. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and results of operations significantly.

Moreover, if our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, if approved.

Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others or with commercial products offered by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or change the requirements for approval of any of our product candidates or otherwise adversely impact the clinical and commercial development of our product candidates. Such adverse developments may cause the FDA to perceive CP101 as unsafe and bring increased regulatory scrutiny to our clinical operations more broadly, lead to decreased confidence by patients, physicians and contract research organizations, or CROs, in our product candidates, and result in reduced demand for any product that we may develop if approved. For example, in June 2019, the FDA issued a safety alert regarding the risk of serious adverse reactions due to the transmission of multi-drug resistant organisms in connection with FMT treatment provided by a local, hospital-based FMT program. Two immunocompromised adults, one of whom later died, received FMT treatment from this hospital-based FMT program and subsequently developed infections caused by extended-spectrum beta-lactamase-producing E. coli. Additionally, in March 2020, the FDA issued another safety alert regarding the potential of serious or life-threatening infections with the use of FMT treatment after OpenBiome reported occurrences of enteropathogenic E. coli and shigatoxin-producing E. coli in FMT recipients.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- site IRBs or safety monitoring committees may recommend that enrollment or dosing be placed on hold or that additional safety measures be implemented for ongoing trials;
- regulatory authorities may withdraw or limit approvals of such product and require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way the product is dosed, distributed or administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates, if approved.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with, or otherwise adversely affect, clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timely completion of our clinical trials in accordance with their protocols depends, among other things, on our ability to recruit a sufficient number of eligible patients to participate and remain in the trial until its conclusion. Patients may be unwilling to participate in our clinical trials because of negative publicity from adverse events related to novel therapeutic approaches, competitive clinical trials for similar patient populations, the existence of current treatments, such as FMT, or for other reasons, including the ongoing COVID-19 pandemic and negative perceptions of our product candidates. Any delays related to patient enrollment could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the

clinical trials altogether. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with the required or desired characteristics, to complete our clinical trials in a timely manner. Patient enrollment and trial completion is affected by many factors, including the:

- size and nature of the patient population and process for identifying patients;
- proximity and availability of clinical trial sites for prospective patients;
- eligibility and exclusion criteria for the trial;
- design of the clinical trial;
- safety profile, to date, of the product candidate under study;
- perceived risks and benefits of the product candidate under study;
- perceived risks and benefits of our approach;
- approval and availability of competing product candidates currently under investigation for the treatment of similar diseases or conditions, or competing clinical trials for similar product candidates or targeting patient populations meeting our patient eligibility criteria;
- severity of the disease under investigation;
- degree of progression or stage of the patient's disease at the time of enrollment;
- ability to obtain and maintain patient consent;
- risk that enrolled patients will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to adequately monitor patients during and after treatment.

Enrollment risks are heightened with respect to indications that are rare or orphan diseases, which may limit the pool of patients that may be enrolled in our planned clinical trials. For example, we are developing CP101 for the treatment of recurrent CDI, which does not have a large patient population, and, as a result, we may encounter difficulties enrolling subjects in our clinical trials evaluating CP101 for the treatment of recurrent CDI due, in part, to the small size of this patient population.

In addition, our clinical trials will compete with products that are available for use in the same therapeutic areas of our product candidates, and other clinical 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 trials may instead opt to enroll in a trial being conducted by one of our competitors. For example, the availability of FMT materials for CDI not responding to standard therapies may affect our ability to enroll patients in our studies of CP101 in CDI. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical 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.

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

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

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report.

Interim, topline and preliminary 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, preliminary, topline and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects. In addition, certain patient and product samples from our clinical trials are or will be retained by third parties and used by them for further research and studies, and the data from such studies may be inconsistent or contrary to the results from our earlier clinical trials.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, interpretations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, if any, and our company in general. For example, regulatory agencies may disagree with our inclusion or exclusion of certain trial subjects from our clinical trial data or our interpretation of such data. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, if any, product candidate or our business. If the preliminary and interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

Before we can commence clinical trials for any product candidate, we may be required to complete extensive preclinical studies that support any future Investigational New Drug, or IND, applications in the United States, or similar applications in other jurisdictions. Conducting preclinical testing is a lengthy, time-consuming and expensive process and delays associated with product candidates for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. We cannot be certain of the timely completion or outcome of our preclinical testing and studies for CP101 or our other product candidates and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and foreign clinical trials will ultimately support the further development of our other product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs 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 comparable foreign regulatory authorities allowing clinical trials to begin.

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

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, laws or regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including requiring us to enroll more patients than originally expected, including with respect to the anticipated size of the safety database to be collected to support a biologics license application, or BLA, filing and possible approval;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective as a treatment for our targeted indications, or, in the case of a product candidate regulated as a biological product, that the product candidate is safe, pure and potent for its proposed indication;

- the population studied may not be sufficiently broad or representative to assure safety or efficacy in the population for which we seek approval, including as a result of our agreement with the FDA prior to unblinding to exclude certain patients enrolled at two GCP-non-compliant trial sites from adjudication and inclusion in our efficacy analysis;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including whether our statistical analysis plan meets FDA expectations;

- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the FDA or comparable foreign regulatory authorities may require additional preclinical studies or clinical trials beyond those that we currently anticipate;

- the FDA may conclude that our product candidate is the "same drug" as a competitor product that has been approved and has received orphan drug exclusivity for the same intended use;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA or other submission or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes, testing regime or facilities operated by us or third-party manufacturers with which we contract for clinical and commercial supplies, including with certain technology transfer initiatives; and

- the approval policies or regulations of the FDA or any comparable foreign regulatory authorities or the laws they enforce may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, financial condition and results of operations. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, if any, 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.

