UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

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 November 7, 2022 there were 47,897,675 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 September 30, 2022

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. 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, including our ability to satisfactorily address FDA correspondence;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to obtain regulatory approval of CP101, and any other current or 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;
- our ability to contract with contract research organizations, contract manufacturing organizations, third-party suppliers and manufacturers and other third parties with which we do business and their ability to perform adequately;
- our expectations regarding the potential market size and the rate and degree of market acceptance for any product candidates that we develop;
- our ability to fund our working capital requirements and to service any debt obligations we may incur;
- 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; and
- our ability to obtain additional funding for our operations;

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: uncertainties relating to regulatory applications and related filing and approval timelines; our limited operating history and historical losses; our ability to raise additional funding to complete the development and any commercialization of our product candidates and the potential impact of termination of our collaboration with Takeda on such funding requirements and our ability to obtain funding; the possibility that we may be delayed in initiating, enrolling or completing any clinical trials; results of clinical trials may not be sufficient to satisfy regulatory authorities to approve our product candidates in their targeted or other indications (or such authorities may request additional trials or additional information); results of clinical trials may not be indicative of final or future results from later stage or larger clinical trials (or in broader patient populations once the product is approved for use by regulatory agencies) or may not be favorable or may not support further development; unexpected regulatory actions or delays, such as requests for additional safety and/or efficacy data or analysis of data, and including with respect to the FDA's planned review of the validation package for one of our release tests, which is utilized for CP101, or government regulation generally; the possibility that we may experience unanticipated regulatory or other development problems with any of our product candidates; our ability to comply with regulatory requirements and continued regulatory review, which may result in significant additional expense and with respect to which we may be subject to penalties for failure to comply; our ability to maintain patent and other intellectual property protection and the possibility that our intellectual property rights may be infringed, invalid or unenforceable or will be threatened by third parties; the possibility that third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights; our ability to qualify and scale our manufacturing capabilities to support multiple global clinical trials; our dependence on third parties in connection with manufacturing, clinical trials and preclinical studies; the impact and duration of the COVID-19 pandemic on our business, as well as those described under "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, and in any other reports we file with the Securities and Exchange Commission, including this Quarterly Report on Form 10-Q. 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 such information may be limited or incomplete. These 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 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 our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in our 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.

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)

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 85,292	$ 133,481
Accounts receivable	—	494
Prepaid expenses and other current assets	5,324	8,576
Total current assets	90,616	142,551
Property and equipment, net	17,280	19,635
Operating right-of-use assets	40,355	5,053
In-process research and development	32,900	32,900
Goodwill	—	18,057
Restricted cash, non-current	2,568	2,268
Other assets	4,249	4,905
TOTAL ASSETS	$ 187,968	$ 225,369
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,060	$ 3,737
Accrued expenses and other current liabilities	10,107	9,925
Operating lease liabilities, current	2,641	1,128
Total current liabilities	13,808	14,790
Deferred tax liability	3,461	3,461
Loan payable, non-current	14,636	—
Operating lease liabilities, non-current	35,072	4,887
Other liabilities	125	7
Total liabilities	67,102	23,145
COMMITMENTS AND CONTINGENCIES (Note 11)		
STOCKHOLDERS' EQUITY:		
Common stock, $0.001 par value; 200,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 47,826,506 and 47,512,182 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	48	47
Additional paid-in capital	369,451	363,172
Accumulated deficit	(248,633)	(160,995)
Total stockholders' equity	120,866	202,224
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 187,968	$ 225,369

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 SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
REVENUE:				
Collaboration revenue	$ 138	$ 11,343	$ 853	$ 17,726
Total revenue	138	11,343	853	17,726
OPERATING EXPENSES:				
Research and development	(11,859)	(15,537)	(41,312)	(42,476)
General and administrative	(9,584)	(5,739)	(27,152)	(16,173)
Impairment of goodwill	(18,057)	—	(18,057)	—
Restructuring expense	(1,270)	—	(2,173)	—
Total operating expenses	(40,770)	(21,276)	(88,694)	(58,649)
Net loss from operations	(40,632)	(9,933)	(87,841)	(40,923)
OTHER INCOME (EXPENSE), NET:				
Gain on extinguishment of PPP Loan	—	—	—	1,827
Interest income (expense), net	45	8	(7)	14
(Loss) gain on disposal of fixed assets, net	—	—	(6)	28
Other income (expense), net	216	(30)	216	(51)
Total other income (expense), net	261	(22)	203	1,818
Loss before income taxes	(40,371)	(9,955)	(87,638)	(39,105)
Income tax provision	—	—	—	—
Net loss	$ (40,371)	$ (9,955)	$ (87,638)	$ (39,105)
Net loss attributable to common stockholders—basic and diluted (Note 17)	$ (40,371)	$ (9,955)	$ (87,638)	$ (39,105)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.85)	$ (0.21)	$ (1.84)	$ (1.07)
Weighted-average common stock outstanding—basic and diluted	47,728,130	47,445,195	47,611,872	36,408,506

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	EQUITY (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
Exercise of common stock options	—	—	—	—	—	—	—	—	29,210	—	48	—	48
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	1,515	—	1,515
Net loss	—	—	—	—	—	—	—	—	—	—	—	(9,955)	(9,955)
BALANCE, September 30, 2021	—	$ —	—	$ —	—	$ —	—	$ —	47,454,962	$ 47	$ 361,694	$ (141,940)	$ 219,801

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

	COMMON STOCK $0.001 PAR VALUE		ADDITIONAL PAID-IN	ACCUMULATED	TOTAL STOCKHOLDERS'
	SHARES	AMOUNT	CAPITAL	DEFICIT	EQUITY
BALANCE, January 1, 2022	47,512,182	$ 47	$ 363,172	$ (160,995)	$ 202,224
Exercise of common stock options	20,406	1	13	—	14
Stock-based compensation	—	—	2,120	—	2,120
Net loss	—	—	—	(24,567)	(24,567)
BALANCE, March 31, 2022	47,532,588	$ 48	$ 365,305	$ (185,562)	$ 179,791
Exercise of common stock options	98,370	—	61	—	61
Issuance of common stock under employee stock purchase plan	54,755	—	110	—	110
Stock-based compensation	—	—	1,830	—	1,830
Net loss	—	—	—	(22,700)	(22,700)
BALANCE, June 30, 2022	47,685,713	$ 48	$ 367,306	$ (208,262)	$ 159,092
Exercise of common stock options	40,328	—	44	—	44
Vesting of restricted stock units	100,465	—	—	—	—
Stock-based compensation	—	—	2,101	—	2,101
Net loss	—	—	—	(40,371)	(40,371)
BALANCE, September 30, 2022	47,826,506	$ 48	$ 369,451	$ (248,633)	$ 120,866

See notes to unaudited condensed consolidated financial statements.

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (87,638)	$ (39,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	4,099	1,623
Stock-based compensation expense	6,051	2,755
Impairment of goodwill	18,057	—
Gain on extinguishment of PPP Loan	—	(1,808)
Non-cash interest expense	105	—
Loss (gain) on sale of property and equipment	6	(28)
Other non-cash operating lease cost	1,898	674
Changes in operating assets and liabilities:		
Accounts receivable	494	(1,365)
Due from related party	—	61
Prepaid expenses and other current assets	(4,484)	791
Other non-current assets	656	(3,824)
Accounts payable	(2,296)	(1,297)
Accrued expenses and other current liabilities	189	2,811
Other non-current liabilities	50	—
Due to related party	—	(266)
Deferred revenue	—	(13,630)
Operating lease liabilities	2,234	(738)
Net cash used in operating activities	(60,579)	(53,346)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(2,131)	(13,981)
Proceeds from sale of property and equipment	—	62
Net cash used in investing activities	(2,131)	(13,919)
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 finance lease obligation	(14)	(25)
Proceeds from exercise of stock options and issuance of common stock under employee stock purchase plan	229	100
Proceeds from borrowings under loan agreement, net	14,738	—
Payment of deferred offering costs	(132)	(2,659)
Net cash provided by financing activities	14,821	119,040
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(47,889)	51,775
Cash, cash equivalents and restricted cash at beginning of period	135,965	99,909
Cash, cash equivalents and restricted cash at end of period	$ 88,076	$ 151,684
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 407	$ 7
Cash received (paid) in connection with operating lease liabilities	$ 809	$ (1,064)
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment in accounts payable and accrued liabilities	$ —	$ 218
Conversion of redeemable convertible preferred stock into common stock	$ —	$ 233,053
Operating right-of-use assets obtained in exchange for new operating leases upon adoption of ASC 842	$ —	$ 5,965
Remeasurement of right-of-use asset	$ 106	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 37,094	$ —
Prepaid rent reclassified to right-of-use assets	$ 7,736	$ 824
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:

	NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021
Cash and cash equivalents	$ 85,292	$ 149,200
Restricted cash	2,784	2,484
Total cash, cash equivalents and restricted cash	$ 88,076	$ 151,684

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, 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, is an orally administered complete microbiome therapeutic in development for the prevention of recurrent *Clostridioides difficile* infection ("CDI").

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 due to the emergence of variants of the virus, and the impact of the ongoing pandemic on clinical trial enrollment, trial sites, contract research organizations, contract manufacturing organizations, and other third parties with which 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 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 cash and cash equivalents of $85.3 million as of September 30, 2022 will allow the Company to continue its operations for at least the next 12 months from the date these financial statements are issued. 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 its ongoing research and development ("R&D") efforts, 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 of 1933, as amended, 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, 2021 included in the Company's Annual Report on Form 10-K, filed with the SEC on March 31, 2022.

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 that are necessary for a fair presentation of the Company's condensed consolidated balance sheets as of September 30, 2022 and December 31, 2021, condensed consolidated statements of operations for the three and nine months ended September 30, 2022 and 2021, condensed consolidated statements of stockholders' equity (deficit) for the three and nine months ended September 30, 2022 and 2021, and condensed consolidated cash flows for the nine months ended September 30, 2022 and 2021. Such adjustments are of a normal and recurring nature. The results of operations for the nine months ended September 30, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Significant Accounting Policies

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other accounting standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on the condensed consolidated statements or disclosures.

The significant accounting policies and estimates used in preparation of the unaudited interim condensed consolidated financial statements are described in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 31, 2022. There have been no material changes to the Company's significant accounting policies during the nine months ended September 30, 2022.

