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

FORM 10-Q

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

For the quarterly period ended March 31, 2020

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 001-35366

FORTRESS BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-5157386**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address including zip code of principal executive offices)

(781) 652-4500
(Registrant's telephone number, including area code)

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

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	FBIO	Nasdaq Capital Market
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock	FBIOP	Nasdaq Capital Market

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

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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

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

Class of Stock	Outstanding Shares as of May 7, 2020
Common Stock, $0.001 par value	82,474,127
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock, $0.001 par value	2,059,917

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Quarterly Report on Form 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
($ in thousands except for share and per share amounts)

	March 31, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 135,943	$ 136,858
Accounts receivable (net of allowance for doubtful accounts of $0 and $100 at March 31, 2020 and December 31, 2019, respectively)	15,810	13,539
Inventory	769	857
Other receivables - related party	1,753	865
Prepaid expenses and other current assets	4,526	4,133
Total current assets	158,801	156,252
Property and equipment, net	12,785	12,433
Operating lease right-of-use asset, net	21,076	21,480
Restricted cash	16,574	16,574
Long-term investment, at fair value	11,148	11,148
Intangible asset, net	7,022	7,377
Other assets	1,353	1,158
Total assets	**$ 228,759**	$ 226,422
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 34,200	$ 35,451
Accounts payable and accrued expenses – related party	13	-
Interest payable	1,081	1,042
Interest payable - related party	53	92
Notes payable, short-term (net of debt discount of $0 at March 31, 2020 and December 31, 2019)	14,522	7,220
Operating lease liabilities - short-term	1,794	1,784
Derivative warrant liability	69	27
Total current liabilities	51,732	45,616
Notes payable, long-term (net of debt discount of $4,354 and $5,086 at March 31, 2020 and December 31, 2019, respectively)	70,866	77,436
Operating lease liabilities - long-term	23,647	23,712
Other long-term liabilities	7,229	7,126
Total liabilities	**153,474**	**153,890**
Commitments and contingencies		

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
($ in thousands except for share and per share amounts)

	March 31, 2020 (Unaudited)	December 31, 2019
Stockholders' equity		
Preferred stock, $.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 2,059,917 and 1,341,167 shares issued as of March 31, 2020 and December 31, 2019, respectively; 2,054,917 and 1,341,167 shares outstanding as of March 31, 2020 and December 31, 2019, respectively; liquidation value of $25.00 per share	2	1
Common stock, $.001 par value, 100,000,000 shares authorized, 78,572,169 and 74,027,425 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	79	74
Common stock issuable, 489,095 and 251,337 shares as of March 31, 2020 and December 31, 2019, respectively	661	500
Treasury stock	(70)	-
Additional paid-in-capital	485,160	461,874
Accumulated deficit	(448,604)	(436,234)
Total stockholders' equity attributed to the Company	37,228	26,215
Non-controlling interests	38,057	46,317
Total stockholders' equity	75,285	72,532
Total liabilities and stockholders' equity	**$ 228,759**	**$ 226,422**

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
($ in thousands except for share and per share amounts)
(Unaudited)

	For the Three Months Ended March 31,	
	2020	**2019**
Revenue		
Product revenue, net	$ 11,946	$ 6,125
Revenue - related party	972	352
Net revenue	12,918	6,477
Operating expenses		
Cost of goods sold - product revenue	3,810	1,884
Research and development	14,867	23,273
Research and development - licenses acquired	250	450
General and administrative	15,519	13,478
Total operating expenses	34,446	39,085
Loss from operations	(21,528)	(32,608)
Other income (expense)		
Interest income	627	438
Interest expense and financing fee	(3,125)	(2,469)
Change in fair value of derivative liability	(42)	-
Gain on deconsolidation of Caelum	-	18,384
Total other income (expense)	(2,540)	16,353
Net loss	**(24,068)**	**(16,255)**
Less: net loss attributable to non-controlling interests	11,698	17,647
Net income (loss) attributable to common stockholders	**$ (12,370)**	**$ 1,392**
Net loss per common share - basic	$ (0.38)	$ (0.34)
Net loss per common share – diluted	$ (0.38)	(0.25)
Net income (loss) per common share attributable to common stockholders - basic	$ (0.19)	$ 0.03
Net income (loss) per common share attributable to common stockholders - diluted	$ (0.19)	$ 0.02
Weighted average common shares outstanding - basic	63,496,256	48,506,994
Weighted average common shares outstanding - diluted	63,496,256	63,811,136

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Statement of Changes in Stockholders' Equity
($ in thousands)
(Unaudited)

For the Three Months Ended March 31, 2020

	Series A Preferred Stock		Common Stock		Shares	Treasury	Paid-In	Accumulated	Non-Controlling	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Issuable	Stock	Capital	Deficit	Interests	(Deficit)
Balance at December 31, 2019	**1,341,167**	**$ 1**	**74,027,425**	**$ 74**	**$ 500**	**$ -**	**$ 461,874**	**$ (436,234)**	**$ 46,317**	**$ 72,532**
Stock-based compensation expense	-	-	-	-	-	-	3,400	-	-	3,400
Issuance of common stock related to equity plans	-	-	1,952,407	2	-	-	(2)	-	-	-
Issuance of common stock for at-the-market offering, net	-	-	2,341,000	3	-	-	5,877	-	-	5,880
Preferred A dividends declared and paid	-	-	-	-	-	-	(1,207)	-	-	(1,207)
Repurchase of Series A preferred stock, net	(5,000)	-	-	-	-	(70)	(2)	-	-	(72)
Issuance of Series A preferred stock for cash, net	718,750	1	-	-	-	-	13,066	-	-	13,067
Partner company's at-the-market offering, net	-	-	-	-	-	-	4,910	-	-	4,910
Partner company's exercise of warrants for cash	-	-	-	-	-	-	13	-	-	13
Partner company's ESPP	-	-	-	-	-	-	169	-	-	169
Common shares issued for NHLD interest expense	-	-	251,337	-	(500)	-	500	-	-	-
Common shares issuable for NHLD interest expense	-	-	-	-	506	-	-	-	-	506
Common shares issuable for Opus interest expense	-	-	-	-	155	-	-	-	-	155
Non-controlling interest in partner companies	-	-	-	-	-	-	(3,438)	-	3,438	-
Net loss attributable to non-controlling interest	-	-	-	-	-	-	-	-	(11,698)	(11,698)
Net loss attributable to common stockholders	-	-	-	-	-	-	-	(12,370)	-	(12,370)
Balance at March 31, 2020	**2,054,917**	**$ 2**	**78,572,169**	**$ 79**	**$ 661**	**$ (70)**	**$ 485,160**	**$ (448,604)**	**$ 38,057**	**$ 75,285**

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Statement of Changes in Stockholders' Equity
($ in thousands)
(Unaudited)

For the Three Months Ended March 31, 2019

	Series A Preferred Stock		Common Stock		Common Shares Issuable	Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2018	**1,000,000**	**$ 1**	**57,845,447**	**$ 58**	**$ 659**	**$ 397,408**	**$ (396,274)**	**$ 17,891**	**$ 19,743**
Stock-based compensation expense	-	-	-	-	-	3,309	-	-	3,309
Issuance of restricted stock	-	-	1,609,325	2	-	(2)	-	-	-
Issuance of subsidiaries' common shares for license expenses	-	-	-	-	(164)	164	-	-	-
Issuance of common stock for at-the-market offering, net	-	-	2,927,427	3	-	6,139	-	-	6,142
Preferred A dividends declared and paid	-	-	-	-	-	(586)	-	-	(586)
Partner company's sale of stock, net	-	-	-	-	-	31,499	-	-	31,499
Partner company's at-the-market offering, net	-	-	-	-	-	355	-	-	355
Issuance of partner company warrants in conjunction with Horizon Notes						888			888
Common shares issuable for 2017 Subordinated Note Financing interest expense	-	-	-	-	484	-	-	-	484
Common shares issued for 2017 Subordinated Note Financing interest expense	-	-	744,322	-	(495)	495	-	-	-
Common shares issuable for Opus interest expense	-	-	-	-	281	-	-	-	281
Non-controlling interest in subsidiaries	-	-	-	-	-	(24,799)	-	24,799	-
Deconsolidation of Caelum non-controlling interest	-	-	-	-	-	-	-	4,849	4,849
Net loss attributable to non-controlling interest	-	-	-	-	-	-	-	(17,647)	(17,647)
Net income attributable to common stockholders	-	-	-	-	-	-	1,392	-	1,392
Balance at March 31, 2019	**1,000,000**	**$ 1**	**63,126,521**	**$ 63**	**$ 765**	**$ 414,870**	**$ (394,882)**	**$ 29,892**	**$ 50,709**

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
($ in thousands)
(Unaudited)