Even if we receive regulatory approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with such product candidate.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, testing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, 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 BLA, 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.

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 and testing 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 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;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- 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. 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 including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling.

The holder of a BLA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

The policies of the FDA and of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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.

We may in the future conduct clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have previously conducted, and plan in the future to conduct, one or more clinical trials outside the United States, including in, but not limited to, Canada, Europe, Australia, New Zealand and Hong Kong. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. Results for our clinical trials may differ by jurisdiction as a result of varying standards of care or local restrictions on reimbursement from third-party payors for clinical trials, thereby affecting the willingness of the FDA or any comparable foreign regulatory authority to accept such data. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We may pursue the development of certain of our product candidates in combination with other therapies, and regulatory approval, safety or supply issues with these other therapies may delay or prevent the development and approval of our product candidates.

In the near future, we may explore the use of our product candidates in combination with other therapies, including those that are not yet approved. If we choose to develop a product candidate for use in combination with an approved therapy, we are subject to the risk that the FDA or comparable foreign regulatory authorities could revoke approval of, or that safety, efficacy, manufacturing or supply issues could arise with, the therapy used in combination with our product candidate. If the therapies we use in combination with our product candidates are replaced as the standard of care, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials, or we may not be able to obtain adequate reimbursement from third-party payors. The occurrence of any of these risks could result in our product candidates, if approved, being removed from the market or being less successful commercially.

Where we develop a product candidate for use in combination with a therapy that has not been approved by the FDA or comparable foreign regulatory authorities, we will not be able to market our product candidate for use in combination with such an unapproved therapy, unless and until the unapproved therapy receives regulatory approval. These unapproved therapies face the same risks described with respect to our product candidates currently in development, including serious adverse effects and delays in their clinical trials. In addition, other companies may also develop their products or product candidates in combination with the unapproved therapies with which we are developing our product candidates for use in combination. Any setbacks in these companies' clinical trials, including the emergence of serious adverse effects, may delay or prevent the development and approval of our product candidates.

If the FDA or comparable foreign regulatory authorities do not approve or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, therapies we choose to evaluate in combination with any of our product candidates, we may be unable to obtain regulatory approval of or to commercialize such product candidates in combination with these therapies.

Risks Related to the Manufacture of Our Product Candidates

The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities.

Our product candidates are biologics that consist of bacteria and may include other microorganisms. The process of manufacturing our products is complex, highly-regulated and subject to multiple risks. The manufacture of our product candidates involves complex processes, including obtaining biological material (human stool) from qualified third-party donors for CP101 and FIN-211. As a result of these complexities, the cost to manufacture our product candidates in particular is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce.

Further, as our product candidates are developed through early- to late-stage clinical trials towards approval and commercialization, we may make alterations to these products and their method of manufacture and use, including changes to our manufacturing processes, 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 than they did in the past and affect the results of planned clinical trials or other future clinical trials. In such circumstances, the FDA or foreign regulatory authorities may require that we conduct bridging comparability testing to confirm the clinical relevance of prior data. For example, early prototype versions of CP101 were manufactured by investigators at the University of Minnesota using certain different techniques and equipment than we have used and intend to use as we continue to advance CP101.

Historically, early versions of CP101 were manufactured using unoptimized processes by third-party research collaborators that we have not used, or do not intend to use, in more advanced clinical trials or commercialization. We have, and may continue to, alter our manufacturing processes, product release criteria, dose strength or dosing regimen, and other aspects of CP101 to optimize it for late-stage clinical trials or commercialization. Although we are working to develop commercially viable processes, 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-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. As a result of these challenges, we may experience delays in our clinical development and/or commercialization plans.

We are still in the process of developing and scaling-up our manufacturing processes and quality systems for certain of our other product candidates, including FIN-524. These products contain proprietary bacterial strains that have never been manufactured in a scale sufficient for use in a clinical trial or for commercialization. We can make no assurances that we will be able to manufacture these products, or components of these products, in a cost effective manner or at the level required for clinical trials or commercialization.

We rely on third-party donors of biological material to manufacture certain product candidates such as CP101, and if we do not obtain an adequate supply of acceptable material from those qualified donors, the clinical and commercial supply of these product candidates may be adversely impacted.

We use human stool from extensively-screened third-party donors as starting material in the manufacture of several of our product candidates, including CP101. The stool that is received from these third-party donors is tested for certain pathogens and processed without the use of replication or culturing to form an active ingredient in our products. Our ability to manufacture CP101 and other product candidates using donor-derived materials at clinical and commercial scale depends on obtaining a consistent and adequate supply of stool material. There are, in general, relatively few alternative sources of supply that would be sufficient to meet our clinical and commercial needs.

In the past, we have relied on stool donor programs operated by OpenBiome and the University of Minnesota for the supply of human stool material used in the manufacture of our product candidates, including CP101. In connection with the Asset Purchase Agreement with OpenBiome, we have licensed certain technology and will acquire assets that will enable our stool donor program in support of the clinical development and commercialization of CP101 and our other product candidates.

The stool donor program on which we rely involves the screening of potential human stool donors using defined screening criteria. Only a small fraction of potential human donors that we will evaluate will be able to meet these criteria and enroll in our donor program. There can be no assurances that we will have enough qualified third-party donors within our donor program, or enough material derived from donors in our program, to meet clinical or commercial demand. We may also have difficulty enrolling and retaining enough qualified donors in our donor program. If we are unable to enroll a sufficient number of qualified donors in our stool donor program, or if we are unable to retain donors within our program or receive enough stool from donors within our program, our ability to manufacture CP101 and other product candidates may be delayed or adversely impacted.