Goodwill and Acquired In-Process Research and Development

Goodwill and in-process research and development ("IPR&D") are evaluated annually for impairment on October 1, or more frequently if events or changes in circumstances indicate that the asset might be impaired. To conduct impairment tests of goodwill, the fair value of the Company's single reporting unit is compared to its carrying value. If the reporting unit's carrying value exceeds its fair value, the Company records an impairment loss to the extent that the carrying value of goodwill exceeds its fair value.

To conduct impairment tests of IPR&D, the fair value of the IPR&D asset is compared to its carrying value. If the carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of the IPR&D asset exceeds its fair value. We estimate the fair value for our IPR&D asset using discounted cash flow valuation models, which require the use of significant estimates and assumptions, including, but not limited to, estimating the timing of and expected costs to complete in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed projects and in-process projects, and developing appropriate discount rates.

In connection with its preparation of the financial statements for the third quarter of 2022, management identified factors that could trigger impairment including a sustained decline in the Company's stock price throughout the third quarter of 2022, resulting in a reduction of the Company's market capitalization below net book value. As a result of the triggering event identified, management concluded that this impairment indicator required the Company to perform an interim impairment test of goodwill and IPR&D as of September 30, 2022.

Management utilized the discounted cash flow ("DCF") and multi-period excess earnings method ("MPEEM"), both variations of the income approach, to derive the fair values of the Company and the CP101 IPR&D asset as of September 30, 2022, respectively. The DCF method was leveraged to calculate the fair value of the Company on an equity level basis for Management's use in goodwill impairment testing procedures. The MPEEM was leveraged to calculate the fair value of the CP101 IPR&D for Management's use in IPR&D impairment testing procedures. The MPEEM approach calculates the fair value of an asset or entity by estimating the after-tax cash-flows attributable to an asset or entity, applying contributory asset charges to reflect other tangible and intangible assets being in place to help achieve the subject item's future cash flows, and then discounting the net cash flows to a present value using a risk-adjusted discount rate.

The cash flow projections in these fair value analyses for the Company and the CP101 IPR&D are considered Level 3 inputs, and consist of Management's estimates of revenue growth rates and operating margins, taking into consideration historical results in addition to applicable industry and market conditions. The discount rate used in the fair value analysis for the Company is based on a weighted average cost of capital, which represents the weighted average rate a business must pay its providers of debt and equity. The

discount rate used in the fair value analysis for the CP101 IPR&D is based on the weighted average cost of capital in addition to consideration of various industry resources for venture capital rates of return.

Management's assessment for the impairment of goodwill indicated that the fair value of the Company's reporting unit was less than its carrying value at September 30, 2022, resulting in a full impairment charge of $18.1 million included as impairment of goodwill on the Company's statement of operations.

Management's assessment for the impairment of IPR&D indicated that the fair value of the Company's IPR&D asset at September 30, 2022 exceeded its carrying value, resulting in no impairment to IPR&D as of September 30, 2022.

The assumptions related to the development of fair value for IPR&D could deviate materially from actual results and forecasts used to support the asset's carrying value and may change in the future, which could result in impairment charges that would adversely affect financial results of operations.

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 nine months ended September 30, 2022, as compared to the recent accounting pronouncements described in Note 2 of the Company's condensed consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2021.

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	SEPTEMBER 30, 2022	QUOTED PRICES IN ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 3)
Asset				
Money market funds	$ 83,885	$ 83,885	$ —	$ —
Total financial assets	$ 83,885	$ 83,885	$ —	$ —

DESCRIPTION	DECEMBER 31, 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	$ 132,275	$ 132,275	$ —	$ —
Total financial assets	$ 132,275	$ 132,275	$ —	$ —

There were no transfers between fair value levels during the nine months ended September 30, 2022 and the year ended December 31, 2021. 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. The carrying value of the loan payable on the Company's balance sheet is estimated to approximate its fair value as the interest rate approximates the market rate for loans with similar terms and risk characteristics.

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following as of September 30, 2022 and December 31, 2021 (in thousands):

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Lab equipment	$ 4,460	$ 3,850
Office furniture and fixtures	1,354	537
Leasehold improvements	13,972	13,894
Construction work-in-progress	564	329
Software	4,883	4,883
Computer equipment	368	368
Total	$ 25,601	$ 23,861
Less: Accumulated depreciation	(8,321)	(4,226)
Property and equipment, net	$ 17,280	$ 19,635

Depreciation expense was $4.1 million and $1.6 million for the nine months ended September 30, 2022 and 2021, respectively. During the year ended December 31, 2021, the Company purchased $3.9 million of software, property, and equipment from Microbiome Health Research Institute Inc. doing business as OpenBiome ("OpenBiome"), under the Asset Purchase Agreement, dated as of November 19, 2020 between the Company and OpenBiome (the "OpenBiome Agreement"). As of September 30, 2022, the Company held $2.3 million of the assets purchased from OpenBiome. For additional information on the OpenBiome Agreement, see Note 15.

5. LEASES

The Company adopted Accounting Standards Codification ("ASC") 842, *Leases*, during the quarter ended December 31, 2021, with an effective date of January 1, 2021, using the modified retrospective approach and utilizing the effective date as its date of initial application. The Company's condensed consolidated financial statements presented for fiscal year 2021 have been adjusted to reflect the impact of adoption of ASC 842 as of the effective date of January 1, 2021. The adoption of this standard resulted in the recognition of operating lease right-of-use assets of $5.8 million and current and noncurrent operating lease liabilities of $0.9 million and $5.9 million, respectively, and the derecognition of deferred rent liabilities and unamortized lease incentives of $0.8 million and $0.2 million, respectively, on the Company's balance sheet as of January 1, 2021 relating to its office lease in Somerville, Massachusetts. The adoption of this standard did not have a significant impact on the Company's consolidated Statements of Operations or Statements of Cash Flows as of January 1, 2021.

As of September 30, 2021 the adoption of ASC 842 resulted in the recognition of operating lease right-of-use assets of $5.3 million and current and noncurrent operating lease liabilities of $1.1 million and $5.2 million, respectively, and the derecognition of deferred rent liabilities and unamortized lease incentives of $0.7 million and $0.2 million, respectively, on the Company's condensed consolidated balance sheet, relating to its office lease in Somerville, Massachusetts. The adoption of ASC 842 for the nine months ended September 30, 2021 resulted in an impact to the condensed consolidated statement of cash flows of an increase of $0.7 million in other non-cash operating lease cost, a decrease of $0.7 million in operating lease liabilities and a net change in both accrued expenses and other liabilities and deferred rent of less than $0.1 million, respectively. Additionally, in the supplemental disclosure of cash flow information, the Company recognized $1.1 million in cash paid in connection with operating lease liabilities and $6.0 million in operating right-of use assets obtained in exchange for new operating leases upon adoption of ASC 842. The adoption of ASC 842 had no material impact to the condensed consolidated statement of operations for the nine months ended September 30, 2021.

Inner Belt Road Lease

In December 2015, the Company entered into a 10-year lease agreement (the "Inner Belt Road Lease") for approximately 25,785 square feet of space for its primary office and laboratory space in Somerville, Massachusetts. 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 (the "Inner Belt Road Sublease") to share its leased space under the Inner Belt Road Lease with OpenBiome, a related party, as sub-tenant. The Inner Belt Road Sublease provided for an allocation, based on OpenBiome's proportionate share, of base rent and other expenses under the Inner Belt Road Lease, which was subject to change each year based on headcount and space used. In November 2020, pursuant to the OpenBiome Agreement, the Company and

OpenBiome amended the terms of the Inner Belt Road Sublease to provide for a reduction in the size of the subleased premises upon the closing of the OpenBiome Agreement (see Note 15), which occurred on March 1, 2021. The Inner Belt Road Sublease was further amended on January 15, 2021 and June 22, 2021 and terminated on December 31, 2021.

The Company's lease expense under the Inner Belt Road Lease was $0.9 million and $1.0 million for the nine months ended September 30, 2022 and 2021, respectively. The Company recognized sublease income under the sublease to OpenBiome as rent was received over the sublease term. Gross lease income under the sublease to OpenBiome for the nine months ended September 30, 2021 was $0.1 million and is presented as an offset to lease expense on the condensed consolidated statements of operations.

Cherry Street Lease

On March 1, 2021, the Company assumed a lease agreement (the “Cherry Street Lease”) in conjunction with the closing of the OpenBiome Agreement. The lease term is from March 2021 through February 2023. The Company’s lease expense under the Cherry Street Lease for the nine months ended September 30, 2022 and 2021 was $74,700 and approximately $58,000, respectively.

Concord Avenue Lease

On May 25, 2021, Finch entered into a lease agreement (the "Concord Avenue Lease") from May 2021 through February 2022. The Company’s lease expense under the Concord Avenue Lease was $0.1 million for each of the nine months ended September 30, 2022 and 2021. On August 17, 2021 Finch extended the term of the lease for an additional two-month period through April 2022 and on February 4, 2022, Finch further extended the lease for an additional month through May 2022. The Concord Avenue Lease qualifies as a short-term lease and will be excluded from the balance sheet.

Hood Lease

On August 3, 2021, Finch entered into a 10-year lease agreement (the "Hood Lease") with Hood Park LLC, pursuant to which Finch will lease approximately 61,139 square feet of office and laboratory space (the "Premises"). The Hood Lease provides Finch with an option to extend the lease for one additional five-year term. Finch’s annual base rent for the Premises started at approximately $4.5 million, and the lease contains annual rent escalations. Finch became responsible for paying rent under the Hood Lease on January 1, 2022 and commenced business operations in the Premises in the second quarter of 2022, which triggered recognition of the lease for accounting purposes. The Company recognized a right-of-use asset totaling $37.1 million and lease liability of $29.4 million upon the commencement of the lease. Lease expense related to the Hood Lease of $2.3 million was recorded for the nine months ended September 30, 2022.

The Hood Lease provided for a tenant improvement allowance of approximately $14.8 million for the cost of Finch’s work on the Premises. As of September 30, 2022, $14.8 million of lessor owned tenant improvements were completed by the Company, $0.5 million of which is the outstanding remaining balance owed to the Company by the lessor as of September 30, 2022.

Finch posted 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. This is included in restricted cash, non-current on the condensed consolidated balance sheet as of September 30, 2022 and December 31, 2021.

In the third quarter of 2022, Finch entered into a sublease agreement to sublet approximately one third of its leased space under the Hood Lease, which commenced on August 10, 2022, for an initial term of two years, with an option for Finch to extend the sublease for up to one additional year. In the fourth quarter of 2022, Finch entered into a second sublease agreement to sublet the remainder of its leased space under the Hood Lease for a three-year term. For the nine months ended September 30, 2022, Finch recognized sublease income of $0.2 million, which is presented as other income in the condensed consolidated statements of operations.