	For the Three Months Ended March 31,	
	2020	**2019**
Cash Flows from Operating Activities:		
Net loss	$ (24,068)	$ (16,255)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation expense	527	481
Amortization of debt discount	747	622
Non cash interest expense	150	-
Amortization of product revenue license fee	355	234
Amortization of operating lease right-of-use assets	403	381
Stock-based compensation expense	3,400	3,309
Common shares issuable for Opus interest expense	155	281
Common shares issuable for 2017 Subordinated Note Financing interest expense	506	484
Change in fair value of derivative liability	42	-
Gain on deconsolidation of Caelum	-	(18,384)
Research and development-licenses acquired, expense	250	450
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:		
Accounts receivable	(2,271)	(2,524)
Inventory	88	49
Other receivables - related party	(888)	(34)
Prepaid expenses and other current assets	(393)	2,483
Other assets	(195)	(949)
Accounts payable and accrued expenses	(612)	3,664
Accounts payable and accrued expenses - related party	13	(133)
Interest payable	39	(21)
Interest payable – related party	(39)	-
Lease liabilities	(54)	(351)
Other long-term liabilities	(47)	888
Net cash used in operating activities	(21,892)	(25,325)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(526)	(300)
Purchase of intangible assets	(1,250)	-
Redemption of short-term investment (certificates of deposit)	-	12,560
Deconsolidation of Caelum	-	(1,201)
Net cash provided by (used in) continuing investing activities	(1,776)	11,059
Net cash provided by discontinued investing activities	-	13,089
Net cash provided by (used in) investing activities	(1,776)	24,148
Cash Flows from Financing Activities:		
Payment of Preferred A dividends	(1,207)	(586)
Purchase of treasury stock	(70)	-
Payment of costs related to purchase of treasury stock	(2)	-
Proceeds from issuance of Series A preferred stock	14,375	-
Payment of costs related to issuance of Series A preferred stock	(1,213)	-
Proceeds from at-the-market offering	6,068	6,251
Payment of cost related to at-the-market offering	(188)	(109)
Proceeds from partner company's ESPP	169	-
Proceeds from partner company's sale of stock	-	34,999
Payment of costs related to partner company's sale of stock	(69)	(3,500)
Proceeds from partner company's at-the-market offering	4,997	366
Payment of costs related to partner company's at-the-market offering	(87)	(11)
Proceeds from exercise of partner company's warrants	13	-
Payment of debt issue costs associated with 2017 Subordinated Note Financing	(26)	-
Payment of debt issue costs associated with 2018 Venture Notes	(7)	(67)
Proceeds from partner company's Horizon Notes	-	15,000
Payment of debt issuance costs associated with partner company's Horizon Notes	-	(230)
Net cash provided by financing activities	22,753	52,113
Net (decrease) increase in cash and cash equivalents and restricted cash	(915)	50,936
Cash and cash equivalents and restricted cash at beginning of period	153,432	81,582
Cash and cash equivalents and restricted cash at end of period	$ 152,517	$ 132,518
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,609	$ 1,100
Supplemental disclosure of non-cash financing and investing activities:		
Settlement of restricted stock units into common stock	$ 2	$ 2
Unpaid debt offering costs	$ 8	$ 1,202
Common shares issuable for license acquired	$ -	$ 164
Common shares issued for 2017 Subordinated Note Financing interest expense	$ 500	$ 495
Issuance of partner company warrants in conjunction with Horizon Notes	$ -	$ 888
Unpaid fixed assets	$ 540	$ 191

Unpaid at-the-market offering cost	$	6	$	-
Unpaid Preferred A offering cost	$	98	$	-
Unpaid research and development licenses acquired	$	350	$	250

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

1. Organization and Description of Business

Fortress Biotech, Inc. ("Fortress" or the "Company") is a biopharmaceutical company dedicated to acquiring, developing and commercializing pharmaceutical and biotechnology products and product candidates, which the Company does at the Fortress level, at its majority-owned and majority-controlled subsidiaries and joint ventures, and at entities the Company founded and in which it maintains significant minority ownership positions. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who identify and evaluate promising products and product candidates for potential acquisition by new or existing partner companies. Fortress through its partner companies has executed such arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center, Fred Hutchinson Cancer Research Center, St. Jude Children's Research Hospital, Dana-Farber Cancer Institute, Nationwide Children's Hospital, Cincinnati Children's Hospital Medical Center, Columbia University, the University of Pennsylvania, and AstraZeneca plc.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and finance expertise to help the partners achieve their goals. Partner companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out-licensings, and public and private financings; to date, three partner companies are publicly-traded, and two have consummated strategic partnerships with industry leaders Alexion Pharmaceuticals, Inc. and InvaGen Pharmaceuticals, Inc. (a subsidiary of Cipla Limited).

Several of our partner companies possess licenses to product candidate intellectual property, including Aevitas Therapeutics, Inc. ("Aevitas"), Avenue Therapeutics, Inc. ("Avenue"), Baergic Bio, Inc. ("Baergic"), Caelum Biosciences, Inc. ("Caelum"), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. ("Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Hepla Sciences, Inc. ("Hepla"), Journey Medical Corporation ("Journey" or "JMC"), Mustang Bio, Inc. ("Mustang") and Oncogenuity, Inc. ("Oncogenuity").

Liquidity and Capital Resources

Since inception, the Company's operations have been financed primarily through the sale of equity and debt securities, from the sale of partner companies, the proceeds from the exercise of warrants and stock options. The Company has incurred losses from operations and negative cash flows from operating activities since inception and expects to continue to incur substantial losses for the next several years as it continues to fully develop and prepare regulatory filings and obtain regulatory approvals for its existing and new product candidates. The Company's current cash and cash equivalents are sufficient to fund operations for at least the next 12 months. However, the Company will need to raise additional funding through strategic relationships, public or private equity or debt financings, sale of a partner company, grants or other arrangements to fully develop and prepare regulatory filings and obtain regulatory approvals for the existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for the potential products, sales and marketing capabilities. If such funding is not available or not available on terms acceptable to the Company, the Company's current development plan and plans for expansion of its general and administrative infrastructure will be curtailed. The Company also has the ability, subject to limitations imposed by Rule 144 of the Securities Act of 1933 and other applicable laws and regulations, to raise money from the sale of common stock of the public companies in which it has ownership positions. In addition to the foregoing, the Company cannot predict the long-term impact on its development timelines, revenue levels and its liquidity due to the worldwide spread of COVID-19. Based upon the Company's current assessment, it does not expect the impact to be material. However, the Company is continuing to assess the impact the spread of COVID-19 may have on its operations.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with GAAP have been condensed or omitted. These condensed consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the unaudited condensed consolidated financial statements have read or have access to the audited financial statements for the preceding fiscal year for each of the companies: Avenue, Checkpoint and Mustang. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the Company's Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 16, 2020, from which the Company derived the balance sheet data at December 31, 2019, as well as Checkpoint's Form 10-K, filed with the SEC on March 11, 2020, Mustang's Form 10-K, filed with the SEC on March 16, 2020, and Avenue's Form 10-K, filed with the SEC on March 30, 2020.

The Company's unaudited condensed consolidated financial statements include the accounts of the Company's subsidiaries. For consolidated entities where the Company owns less than 100% of the subsidiary, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations equal to the percentage of the economic or ownership interest retained in such entities by the respective non-controlling parties. The Company also consolidates subsidiaries in which it owns less than 50% of the subsidiary but maintains voting control. The Company continually assesses whether changes to existing relationships or future transactions may result in the consolidation or deconsolidation of partner companies.

The preparation of the Company's unaudited condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of expenses during the reporting period.

Use of Estimates

The Company's unaudited condensed consolidated financial statements include certain amounts that are based on management's best estimates and judgments. The Company's significant estimates include, but are not limited to, useful lives assigned to long-lived assets, fair value of stock options and warrants, stock-based compensation, common stock issued to acquire licenses, investments, accrued expenses, provisions for income taxes and contingencies. Due to the uncertainty inherent in such estimates, actual results may differ from these estimates.

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2019 Annual Report.

Recently Adopted Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-13, *Fair Value Measurement (Topic 820), - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. On January 1, 2020, the Company's adoption of this guidance to did not have a material impact on its financial statements.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *"Financial Instruments – Credit Losses"*. The ASU sets forth a "current expected credit loss" (CECL) model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. This ASU is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, with early adoption permitted. Recently, the FASB issued the final ASU to delay adoption for smaller reporting companies to calendar year 2023 The Company is currently assessing the impact of the adoption of this ASU on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12, "*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

3. Discontinued Operations

The table below depicts the cash flows from the sale of the Company's investment inNational Holdings Corporation, a diversified independent brokerage company (together with its subsidiaries, herein referred to as "NHLD" or "National") for the three months ended March 31, 2019:

($ in thousands)	**March 31, 2019**
Investing activities	
Proceeds from sale of National	$ 13,089
Total cash provided by discontinued investing activities	$ 13,089

At March 31, 2020, the Company had no ownership interest in National.

4. Collaboration and Stock Purchase Agreements

Caelum

Agreement with Alexion

In January 2019, Caelum, a subsidiary of the Company, entered into a Development, Option and Stock Purchase Agreement (the "DOSPA") and related documents by and among Caelum, Alexion Therapeutics, Inc. ("Alexion"), the Company and Caelum security holders parties thereto (including Fortress, the "Sellers"). Under the terms of the agreement, Alexion purchased a 19.9% minority equity interest in Caelum for $30 million. Additionally, Alexion has agreed to make potential payments to Caelum upon the achievement of certain developmental milestones, in exchange for which Alexion obtained a contingent exclusive option to acquire the remaining equity in Caelum. The agreement also provides for potential additional payments, in the event Alexion exercises the purchase option, for up to $500 million, which includes an upfront option exercise payment and potential regulatory and commercial milestone payments.