While the stool donor program on which we rely involves extensive screening of potential entrants, we can make no assurances that it will screen for, or be able to identify, all diseases and conditions that could adversely affect the health of persons who use or consume products that contain biological material from those donors. The screening processes may fail to identify certain existing diseases or conditions in the humans that we evaluate for entry into our donor program. In addition, donors enrolled in our donor program may develop new diseases or conditions, or the worsening of pre-existing or underlying diseases or conditions, that we may fail to identify. The use of stool material from a third-party donor who has a certain condition or disease may result in material adverse effects to our business, including supply chain disruptions resulting from the recall or destruction of affected starting material or product, or adverse reactions in patients who use or consume products derived from that donor. For example, in March 2020, the FDA required retrospective testing and the recall and destruction of the affected product after OpenBiome, a supplier of human stool material, reported occurrences of enteropathogenic E. coli and shigatoxin-producing E. coli in FMT recipients.

While we will extensively test the biological materials that we receive from qualified third-party donors or suppliers for the presence of certain pathogens and other microorganisms, there can be no assurances that we will detect all pathogens and other microorganisms in our products, which could result in an adverse reaction in persons who use or consume our products. Our testing processes may fail to identify pathogens in the stool that we receive from donors within our donor program. In addition, the emergence of new pathogens could affect the availability of stool donors, or require us to develop new testing processes to test both new and existing material and product, either of which could cause delays or shortage in the manufacture and distribution of our products. The presence of pathogens in the stool material that we receive from third-party donors may also result in adverse reactions in persons who use or consume products that are derived from that material. Additionally, regulatory or industry pathogen testing requirements may change over time, possibly making it more challenging to locate qualified donors, or requiring the development and validation of new test methods, which could adversely affect our ability to collect adequate supply and increase costs related to product manufacturing.

We operate our own manufacturing facility for certain product candidates, which requires significant resources and we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.

We are completing construction of our manufacturing facility to support the manufacture of our product candidates, including CP101, for use in clinical development or for potential commercial sale. We may not be able to manufacture enough product at this facility to meet the clinical and commercial demand for our product candidates. We also cannot be sure that the manufacturing processes employed by us will result in products that will be safe and effective. Moreover, we may run into delays or cost overruns in connection with the development of our manufacturing facility, including the transfer of technology from our manufacturing operations at the University of Minnesota, which would increase our net losses and have an adverse effect on our stockholders' equity and working capital. For example, the FDA may find deficiencies in our technology transfer process or require one or more comparability studies of our drug product using test methods that we would need to develop. 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, if approved. There is a lack of third-party CMOs willing or able to manufacture whole community product candidates like CP101. If we are unable to successfully manufacture and process our product candidates, we might not be able to produce some of our products at a level that would be sufficient to meet our clinical and commercial needs.

The manufacture of microbiome therapeutics is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of products derived from human biological material often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of raw materials or in our manufacturing facilities or manufacturing facilities operated by our third-party suppliers, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of our product candidates will not occur in the future.

Our operations will remain subject to review and oversight by the FDA and the FDA could object to our use of our manufacturing facility. Prior to licensure to manufacture our product candidates, we must first receive approval from the FDA, which we may never obtain. Such approval may be contingent on a pre-approval inspection of our manufacturing facility. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel on account of the COVID-19 pandemic, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Even if approved, we would be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review.

In addition, we may fail to manage the logistics of storing and shipping our product candidates, particularly as our product candidates are required to be stored at certain pre-defined refrigerated temperatures. Storage failures and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could result in loss of usable product or prevent or delay the delivery of product candidates to patients. We may also experience manufacturing difficulties due to resource constraints or as a result of labor disputes. If we were to encounter any of these difficulties, our ability to develop and commercialize our product candidates would be jeopardized.

Risks Related to the Commercialization of Our Product Candidates

We have never commercialized a product candidate and may experience delays or unexpected difficulties in obtaining regulatory approval for our current or future product candidates for our initial or potential additional indications.

We have never obtained regulatory approval for, or commercialized, a drug. It is possible that the FDA may refuse to accept any or all of our planned BLAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any product candidates. If the FDA does not approve any of our planned BLAs, it may require that we conduct additional costly clinical, nonclinical or manufacturing validation studies before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any BLA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing our current or future product candidates, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any BLA or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

We currently have no marketing and sales organization and have no experience as a company in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, 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. 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 pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. 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.

We have received Fast Track designation for CP101 for the prevention of recurrent CDI, and we may seek Fast Track designation for our other product candidates. Even if received, Fast Track designation may not actually lead to a faster review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We have received Fast Track designation for CP101 for the prevention of recurrent CDI, and we may seek Fast Track designation for our other product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track designation for a particular indication. There is no assurance that the FDA will grant this status to any of our other proposed product candidates. If granted, Fast Track designation makes a product eligible for more frequent interactions with FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Marketing applications of products candidates with Fast Track designation may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance 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, and receiving a Fast Track designation does not provide any assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation at any time if it believes that the designation is no longer supported by data from our clinical development program.

We have received Breakthrough Therapy designation for CP101 for the prevention of recurrent CDI, and we may seek Breakthrough Therapy designation for our other product candidates. Even if received, Breakthrough Therapy designation may not

actually lead to a faster review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We have received Breakthrough Therapy designation for CP101 for the prevention of recurrent CDI, and may, in the future, apply for Breakthrough Therapy designation for other product candidates in the United States. A Breakthrough Therapy product candidate is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that such product candidate may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a Breakthrough Therapy product candidate receives: (i) intensive guidance on an efficient drug development program; (ii) intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review; and (iii) a rolling review process whereby the FDA may consider reviewing portions of a BLA before the sponsor submits the complete application. Product candidates designated as breakthrough therapies by the FDA may be eligible for priority review if supported by clinical data.