The following table presents the classification of right-of-use assets and lease liabilities as of September 30, 2022 and December 31, 2021 (in thousands):

	BALANCE SHEET CLASSIFICATION	SEPTEMBER 30, 2022	DECEMBER 31, 2021
ASSETS			
Operating lease assets	Operating right-of-use assets	$ 40,355	$ 5,053
Finance lease assets	Property and equipment, net	5	22
Total lease assets		40,360	5,075
Liabilities			
Current			
Operating lease liabilities	Operating lease liabilities, current	$ 2,641	$ 1,128
Finance lease liabilities	Other current liabilities	11	19
Noncurrent			
Operating lease liabilities	Operating lease liabilities, non-current	35,072	4,887
Finance lease liabilities	Other liabilities	—	7
Total lease liabilities		$ 37,724	$ 6,041

The following table represents the components of lease cost, which are included in general and administrative and research and development expense on the statement of operations, for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
LEASE COST	**2022**	**2021**	**2022**	**2021**
Finance lease cost:				
Amortization of right-of-use assets	$ 3	$ 4	$ 14	$ 25
Interest on lease liabilities	1	2	4	7
Operating lease cost	1,724	435	3,374	1,122
Short-term lease cost	18	11	157	25
Variable lease cost	481	131	1,445	271
Sublease income	(216)	(9)	(216)	(79)
Total lease cost	$ 2,011	$ 574	$ 4,778	$ 1,371

The weighted-average remaining lease term and discount rate as of September 30, 2022 and December 31, 2021 were as follows (in thousands):

LEASE TERM AND DISCOUNT RATE	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Weighted-average remaining lease term (years)		
Operating leases	8.7	4.6
Finance Leases	0.5	1.2
Weighted-average discount rate		
Operating leases	8.3%	6.7%
Finance Leases	30.6%	30.6%

Supplemental disclosure of cash flow information related to leases for the nine months ended September 30, 2022 and 2021 was as follows (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,	
SUPPLEMENTAL CASH FLOW INFORMATION	**2022**	**2021**
Cash paid for amounts included in measurement of lease liabilities		
Operating cash flows from operating leases	$ (2,234)	$ 738
Financing cash flows from finance leases	14	25

The following table represents a summary of the Company's future lease payments required as of September 30, 2022 (in thousands):

	OPERATING LEASE OBLIGATIONS	FINANCE LEASE OBLIGATIONS	TOTAL LEASE OBLIGATIONS
2022	$ 1,065	$ 12	$ 1,077
2023	6,103	—	6,103
2024	6,255	—	6,255
2025	6,427	—	6,427
2026	6,187	—	6,187
Thereafter	27,605	—	27,605
Total future minimum lease payments	$ 53,642	$ 12	$ 53,654
Less: amount representing interest	(15,929)	(1)	(15,930)
Present value of future minimum lease payments	$ 37,713	$ 11	$ 37,724

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following as of September 30, 2022 and December 31, 2021 (in thousands):

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Accrued research and development	$ 907	$ 1,345
Accrued legal and professional fees	5,087	1,117
Accrued compensation and benefits	2,553	4,401
Accrued other	1,560	3,062
Total accrued expenses and other current liabilities	$ 10,107	$ 9,925

7. LOAN PAYABLE

Hercules Loan and Security Agreement

On May 11, 2022 (the "Closing Date") the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc., which provides for a term loan with aggregate maximum borrowings of up to $55.0 million (the "Term Loan"). Under the Loan Agreement, the Company borrowed an initial amount of $15.0 million, and, subject to the terms of the Loan Agreement and conditioned upon the Company's compliance with certain operating covenants contained therein, the Loan Agreement provides for an additional $20.0 million under the first tranche of the Term Loan, and an additional $20.0 million from the second tranche subject to certain milestones and conditions. Although the Company is currently in compliance with its obligations under the Loan Agreement, following Takeda's election to terminate the Takeda Agreement, the Company is unable to draw future amounts under the Loan Agreement without the consent of the lender.

The Term Loan bears interest at a variable annual rate equal to the greater of (i)(a) 4.05% plus (b) the Prime Rate (as reported in the Wall Street Journal) and (ii) 7.55%. Borrowings under the Loan Agreement are repayable in monthly interest-only payments through December 1, 2024, or December 1, 2025 if certain conditions have been achieved prior to December 1, 2024. After the interest-only payment period, borrowings under the Loan Agreement are repayable in equal monthly payments of principal and accrued interest

until November 1, 2026. At the Company's option, the Company may prepay all or a portion of the outstanding borrowings, subject to a prepayment fee of 3.0% of the principal amount if prepayment occurs during the 12 months following the Closing Date, 2.0% after 12 months following the Closing Date and 1.0% after 24 months but on or prior to 36 months following the Closing Date.

The Company paid a $0.3 million facility charge upon closing and will pay a facility charge in connection with a draw under the second tranche of the Term Loan equal to 0.75% of the amount drawn. The Loan Agreement also provides for a final payment, payable upon maturity or the repayment of the obligations in full or in part (on a pro rata basis), equal to 5.50% of the aggregate principal amount of Term Loans advanced to the Borrower and repaid on such date, which is being accrued to other liabilities. The Loan Agreement includes a minimum cash covenant of $12.5 million that applies commencing on the date the principal amount borrowed under the Term Loan exceeds $25.0 million, subject to waiver upon satisfaction of certain conditions as set forth in the Loan Agreement. Borrowings under the Loan Agreement are collateralized by substantially all of the Company’s personal property and other assets, other than its intellectual property. In addition, the Loan Agreement includes certain customary affirmative and restrictive covenants, representations and warranties, and requires the Company to maintain its cash in controlled deposit accounts.

The loan payable balance as of September 30, 2022 consisted of the following (in thousands):

	SEPTEMBER 30, 2022
Principal amount of loan payable	$ 15,000
Less: current portion of loan payable	—
Loan payable, net of current portion	15,000
Facility charge	(242)
Unamortized issuance costs	(122)
Loan payable, including accretion, net of current portion	$ 14,636

The estimated future principal payments as of September 30, 2022 were due as follows (in thousands):

	SEPTEMBER 30, 2022
2022	$ —
2023	—
2024	574
2025	7,210
2026	7,216
Total	$ 15,000

8. RESTRUCTURING

During the three and nine months ended September 30, 2022 the Company recognized restructuring charges of $1.3 million and $2.2 million consisting of one-time severance payments, healthcare coverage, outplacement services and related expenses in connection with the Company's April 2022 restructuring action (the "April Restructuring") and September 2022 restructuring action (the "September Restructuring"). The April Restructuring was substantially completed by the end of the second quarter of 2022 and the remaining charges were incurred in the third quarter of 2022.

The September Restructuring began in the third quarter of 2022 and is expected to be substantially complete in the fourth quarter of 2022, and the Company expects to incur approximately $0.3 million in future periods related to this restructuring action. The accrued restructuring liability is included in accrued compensation and benefits as of September 30, 2022.

The following table summarizes the restructuring accrual activity for the nine months ended September 30, 2022 (in thousands):

	SEVERANCE AND RELATED BENEFITS
Accrued restructuring liability as of December 31, 2021	$ —
Restructuring charges	2,173
Cash payments	(1,161)
Accrued restructuring liability as of September 30, 2022	$ 1,012

9. REVENUE

Takeda Pharmaceutical Company Limited

In January 2017, the Company entered into an agreement (as amended, the "Takeda Agreement") with 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 (formerly known as "TAK-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. The Company further amended the Takeda Agreement in August 2021 to transition primary responsibility for further development and manufacturing activities with respect to FIN-524 from the Company to Takeda in accordance with a transition plan, and Takeda assumed sole responsibility for regulatory matters with respect to FIN-524. In November 2021, the Takeda Agreement was amended again to enable the Company to carry out certain preliminary evaluation activities with respect to FIN-525. In August of 2022, Takeda elected to terminate the Takeda Agreement and in October of 2022, the Takeda Agreement was amended to reflect the parties' transition plans.

Under the terms of the Takeda Agreement, the Company 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 program to develop a live biotherapeutic product optimized for the treatment of Crohn's disease. The Company assessed this arrangement in accordance with ASC 606, *Revenue from Contracts with Customers,* and concluded that the contract counterparty, Takeda, is a customer. The Company identified the following material promises at the outset of the Takeda Agreement: (1) an exclusive license to use the Company's rights in intellectual property to conduct research activities; (2) R&D services for activities under the development plan; (3) two options to pursue different indications of research for the Company's right in product candidates; (4) manufacturing and supply for the Company's clinical trials; and (5) participation on a joint steering committee and joint development committee. The options were considered distinct from the other promises in the arrangement and analyzed for material rights; the Company concluded these were not material rights and the consideration related to them should be excluded as a performance obligation until the option is exercised. The Company determined that the remaining promises were not capable of being distinct from one another and were not distinct in the context of the contract. In accordance with the Company's ASC 606 assessment, the Takeda Agreement was determined to contain a single combined performance obligation made up of the promises above, excluding the options. The FIN-525 feasibility study was determined to be part of the single combined performance obligation due to its connection to the original license and research and development activities. The FIN-525 feasibility study was completed in March 2021.

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 included the upfront payment and the estimable reimbursable R&D costs in the transaction price and recognized revenue associated with it over the period it expected to perform R&D services. Under the original agreement the estimated term for the R&D and manufacturing services for which the Company had primary responsibility, was through Phase 1 clinical trials.

On August 9, 2021, the Company and Takeda entered into an amendment to the amended and restated Takeda Agreement (the "Amendment"). Pursuant to the Amendment, Finch and Takeda transitioned primary responsibility for such development and manufacturing activities from Finch to Takeda in accordance with an agreed upon transition plan, and Takeda also assumed sole responsibility for regulatory matters with respect to FIN-524. The Company accounted for the Amendment as a modification to the existing contract under ASC 606, as the Amendment significantly reduced the remaining performance obligations, which were then completed by September 30, 2021. As a result, the remaining revenue that had been deferred under the Takeda Agreement was recognized in the third quarter of 2021.