In December 2019, following the U.S. Food and Drug Administration ("FDA") feedback which resulted in the redesign and expansion of Caelum's planned clinical development program for CAEL-101, Caelum entered into an Amended and Restated DOSPA, which amended the terms of the existing agreement with Alexion. The amendment modified the terms of Alexion's option to acquire the remaining equity in Caelum based on data from the expanded Phase II/III trials. The amendment also modified the development-related milestone events associated with the initial $30.0 million in contingent payments, provided for an additional $20.0 million in upfront funding, as well as funding of $60.0 million in exchange for an additional equity interest in Caelum at fair value upon achievement of a specific development-related milestone event.

Avenue

Agreement with InvaGen

On November 12, 2018, the Company's partner company Avenue entered into a Stock Purchase and Merger Agreement ("SPMA") with InvaGen Pharmaceuticals Inc. ("InvaGen") and Madison Pharmaceuticals Inc., a newly formed, wholly-owned subsidiary of InvaGen. Pursuant to the SPMA, and following approval by Avenue's stockholders on February 8, 2019, InvaGen purchased a number of shares of Avenue common stock representing 33.3% of Avenue's fully diluted capital stock for net proceeds to Avenue of $31.5 million (after deducting fees and other offering-related costs).

Upon the achievement of certain closing conditions (including most notably U.S. Food and Drug Administration approval for IV Tramadol, Avenue's product candidate), InvaGen will be obligated to acquire Avenue via reverse subsidiary merger (the "Merger Transaction"). Under the Merger Transaction, InvaGen will pay $180 million (subject to certain potential reductions) to the holders of Avenue's capital stock (other than InvaGen itself).

Subject to the terms and conditions described in the SPMA, InvaGen may also provide interim financing to Avenue in an amount of up to $7.0 million during the time period between February 8, 2019 and the Merger Transaction. Any amounts drawn on the interim financing will be deducted from the aggregate consideration payable to Company stockholders by virtue of the Merger Transaction.

Prior to the closing of the Merger Transaction, Avenue will enter into a Contingent Value Rights Agreement (the "CVR Agreement") with a trust company as rights agent, pursuant to which holders of common shares of Avenue, other than InvaGen (each, a "Holder"), will be entitled to receive on Contingent Value Right ("CVR") for each share held immediately prior to the Merger Transaction.

Each CVR represents the right of its holder to receive a contingent cash payment pursuant to the CVR Agreement upon the achievement of certain milestones. If, during the period commencing on the day following the closing of the Merger Transaction until December 31, 2028, IV Tramadol generates at least $325 million or more in Net Sales (as defined in the CVR Agreement) in a calendar year, each Holder shall be entitled to receive their pro rata share of (i) if the product generated less than $400 million in Net Sales during such calendar year, 10% of Gross Profit (as defined in the CVR Agreement), (ii) if the product generated between $400 million and $500 million in Net Sales during such calendar year, 12.5% of Gross Profit, or (iii) if the product generated more than $500 million in Net Sales during such calendar year, 15% of Gross Profit. Additionally, at any time beginning on January 1, 2029 that IV Tramadol has generated at least $1.5 billion in aggregate Net Sales, then with respect to each calendar year in which IV Tramadol generates $100 million or more in Net Sales, each Holder shall be entitled to receive their pro rata share of an amount equal to 20% of the Gross Profit generated by IV Tramadol. These additional payments will terminate on the earlier of December 31, 2036 and the date (which may be extended by up to 6 months) that any person has received approval from the FDA for an Abbreviated New Drug Application or an FDA AP-rated 505(b)(2) NDA using IV Tramadol.

5. Property and Equipment

Fortress' property and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	March 31, 2020	December 31, 2019
		(Unaudited)	
Computer equipment	3	$ 663	$ 648
Furniture and fixtures	5	1,199	1,162
Machinery & equipment	5	4,644	4,594
Leasehold improvements	5-15	10,580	9,358
Construction in progress [1]	N/A	712	1,157
Total property and equipment		17,798	16,919
Less: Accumulated depreciation		(5,013)	(4,486)
Property and equipment, net		$ 12,785	$ 12,433

Note 1: Relates to the Mustang cell processing facility.

Fortress' depreciation expense for the three months ended March 31, 2020 and 2019 was approximately $0.5 million and $0.5 million, respectively, and was recorded in both research and development expense and general and administrative expense in the Condensed Consolidated Statements of Operations.

6. Fair Value Measurements

Certain of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as accounts payable, accrued expenses and other current liabilities.

Fair Value of Caelum

The Company valued its investment in Caelum in accordance with ASC Topic 820,*Fair Value Measurements and Disclosures*, and estimated the fair value to be $11.1 million based on a per share value of $1.543. The following inputs were utilized to derive the value: risk free rate of return of 1.6%, volatility of 70% and a discount for lack of marketability of 28.7%.

In connection with the DOSPA Caelum's convertible notes automatically converted into common shares of Caelum and the warrant liability payable to the placement agent in connection with the placement of the convertible notes was also issued (see Note 10).

Cyprium Warrant Liability

The fair value of the Cyprium Contingently Issuable Warrants in connection with the 2018 Venture Debt was determined by applying management's estimate of the probability of issuance of the Contingently Issuable Warrants together with an option-pricing model, with the following key assumptions:

	March 31, 2020	December 31, 2019
Risk-free interest rate	0.70%	1.92%
Expected dividend yield	–	–
Expected term in years	10.0	10.0
Expected volatility	93%	93%
Probability of issuance of the warrant	10%	5%

($ in thousands)	Cyprium Contingently Issuable Warrant Liability
Ending balance at January 1, 2020	$ 27
Change in fair value	42
Ending balance at March 31, 2020	$ 69

The following tables classify into the fair value hierarchy of Fortress' financial instruments, measured at fair value as of March 31, 2020 and December 31, 2019:

	Fair Value Measurement as of March 31, 2020			
($ in thousands)	Level 1	Level 2	Level 3	Total
Assets				
Fair value of investment in Caelum	$ –	$ –	$ 11,148	$ 11,148
Total	$ –	$ –	$ 11,148	$ 11,148

	Fair Value Measurement as of March 31, 2020			
($ in thousands)	Level 1	Level 2	Level 3	Total
Liabilities				
Warrant liabilities	$ –	$ –	$ 69	$ 69
Total	$ –	$ –	$ 69	$ 69

	Fair Value Measurement as of December 31, 2019			
($ in thousands)	Level 1	Level 2	Level 3	Total
Assets				
Fair value of investment in Caelum	$ –	$ –	$ 11,148	$ 11,148
Total	$ –	$ –	$ 11,148	$ 11,148

	Fair Value Measurement as of December 31, 2019			
($ in thousands)	Level 1	Level 2	Level 3	Total
Liabilities				
Warrant liabilities	$ –	$ –	$ 27	$ 27
Total	$ –	$ –	$ 27	$ 27

The table below provides a roll-forward of the changes in fair value of Level 3 financial instruments as of March 31, 2020:

($ in thousands)	Investment in Caelum	Warrant Liabilities	Total
Balance at December 31, 2019	$ 11,148	$ 27	$ 11,175
Fair value of investment	-	42	42
Balance at March 31, 2020	$ 11,148	$ 69	$ 11,217

As of March 31, 2020, no transfers occurred between Level 1, Level 2 and Level 3 instruments.

7. Licenses Acquired

In accordance with ASC 730-10-25-1, *Research and Development*, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future use. The licenses purchased by Fortress, Aevitas, Avenue, Cellvation, Checkpoint, Cyprium, Helocyte, Mustang and Baergic require substantial completion of research and development, and regulatory and marketing approval efforts in order to reach technological feasibility. As such, for the three months ended March 31, 2020 and 2019, the purchase price of licenses acquired was classified as research and development-licenses acquired in the Condensed Consolidated Statements of Operations as reflected in the table below:

	For the Three Months Ended March 31,	
($ in thousands)	2020	2019
Partner company:		
Mustang	$ 250	$ 450
Total Research and Development – Licenses Acquired	$ 250	$ 450

Mustang

For the three months ended March 31, 2020 and 2019, Mustang recorded the following expense in research and development for licenses acquired:

	For the Three Months Ended March 31,	
($ in thousands)	2020	2019
City of Hope (COH) – CD123 (MB-102)	$ -	$ 250
COH – HER2 (MB-103)[1]	250	–
Nationwide Children's Hospital – C134 (MB-108)	-	200
Total	$ 250	$ 450

Note 1: Represents a non-refundable milestone payment in connection with the twentieth patient treated in the Phase 1 clinical study of MB-103 at COH.

8. Sponsored Research and Clinical Trial Agreements

Aevitas

In 2018, Aevitas entered into a Sponsored Research Agreement ("SRA") with the Trustees of the University of Pennsylvania ("UPenn SRA"), as amended in January 2020, for certain continued research and development activities related to the development of AAV gene therapies in complement-mediated diseases. For the three months ended March 31, 2020 and 2019, Aevitas recorded expense of $0.3 million and $0.3 million, respectively, in research and development associated with the UPenn SRA.