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. 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 products considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by the FDA. In addition, even though CP101 has been designated as a Breakthrough Therapy product candidate, the FDA may later decide that it no longer meets the conditions for designation or decide that the time period for FDA review or approval will not be shortened.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs, our attractiveness as a commercial partner and may ultimately have an impact on our commercial success.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, in particular for our lead product candidate, our business, financial condition and results of operations could be materially adversely affected and may cause us to reprioritize our planned trials and use of funds for planned trials.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals and others in the medical community.

The use of microbiome therapies is a recent development and may not become broadly accepted by physicians, patients, hospitals and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over current or future alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other microbiome therapies;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other microbiome medicines and public perception of other microbiome medicines;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;

- the FDA's policy of enforcement discretion for FMT materials to treat CDI not responding to standard therapies;
- the cost of treatment and the availability of testing for patient selection;
- the pricing of our products, if approved, and the availability of adequate coverage and reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved for commercialization but fail to achieve market acceptance among physicians, patients, hospitals or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other microbiome approaches, SAEs or deaths in other clinical trials involving the microbiome, or in clinical trials involving therapeutic approaches similar to ours, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

If the market opportunities for our product candidates are smaller than we believe they are, even assuming approval of a product candidate, our business may suffer.

Our projections of both the number of people who are affected by diseases within our potential target indications, as well as the subset of these people who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, healthcare utilization databases and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition and results of operations.

We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other drugs that are able to achieve similar or better results that our product candidates. Our potential competitors include major multinational pharmaceutical 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 and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. 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 biotechnology and pharmaceutical industries may result in even more resources being concentrated in 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 drug or biologic products 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 face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of microbiome therapies. We are aware of a number of companies focused on developing microbiome therapeutics in various indications. For CP101, we are aware that Seres Therapeutics, Inc., Rebiotix, Inc. and Vedanta Biosciences, Inc. each have a product candidate being evaluated in clinical trials for recurrent CDI. In addition, we face competition from other therapies which are designed to treat the indications targeted by our product candidates.

We anticipate that we will continue to face intense and increasing competition as new treatments enter the market and advanced technologies become available. There can be no assurance that our competitors are not currently developing, or will not in the future develop, products that are equally or more effective or are more economically attractive than any of our current or future product candidates. Competing products may gain faster or greater market acceptance than our products, if any, and medical advances or rapid technological development by competitors may result in our product candidates becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we or our product candidates do not compete effectively, it may have a material adverse effect on our business, financial condition and results of operations.

If either we or our collaborators obtain approval to commercialize any of our product candidates outside of the United States, a variety of risks associated with international operations could adversely affect our business.

If any of our product candidates are approved for commercialization, we may seek to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we would be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, or from economic or political instability, or public health emergencies, such as the ongoing COVID-19 pandemic and related shelter-in-place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions;
- greater difficulty with enforcing our contracts;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- increased complexity and costs if foreign regulators require that certain manufacturing facilities, such as a stool donor program facility, be operated locally; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

As an organization, we have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by individual countries in Europe with which we may need to comply. If we are unable to successfully manage the challenges of international expansion and operations, our business and operating results could be harmed.

Coverage and adequate reimbursement may not be available for CP101 or any future product candidates, which could make it difficult for us to sell profitably or at all, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health

administration authorities, managed care organizations, pharmacy benefit management organizations, and other private health insurers. Microbiome therapy is a novel therapeutic approach and neither we nor, to our knowledge, any other company has received regulatory approval for a therapeutic based on this approach. We cannot be certain that third-party payors will provide sufficient reimbursement for any product candidates that we commercialize, if approved. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, 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.

While no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Therefore, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Obtaining positive Medicare coverage and reimbursement will be critical to the commercial success of CP101, if approved, as a large portion of the patient population with CDI are Medicare beneficiaries. Thus, if we are not able to secure coverage and Medicare reimbursement at sufficient levels, we may not be able to reach our intended target market for CP101, once approved, which would adversely affect our revenue and profits. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. We expect that the price of CP101, once approved, will be substantial, so the availability of coverage and reimbursement from third-party payors will be necessary to make CP101 assessable to patients. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize CP101 or any future product candidates that we develop. Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Even if we are successful in obtaining regulatory approval, commercial success of any approved products will also depend in large part on 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. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. If government and other healthcare payors were not to provide adequate insurance coverage and reimbursement levels for one any of our products once approved, market acceptance and commercial success would be limited.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. While we currently have no products that have been approved for commercial sale, from 2017 to 2019, we manufactured FMT materials, produced to specifications defined by OpenBiome, that were and may still be distributed and sold by OpenBiome for use under its interpretation of the FDA's policy of enforcement discretion for CDI not responding to standard therapies and for use in clinical research. This past use, as well as the current and future use of product candidates by us and our collaborators in clinical trials, and the potential sale of any approved products in the future, may expose us to liability claims. The FDA may not agree with OpenBiome's interpretation or application of the FDA's enforcement discretion policy to its product distribution activities, including its distributions to clinical sites without an IND in place with the FDA. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, our collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a product, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of our product candidates, if approved.