In November 2021, Takeda and Finch entered into an amendment to the Takeda Agreement ("Amendment #2"). Pursuant to Amendment #2, Finch was obligated to perform certain additional research activities related to the feasibility of the FIN-525 program prior to Takeda making the decision to initiate the full development program. Under Amendment #2, Takeda paid Finch for pass-through costs incurred and research services performed at the agreed-upon full-time equivalent rate. The additional feasibility work was completed in the second quarter of 2022.

In August 2022, the Company received written notice from Takeda that, following a review of its pipeline, Takeda had elected to exercise its right to terminate the Takeda Agreement, including the associated amendments. In accordance with the terms of the Takeda Agreement, the termination will be effective on November 17, 2022 (the "Termination Effective Date"). Pursuant to a further amendment to the Takeda Agreement, dated October 19, 2022 ("Amendment #3"), the Company is in the process of winding down and transitioning activities under the Takeda Agreement. As of the Termination Effective Date, the license rights granted to Takeda will terminate, Takeda will cease to accrue any financial obligations to the Company and the Company will be entitled to pursue FIN-524 and FIN-525, and any other microbiome product candidates for inflammatory bowel disease, in all fields worldwide.

The Company recognized revenue related to the Takeda Agreement of $0.1 million and $11.3 million in the three months ended September 30, 2022 and 2021, respectively, and $0.9 million and $17.7 million in the nine months ended September 30, 2022 and 2021, respectively, which is included under collaboration revenue in the condensed consolidated statements of operations.

Takeda reimburses the Company for certain R&D costs on a quarterly basis, and will continue to do so for any applicable costs incurred through the Termination Effective Date. The Company recorded accounts receivable of zero and $0.5 million on its condensed consolidated balance sheets as of September 30, 2022, and December 31, 2021, respectively. As of September 30, 2022, there is no remaining deferred revenue due to the Company's satisfaction of the performance obligation.

The Takeda Agreement contained various milestone payments associated with development and commercialization efforts that provided for a maximum available amount of $180.0 million had all of the milestones been achieved. Upon the Termination Effective Date, the Company will no longer be eligible to receive future milestones. As of September 30, 2022, the Company had earned and received $4.0 million in milestone payments.

The Company was previously eligible to receive royalties under the Amendment and Takeda was 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 nine months ended September 30, 2022 and 2021.

OpenBiome

On November 19, 2020, the Company entered into the LMIC 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 to OpenBiome 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 15) and the license granted under the LMIC Agreement is unrelated to the assets acquired under the OpenBiome Agreement. 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 had not earned any of these royalty payments pursuant to the LMIC Agreement as of September 30, 2022.

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.

The Company did not recognize any revenue related to the LMIC Agreement for the nine months ended September 30, 2022 and 2021, as there were no marketable OpenBiome Royalty Products in these periods.

10. INCOME TAXES

During the nine months ended September 30, 2022 and the year ended December 31, 2021, 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 nine months ended September 30, 2022 as compared to the year ended December 31, 2021.

11. COMMITMENTS AND CONTINGENCIES

Legal Contingencies

On December 1, 2021, Rebiotix Inc. and Ferring Pharmaceuticals Inc. (collectively, "Rebiotix") filed a complaint against the Company in the U.S. District Court for the District of Delaware. The complaint seeks a declaratory judgment of non-infringement and invalidity with respect to seven United States Patents owned by the Company: U.S. Patent Nos. 10,675,309 (the "'309 Patent"); 10,463,702 (the "'702 Patent"); 10,328,107 (the "'107 Patent"); 10,064,899; 10,022,406 (the "'406 Patent"); 9,962,413 (the "'413 Patent"); and 9,308,226. On February 7, 2022, the Company filed an answer and counterclaims against Rebiotix for infringement of the '107, '702, and '309 Patents. In June 2022, Finch alleged infringement of the '406 and '413 Patents by Rebiotix. On March 7, 2022, the Company filed an amended answer and counterclaims, in which the Company, together with the Regents of the University of Minnesota ("UMN"), alleged infringement by Rebiotix of three U.S. Patents owned by UMN and exclusively licensed to the Company: U.S. Patent Nos. 10,251,914, 10,286,011, and 10,286,012, (collectively, the "UMN Patents). On April 4, 2022, Rebiotix filed counterclaims for declaratory judgment of non-infringement and invalidity of the UMN Patents. On May 2, 2022, the Company and UMN responded, denying such counterclaims. The U.S District Court for the District of Delaware set a trial date for a five-day trial beginning on May 20, 2024. The pending lawsuit is subject to inherent uncertainties, and the actual legal fees and costs will depend upon many unknown factors. The outcome of the pending lawsuit cannot be predicted with certainty. The Company has determined under ASC 450, *Contingencies*, that there is no probable or estimable loss contingency that is required to be recorded as of September 30, 2022.

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 the Company's 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 15) and the closing of the OpenBiome Agreement occurred on March 1, 2021. Under the terms of the OpenBiome Agreement, the Company was 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 chemistry, manufacturing, and controls ("CMC") process used to manufacture materials for its clinical trials.

Leases

The Company's commitments under its lease agreements are described in Note 5.

12. REDEEMABLE CONVERTIBLE PREFERRED STOCK

Upon the completion of the Company's initial public offering (the "IPO"), all 31,253,609 shares of outstanding preferred stock automatically converted into 31,253,609 shares of common stock. As of September 30, 2022, there were no shares of preferred stock outstanding.

13. STOCKHOLDERS' EQUITY

On February 24, 2021, the board of directors of the Company ("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 the Company's common stock, diluting the voting power of the Company's common stock, impairing the liquidation rights of the Company's common stock, or delaying or preventing a change in control. As of September 30, 2022, 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 any preferred stock outstanding, on all matters submitted to the stockholders for a vote. Common stockholders are also entitled to receive dividends. As of September 30, 2022, no cash dividends have been declared or paid.

As of September 30, 2022 and December 31, 2021 the Company has reserved the following shares of common stock for the exercise of stock options, common stock warrants, vesting of restricted stock and shares issuable under the employee stock purchase plan:

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Options to purchase common stock	4,097,094	3,264,770
Unvested restricted stock units	486,244	—
Shares issuable under employee stock purchase plan	7,926	45,195
	4,591,264	3,309,965

14. STOCK-BASED COMPENSATION

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 as a result no further grants will be made under the 2017 Equity Incentive Plan (the "2017 Plan"). However, any outstanding grants made under the 2017 Plan remain effective.

The 2021 Plan provides for the grant of incentive stock options to employees, including employees of any parent or subsidiary of the Company, 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 the 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.

On March 31, 2022, the Company registered 2,375,609 additional shares of common stock under the 2021 Plan, pursuant to the provisions of the 2021 Plan providing for an automatic increase in the number of shares common stock reserved and available for issuance under the 2021 Plan on January 1, 2022.

As of September 30, 2022, there were 4,097,094 shares of common stock issuable upon the exercise of outstanding options and there were 1,004,574 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 provided participating employees with the opportunity to purchase up to an aggregate of 500,000 shares of common stock. The first offering period under the 2021 ESPP commenced on December 1, 2021.

Each offering to employees to purchase shares will begin on each June 1 and December 1 and will end on the following November 30 and May 31, respectively. On each purchase date, which will fall on the last date of each offering period, participants in the 2021 ESPP will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value of the shares on the offering date or (2) the fair market value of the shares on the purchase date. The occurrence and duration of offering periods under the 2021 ESPP are subject to the determinations of the compensation committee of the Board. On March 31, 2022, the Company registered 475,121 additional shares of its common stock under the 2021 ESPP, pursuant to the provisions of the 2021 ESPP, providing for an automatic increase in the number of shares of common stock reserved and available for issuance under the 2021 ESPP on January 1, 2022. As of September 30, 2022, 54,755 shares were issued under the 2021 ESPP in 2022 and 920,366 shares were available for future issuance.

Stock Options

The following table summarizes the activity of the Company's stock options under the 2017 Plan and 2021 Plan for the nine months ended September 30, 2022:

	SHARES	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (in years)	AGGREGATE INTRINSIC VALUE (in thousands)
Outstanding as of December 31, 2021	3,264,770	$ 11.04	8.4	$ 7,228
Granted	2,114,394	7.12		
Exercised	(159,104)	0.74		
Cancelled or forfeited	(1,042,040)	10.34		
Expired	(80,926)	11.76		
Outstanding as of September 30, 2022	4,097,094	$ 9.58	7.3	$ 187
Options exercisable as of September 30, 2022	1,492,213	$ 8.42	5.5	$ 171
Options vested or expected to vest as of September 30, 2022	4,097,094	$ 9.58	7.3	$ 187

As of September 30, 2022, there was approximately $19.5 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 2.71 years.

Restricted Stock Unit Awards

In June 2022 the Company issued restricted stock unit ("RSU") awards with time-based vesting conditions to employees. The fair value of an RSU award is equal to the fair market value of the Company's ordinary shares on the date of grant and the expense is recognized on a straight-line basis over the requisite service period. The RSUs primarily vest over one year from the grant date.

The following table summarizes the activity of the Company's RSUs under the 2021 Plan for the nine months ended September 30, 2022:

	RSUs	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE	AGGREGATE INTRINSIC VALUE (in thousands)
Outstanding as of December 31, 2021	—	$ —	$ —
Granted	623,260	2.79	
Vested and distributed	(100,465)	2.79	
Forfeited	(36,551)	2.79	
Unvested as of September 30, 2022	486,244	$ 2.79	$ 812

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 SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Research and development	$ 886	$ 712	$ 2,655	$ 1,115
General and administrative	1,215	803	3,396	1,640
Total	$ 2,101	$ 1,515	$ 6,051	$ 2,755

15. RELATED PARTY TRANSACTIONS

Master Strategic Affiliation Agreement

Under the 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 the Board is the spouse of the co-founder and former executive director of OpenBiome, and certain of the OpenBiome directors are stockholders of the Company. The Strategic Agreement was amended and restated in its entirety upon execution of the OpenBiome Agreement in November 2020 (as amended, the "A&R Strategic Agreement").

The Company did not record any reimbursements to or from OpenBiome under the A&R Strategic Agreement during the nine months ended September 30, 2022. For the nine months ended September 30, 2021, the Company reimbursed OpenBiome $0.1 million, and OpenBiome reimbursed the Company $0.1 million under the A&R Strategic Agreement. As of September 30, 2022 and December 31, 2021, the Company recorded zero payable balance due to OpenBiome.

OpenBiome subleased office and lab space from the Company through December 31, 2021 (see Note 5). The Company's rent income under the sublease was $0.1 million for the nine months ended September 30, 2021.