Cellvation

For the three months ended March 31, 2020 and 2019 Cellvation recorded expense of nil and $0.1 million, respectively, in connection with its sponsored research arrangement with the University of Texas. The expense was recorded in research and development expense in the Company's condensed consolidated statements of operations.

Mustang

For the three months ended March 31, 2020 and 2019, Mustang recorded the following expense in research and development for sponsored research and clinical trial agreements:

	For the Three Months Ended March 31,	
($ in thousands)	**2020**	**2019**
City of Hope (COH)	$ 500	$ 500
COH – CD123 (MB-102)	230	303
COH – IL13Rα2 (MB-101)	92	342
COH – manufacturing	-	114
Fred Hutch-CD20 (MB-106)	527	267
Beth Israel Deaconess Medical Center (BIDMC) – CRISPR	-	69
Total	$ 1,349	$ 1,595

9. Intangibles, net

On July 22, 2019 Journey purchased Ximino®, a minocycline hydrochloride used to treat acne from a third party. Pursuant to the terms and conditions of the Asset Purchase Agreement ("APA"), total consideration for the APA is $9.4 million, comprised of an upfront payment of $2.4 million payable within 60 days after execution on September 22, 2019. The remaining four payments totaling $7.0 million are due in consecutive years commencing on the second anniversary of execution of the APA. In addition, Journey is obligated to pay royalties in the mid-teens based on net sales of Ximino, subject to specified reductions.

The Company, in accordance with ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, determined the purchase of Ximino did not constitute the purchase of a business, and therefore recorded the purchase price of Ximino as an asset, to be amortized over the life of the product, which is deemed to be seven years. In addition, the Company determined pursuant to ASC 450, *Contingencies,* that royalty payments in connection with the APA will be recorded when they become payable with a corresponding charge to cost of goods sold.

In accordance with the terms of the APA, Journey will incur interest expense in the event of payment default. As such per ASC 835-30 *Interest-Imputed Interest,* Journey recorded an initial discount for imputed interest of $2.3 million. As of March 31, 2020, Journey recorded an intangible asset related to this transaction of $7.1 million which was recorded on the condensed consolidated balance sheet of Fortress.

The table below provides a summary of the Journey intangible assets as of March 31, 2020 and December 31, 2019, respectively:

($ in thousands)	**Estimated Useful Lives (Years)**	**March 31, 2020**	**December 31, 2019**
		(Unaudited)	
Intangible assets – asset purchases	3 to 7	$ 9,934	$ 9,934
Total		9,934	9,934
Accumulated amortization		(2,912)	(2,557)
Net intangible assets		$ 7,022	$ 7,377

The table below provides a summary for the three months ended March 31, 2020, of Journey's recognized expense related to its product licenses, which was recorded in costs of goods sold on the Condensed Consolidated Statement of Operations:

($ in thousands)	**Intangible Assets, Net**
Beginning balance at January 1, 2020	$ 7,377
Amortization expense	(355)
Ending balance at March 31, 2020	$ 7,022

The future amortization of these intangible assets is as follows ($ in thousands):

	Ximino®	Exelderm®	Total Amortization
Nine Months Ended December 31, 2020	$ 764	$ 300	$ 1,064
Year Ended December 31, 2021	1,019	267	1,286
Year Ended December 31, 2022	1,019	-	1,019
Year Ended December 31, 2023	1,019	-	1,019
Year Ended December 31, 2024	1,019	-	1,019
Thereafter	1,615		1,615
Total[1]	$ 6,455	$ 567	$ 7,022

10. Debt and Interest

Debt

Total debt consists of the following as of March 31, 2020 and December 31, 2019:

($ in thousands)	March 31, 2020	December 31, 2019	Interest rate	Maturity
IDB Note	$ 14,929	$ 14,929	2.25%	Aug – 2021
2017 Subordinated Note Financing	3,254	3,254	8.00%[3]	March - 2022
2017 Subordinated Note Financing	13,893	13,893	8.00%[3]	May - 2022
2017 Subordinated Note Financing	1,820	1,820	8.00%[3]	June - 2022
2017 Subordinated Note Financing	3,018	3,018	8.00%[3]	August - 2022
2017 Subordinated Note Financing	6,371	6,371	8.00%[3]	September - 2022
2018 Venture Notes	6,517	6,517	8.00%	August - 2021
2018 Venture Notes	15,190	15,190	8.00%	September - 2021
2019 Notes[1]	9,000	9,000	12.00%	September - 2021
Mustang Horizon Notes[2]	15,750	15,750	9.00%	October - 2022
Total notes payable	89,742	89,742		
Less: Discount on notes payable	4,354	5,086		
Total notes payable	$ 85,388	$ 84,656		

Note 1: Formerly the Opus Credit Facility
Note 2: Interest rate is 9.0% plus one-month LIBOR Rate in excess of 2.5%.
Note 3: As a result of a one-year maturity date extension effective 2020, the interest rate increased by 1% to 9.0%.
Note 4: At March 31, 2020 and December 31, 2019, $11.4 million and $6.0 million, respectively, are included in Notes payable, short-term on the condensed consolidated balance sheets.

2019 Notes (formerly the Opus Credit Facility Agreement)

As of December 31, 2019, Opus Point Healthcare Innovations Fund, LP (“OPHIF”) dissolved and distributed it assets among its limited partners. Following the distribution, the facility is comprised of three separate notes herein referred to as the 2019 Notes. The allocation of the $9.0 million facility was as follows: DAK Capital Inc.: $3.8 million; Fortress’s Chairman, President and Chief Executive Officer (Lindsay A. Rosenwald): $2.9 million; and Fortress’s Executive Vice President, Strategic Development (Michael S. Weiss): $2.3 million. Terms of the 2019 Notes did not change.

Interest Expense

The following table shows the details of interest expense for all debt arrangements during the periods presented. Interest expense includes contractual interest and amortization of the debt discount and amortization of fees represents fees associated with loan transaction costs, amortized over the life of the loan:

	Three Months Ended March 31,					
	2020			2019		
($ in thousands)	*Interest*	*Fees [1]*	Total	*Interest*	*Fees [1]*	Total
IDB Note	$ 84	$ -	$ 84	$ 83	$ -	$ 83
2017 Subordinated Note Financing	1,084	312	1,396	1,028	363	1,391
2019 Notes	269	-	269	281	113	394
2018 Venture Notes	433	176	609	429	146	575
LOC Fees	15	–	15	15	–	15
Mustang Horizon Notes	341	259	600	11	–	11
Note Payable[2]	150	–	150	–	–	–
Other	2	–	2	–	–	–
Total Interest Expense and Financing Fee	$ 2,378	$ 747	$ 3,125	$ 1,847	$ 622	$ 2,469

Note 1: Amortization of fees
Note 2: Imputed interest expense related to Ximino purchase (see Note 9).

11. Accrued Liabilities and other Long-Term Liabilities

Accrued expenses and other long-term liabilities consisted of the following:

($ in thousands)	March 31, 2020	December 31, 2019
Accrued expenses:		
Professional fees	$ 1,050	$ 1,153
Salaries, bonuses and related benefits	6,139	6,683
Accrued expense – related party	13	-
Research and development	2,096	4,215
Research and development - manufacturing	1,032	1,017
Research and development – clinical supplies	2,055	-
Research and development - license maintenance fees	133	361
Research and development - milestones	850	-
Accrued royalties payable	2,456	2,320
Accrued coupon expense	8,735	8,391
Other	1,311	1,259
Total accrued expenses	$ 25,870	$ 25,399
Other long-term liabilities:		
Deferred rent and long-term lease abandonment charge[1]	$ 2,089	$ 2,136
Long-term note payable [2]	5,140	4,990
Total other long-term liabilities	$ 7,229	$ 7,126

Note 1: As of March 31, 2020, and December 31, 2019, balance consists of deferred charges related to build-out of the New York facility.
Note 2: As of March 31, 2020 and December 31, 2019, balance consists of Journey's note payable of $7.0 million, net of an imputed interest discount of $1.9 million and $2.0 million, respectively, in connection with its acquisition of Ximino in July 2019 (see Note 9). The imputed interest discount was calculated utilizing an 11.96% effective interest rate based upon a non-investment grade "CCC" rate over a five-year period. Amortization of interest discount was $0.1 million for the three months ended March 31, 2020. No expense was recorded for the three months ended March 31, 2019.