Although we believe we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Government Regulation

Our relationships with customers, healthcare providers, including physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from 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, in return for, or to induce, either the referral of an individual for, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for 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. 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. The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, signed into law in 2010, provides that the government may assert that 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 federal False Claims Act;

- the federal civil and criminal false claims laws, including, without limitation, the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and the federal Civil Monetary Penalty Law that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the United States federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, a person from 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), or knowingly and willfully falsifying, concealing or covering up, by any trick or device, a material fact or making any materially false, fictitious or fraudulent statement 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 does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which impose, among other things, requirements on health plans, healthcare clearinghouses and certain healthcare providers, known as “covered entities”, and their respective HIPAA “business associates”, which are independent contractors that perform certain services for or on behalf of covered entities involving the use or disclosure of

individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information. 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 HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value'' made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include information related to payments and other transfers of value provided in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives; and

- analogous state and foreign laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state 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 that otherwise restrict payments that may be made to healthcare providers; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.
The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action taken against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials that could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates

approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

If approved, our product candidates will be regulated as biologics, and thus may face competition from biosimilars approved through an abbreviated regulatory pathway.

We anticipate that our product candidates will be regulated as biological products. The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the United States pharmaceutical industry. The ACA, among other things: (i) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (ii) expanded the entities eligible for discounts under the 340B drug pricing program; (iii) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP; (iv) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (v) created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (vi) created a new Medicare Part D coverage gap discount program in which, as a condition of coverage of its products under Medicare Part D, manufacturers must now agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of 2019); (vii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (viii) established the Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law.

The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate."

Further, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform efforts of the Biden Administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030, unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. These laws may result in additional reductions in Medicare, Medicaid and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, former President Trump announced several executive orders related to prescription drug pricing that sought to implement several of the former administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The Trump administration took 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 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 requirements will be interpreted and implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for CP101 or any future product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of CP101 or other product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns 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 or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently from December 22, 2018 to January 25, 2019, 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.

Separately, in response to the COVID-19 pandemic, in March 2020 the FDA announced its intention to postpone most inspections and in July 2020 resumed them on a risk-based rating system. Should the FDA determine that a pre-approval inspection is necessary for approval of any of our product candidates and an inspection cannot be completed during the review cycle due to restrictions on travel, we may be issued a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

If we or our third-party manufacturers and suppliers 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 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, 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.

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

We are subject to anti-corruption laws, including the U.S. domestic bribery statute contained in 18 U.S.C. 201, the U.S. Travel Act, and the U.S. Foreign Corrupt Practices Act of 1977, as amended. These anti-corruption laws generally prohibit companies and their employees, agents, and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to recipients in the public or private sector. We can be held liable for the corrupt or illegal activities of our agents and intermediaries, even if we do not explicitly authorize or have actual knowledge of such activities. We are also subject to other U.S. laws and regulations governing export controls, as well as economic sanctions and embargoes on certain countries and persons.

Violations of these 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. Likewise, any investigation of potential violations of such laws could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third-party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third party contractors and CROs are required to comply with good laboratory practices, or GLPs, as applicable, and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GLPs and GCPs through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLPs and GCPs, the clinical data generated in our clinical trials may be deemed unreliable, the statistical analysis and clinical meaning of our datasets could be compromised and the FDA or comparable foreign regulatory authorities may limit our ability to include impacted data or require us to perform additional preclinical studies or clinical trials before approving our marketing applications. For example, we identified GCP compliance issues at two clinical trial sites that participated in

our PRISM3 study. In consultation with the FDA, we terminated those two sites and excluded data from the trial participants at those sites. While we monitor our clinical trial sites, we cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies or clinical trials comply with all applicable GLP or GCP regulations. In addition, our clinical trials must be conducted with product, including biologic product, produced in compliance with applicable cGMP regulations. Our failure or the failure of any third parties with whom we may contract comply with these regulations may require us to repeat preclinical studies or clinical trials, which would delay the regulatory approval process.

Further, these laboratories, investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent laboratories, investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is noncompliant, fraudulent or substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. Such laboratories, investigators and CROs may make errors while conducting trials or other clinical development activities, which could render any data derived therefrom incorrect or unusable. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs or clinical investigators do not successfully carry out their legal, regulatory or 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 preclinical or clinical protocols, regulatory requirements, professional standards of integrity or for other reasons, our preclinical or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional laboratories or CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our contracted laboratories and 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 results of operations.

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the integrity or validity of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient quantities of product candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance. We have not, nor to our knowledge, has any other company, received regulatory approval for a therapeutic based on this approach.

We do not currently have the infrastructure or capability internally to manufacture all our product candidates for use in the conduct of our preclinical studies and clinical trials or for commercial supply, if our products are approved. We rely on, and expect to continue to rely on, contract manufacturing organizations, or CMOs. Any replacement of our CMOs could require significant effort and expertise because there may be a limited number of qualified CMOs. This could be particularly problematic where we rely on a single-source supplier. For example, to date we have identified only one CMO that appears to be capable of manufacturing certain of the proprietary bacterial strains within FIN-524 with the yields and quality necessary to support our clinical development efforts. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We are dependent on our CMOs for the production of our product candidates in accordance with relevant regulations, such as cGMP, which includes, among

other things, quality control, quality assurance and the maintenance of records and documentation. Moreover, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position.

Our third-party manufacturers may be subject to damage or interruption from, among other things, fire, natural or man-made disaster, disease outbreaks or public health pandemics, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy and similar events. For example, the extent to which COVID-19 may impact our manufacturing and supply chain will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our demand for any of our product candidates, we could experience delays in our research or planned clinical trials or commercialization. We could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes who could meet our timelines at an acceptable cost. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, could significantly delay our preclinical studies, our clinical trials and the commercialization of our products, if approved, which could materially adversely affect our business, financial condition and results of operation.