Clinical Supply and Services Agreement

On February 10, 2020, the Company entered into a Clinical Supply and Services Agreement (the "CSA") with OpenBiome, which terminated upon closing of the OpenBiome Agreement in March 2021. 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 OpenBiome $1.1 million under the CSA for the nine months ended September 30, 2021.

OpenBiome Agreement

On November 19, 2020, the Company entered into the OpenBiome Agreement in order to obtain OpenBiome's CMC manufacturing process to enhance the Company's then 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 Material Access License Agreement ("MAL Agreement"), the CSA and the Asset Purchase and License Agreement ("APL Agreement"), as well as certain subject matter agreements, and executed the 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.

Under the OpenBiome Agreement, the Company is also required to pay certain milestones of up to $26.0 million upon the occurrence of certain R&D 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 will continue to earn royalties under the OpenBiome Agreement, which serve as reimbursement for third party license fees, based on sales of fecal microbiota transplantation ("FMT") materials.

16. 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 at their hire date. 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 $0.6 million in each of the nine months ended September 30, 2022 and 2021.

17. 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 SEPTEMBER 30,		FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	$ (40,371)	$ (9,955)	$ (87,638)	$ (39,105)
Net loss attributable to common stockholders—basic and diluted	(40,371)	(9,955)	(87,638)	(39,105)
Denominator:				
Weighted-average common stock outstanding—basic and diluted	47,728,130	47,445,195	47,611,872	36,408,506
Net loss per share attributable to common stockholders—basic and diluted	$ (0.85)	$ (0.21)	$ (1.84)	$ (1.07)

The Company's potentially dilutive securities, which include stock options, warrants, RSU awards and shares issuable under the employee stock purchase plan 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 September 30, 2022 and 2021 because including them would have had an anti-dilutive effect:

	NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021
Options to purchase common stock	4,097,094	3,172,369
Common stock warrants	—	19,346
Unvested restricted stock units	486,244	—
Shares issuable under employee stock purchase plan	7,926	—
	4,591,264	3,191,715

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, 2021 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or SEC, on March 31, 2022, which we refer to as the 2021 10-K.

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. We believe that our differentiated platform and 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.

Our lead product candidate, CP101, is an orally administered complete microbiome therapeutic in development for the prevention of recurrent *Clostridioides difficile* infection, or CDI. In June 2020, we reported positive topline data from our Phase 2 placebo-controlled clinical trial of CP101 for the prevention of recurrent CDI, which we refer to as the PRISM3 trial, and in November 2021, we reported positive topline data from our open-label, Phase 2 clinical trial of CP101 for the prevention of recurrent CDI, which we refer to as the PRISM-EXT trial. In October 2022, we proceeded with patient dosing in our Phase 3 clinical trial, which we refer to as the PRISM4 trial, which is designed to serve as our second pivotal trial of CP101 for the prevention of recurrent CDI. We anticipate that topline data from PRISM4 will be available in the first half of 2024. In an effort to accelerate our timeline to topline PRISM4 data and conserve capital, we are evaluating possible modifications to PRISM4 for future discussion with the FDA, such as a reduction in the size of the randomized portion of the trial, an approach that may be informed in part by regulatory insights from a recent FDA advisory committee meeting for an enema-based microbiome product candidate. We also expect to allow direct entry into the open-label portion of PRISM4 following completion of enrollment in the randomized portion of the trial in order to help satisfy the FDA's requirements regarding the safety database for CP101.

Following a recent strategic review of our pipeline, we have decided to suspend efforts to initiate a Phase 1 clinical trial of FIN-211 in autism spectrum disorder, or ASD. We are exploring strategic options to advance our ASD program, including opportunities to leverage clinical data generated by ongoing third-party studies.

Effective November 17, 2022, our collaboration agreement with Takeda Pharmaceutical Company Limited will terminate. Upon termination of the collaboration agreement, we will regain full rights to develop and commercialize FIN-524 and FIN-525, our targeted microbiome product candidates for the treatment of ulcerative colitis and Crohn's disease, respectively, and any other microbiome product candidates for the treatment of inflammatory bowel disease. We are currently exploring opportunities to advance the development of FIN-524 and FIN-525 through strategic partnerships.

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 our initial public offering, or the IPO, the sale of convertible preferred stock, our loan agreement with Hercules Capital and from collaboration revenue.

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 additional funding, we will be forced to delay, reduce or eliminate our research and development efforts, 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 believe that our existing cash and cash equivalents of $85.3 million as of September 30, 2022, together with anticipated cash inflows from executed subleases for one of the Company's office and lab facilities, will fund our operations into the second quarter of 2024. 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

We continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans, clinical development plans and response strategy. The extent of the impact of the COVID-19 pandemic, including variants of COVID-19, 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 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 regulatory authorities and our key scientific and management personnel.

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 collaboration agreements 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. Additionally, we will continue to earn royalties under our Asset Purchase Agreement, dated as of November 19, 2020, or the OpenBiome Agreement, with Microbiome Health Research Institute, Inc., doing business as OpenBiome, or OpenBiome, based on sales of fecal microbiota transplantation, or FMT, materials, which we receive as reimbursement for the payment of third-party license fees.

Collaboration and License Agreement with Takeda

In January 2017, we entered into a research collaboration and exclusive license agreement, or as amended and restated, the Takeda Agreement, with Takeda, pursuant to which we granted Takeda a worldwide, exclusive license, with the right to grant sublicenses, under our rights in certain 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. We amended the Takeda Agreement in August 2021 to transition primary responsibility for further development and manufacturing activities with respect to FIN-524 from us to Takeda in accordance with a transition plan, and Takeda would assume sole responsibility for regulatory matters with respect to FIN-524. In November 2021, we amended the Takeda Agreement to enable us to carry out certain FIN-525 preliminary evaluation activities.

In August 2022, we received written notice from Takeda that, following a review of its pipeline, Takeda had elected to exercise its right to terminate the Takeda Agreement, including the associated amendments. In accordance with the terms of the Takeda Agreement, the termination will be effective on November 17, 2022, or the Termination Effective Date. Pursuant to a further amendment to the Takeda Agreement, dated October 19, 2022, we are in the process of winding down and transitioning activities under the Takeda Agreement. As of the Termination Effective Date, the license rights granted to Takeda will terminate and Takeda will cease to accrue any financial obligations to us. We will be entitled to pursue FIN-524 and FIN-525, and any other microbiome product candidates for inflammatory bowel disease, in all fields worldwide. Revenue earned to date under the Takeda Agreement is

recognized as our research and development services are provided and is recorded as collaboration revenue on our condensed consolidated statement of operations.

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 have received an aggregate of $4.0 million in additional payments upon the achievement of certain development milestones for FIN-524 therapeutic products. Upon the Termination Effective Date, we will no longer be eligible to receive future milestones under the Takeda Agreement.

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.

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 to OpenBiome 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 three and nine months ended September 30, 2022 and 2021, as there are currently no products available for sale.

Also on November 19, 2020, we entered into the OpenBiome Agreement. The OpenBiome Agreement effectively terminated certain existing agreements with OpenBiome and internalized certain functions for which we 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 on March 1, 2021, we acquired certain additional assets, including biological samples, a commercial lease, intellectual property, capital equipment and contracts. As of September 30, 2022, 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 condensed 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. We do not allocate certain employee-related costs, external costs directly related to our Human First Discovery platform, and other indirect costs to specific research and development programs because these costs are deployed across multiple product programs under development and, as such, are classified as costs of our platform research.

Research and development activities are central to our business model. We expect that our research and development expenses will decrease in the foreseeable future due to our reduced headcount and our decision to suspend our hepatitis B, or HBV program, announced on March 31, 2022, and our subsequent decision, announced on September 1, 2022, to suspend our Phase 1 clinical trial in ASD. Our research and development expenses are primarily focused on supporting clinical trials for CP101, and have the potential to increase in the future as we may advance our efforts 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 decrease in the foreseeable future due to headcount reductions as we have optimized operations to support our continued research and development and potential commercialization of CP101. We expect to continue 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.

Impairment of Goodwill

Goodwill and IPR&D are evaluated for impairment annually on October 1, or more frequently if events or changes in circumstances indicate that the asset might be impaired. Factors we consider important, on an overall company basis, that could trigger an impairment review include significant underperformance relative to historical or projected future operating results, significant changes in our use of the acquired asset or the strategy for its overall business, significant negative industry or economic trends, a significant decline in the Company's stock price for a sustained period, or a reduction of its market capitalization relative to net book value.

To conduct impairment tests of goodwill, the fair value of the Company's single reporting unit is compared to its carrying value. If the reporting unit's carrying value exceeds its fair value, the Company records an impairment loss to the extent that the carrying value of goodwill exceeds its fair value.

Restructuring Expense

Restructuring expense consists of costs directly incurred as a result of restructuring initiatives, and includes one-time severance payments, healthcare coverage, outplacement services and related expenses.

Total Other Income (Expense), Net

Other Income (Expense), Net

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

Interest Income (Expense)

Interest income primarily consists of interest earned on our cash and cash equivalents. Interest expense consists primarily of interest on borrowings under our Loan Agreement with Hercules Capital, Inc., or the Loan Agreement.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021 (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,	
	2022	2021
REVENUE:		
Collaboration revenue	$ 138	$ 11,343
Total revenue	138	11,343
OPERATING EXPENSES:		
Research and development	(11,859)	(15,537)
General and administrative	(9,584)	(5,739)
Impairment of goodwill	(18,057)	—
Restructuring expense	(1,270)	—
Total operating expenses	(40,770)	(21,276)
Net operating loss	(40,632)	(9,933)
OTHER INCOME (EXPENSE):		
Interest income, net	45	8
Other income (expense), net	216	(30)
Total other income (expense)	261	(22)
Net loss	$ (40,371)	$ (9,955)

Revenue

Revenue of $0.1 million and $11.3 million for the three months ended September 30, 2022 and 2021, respectively, primarily consisted of collaboration revenue earned under the Takeda Agreement. Our collaboration revenue decreased by $11.2 million in the three months ended September 30, 2022 compared to the three months ended September 30, 2021 due to changes under our collaboration agreement with Takeda, including Takeda's election in August 2022 to terminate the agreement, with an effective termination date of November 17, 2022. We are currently winding down and transitioning activities under the agreement, and upon termination, we will be entitled to pursue FIN-524 and FIN-525, and any other microbiome product candidates for inflammatory bowel disease, in all fields worldwide.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2022 and 2021 (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		
	2022	2021	Increase (Decrease)
CDI	$ 3,661	$ 5,491	$ (1,830)
Inflammatory Bowel Diseases (IBD)	124	596	(472)
Autism Spectrum Disorder (ASD)	1,273	1,505	(232)
Hepatitis B (HBV)	(36)	912	(948)
Platform	5,735	6,131	(396)
Unallocated	1,102	902	200
	$ 11,859	$ 15,537	$ (3,678)