12. Non-Controlling Interests

Non-controlling interests in consolidated entities are as follows:

($ in thousands)	As of March 31, 2020 NCI equity share	For the three months ended March 31, 2020 Net loss attributable to non-controlling interests	As of March 31, 2020 Non-controlling interests in consolidated entities	Non-controlling ownership
Aevitas	$ (1,989)	$ (186)	$ (2,175)	35.8%
Avenue [2]	5,419	(955)	4,464	77.3%
Baergic	(1,201)	(3)	(1,204)	33.0%
Cellvation	(917)	(38)	(955)	20.6%
Checkpoint [1]	15,121	(2,403)	12,718	78.4%
Coronado SO	(290)	-	(290)	13.0%
Cyprium	(795)	(89)	(884)	18.9%
Helocyte	(4,700)	(165)	(4,865)	18.8%
JMC	118	159	277	6.9%
Mustang [2]	39,640	(8,008)	31,632	69.0%
Tamid	(651)	(10)	(661)	22.8%
Total	$ 49,755	$ (11,698)	$ 38,057	

($ in thousands)	As of December 31, 2019 NCI equity share	For the twelve months ended December 31, 2019 Net loss attributable to non-controlling interests	As of December 31, 2019 Non-controlling interests in consolidated entities	Non-controlling ownership
Aevitas	$ (1,249)	$ (694)	$ (1,943)	35.8%
Avenue [2]	24,269	(19,011)	5,258	77.3%
Baergic	23	(1,162)	(1,139)	33.0%
Cellvation	(732)	(158)	(890)	20.6%
Checkpoint [1]	29,389	(14,687)	14,702	78.0%
Coronado SO	(290)	-	(290)	13.0%
Cyprium	(320)	(99)	(419)	10.6%
Helocyte	(4,322)	(402)	(4,724)	19.3%
JMC	(211)	325	114	6.9%
Mustang [2]	62,025	(25,727)	36,298	70.3%
Tamid	(565)	(85)	(650)	22.8%
Total	$ 108,017	$ (61,700)	$ 46,317	

Note 1: Checkpoint is consolidated with Fortress' operations because Fortress maintains voting control through its ownership of Checkpoint's Class A Common Shares which provide super-majority voting rights.

Note 2: Avenue and Mustang are consolidated with Fortress' operations because Fortress maintains voting control through its ownership of Preferred Class A Shares which provide super-majority voting rights.

13. Net Loss per Common Share

The Company calculates loss per share using the two-class method, which is an earnings allocation formula that determines earnings per share for Common Stock and participating securities, if any, according to dividends declared and non-forfeitable participation rights in undistributed earnings. Under this method, all earnings (distributed and undistributed) are allocated to Common Stock and participating securities, if any, based on their respective rights to receive dividends. Holders of restricted Common Stock were entitled to all cash dividends, when and if declared, and such dividends are non-forfeitable. The participating securities do not have a contractual obligation to share in any losses of the Company. As a result, net losses are not allocated to the participating securities for any periods presented.

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of Common Stock outstanding during the period, without consideration for Common Stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of Common Stock and Common Stock equivalents outstanding for the period.

Included in Common Stock issued and outstanding as of March 31, 2020 and 2019 were 14,307,564 and 12,622,076 shares of unvested restricted stock, which is excluded from the weighted average Common Stock outstanding for the quarter ended March 31, 2020 since its effect would be dilutive.

The following table sets forth the computation of earnings per share attributable to common stockholders for the quarter ended March 31, 2019 (amounts in thousands except share and per share data):

	Three Months Ended March 31, 2019
Net income attributable to common stockholders	$ 1,392
Weighted average shares outstanding - basic	48,506,994
Preferred stock, Series A	1,000,000
Stock options	378,835
Warrants	60,000
Unvested restricted stock	12,622,076
Unvested restricted stock units	1,243,231
Weighted average shares outstanding - diluted	63,811,136
Per share data:	
Basic	$ 0.03
Diluted	$ 0.02

The Company's common stock equivalents, including unvested restricted stock, options, and warrants have been excluded from the computation of diluted loss per share for the three months ended March 31, 2020 as the effect would be to reduce the loss per share. Therefore, the weighted average common stock outstanding used to calculate both basic and diluted income loss per share is the same for the quarter ended March 31, 2020.

The following shares of potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding, as the effect of including such securities would be anti-dilutive for the three months ended March 31, 2020:

	March 31, 2020
Warrants to purchase Common Stock	773,234
Opus warrants to purchase Common Stock	1,880,000
Options to purchase Common Stock	1,210,502
Convertible Preferred Stock	1,706,208
Unvested Restricted Stock	14,307,564
Unvested Restricted Stock Units	487,996
Total	20,365,504

14. Stockholders' Equity

Stock-based Compensation

The following table summarizes the stock-based compensation expense from stock option, employee stock purchase programs and restricted Common Stock awards and warrants for the three months ended March 31, 2020 and 2019:

	For the Three Months Ended March 31,	
($ in thousands)	**2020**	**2019**
Employee awards	$ 1,217	$ 935
Executive awards of Fortress partner companies' stock	401	352
Non-employee awards	54	(2)
Fortress partner companies:		
Avenue	215	751
Checkpoint	639	798
Mustang	805	432
Other	69	43
Total stock-based compensation	$ 3,400	$ 3,309

For the three months ended March 31, 2020 and 2019, approximately $0.9 million and $0.6 million, respectively, of stock-based compensation expense was included in research and development expenses in connection with equity grants made to employees and consultants and approximately $2.5 million and $2.7 million, respectively, was included in general and administrative expenses in connection with grants made to employees, members of the board of directors and consultants.

Stock Options

The following table summarizes Fortress stock option activities excluding activity related to Fortress partner companies:

	Number of shares	Weighted average exercise price	Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Options vested and expected to vest at December 31, 2019	1,410,501	$ 4.30	$ 684,752	2.33
Options vested and expected to vest at March 31, 2020	1,410,501	$ 4.30	$ 285,744	2.08
Options vested and exercisable at March 31, 2020	1,310,501	$ 4.54	$ 214,744	1.95

As of March 31, 2020, Fortress had no unrecognized stock-based compensation expense related to options.

Restricted Stock and Restricted Stock Units

The following table summarizes Fortress restricted stock awards and restricted stock units activities, excluding activities related to Fortress Companies:

	Number of shares	Weighted average grant price
Unvested balance at December 31, 2019	13,768,014	$ 2.46
Restricted stock granted	1,873,072	2.57
Restricted stock vested	(1,539,564)	2.69
Restricted stock units granted	6,836	2.56
Restricted stock units forfeited	(81,250)	3.28
Restricted stock units vested	(79,335)	3.56
Unvested balance at March 31, 2020	13,947,773	$ 2.47

As of March 31, 2020 and 2019, the Company had unrecognized stock-based compensation expense related to restricted stock and restricted stock unit awards of approximately $17.9 million and $14.8 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 4.2 years and 5.4 years, respectively.

Warrants

The following table summarizes Fortress warrant activities, excluding activities related to Fortress Companies:

	Number of shares	Weighted average exercise price	Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Outstanding as of December 31, 2019	2,741,180	$ 3.19	$ 111,000	2.73
Granted	–	–	–	–
Forfeited	–	–	–	–
Outstanding as of March 31, 2020	2,741,180	$ 3.19	$ 31,200	2.48
Exercisable as of March 31, 2020	2,656,180	$ 2.79	$ 31,200	1.99

Employee Stock Purchase Plan

Eligible employees can purchase the Company's Common Stock at the end of a predetermined offering period at 85% of the lower of the fair market value at the beginning or end of the offering period. The ESPP is compensatory and results in stock-based compensation expense.

As of March 31, 2020, 454,515 shares have been purchased and 545,485 shares are available for future sale under the Company's ESPP. Share-based compensation expense recorded was approximately $18,000 and $20,000, respectively, for the three months ended March 31, 2020 and 2019.

Capital Raises

At-the-Market Offering

Pursuant to the terms of the Company's Amended and Restated At Market Issuance Sales Agreement, or Sales Agreement, with B. Riley FBR, Inc. ("B. Riley," f/k/a MLV & Co. LLC, and FBR Capital Markets & Co.) (the "ATM"), for the three-month period ended March 31, 2020, the Company issued approximately 2.3 million shares of common stock at an average price of $2.59 per share for gross proceeds of $6.1 million. In connection with these sales, the Company paid aggregate fees of approximately $0.2 million.

These shares were sold pursuant to the current shelf registration statement on Form S-3; approximately $17.9 million of the shelf remains available for sale at March 31, 2020.

9.375% Series A Cumulative Redeemable Perpetual Preferred Stock Offering

On February 14, 2020, the Company announced the closing of an underwritten public offering, whereby it sold 625,000 shares of its 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (Nasdaq: FBIOP) (the "Preferred Stock"), (plus a 45-day option to purchase up to an additional 93,750 shares, which was exercised in February 2020) at a price of $20.00 per share for gross proceeds of approximately $14.4 million, before deducting underwriting discounts and commissions and offering expenses of approximately $1.3 million.

The shares of Preferred Stock were sold under the Company's shelf registration statement on Form S-3 originally filed on July 6, 2018 and declared effective July 23, 2019 (the "2019 Shelf"). Approximately $17.9 million of securities remain available for sale under the 2019 Shelf at March 31, 2020.

Mustang Bio, Inc.

Mustang At-the-Market Offering

On July 13, 2018, Mustang filed a shelf registration statement No. 333-226175 on Form S-3, as amended on July 20, 2018 (the "2018 Mustang S-3"), which was declared effective in August 2018. Under the 2018 Mustang S-3, Mustang may sell up to a total of $75.0 million of its securities. In connection with the 2018 Mustang S-3, Mustang entered into an At-the-Market Issuance Sales Agreement (the "Mustang ATM") with B. Riley FBR, Inc., Cantor Fitzgerald & Co., National Securities Corporation, and Oppenheimer & Co. Inc. (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock. Under the Mustang ATM, Mustang pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

During the three months ended March 31, 2020, Mustang issued approximately 1.2 million shares of common stock at an average price of $3.93 per share for gross proceeds of $5.0 million under the Mustang ATM. In connection with these sales, Mustang paid aggregate fees of approximately $0.1 million for net proceeds of approximately $4.9 million. No sales were made under the 2018 Mustang ATM during the three months ended March 31, 2019. Pursuant to the Founders Agreement, Mustang issued 31,220 shares of common stock to Fortress at a weighted average price of $4.00 per share for the ATM offering noted above.