In complying with the applicable manufacturing regulations of the FDA and comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. We and any of these third-party suppliers may also be subject to audits by the FDA and comparable foreign regulatory authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize the products could suffer significant interruptions. We face risks inherent in relying on CMOs, as any disruption, such as a fire, natural hazards, vandalism or an outbreak of contagious disease affecting the CMO or any supplier of the CMO could significantly interrupt our manufacturing capability. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as the CMO builds or locates replacement facilities and seeks and obtains necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all.

Our current and future collaborations will be important to our business. If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into partnerships in the future when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our product could change and our costs of development and commercialization could increase. Furthermore, we may find that our programs require the use of intellectual property rights held by third parties, and the growth of our business may depend in part on our ability to acquire or in-license these intellectual property rights.

For example, we are currently party to a collaboration agreement with Takeda, pursuant to which we have agreed to collaborate in the clinical development of our product candidates FIN-524 for the treatment of ulcerative colitis and FIN-525 for the treatment of Crohn’s disease. This and any future collaborations we enter into may pose a number of risks, including, but not limited to, the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators 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 or license arrangements based on clinical trial results, changes in the collaborators’ strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators 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 collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;

- collaborators 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 collaborators, 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;

- collaborators 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;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- if a collaborator 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

- collaborations 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 collaborations do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. 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 one of our collaborators terminates 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.

We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a partnership will depend, among other things, upon an assessment of the collaborator's resources and expertise, the terms and conditions of the proposed partnership and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of preclinical studies or clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of any uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, 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

capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates.

We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found to be infringed, invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our granted patents will be sufficient to stop a competitor from developing and commercializing a product, including a biosimilar product that would be competitive with one or more of our product candidates. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any of our product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not amenable to patent protection. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products, if approved, and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, our agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman

Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and 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 per approved drug product, and only those claims covering the approved drug product, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be impacted and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

If we fail to comply with our obligations in our current and future intellectual property licenses with third parties, we could lose rights that are important to our business.

We are reliant upon licenses to certain patent rights and proprietary technology for the development of our product candidates, in particular our license agreements with University of Minnesota and Skysong Innovations LLC. These license agreements impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations, our licensors may have the right to terminate our licenses, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in-license from such licensor and may face other penalties. Such an occurrence would materially adversely affect our business prospects.

Licenses to additional third-party technology and materials that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. We do not control the prosecution, maintenance and enforcement of all of our licensed and sublicensed intellectual property relating to our product candidates, and we thus require the cooperation of our licensors and any upstream licensor, including Skysong Innovations LLC and the University of Minnesota, which may not be forthcoming. Therefore, we cannot be certain that the prosecution, maintenance and enforcement of these patent rights will be in a manner consistent with the best interests of our business. If we or our licensor fail to maintain such patents, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we may own in the future. Further, if we fail to comply with our development obligations under our license agreements, we may lose our patent rights with respect to such agreement on a territory-by-territory basis, which would affect our patent rights worldwide.

Termination of our current or any future license agreements would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other product candidates, which could have a material adverse effect on our operating results and overall financial condition.

In addition, intellectual property rights that we in-license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the United States Patent and

Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States and Europe. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe the patents for which we have applied. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In certain circumstances it may not be practicable or cost effective for us to enforce our intellectual property rights fully, particularly in certain developing countries or where the initiation of a claim might harm our business relationships. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity.

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In an infringement proceeding, a court may decide that the patent claims we are asserting are invalid and/or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover the technology in question. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates. 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, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose some, and perhaps all, of the patent protection on our product candidates. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business. Moreover, even if we are successful in any litigation, we may incur significant expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patent applications. An unfavorable outcome could require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our product candidates.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or 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. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of future collaborators, if any, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference proceedings, post grant review and *inter partes* review before the USPTO or equivalent foreign regulatory authority. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Numerous patents and pending applications are owned by third parties in the fields in which we are developing product candidates, both in the United States and elsewhere. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products.

There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Foreign courts will have similar burdens to overcome in order to successfully challenge a third party claim of patent infringement.

We are aware of a patent estate with granted claims in the United States, Japan and China that may impact our competitive position with respect to one of our preclinical product candidates. While we believe that the granted claims may not be valid and that they may be reasonably challenged for validity, there can be no assurance that any such challenge would be successful. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. In addition, we use publications that are subject to copyright, as well as proprietary information and materials from third parties in our research. Some of the information and materials we use from third parties may be subject to agreements that include restrictions on use or disclosure. Although we strive to ensure proper safeguards, we cannot guarantee strict compliance with such agreements, nor can we be sure that our employees, consultants and advisors do not use proprietary information, materials, or know-how of others in their work for us. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

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

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents, or other intellectual property, including as an inventor or co-inventor. We may be subject to ownership or inventorship disputes in the future arising, for example, from conflicting obligations of consultants, contractors or others who are involved in developing our product candidates. Although 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, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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, valuable intellectual property. Such an outcome could have a material adverse effect on our business. 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.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed to others.

If we rely on third parties to manufacture or commercialize our product candidates, or if we collaborate with additional third parties for the development of such product candidates, we may need to, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our trade secrets and other proprietary technology in part by entering into confidentiality agreements with third parties prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. 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 the collaborators, 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 third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where enforcement rights are not as strong as those in the United States or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient defend our rights adequately.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. For example, certain jurisdictions do not allow for patent protection with respect to method of treatment.

While we seek to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, 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.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. 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.