Research and development expenses for the three months ended September 30, 2022 were $11.9 million, compared to $15.5 million for the three months ended September 30, 2021. The decrease in expenses for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 was driven by a $1.8 million decrease in expenses related to our CP101 program, primarily due to a decrease in external clinical research organization costs. In addition, there was a decrease of a $0.9 million in our HBV program expenses and a decrease of $0.2 million in our ASD program expenses due to our decision to suspend our HBV program, announced on March 31, 2022, and our subsequent decision, announced on September 1, 2022, to suspend our Phase 1

clinical trial in ASD. In addition, there was a decrease in platform-related costs of $0.4 million and a decrease of $0.5 million in IBD program expenses due to the termination of our collaboration agreement with Takeda, which will be completed in the fourth quarter of 2022.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2022 and 2021 (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		
	2022	2021	Increase (Decrease)
Personnel expenses (including stock-based compensation)	$ 2,601	$ 3,276	$ (675)
Facilities and supplies	1,395	83	1,312
Professional fees	3,964	992	2,972
Other expenses	1,624	1,388	236
	$ 9,584	$ 5,739	$ 3,845

General and administrative expenses were $9.6 million for the three months ended September 30, 2022, compared to $5.7 million for the three months ended September 30, 2021. The increase of $3.8 million for the three months ended September 30, 2022 was primarily due to a $3.0 million increase in professional fees, a $1.3 million increase in facilities and supplies, and a $0.2 million increase in other expenses. The increase in professional fees was primarily related to $2.8 million increase in legal expenses, in addition to a $0.3 million increase in consulting costs, partially offset by a $0.2 million decrease in audit and tax related expenses. This increase was further offset by a $0.7 million decrease in personnel expenses comprised of a $1.1 million decrease in employee-related costs and a $0.4 million increase in stock-based compensation expense.

Other Income (Expense), Net

Total other income, net for the three months ended September 30, 2022 was $0.3 million, compared to expense of approximately $22,000 for the three months ended September 30, 2021. Other income increased by $0.3 million due to sublease income earned during the three months ended September 30, 2022.

Impairment of Goodwill

For the three months ended September 30, 2022, we recognized a goodwill impairment charge of $18.1 million, as the fair value of the Company's reporting unit was determined to be less than its carrying value, primarily due to a sustained decline in market conditions which drove our market capitalization below our net book value. As part of this assessment, we also performed a valuation of our CP101 IPR&D asset which resulted in no impairment, as the fair value of the asset exceeded the carrying value as of September 30, 2022. No impairment charge to goodwill or IPR&D was recognized for the three months ended September 30, 2021.

Restructuring Expense

Restructuring expense for the three months ended September 30, 2022 was $1.3 million, compared to zero for the three months ended September 30, 2021. The increase is due to the costs associated with the implementation of certain expense reduction measures in September 2022. Refer to Note 8 within the condensed consolidated financial statements for further information.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021 (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021
REVENUE:		
Collaboration revenue	$ 853	$ 17,726
Total revenue	853	17,726
OPERATING EXPENSES:		
Research and development	(41,312)	(42,476)
General and administrative	(27,152)	(16,173)
Impairment of goodwill	(18,057)	—
Restructuring expense	(2,173)	—
Total operating expenses	(88,694)	(58,649)
Net operating loss	(87,841)	(40,923)
OTHER INCOME (EXPENSE), NET:		
Gain on extinguishment of PPP Loan	—	1,827
Interest (expense) income, net	(7)	14
(Loss) gain on disposal of fixed assets, net	(6)	28
Other income (expense), net	216	(51)
Total other income, net	203	1,818
Net loss	$ (87,638)	$ (39,105)

Revenue of $0.9 million and $17.7 million for the nine months ended September 30, 2022 and 2021, respectively, primarily consisted of collaboration revenue earned under the Takeda Agreement. Our collaboration revenue decreased by $16.9 million in the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 due to changes under our collaboration agreement with Takeda, including Takeda's election in August 2022 to terminate the agreement, with an effective termination date of November 17, 2022. We are currently winding down and transitioning activities under the agreement, and upon termination, we will be entitled to pursue FIN-524 and FIN-525, and any other microbiome product candidates for inflammatory bowel disease, in all fields worldwide.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2022 and 2021 (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,		
	2022	2021	Increase (Decrease)
CDI	$ 11,257	$ 13,525	$ (2,268)
Inflammatory Bowel Diseases (IBD)	1,014	5,498	(4,484)
Autism Spectrum Disorder (ASD)	4,548	4,735	(187)
Hepatitis B (HBV)	259	2,364	(2,105)
Platform	20,881	14,596	6,285
Unallocated	3,353	1,758	1,595
	$ 41,312	$ 42,476	$ (1,164)

Research and development expenses for the nine months ended September 30, 2022 were $41.3 million compared to $42.5 million for the nine months ended September 30, 2021. The decrease of $1.2 million for the nine months ended September 30, 2022 included a $4.5 million decrease in IBD program expenses due to the termination of our collaboration agreement with Takeda, which will be completed in the fourth quarter of 2022. Additionally, there was a $2.3 million decrease in costs related to our CDI program, primarily due to a decrease in external clinical research organization costs. Program expenses related to HBV decreased by $2.1 million, while

costs related to our ASD program decreased by $0.2 million in connection with our decision to suspend our HBV program, announced on March 31, 2022, and our subsequent decision, announced on September 1, 2022, to suspend our Phase 1 clinical trial in ASD.

The decrease in research and development expenses was offset by a $6.3 million increase in our platform-related costs, primarily driven by a $4.1 million increase in manufacturing-related expenses, a $2.3 million increase in personnel expenses, and a $0.5 million increase in consulting costs, partially offset by a $0.7 million decrease in external costs. Additionally, unallocated costs increased by $1.6 million, driven by an increase in stock-based compensation expense.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2022 and 2021 (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,		
	2022	2021	Increase
Personnel expenses (including stock-based compensation)	$ 9,492	$ 8,633	$ 859
Facilities and supplies	2,056	200	1,856
Professional fees	10,250	4,300	5,950
Other expenses	5,354	3,040	2,314
	$ 27,152	$ 16,173	$ 10,979

General and administrative expenses were $27.2 million for the nine months ended September 30, 2022 compared to $16.2 million for the nine months ended September 30, 2021. The increase of $11.0 million for the nine months ended September 30, 2022 was due to a $6.0 million increase in professional fees, a $2.3 million increase in other expenses, a $1.9 million increase in facilities and supplies, and a $0.9 million increase in personnel expenses. The increase in professional fees was primarily related to $7.2 million increase in legal expenses, partially offset by a $0.7 million decrease in consulting expenses and a $0.6 million decrease in audit and tax services. The increase in other expenses was primarily related to an increase of $1.2 million in business insurance and $0.9 million in state excise taxes.

Other Income (Expense), Net

Total other income, net for the nine months ended September 30, 2022 was $0.2 million, compared to $1.8 million for the nine months ended September 30, 2021. The decrease of $1.6 million for the nine months ended September 30, 2022 was primarily due to the forgiveness of the PPP Loan of $1.8 million in May 2021, offset by sublease income of $0.2 million earned during the nine months ended September 30, 2022.

Impairment of Goodwill

For the nine months ended September 30, 2022, we recognized a goodwill impairment charge of $18.1 million, as the fair value of the Company's reporting unit was determined to be less than its carrying value, primarily due to a sustained decline in market conditions which drove our market capitalization below our net book value. As part of this assessment, we also performed a valuation of our CP101 IPR&D asset which resulted in no impairment, as the fair value of the asset exceeded the carrying value as of September 30, 2022. No impairment charge to goodwill or IPR&D was recognized for the nine months ended September 30, 2021.

Restructuring Expense

Restructuring expense for the nine months ended September 30, 2022 was $2.2 million, compared to zero for the nine months ended September 30, 2021. The increase is due to the costs associated with the implementation of certain expense reduction measures in both April and September 2022. Refer to Note 8 within the condensed consolidated financial statements for further information.

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, the Loan Agreement, 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 with Takeda. In May 2022, we borrowed $15.0 million under the Loan 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.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021
Net cash used in operating activities	$ (60,579)	$ (53,346)
Net cash used in investing activities	(2,131)	(13,919)
Net cash provided by financing activities	14,821	119,040
Net (decrease) increase in cash and cash equivalents, and restricted cash	$ (47,889)	$ 51,775

Operating Activities

During the nine months ended September 30, 2022, cash used in operating activities was $60.6 million. This cash outflow was primarily related to our net loss of $87.6 million in addition to a net decrease in our operating assets and liabilities of $3.2 million. The cash outflow reflected an $18.1 million goodwill impairment charge, $6.1 million in stock-based compensation expense, $4.1 million in non-cash depreciation and amortization, and $1.9 million in other non-cash operating lease cost. The net decrease in our operating assets and liabilities of $3.2 million included a $4.5 million decrease in prepaid expenses and other current assets and a $2.3 million decrease in accounts payable. Additionally, there was a $2.3 million increase in operating lease liabilities, a $0.7 million increase in other non-current assets, a $0.5 million increase in accounts receivable, and a $0.2 million increase in accrued expenses and other current liabilities.

During the nine months ended September 30, 2021, cash used in operating activities was $53.3 million. This cash outflow was primarily related to our net loss of $39.1 million and reflected $2.8 million in stock-based compensation expense and $1.6 million in non-cash depreciation and amortization. The outflow was also impacted by a net decrease in our operating assets and liabilities of $16.8 million. The net decrease includes a $13.6 million decrease in deferred revenue, a $3.8 million decrease in other non-current assets, a $1.4 million decrease in accounts receivable, and a $1.3 million decrease in accounts payable. This was offset by a $2.8 million increase in accrued expenses and other current liabilities.

Investing Activities

During the nine months ended September 30, 2022 and 2021, we used $2.1 million and $13.9 million, respectively, of cash in investing activities. The $2.1 million used during the nine months ended September 30, 2022 was due to purchases of property and equipment. The $13.9 million used during the nine months ended September 30, 2021 due to $8.8 million in leasehold improvements, $3.7 million in software purchases, and $1.5 million in purchases of lab equipment.