Approximately $15.9 million of the shelf remains available for sale under the 2018 Mustang S-3, following the offerings noted above. Mustang may offer the securities under the 2018 Mustang S-3 from time to time in response to market conditions or other circumstances if it believes such a plan of financing is in the best interests of its stockholders.

Share Repurchase Program

On March 23, 2020, the Company announced that its Board of Directors had approved a share repurchase program of the Company's outstanding Preferred Stock in an aggregate amount of up to $5 million. Repurchases under the program may be made in the open market or through privately-negotiated transactions from time to time up until the earlier to occur of the repurchase of $5 million of the Company's Preferred Stock or the close of trading on May 31, 2020, subject to applicable laws and regulations. The program may be amended, suspended, or discontinued at any time and does not commit the Company to repurchase any shares of Preferred Stock. As of March 31, 2020, 5,000 Preferred Stock shares have been repurchased under this program for total consideration of $0.1 million, net of fees of approximately $2,000, and are recorded as Treasury stock on the consolidated balance sheet.

15. Commitments and Contingencies

Most of the Company's lease liabilities result from the lease of its New York City, NY office, which expires in 2031, and Mustang's Worcester, MA cell processing facility lease, which expires in 2026. Such leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Certain of the Company's leases include renewal options and escalation clauses; renewal options have not been included in the calculation of the lease liabilities and right of use assets as the Company is not reasonably certain to exercise the options. The Company does not act as a lessor or have any leases classified as financing leases. On March 31, 2020, the Company had operating lease liabilities of $23.7 million and right of use assets of $21.1 million, which were included in the condensed consolidated balance sheet.

During the three months ended March 31, 2020 and 2019, the Company recorded the following as lease expense.

($ in thousands)	**As of March 31, 2020**	**As of March 31, 2019**
Lease cost		
Operating lease cost	$ 809	$ 796
Shared lease costs	(470)	(477)
Variable lease cost	264	26
Total lease cost	$ 603	$ 345

The following tables summarize quantitative information about the Company's operating leases, under the adoption of*Topic 842*:

($ in thousands)	**Three Month Ended March 31, 2020**	**Three Months Ended March 31, 2019**
Operating cash flows from operating leases	$ (451)	$ (767)
Right-of-use assets exchanged for new operating lease liabilities	$ 21,076	$ 22,618
Weighted-average remaining lease term – operating leases (years)	6.1	6.7
Weighted-average discount rate – operating leases	6.2%	6.2%

($ in thousands)	**Future Lease Liability**
Nine months ended December 31, 2020	$ 2,515
Year ended December 31, 2021	3,114
Year ended December 31, 2022	3,084
Year ended December 31, 2023	3,137
Year ended December 31, 2024	3,190
Other	20,273
Total operating lease liabilities	35,313
Less: present value discount	(9,872)
Net operating lease liabilities, short-term and long-term	$ 25,441

Indemnification

In accordance with its certificate of incorporation, bylaws and indemnification agreements, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date, and the Company has director and officer insurance to address such claims. Pursuant to agreements with clinical trial sites, the Company provides indemnification to such sites in certain conditions.

Legal Proceedings

Fortress Biotech, Inc.

In the ordinary course of business, the Company and its subsidiaries may be subject to both insured and uninsured litigation. Suits and claims may be brought against the Company by customers, suppliers, partners and/or third parties (including tort claims for personal injury arising from clinical trials of the Company's product candidates and property damage) alleging deficiencies in performance, breach of contract, etc., and seeking resulting alleged damages.

16. Related Party Transactions

Other Related Parties

The Company's Chairman, President and Chief Executive Officer, individually and through certain trusts over which he has voting and dispositive control, beneficially owned approximately 11.9% of the Company's issued and outstanding Common Stock as of March 31, 2020. The Company's Executive Vice Chairman, Strategic Development owns approximately 13.0% of the Company's issued and outstanding Common Stock at March 31, 2020.

Shared Services Agreement with TGTX

TGTX and the Company entered into an arrangement to share the cost of certain research and development employees. The Company's Executive Vice Chairman, Strategic Development, is Executive Chairman and Interim Chief Executive Officer of TGTX. Under the terms of the Agreement, TGTX will reimburse the Company for the salary and benefit costs associated with these employees based upon actual hours worked on TGTX related projects. For the three months ended March 31, 2020 and 2019, the Company invoiced TGTX $0.1 million and $0.1 million, respectively. On March 31, 2020, the amount receivable from TGTX related to this arrangement approximated $36,000.

Desk Space Agreements with TGTX and OPPM

In connection with the Company's Desk Space Agreements with TGTX and Opus Point Partners Management, LLC ("OPPM"), as of March 31, 2020, the Company had paid $0.7 million in rent under the Desk Space Agreements, and invoiced TGTX and OPPM approximately $0.4 million and nil, respectively, for their prorated share of the rent base. On March 31, 2020, the amount due from TGTX approximated $0.1 million and the amount due from OPPM approximated $0.4 million.

2019 Notes (formerly the Opus Credit Facility)

On March 12, 2018, the Company and OPHIF amended and restated the Opus Credit Facility (the "A&R Opus Credit Facility"). The A&R Opus Credit Facility extended the maturity date of the notes issued under the Opus Credit Facility from September 14, 2018 by one year to September 14, 2019. The A&R Opus Credit Facility also permits the Company to make portions of interest and principal repayments in the form of shares of the Company's common stock and/or in common stock of the Company's publicly-traded subsidiaries, subject to certain conditions. On September 13, 2019, the Company and OPHIF extended the maturity dates of the notes from September 14, 2019 by two years to September 14, 2021. Fortress retains the ability to prepay the Notes at any time without penalty. The notes payable under the A&R Opus Credit Facility continue to bear interest at 12% per annum.

As of December 31, 2019, OPHIF dissolved and distributed it assets among its limited partners. Following the distribution, the facility is comprised of three separate notes herein referred to as the 2019 Notes. The allocation of the $9.0 million Opus Credit Facility was as follows: DAK Capital Inc.: $3.8 million; Fortress's Chairman, President and Chief Executive Officer (Lindsay A. Rosenwald): $2.9 million; and Fortress's Executive Vice President, Strategic Development (Michael S. Weiss): $2.3 million. Terms of the 2019 Notes did not change.

For the three months ended March 31, 2020 and 2019, the Company paid interest in the Company's common stock of $0.2 million or 60,245 shares at $2.58 and $0.3 million or 131,353 shares at $2.14, respectively, in connection with the 2019 Notes.

Founders Agreements

The Company has entered into Founders Agreements and, in some cases, Exchange Agreements with certain of its subsidiaries as described in the Company's Form 10-K for the year ended December 31, 2018, filed with the SEC on March 16, 2020. The following table summarizes, by subsidiary, the effective date of the Founders Agreements and PIK dividend or equity fee payable to the Company in accordance with the terms of the Founders Agreements, Exchange Agreements, and the subsidiaries' certificates of incorporation.

Founders Agreements

The Company has entered into Founders Agreements and, in some cases, Exchange Agreements with certain of its subsidiaries as described in the Company's Form 10-K for the year ended December 31, 2019, filed with the SEC on March 16, 2020. The following table summarizes, by subsidiary, the effective date of the Founders Agreements and PIK dividend or equity fee payable to the Company in accordance with the terms of the Founders Agreements, Exchange Agreements, and the subsidiaries' certificates of incorporation.

Fortress Partner Company	Effective Date [1]	PIK Dividend as a % of fully diluted outstanding capitalization	Class of Stock Issued
Helocyte	March 20, 2015	2.5%	Common Stock
Avenue	February 17, 2015	0.0%[2]	Common Stock
Mustang	March 13, 2015	2.5%	Common Stock
Checkpoint	March 17, 2015	0.0%[3]	Common Stock
Cellvation	October 31, 2016	2.5%	Common Stock
Caelum	January 1, 2017	0.0%[4]	Common Stock
Baergic	December 17, 2019[5]	2.5%	Common Stock
Cyprium	March 13, 2017	2.5%	Common Stock
Aevitas	July 28, 2017	2.5%	Common Stock
Tamid	November 30, 2017 [5]	2.5%	Common Stock

Note 1: Represents the effective date of each subsidiary's Founders Agreement. Each PIK dividend and equity fee is payable on the annual anniversary of the effective date of the original Founders Agreement or has since been amended to January 1 of each calendar year.

Note 2: Concurrently with the execution and delivery of the Stock Purchase and Merger Agreement ("SPMA") entered into between, Avenue, the Company and InvaGen Pharmaceuticals Inc. ("InvaGen") (together, the "SPMA Parties"), the SPMA Parties entered into a waiver agreement (the "Waiver Agreement"), pursuant to which the Company irrevocably waived its right to receive the annual dividend of Avenue's common shares under the terms of the Class A preferred stock and any fees, payments, reimbursements or other distributions under the management services agreement between the Company and Avenue and the Founders Agreement, for the period from the effective date of the Waiver Agreement to the termination of InvaGen's rights under the SPMA. Pursuant to the Waiver Agreement, immediately prior to the closing of the Merger Transaction contemplated under the SPMA, the Company will convert all of its preferred shares into common shares pursuant to the terms of the certificate of incorporation of Avenue, as amended from time to time.