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/or 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 patents and/or applications and any patent rights we may obtain in the future. Furthermore, the USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse of a patent or patent application 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 patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish our product candidates, if approved for marketing, from the drugs of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand

recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. Any of the foregoing events may have a material adverse effect on our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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. The following examples are illustrative:

- others may be able to make products that are similar to or otherwise competitive with our product candidates but that are not covered by the claims of our current or future patents;
- an in-license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our product candidates may be terminated by the licensor;
- we or future collaborators might not have been the first to make the inventions covered by our issued or future issued patents or our pending patent applications;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of our product candidates in all countries;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

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

We are highly dependent on our management team, including Mark Smith, Ph.D., our Chief Executive Officer, and Zain Kassam, M.D., M.P.H., our Chief Medical Officer. Each of them may currently terminate their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in

formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of June 30, 2021, we had 186 full-time employees, including 152 employees engaged in research and development. As our clinical development and commercialization plans and strategies develop, and as we continue operating as a public company, we expect we will need additional managerial, operational, sales, marketing, financial, legal and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our development efforts effectively, including the clinical trials of CP101 and our other product candidates, while complying with our contractual obligations to contractors and other third parties; 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 independent organizations, advisors and consultants to provide certain services. The services include substantially all aspects of clinical trial management and manufacturing for certain of our product candidates. We cannot assure you that the services of independent 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 preclinical studies or clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you 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 qualified 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 internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a significant disruption of our product development programs and our ability to operate our business effectively.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. The COVID-19 pandemic has generally increased the attack surface available for exploitation, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from “hackers” hoping to use the recent COVID-19 pandemic to their advantage.

While we have not experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials by us or our CROs could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, cause us not to comply with federal and/or state breach notification laws and foreign law equivalents and otherwise subject us to

liability under laws and regulations that protect the privacy and security of personal information. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, such measures may not prevent service interruptions or security breaches that could adversely affect our business and 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, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

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

Our operations, and those of our CROs, 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. We rely on third-party manufacturers to produce certain of our product candidates. 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.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business.

We and any current and future collaborators may be subject to federal, state, municipal and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our current or future collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We are subject to a variety of privacy and data security laws, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these laws, the requirements of which sometimes evolve with amendments, regulations and case law, can be subject to varying interpretations. In addition, new laws regulating privacy and data security continue to be passed in jurisdictions all over the world. In May 2018, a new privacy regime, the General Data Protection Regulation, or the GDPR, took effect in the European Economic Area, or the EEA. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data

protection laws, and imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

In addition, within the United States, states regularly adopt new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018. This law, which took effect on January 1, 2020, became enforceable by the California Attorney General on July 1, 2020, and has been dubbed the first "GDPR-like" law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. In addition, some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States as other states develop similar laws and we have already seen other states propose laws that are similar to the CCPA.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

An active trading market for our common stock may not develop and you may not be able to resell your shares of our common stock at an attractive price, if at all.

Prior to our IPO in March 2021, there was no public market for our common stock. Although our common stock is currently listed on The Nasdaq Global Select Market, we cannot assure you that an active trading market for our shares will develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares you purchased at an attractive price or at all.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile and may fluctuate as a result of a variety of factors, some of which are related in complex ways. Since shares of our common stock were sold in our IPO in March 2021 at $17.00 pers share, our stock price has ranged from an intraday low of $11.56 to an intraday high of $22.10 through August 3, 2021. The market price for our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors listed below and other factors described in this "Risk Factors" section:

- the results of our clinical trials of CP101 or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for CP101 or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results from, delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of CP101 or any other product candidate;
- unexpected regulatory actions related to the manufacture and testing of CP101 or any other product candidate;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- our relationships with our collaborators;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- 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;
- changes in the structure of healthcare payment systems;
- general political and economic conditions, including the effects of the ongoing COVID-19 pandemic; and

- other events or factors, many of which are beyond our control.

The stock market in general, and the Nasdaq Global Select Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. If at any time we do have equity research analyst coverage, we do not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

As of June 30, 2021, we had approximately 47.4 million shares of common stock outstanding. Of these shares, approximately 7.7 million shares of common stock sold in the IPO were freely tradeable, and the remaining 39.7 million shares of common stock will be available for sale in the public market following the expiration of lock-up agreements entered into by our stockholders in connection with the IPO. The representatives of the underwriters for our IPO may agree to release these stockholders from their lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market. Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of restrictions in the lock-up agreements, could cause the market price of our common stock to fall or make it more difficult to sell shares.

In addition, on March 26, 2021, we filed a registration statement on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, registering the issuance of the shares of common stock subject to options or other equity awards issued or reserved for future issuance under our 2017 Equity Incentive Plan, as amended, or 2017 Plan, our 2021 Equity Incentive Plan, or 2021 Plan, and our 2021 Employee Stock Purchase Plan, or ESPP. Shares registered under this registration statement on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options or warrants, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Additionally, the holders of an aggregate of 31,665,929 shares of our common stock and the holders of an aggregate of 39,330,184 shares of our common stock, or their transferees, will have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, respectively. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares 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.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

As of June 30, 2021, our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially owned greater than 50% of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from 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 in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will 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. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until December 31, 2026 or, if earlier, (i) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (ii) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, or (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We incur significant costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur significant legal, accounting and other costs. These costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the Securities and Exchange Commission, or SEC, and the Nasdaq Stock Market, or Nasdaq, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to

obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting.

Commencing with our fiscal year ending December 31, 2022, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to our IPO in March 2021, we have never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

In preparation for our IPO in March 2021, we identified a material weakness in our internal control over financial reporting. If we are not able to remediate the material weakness or if we otherwise fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial statements in a timely manner, which may adversely affect our business, investor confidence in our company and the market value of our common stock.

Although we are not yet subject to the certification or attestation requirements of Section 404 of the Sarbanes-Oxley Act, in the course of reviewing our financial statements for our IPO in March 2021, management and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting as we did not design and maintain effective review and approval controls over certain transactions and accounts.