Financing Activities

During the nine months ended September 30, 2022, net cash provided by financing activities of $14.8 million was due to proceeds from borrowings under the Loan Agreement in addition to the exercise of company stock options offset by principal payments on finance lease obligations and payments of debt issuance costs.

During the nine months ended September 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 September 30, 2022, our cash and cash equivalents were $85.3 million. We believe that our existing cash and cash equivalents, together with anticipated cash inflows from executed subleases for one of the Company's office and lab facilities, will fund our operations into the second quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we expect.

Since our inception, we have incurred significant operating losses. Our net losses were $87.6 million and $39.1 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $248.6 million. 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 and conduct 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;
- incur lease expenses in connection with the expansion of our corporate headquarters;
- create additional infrastructure to support our operations and incur increased legal, accounting, investor relations and other expenses; and
- experience delays or encounter issues with any of the above.

Material Cash Requirements

During the nine months ended September 30, 2022, there were no other material changes to our material cash requirements from those described under "Management's Discussion and Analysis of Financial Condition and Results of Operations" discussed in the 2021 10-K.

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 the 2021 10-K.

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 December 31, 2026 or, if earlier, (i) the last day of our first fiscal year in which we have total annual gross revenues of at least $1.235 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 $700.0 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 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 September 30, 2022 and December 31, 2021, we had cash and cash equivalents of $85.3 million and $133.5 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.

We are affected by market risk exposure primarily through the effect of changes in interest rates on amounts payable under the Term Loan. As of September 30, 2022, borrowings under the Term Loan totaled $15.0 million with an average interest rate of 8.65%. Advances under the Loan Agreement bear an interest rate equal to the greater of (i)(a) 4.05% plus (b) the Prime Rate (as reported in the Wall Street Journal) and (ii) 7.55%. Borrowings under the Loan Agreement are repayable in monthly interest-only payments through December 1, 2024, or December 1, 2025 if certain conditions have been achieved prior to December 1, 2024. After the interest-only payment period, borrowings under the Loan Agreement are repayable in equal monthly payments of principal and accrued interest until November 1, 2026. If the total amounts outstanding under the Term Loan remained at this level for an entire year and the Prime Rate increased by 1%, there would be an immaterial impact on interest payments. As of December 31, 2021, we had no debt outstanding that is subject to interest rate variability. See “Note 7. Loan Payable” in the Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional information regarding our borrowings.

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 principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. 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 principal executive officer and our principal 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 the evaluation of our disclosure controls and procedures as of September 30, 2022, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the nine months ended September 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control 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

On December 1, 2021, Rebiotix Inc. and Ferring Pharmaceuticals Inc., or, collectively, Rebiotix, filed a complaint against us in the U.S. District Court for the District of Delaware. The complaint seeks a declaratory judgment of non-infringement and invalidity with respect to seven United States Patents owned by us: U.S. Patent Nos. 10,675,309, or the '309 Patent; 10,463,702, or the ‘702 Patent; 10,328,107, or the ‘107 Patent; 10,064,899; 10,022,406, or the ’406 Patent; 9,962,413, or the ’413 Patent; and 9,308,226. On February 7, 2022, we filed an answer and counterclaims against Rebiotix for infringement of the ’107 Patent, the ’702 Patent, and the ’309 Patent. In June 2022, the Company alleged infringement of the ’406 Patent and ’413 Patent by Rebiotix. On March 7, 2022, we filed an amended answer and counterclaims, in which we, together with the Regents of the University of Minnesota, or UMN, alleged infringement by Rebiotix of three U.S. Patents owned by UMN and exclusively licensed to us: U.S. Patent Nos. 10,251,914, 10,286,011, and 10,286,012, or, collectively, the UMN Patents. On April 4, 2022, Rebiotix filed counterclaims for declaratory judgment of non-infringement and invalidity of the UMN Patents. On May 2, 2022, the Company and UMN responded, denying such counterclaims. The U.S. District Court for the District of Delaware set a trial date for a five-day trial beginning on May 20, 2024. The pending lawsuit is subject to inherent uncertainties, and the actual legal fees and costs will depend upon many unknown factors. The outcome of the pending lawsuit cannot be predicted with certainty.

We may also be a party to litigation and subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021, which could materially affect our business, financial condition or future results. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Other than as described below, there have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 31, 2022.

We have a credit facility that requires us to comply with certain operating covenants and places restrictions on our operating and financial flexibility.

In May 2022, we entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules Capital, Inc., or Hercules, as administrative agent and collateral agent. Pursuant to the Loan Agreement, and conditioned on our compliance with certain operating covenants contained therein, we may borrow up to an aggregate of $55.0 million, which includes $15.0 million available immediately, $10.0 million available at any time after closing but prior to December 15, 2022, $10.0 million available at any time after closing but prior to September 30, 2023 and $20.0 million in a tranche that is subject to meeting certain performance milestones. We are currently in compliance with our obligations under the Loan Agreement. However, following Takeda's election to terminate our collaboration agreement, we are unable to draw future amounts under the Loan Agreement without Hercules' consent. The Loan Agreement is secured by substantially all of our personal property owned or later acquired, excluding intellectual property (but including the right to payments and proceeds from intellectual property), and a negative pledge on intellectual property.

The Loan Agreement also includes customary representations and warranties, affirmative and negative covenants and conditions to drawdowns, as well as customary events of default. Certain of the customary negative covenants limit our ability, among other things, to incur future debt, grant liens, make investments, make acquisitions, distribute dividends, make certain restricted payments and sell assets, subject in each case to certain exceptions. Our failure to comply with these covenants would result in an event of default under the Loan Agreement and could result in the acceleration of any obligations we owe pursuant to the Loan Agreement.
Any additional indebtedness we may assume under the Loan Agreement, combined with our other financial obligations and contractual commitments, could have significant adverse consequences on the operation of our business, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product candidate development and other general corporate purposes;

- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete;
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options; and
- increasing our vulnerability to adverse changes in general economic, industry and market conditions.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due. If we do not make scheduled payments when due, or otherwise experience an event of default under the Loan Agreement, Hercules could accelerate our total loan obligation or enforce its security interest against us.

Failure to satisfy our current and future debt obligations under the Loan Agreement could result in an event of default. In addition, other events, including certain events that are not entirely in our control, such as the occurrence of a material adverse event on our business, could cause an event of default to occur. As a result of the occurrence of an event of default, Hercules could accelerate all of the amounts due under the Loan Agreement. In the event of such an acceleration, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, all obligations under the Loan Agreement are secured by substantially all of our property, excluding our intellectual property (but including proceeds from our intellectual property). Hercules could seek to enforce its security interests in the assets securing such indebtedness. If we are unable to pay amounts due to Hercules upon acceleration of the Loan Agreement or if Hercules enforces its security interest against our assets securing our indebtedness to Hercules, our ability to continue to operate our business may be jeopardized.

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 our initial public offering, private placements of equity securities, upfront and milestone payments received pursuant to our collaboration agreement with Takeda Pharmaceutical Company Limited, or Takeda, and the Loan Agreement. 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, if approved, commercialize, our product candidates. 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. Adequate additional financing may not be available to us on acceptable terms, or at all. Our ability to raise capital is dependent on a number of factors, including the market demand for our common stock, which is uncertain. 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 September 30, 2022, our cash and cash equivalents were $85.3 million. We believe that our existing cash and cash equivalents, together with anticipated cash inflows from executed subleases for one of our office and lab facilities, will fund our operations into the second quarter of 2024. We have based our runway analysis on assumptions including, for example, forecasts of our operational spend, the timely execution of our clinical trials, and expenses associated with IP litigation. If our assumptions prove to be wrong, we could exhaust our available capital resources sooner than we expect and we could be forced to delay, reduce or eliminate certain of our product development programs or other operations.

We will need to obtain substantial additional funding in connection with our continuing operations and planned activities. Our future capital requirements and resources, and the amount of time it takes to exhaust our available resources, will depend on many factors, including:

- the timing, costs, progress and results of our ongoing and planned clinical trials of CP101 and other product candidates, including our ability to gain alignment with the FDA regarding the validation package for one of our release tests, which is utilized for CP101, the review of which the FDA informed us need not delay our resumption of PRISM4;

- 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 providers 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;
- management of our headcount and related potential increased attrition and associated costs as we conduct 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, and the impact of the termination of our collaboration with Takeda;
- 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, including satisfying the FDA's requirements regarding the nature and size of the CP101 safety database, which we expect to satisfy in part by allowing direct entry into the open-label portion of PRISM4 following completion of enrollment in the randomized portion of the trial;
- 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 and the income received from the subletting of one of our office and lab facilities;
- 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 potential stockholder litigation or regulatory investigations, which may involve past or future significant announcements, transactions or disclosures since our IPO; for example, several class action plaintiff law firms have issued press releases announcing that the firms are investigating securities law claims on behalf of our stockholders following our March 1, 2022 announcement that enrollment in PRISM4 was paused following receipt of the clinical hold letter on February 24, 2022;
- the cost of potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our product candidates, such as the complaint filed by Rebiotix Inc. and Ferring Pharmaceuticals Inc., seeking a declaratory judgment of non-infringement and invalidity with respect to seven U.S. patents owned by us;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing capabilities for future product candidates;
- the extent to which we partner our programs, acquire or in-license other product candidates and technologies or enter into additional strategic collaborations, including potential strategic options to advance the development of FIN-524, FIN-525 and our program in autism spectrum disorder;
- 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;
- the costs of operating as a public company, including costs associated with compliance, disclosure and insurance;
- our ability to raise capital, which is dependent on a number of factors, some of which are beyond our control; and
- the scope, progress, results and costs of our research programs and preclinical development of other product candidates that we may pursue.

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.

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 of our other current or 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. For example, we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. Moreover, a clinical trial can fail at any stage of testing and most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. 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 other current or future product candidates in the United States or abroad, we, our collaborators or any of 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 currently expect to allow direct entry into the open-label portion of PRISM4 in order to satisfy in part the FDA's requirements regarding the size and make-up of the safety database for CP101, which will impact 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. We are currently evaluating alternative clinical development strategies for CP101 to potentially accelerate the timeline to topline data and conserve capital, including a possible reduction in the size of the randomized portion of the trial, which may increase the risk that the trial does not demonstrate adequate efficacy and safety necessary to obtain regulatory approval. 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. 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 other current or 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.