Note 3: Instead of a PIK dividend, Checkpoint pays the Company an annual equity fee in shares of Checkpoint's common stock equal to 2.5% of Checkpoint's fully diluted outstanding capitalization.

Note 4: Effective January 31, 2019 the Caelum Founders Agreement and MSA with Fortress were terminated in conjunction with the execution of a Development Option and Share Purchase Agreement ("DOSPA") between Caelum and Alexion Therapeutics, Inc. (See Note 4).

Note 5: Represents the Trigger Date, the date that the Fortress partner company first acquires, whether by license or otherwise, ownership rights in a product.

Management Services Agreements

The Company has entered in Management Services Agreements (the "MSAs") with certain of its subsidiaries as described in the Company's Form 10-K for the year ended December 31, 2019, filed with the SEC on March 16, 2020. The following table summarizes, by subsidiary, the effective date of the MSA and the annual consulting fee payable by the subsidiary to the Company in quarterly installments:

Fortress partner company	**Effective Date**	**Annual MSA Fee (Income)/Expense**
Helocyte	March 20, 2015	$ 500
Avenue [1]	February 17, 2015	–
Mustang	March 13, 2015	500
Checkpoint	March 17, 2015	500
Cellvation	October 31, 2016	500
Baergic	March 9, 2017	500
Cyprium	March 13, 2017	500
Aevitas	July 28, 2017	500
Tamid[2]	November 30, 2017	-
Fortress		(3,500)
Consolidated (Income)/Expense		$ –

Note 1: Concurrently with the execution and delivery of the SPMA entered into between, Avenue, the Company and InvaGen Pharmaceuticals Inc. ("InvaGen") (together, the "SPMA Parties"), the SPMA Parties entered into a waiver agreement (the "Waiver Agreement"), pursuant to which the Company irrevocably waived its right to receive the annual dividend of Avenue's common shares under the terms of the Class A preferred stock and any fees, payments, reimbursements or other distributions under the management services agreement between the Company and Avenue and the Founders Agreement, for the period from the effective date of the Waiver Agreement to the termination of InvaGen's rights under the SPMA. Pursuant to the Waiver Agreement, immediately prior to the closing of the Merger Transaction contemplated under the SPMA, the Company will convert all of its preferred shares into common shares pursuant to the terms of the certificate of incorporation of Avenue, as amended from time to time. (See Note 4).

Note 2: In December 2019, Tamid discontinued development and terminated the related licenses and clinical trial agreements with the University of North Carolina at Chapel Hill for all three of its preclinical product candidates, effectively terminating their MSA with the Company.

17. Segment Information

The Company operates in two reportable segments, Dermatology Product Sales and Pharmaceutical and Biotechnology Product Development. The accounting policies of the Company's segments are the same as those described in Note 2. The following tables summarize, for the periods indicated, operating results from continued operations by reportable segment:

($ in thousands) **Three Months Ended March 31, 2020**	**Dermatology Products Sales**	**Pharmaceutical and Biotechnology Product Development**	**Consolidated**
Net revenue	$ 11,946	$ 972	$ 12,918
Direct cost of goods	(3,810)	–	(3,810)
Sales and marketing costs	(4,679)	–	(4,679)
Research and development	–	(15,117)	(15,117)
General and administrative	(953)	(9,887)	(10,840)
Other expense	(207)	(2,333)	(2,540)
Segment income (loss)	$ 2,297	(26,365)	$ (24,068)
Segment assets			
Intangible assets, net	7,022	-	7,022
Tangible assets	23,550	198,187	221,737
Total segment assets	$ 30,572	$ 198,187	$ 228,759

($ in thousands) **Three Months Ended March 31, 2019**	**Dermatology Products Sales**	**Pharmaceutical and Biotechnology Product Development**	**Consolidated**
Net revenue	$ 6,125	$ 352	$ 6,477
Direct cost of goods	(1,884)	–	(1,884)
Sales and marketing costs	(3,493)	–	(3,493)
Research and development	–	(23,723)	(23,723)
General and administrative	(387)	(9,598)	(9,985)
Other expense	-	16,353	16,353
Segment income (loss)	$ 361	$ (16,616)	$ (16,255)
Segment assets			
Intangible assets, net	1,183	-	1,183
Tangible assets	9,896	189,459	199,355
Total segment assets	$ 11,079	$ 189,459	$ 200,538

18. Revenues from Contracts and Significant Customers

Disaggregation of Total Revenue

Product revenue is comprised of Journey's five marketed products: Targadox®, Luxamend®, Ceracade®, Exelderm® and Ximino®. Substantially all of the product revenue is recorded in the U.S. The Company's related party revenue is from Checkpoint's collaboration with TGTX. The table below summarizes the Company's revenue for the three months ending March 31, 2020 and 2019:

	Three months ended March 31,	
($ in thousands)	**2020**	**2019**
Product revenue, net	$ 11,946	$ 6,125
Revenue – related party	972	352
Net Revenue	$ 12,918	$ 6,477

Significant Customers

For the three months ended March 31, 2020, two of the Company's Dermatology Products customers accounted for more than 10.0% of its total gross product revenue in the amount of $7.7 million and $5.1 million.

For the three months ended March 31, 2019, one of the Company's Dermatology Products customers accounted for more than 10.0% of its total gross product revenue in the amount of $19.9 million.

At March 31, 2020, two of the Company's Dermatology Products customers accounted for more than 10.0% of its total accounts receivable balance in the amount of $5.4 million and $2.5 million.

At March 31, 2019, one of the Company's Dermatology Products customers accounted for more than 10.0% of its total accounts receivable balance in the amount of $7.7 million.

19. Incomes taxes

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods and modifications to the net interest deduction limitations. At this time, the Company does not believe that the CARES Act will have a material impact on its income tax provision for 2020. The Company will continue to evaluate the impact of the CARES Act on its financial position, results of operations and cash flows.

The Company and its subsidiaries are subject to US federal and state income taxes. Income tax expense is the total of the current year income tax due or refundable and the change in deferred tax assets and liabilities. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of Management, it is more likely than not that some portion, or all, of the deferred tax asset will not be realized.

The Company files a consolidated income tax return with subsidiaries for which the Company has an 80% or greater ownership interest. Subsidiaries for which the Company does not have an 80% or more ownership are not included in the Company's consolidated income tax group and file their own separate income tax return. As a result, certain corporate entities included in these financial statements are not able to combine or offset their taxable income or losses with other entities' tax attributes.

Income tax expense for the three months ended March 31, 2020 and 2019 is based on the estimated annual effective tax rate.

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

Forward-Looking Statements

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes included elsewhere in this Form 10-Q. Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," "may," "plan", "seek" or similar language. All forward-looking statements included in this document are based on information available to us on the date hereof and we assume no obligation to update any such forward-looking statements. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially, from those projected in the forward-looking statements. In evaluating our business, you should carefully consider the information set forth under the heading "Risk Factors" herein and in our Annual Report on Form 10-K for the year ended December 31, 2019.

Overview

We are a biopharmaceutical company dedicated to acquiring, developing and commercializing pharmaceutical and biotechnology products and product candidates, which we do at the Fortress level, at our majority-owned and majority-controlled subsidiaries and joint ventures, and at entities we founded and in which we maintain significant minority ownership positions. Fortress has a talented and experienced business development team, comprising scientists, doctors, and finance professionals, who identify and evaluate promising products and product candidates for potential acquisition by new or existing partner companies. Through our partner companies, we have executed such arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center, Fred Hutchinson Cancer Research Center, St. Jude Children's Research Hospital, Dana-Farber Cancer Institute, Nationwide Children's Hospital, Cincinnati Children's Hospital Medical Center, Columbia University, the University of Pennsylvania, and AstraZeneca plc.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, we leverage our business, scientific, regulatory, legal and finance expertise to help our partners achieve their goals. Our partner companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out-licensings, and public and private financings; to date, three partner companies are publicly-traded, and two have consummated strategic partnerships with industry leaders Alexion Pharmaceuticals, Inc. and InvaGen Pharmaceuticals, Inc. (a subsidiary of Cipla Limited).

Recent Events

Marketed Dermatology Products

During the three months ended March 31, 2020, through our partner company Journey Medical Corporation ("Journey" or "JMC"), our marketed products generated net revenue of $11.9 million.

Late Stage Product Candidates

Intravenous (IV) Tramadol

IV Tramadol is currently in development with our partner company, Avenue Therapeutics, Inc. ("Avenue") (NASDAQ: ATXI). Avenue submitted a new drug application ("NDA") for IV Tramadol to treat moderate to moderately severe postoperative pain pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA") in December 2019. In February 2020, the FDA accepted Avenue's NDA submission and set a Prescription Drug User Fee Act goal date of October 10, 2020.