A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. This material weakness in our system of internal controls as of December 31, 2019 relates to (1) an ineffective control environment, including a lack of sufficient accounting personnel and personnel with financial reporting expertise; (2) ineffective controls over cutoff, recording and classification of certain accounts, and the valuation and recognition of intangible assets acquired in a business combination that occurred in 2017; (3) ineffective risk assessment controls, including those policies and practices that would identify changes in our business practices, which could significantly impact our consolidated financial statements and system of internal controls; and (4) ineffective monitoring of controls related to the financial close and reporting process. As a result, there were adjustments required in connection with closing our books and records and preparing our 2019 financial statements.

We believe progress was made through June 30, 2021, including the efforts outlined in Item 4 of this Quarterly Report on Form 10-Q to enhance and strengthen our internal control over financial reporting. However, our internal controls were not in all cases in place for a sufficient period of time to demonstrate operating effectiveness as of June 30, 2021. As a result, management has concluded that the material weakness was not fully remediated as of June 30, 2021.

There can be no assurance that we will be successful in pursuing these measures or that these measures will significantly improve or remediate the material weakness described above. There is also no assurance that we have identified all of our material weaknesses or that we will not in the future have additional material weaknesses. If we fail to remediate the material weakness or to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results, or report them within the timeframes required by law or Nasdaq. Failure to comply with Section

404 could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. There is no assurance that we will be able to remediate the material weakness in a timely manner, or at all, or that in the future, additional material weaknesses will not exist or otherwise be discovered. If our efforts to remediate the material weakness identified are not successful, or if other material weaknesses or other deficiencies occur, our ability to accurately and timely report our financial position could be impaired, which could result in late filings of our required reports under the Exchange Act, restatements of our consolidated financial statements, a decline in the price of our common stock, suspension or delisting of our common stock from Nasdaq, and could adversely affect our reputation, results of operations and financial condition.

Changes in U.S. tax law could adversely affect our financial condition and results of operations.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. tax laws on an investment in our common stock.

We might not be able to utilize a significant portion of our net operating loss carryforwards.

We expect to generate significant federal and state net operating loss, or NOL, carryforwards in the future. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs, or the Tax Act, as modified by the CARES Act, federal NOLs incurred in taxable years beginning after December 31, 2017 and in future taxable years may be carried forward indefinitely, but the deductibility of such federal NOLs incurred in the taxable year beginning after December 31, 2020 is limited. It is uncertain how various states will respond to the Tax Act and CARES Act. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. The completion of our IPO in March 2021, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. We have not yet completed a Section 382 analysis. We may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

While we have been recently notified of forgiveness of our PPP Loan, our application for the PPP Loan could in the future be determined to have been impermissible or could result in damage to our reputation.

In April 2020, we received proceeds of $1.8 million from the PPP Loan. We have used the PPP Loan to retain current employees, maintain payroll and make lease and utility payments. On May 8, 2021, we received notice from the SBA that the entirety of the PPP Loan we received was forgiven. Accordingly, we are no longer required to repay the $1.8 million in principal and approximately $19,000 in accrued interest borrowed under the PPP Loan.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the PPP. The certification described above does not contain any objective criteria and is subject to interpretation. If, despite our good-faith belief that given our circumstances we satisfied all eligible requirements for the PPP Loan, we are later determined to have violated any of the laws or governmental regulations that apply to us in connection with the PPP Loan, such as the False Claims Act, or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP Loan in its entirety. In addition, receipt of a PPP Loan may result in adverse publicity and damage to reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors will have the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action asserting a breach of fiduciary duty;
- any claim or cause of action against us arising under the Delaware General Corporation Law;
- any claim or cause of action arising under or seeking to interpret our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any claim or cause of action against us that is governed by the internal affairs doctrine.

The provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

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

(a) Recent Sales of Unregistered Securities

None.

(b) Use of Proceeds

On March 23, 2021, we closed our IPO, in which we issued and sold an aggregate of 7,500,000 shares of common stock at a public offering price of $17.00 per share. All of the shares of common stock issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (Registration No. 333-253622), which was declared effective by the SEC on March 18, 2021.

The aggregate net proceeds to us from the public offering were approximately $115.7 million, after deducting underwriting discounts and commissions and offering expenses payable by us of approximately $2.9 million.

There has been no material change in the use of proceeds from our IPO from those disclosed in the final prospectus for our IPO dated March 18, 2021 and filed with the SEC pursuant to Rule 424(b)(4) of the Securities Act on March 22, 2021.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description	Incorporated by Reference			
		Schedule Form	File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Finch Therapeutics Group, Inc.	8-K	001-40227	3.1	March 23, 2021
3.2	Amended and Restated Bylaws of Finch Therapeutics Group, Inc.	8-K	001-40227	3.2	March 23, 2021
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	Inline XBRL Instance Document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith.

\+ This certification is being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

FINCH THERAPEUTICS GROUP, INC.

Date: August 10, 2021

By: /s/ Mark Smith
Mark Smith, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: August 10, 2021

By: /s/ Gregory D. Perry
Gregory D. Perry
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

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

I, Mark Smith, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Finch Therapeutics Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) 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

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2021

By: /s/ Mark Smith
Mark Smith, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Gregory D. Perry, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Finch Therapeutics Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) 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

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2021

By: /s/ Gregory D. Perry
Gregory D. Perry
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Finch Therapeutics Group, Inc. (the "Company") for the quarter ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the company, hereby certifies, pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to his or her knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

Date: August 10, 2021

By: /s/ Mark Smith
Mark Smith, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: August 10, 2021

By: /s/ Gregory D. Perry
Gregory D. Perry
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)