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. Each member of our management team 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. Over the last several years, the challenges of recruiting and retaining employees across the biotechnology industry, and in the Boston area specifically, have increased substantially due to current industry job market dynamics. Because competition for skilled personnel in our industry is intense, companies such as ours sometimes experience high attrition rates with regard to their skilled employees. We expect to continue to face significant competition for talent and employee attrition could have significant adverse consequences on the operation of our business. 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.

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 or may be influenced by our competitors' product candidates if they receive FDA approval before we do. 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 in part 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. For example, in February 2022 the FDA requested additional information about our SARS-CoV-2 donor screening protocols and in August 2022 the FDA issued a safety alert regarding the potential risk of transmission of monkeypox virus through fecal microbiota for transplantation. In the future, the FDA and other regulatory authorities may issue similar alerts regarding other pathogens. Improper storage or shipment 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.

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 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 U.S., Japan and China that may impact our competitive position with respect to one of our preclinical product candidates. We are also aware of an issued U.S. patent containing claims which, if valid and enforceable, could be construed to cover CP101. While we believe that the granted claims within these third party patents may not be valid, may not be construed to cover our products and/or 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.

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
10.1*#	Amendment No. 3, dated October 19, 2022, to the Amended and Restated Agreement by and between Finch Therapeutics, Inc. and Millennium Pharmaceuticals, Inc., dated as of October 21, 2019				
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.

Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to Finch Therapeutics Group, Inc. if publicly disclosed.

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: November 10, 2022

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

Date: November 10, 2022

By: /s/ Marc Blaustein
Marc Blaustein
Chief Operating Officer
(Principal Financial Officer and Principal Accounting Officer)

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE FINCH THERAPEUTICS GROUP, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO FINCH THERAPEUTICS GROUP, INC. IF PUBLICLY DISCLOSED.

Exhibit 10.1

AMENDMENT #3 TO AMENDED AND RESTATED AGREEMENT

This Amendment to Amended and Restated Agreement (this "***Amendment***") is entered into as of October 19, 2022 (the "***Amendment #3 Effective Date***") by and between **Finch Therapeutics, Inc.**, a Delaware corporation having its principal office at 200 Inner Belt Road, 4th Floor, Somerville, Massachusetts 02143 ("***Finch***"), and **Takeda Development Center Americas, Inc.**, a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, having its principal office at 95 Hayden Avenue, Lexington, MA 02421 ("***Takeda***").

Background

Finch and Takeda are the parties to the Amended and Restated Agreement dated October 21, 2019, as amended by the Amendment to the Amended and Restated Agreement dated August 9, 2021 and the Amendment #2 to Amended and Restated Agreement dated November 12, 2021 (the "***Agreement***").

In connection with the FIN-524 Development Program, Finch has been engaging in research activities to develop a certain [***] through its contract research service provider, [***] and Takeda has constructed a [***].

As part of the parties' discussion on the transition plan pursuant to Section 13.3(a-1) of the Agreement, appended hereto as **Exhibit A** (the "***Transition Plan***"), Finch and Takeda have agreed to amend the Agreement as further set forth herein.

NOW THEREFORE, in consideration of mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Finch and Takeda agree as follow:

1. **Definitions.** Unless otherwise specifically set forth herein, all capitalized terms in this Amendment, including the Background stated above, shall have the same meaning as set forth in the Agreement.

2. **Amendments.** The Agreement is hereby amended as follows:

   (1) [***]

   (2) [***]. Subject to the terms and conditions provided in this Amendment, notwithstanding the Agreement (including Section 13.3(a-1)(i)), Finch shall continue to perform [***] during the term and thereafter to its completion; provided:

(a) Finch shall use Commercially Reasonable Efforts to complete [***] no later than [***] and within [***] (or such other date and amount agreed by Takeda pursuant to subsection (d) below);
(b) to the extent expressly described in the Transition Plan, Finch may delegate part of its activities in the [***] to Takeda;
(c) [***]
(d) if Finch reasonably believes that the [***] is likely to exceed the timeline or amount described in subsection (a) above, Finch shall notify Takeda of the latest status of the [***] and updated timeline and costs to its completion and if Takeda agrees, in its discretion, to accept the updated timeline and reimburse the updated costs, Finch will continue the [***] to its completion in accordance with this Section 2(2) of this Amendment; and
(e) in no event shall Finch have an obligation to continue the [***] to the extent it incurs costs related to the [***] in excess of [***] (or such other amount agreed by Takeda pursuant to subsection (d) above).

Any Development Costs that are incurred by Finch in connection with the [***] pursuant to Section 2(2) of this Amendment shall be reimbursed by Takeda in accordance with Section 4.4 and Section 13.3(a-1)(ii) of the Agreement and for the purpose of such reimbursement, all the costs and expenses incurred by Finch in undertaking the [***] after the term of the Agreement shall be deemed as part of the Development Costs; *provided*, in no event shall the total amount of reimbursement payable by Takeda to Finch in connection with the [***] following the Amendment #3 Effective Date exceed [***] (or such other amount agreed by Takeda pursuant to subsection (d) above).

(3) Patent Prosecution of Joint Patent Rights. As of the Amendment #3 Effective Date, the parties acknowledge that there is no patent or patent application that constitutes Joint Patent Rights other than the following patent applications: [***] as set forth in **Exhibit B** appended hereto and all Patent Rights thereto (collectively, "**Joint Patent Rights**"). With respect to the Joint Patent Rights, Finch shall have the sole right, but not the obligation, to prepare, file, prosecute, and maintain the Joint Patent Rights and, if reasonably necessary, Takeda shall cooperate, [***], in such preparation, filing, prosecution and maintenance. Finch shall use outside patent counsel reasonably acceptable to both parties, and unless otherwise mutually agreed by the parties, shall use reasonable efforts to give Takeda the opportunity [***] to review and provide comments on material prosecution matters related to the Joint Patent Rights and consider in good faith Takeda's comments and suggestions, [***]. If Finch determines in its discretion to abandon or not maintain any Joint Patent Rights in any country, then Finch shall provide Takeda with written notice of such determination within a period of time reasonably necessary to allow Takeda to determine, in its discretion, its interest in such Joint Patent Right (which notice by Finch shall be given no later than [***] prior to the final deadline for any pending action or response that may be due with respect to such Joint Patent Right with the applicable patent authority). If Takeda provides written notice expressing its interest in having such Joint Patent Right prosecuted and maintained in any such country(ies), Takeda shall assume the sole right, but not the obligation, to prepare, file, prosecute, and maintain the Joint Patent Rights [***] and, if reasonably necessary, Finch shall cooperate, [***], in such preparation, filing, prosecution and maintenance.

(4) Enforcement of Joint Patent Rights. Finch shall promptly notify Takeda in writing of any existing, alleged or threatened infringement or misappropriation of any Joint Patent Right, of which it becomes aware. Finch shall have the sole right, but not the obligation, to pursue any enforcement or defense of the Joint Patent Rights against infringement or misappropriation using counsel of its choice, including defense against a declaratory judgment alleging invalidity or non-infringement

of any of the Joint Patent Rights; provided, Finch shall keep Takeda reasonably informed of its progress and provide Takeda with copies of any substantive documents related to such proceeding and reasonable notice of all such proceedings. Takeda shall cooperate, [***], in such defense and enforcement, including being named as a party in such defense and/or enforcement to the extent required by Finch to maintain standing to enforce any Joint Patent Right. [***]. Finch shall be solely responsible for any out-of-pocket costs associated with enforcing and defending the Joint Patent Rights, including but not limited to attorneys' fees, court costs, expert witnesses, and electronic discovery. If Finch determines in its discretion not to pursue any enforcement or defense of the Joint Patent Rights against infringement or misappropriation, then Finch shall provide Takeda with written notice of such determination.

3. Agreements and Acknowledgement by the Parties.

(1) Amendment #3 Effective Date. This Amendment shall be effective as of the Amendment #3 Effective, remain effective during the term of the Agreement and survive the termination of the Agreement.

(2) Reaffirmation. The parties hereby confirm all of the terms and covenants, and provisions of the Agreement, and except as provided or modified herein, the Agreement remains unmodified and in full force and effect.

(3) Governing Law. This Amendment shall be governed by and construed in accordance with laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different jurisdiction.

(4) Incorporation of Terms and Provision of Original Agreement. The terms and conditions of the Agreement are hereby incorporated by reference and shall be applicable to this Amendment and the matters addressed herein as if set forth herein in full.

(5) Entire Agreement. This Amendment, along with the Agreement, sets forth the complete, final, and exclusive agreement, and all the covenants, promises, agreements, warranties, representations, conditions, and understandings between the parties with respect to the subject matter hereof, and supersedes, as of the Amendment #3 Effective Date, all prior and contemporaneous agreements and understandings between the parties with respect to the subject matter hereof.

(6) Further Assistance. Each party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments, and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other party may reasonably request in connection with this Amendment or to carry out more effectively the provisions and purposes hereof.

(7) Severability. If any one or more of the provisions of this Amendment is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the

provision shall be considered severed from this Amendment and shall not serve to invalidate any remaining provisions hereof, and the invalid or unenforceable provision shall be replaced with the most nearly coextensive valid and enforceable provision that is acceptable to the court of competent jurisdiction, or otherwise, the parties shall engage in good-faith efforts to replace such invalid or unenforceable provision with a valid and enforceable provision as closely as possible commensurate with the objectives completed by the parties when entering this Amendment.

(8) Counterparts. This Amendment may be executed simultaneously in two counterparts, by facsimile or PDF copy, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed on their behalf by their duly authorized representatives as of the Amendment #3 Effective Date.

FINCH THERAPEUTICS, INC.

By: /s/ Marc Blaustein

Name: Marc Blaustein

Title: Chief Operating Officer

TAKEDA DEVELOPMENT CENTER AMERICAS, INC.

By: /s/ Chinweike Ukomadu

Name: Chinweike Ukomadu

Title: Head of Gastroenterology TAU, Research & Development

EXHIBIT A

FIN-524 TRANSITION PLAN

[***]

EXHIBIT B
JOINT PATENT RIGHTS

[***]

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: November 10, 2022

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, Marc Blaustein, 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: November 10, 2022

By: /s/ Marc Blaustein
Marc Blaustein
Chief Operating 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 September 30, 2022 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: November 10, 2022

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

Date: November 10, 2022

By: /s/ Marc Blaustein
Marc Blaustein
Chief Operating Officer
(Principal Financial Officer and Principal Accounting Officer)