CUTX-101 (Copper Histidinate)

In January 2020, Cyprium Therapeutics, Inc. ("Cyprium") announced that the U.S. Food and Drug Administration ("FDA") had granted Rare Pediatric Disease Designation to Cyprium's Copper Histidinate, also referred to as CUTX-101, for the treatment of Menkes disease. Menkes disease is a rare X-linked recessive pediatric disease caused by genetic mutations of the copper transporter, ATP7A. The FDA previously granted Orphan Drug and Fast Track Designations to CUTX-101 for the treatment of Menkes disease. The FDA grants Rare Pediatric Disease Designation for serious and life-threatening diseases that primarily affect children ages 18 years or younger and fewer than 200,000 people in the United States. If Cyprium's NDA is approved, it may be eligible to receive a priority review voucher, which can be redeemed to obtain priority review for any subsequent marketing application and may be sold or transferred. This program is intended to encourage development of new drugs and biologics for the prevention and treatment of rare pediatric diseases.

MB-107 (Ex vivo Lentiviral Therapy for X-linked Severe Combined Immunodeficiency (XSCID))

In April 2020, Mustang Bio, Inc. ("Mustang") (NASDAQ: MBIO) announced that the European Medicines Agency ("EMA") had granted Advanced Therapy Medicinal Product ("ATMP") classification to MB-107, Mustang's lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency ("XSCID"), also known as bubble boy disease. The FDA previously granted Regenerative Medicine Advanced Therapy ("RMAT") designation to MB-107 for the treatment of XSCID in August 2019.

In May 2020, Mustang submitted an IND application with the FDA to initiate a multicenter Phase 2 clinical trial of MB-107 in newly diagnosed infants with XSCID who are under the age of two. The trial is expected to enroll 10 patients who, together with 15 patients enrolled in the current multicenter trial led by St. Jude Children's Research Hospital, will be compared with 25 matched historical control patients who have undergone hematopoietic stem cell transplant ("HSCT"). The primary efficacy endpoint will be event-free survival. The initiation of this trial is currently on hold pending CMC clearance by the FDA. Mustang is targeting topline data from the trial in the second half of 2022.

Mustang further expects to file an IND in the third quarter of 2020 for a registrational multi-center Phase 2 clinical trial of its lentiviral gene therapy in previously transplanted XSCID patients. This product will be designated MB-207. Mustang anticipates enrolling 20 patients and comparing them to matched historical control patients who have undergone a second HSCT. Mustang is targeting topline data for this trial in the second half of 2022.

Cosibelimab (formerly CK-301)

Our partner company, Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ: CKPT) continues to enroll cutaneous squamous cell carcinoma ("CSCC") patients to support an initial BLA submission for Cosibelimab based on their ongoing clinical trial. Additional information on the Phase 1 trial can be found on www.ClinicalTrials.gov using identifier NCT03212404.

In April 2020, Checkpoint announced that the U.S. Patent and Trademark Office had issued a composition of matter patent for Cosibelimab. U.S. Patent No. 10,590,199 specifically covers the antibody, Cosibelimab, or a fragment thereof, providing protection through at least May 2038, exclusive of any additional patent-term extensions that might become available.

Early Stage Product Candidates

MB-106 (CD20-targeted CAR T cell therapy)

In February 2020, Mustang announced that the first subject treated with the optimized MB-106 manufacturing process, developed in collaboration between Mustang and Fred Hutchinson Cancer Research Center ("Fred Hutch"), has achieved a complete response ("CR") at the lowest starting dose in an ongoing Phase 1/2 clinical trial. The trial is evaluating the safety and efficacy of MB-106 in subjects with relapsed or refractory B-cell non-Hodgkin lymphomas. Additional information on the Phase 1/2 trial can be found on www.ClinicalTrials.gov using identifier NCT03277729.

ONCOlogues (proprietary platform technology using oligonucleotides)

In May 2020, we entered into an exclusive worldwide licensing agreement with Columbia University to develop novel oligonucleotides for the treatment of genetically driven cancers. The proprietary platform produces oligomers, known as "ONCOlogues," which are capable of binding gene sequences 1,000 times more effectively than complementary native DNA. ONCOlogues invade a DNA double helix and displace native mutated strands. This prevents the mRNA that antisense binds to from ever being created. It is higher upstream than an antisense approach as well as potentially more potent and broader in its utility.

In addition, we are exploring the potential of the platform to treat novel coronaviruses, such as COVID-19.

The ONCOlogues platform is currently in development at our partner company, Oncogenuity, Inc.

General Corporate

In February 2020 Fortress announced the pricing of an underwritten public offering of 625,000 shares of its Perpetual Preferred Stock, (plus a 45-day option to purchase up to an additional 93,750 shares, which was exercised in February 2020) at a price of $20.00 per share for gross proceeds of approximately $14.4 million, before deducting underwriting discounts and commissions and offering expenses of $1.3 million.

Critical Accounting Policies and Use of Estimates

See Note 2 to the Condensed Consolidated Financial Statements.

Results of Operations

General

For the three months ended March 31, 2020, we generated $12.9 million of net revenue, of which $11.9 million relates primarily to the sale of Journey branded and generic products and $1.0 million relates to Checkpoint's collaborative agreements with TG Therapeutics Inc. ("TGTX"), including a milestone of $0.9 million upon the 12th patient dosed in a phase 1 clinical trial for Cosibelimab achieved during March 2020. As of March 31, 2020, we had an accumulated deficit of $448.6 million. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our and our subsidiaries' current product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenues.

For the three months ended March 31, 2020, we had $3.8 million of costs of goods sold in connection with the sale of Journey's marketed products, compared to $1.9 million for the three months ended March 31, 2019. The increase is attributed to a growth in sales primarily attributed to the expansion of the marketed product portfolio with the addition of Ximino in the second half of 2019.

Research and Development Expenses

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, laboratory costs and other supplies.

For the three months ended March 31, 2020 and 2019, research and development expenses were approximately $14.9 million and $23.3 million, respectively. Additionally, during the three months ended March 31, 2020 and 2019, we expensed approximately $0.3 million and $0.5 million, respectively, in costs related to the acquisition of licenses. Noncash, stock-based compensation expense included in research and development for the three months ended March 31, 2020 and 2019, was $0.9 million and $0.6 million, respectively.

The table below provides a summary of research and development costs associated with the development of our licenses by entity, for thequarter ended March 31, 2020 and 2019, by entity:

	Three Months Ended March 31,		% of total	
($ in thousands)	**2020**	**2019**	**2020**	**2019**
Research & Development				
Fortress	$ 678	$ 711	5%	3%
Partner Companies:				
Avenue	697	10,242	5%	44%
Checkpoint	2,635	4,581	18%	20%
Mustang	9,251	6,897	62%	30%
Other[1]	1,606	842	10%	3%
Total Research & Development	**$ 14,867**	**$ 23,273**	**100%**	**100%**

Note 1: Includes the following partner companies: Aevitas, Cellvation, Cyprium, Helocyte and Tamid (a Fortress partner company that discontinued development and terminated the related licenses and clinical trial agreements with the University of North Carolina at Chapel Mill for all three of its preclinical product candidates).

General and Administrative Expenses

General and administrative expenses consist principally of sales and marketing costs, personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development expenses. For the three months ended March 31, 2020 and 2019, general and administrative expenses were approximately $15.5 million and $13.5 million, respectively. Noncash, stock-based compensation expense included in general and administrative expenses for the three months March 31, 2020 and 2019, was $2.5 million and $2.7 million, respectively.

The table below provides a summary of general and administrative costs for thequarter ended March 31, 2020 and 2019, by entity:

	Three Months Ended March 31,		% of Total	
($ in thousands)	**2020**	**2019**	**2020**	**2019**
General & Administrative				
Fortress	$ 5,663	$ 4,595	36%	34%
Partner Companies:				
Avenue	577	1,119	4%	8%
Checkpoint	1,553	1,569	10%	12%
JMC[1]	5,689	3,885	37%	29%
Mustang	1,769	1,885	11%	14%
Other[2]	268	425	2%	3%
Total General & Administrative Expense	**$ 15,519**	**$ 13,478**	**100%**	**100%**

Note 1: Includes cost of outsourced sales force for the three months ended March 31, 2020 and 2019 of $3.0 million and $2.3 million, respectively.
Note 2: Includes the following partner companies: Aevitas, Cellvation, Cyprium, Escala, Helocyte and Tamid.

Comparison of three months ended March 31, 2020 and 2019

($ in thousands)	Three Months Ended March 31, 2020	2019	Change $	Change %
Revenue				
Product revenue, net	$ 11,946	$ 6,125	$ 5,821	95%
Revenue – related party	972	352	620	176%
Net revenue	12,918	6,477	6,441	99%
Operating expenses				
Cost of goods sold – product revenue	3,810	1,884	1,926	102%
Research and development	14,867	23,273	(8,406)	-36%
Research and development – licenses acquired	250	450	(200)	-44%
General and administrative	15,519	13,478	2,041	15%
Total operating expenses	34,446	39,085	(4,639)	-12%
Loss from operations	(21,528)	(32,608)	11,080	-34%
Other income (expense)				
Interest income	627	438	189	43%
Interest expense and financing fee	(3,125)	(2,469)	(656)	27%
Change in fair value of derivative liability	(42)	-	(42)	100%
Gain on deconsolidation of Caelum	-	18,384	(18,384)	-100%
Total other (expense) income	(2,540)	16,353	(18,893)	-116%
Net Loss	**(24,068)**	**(16,255)**	**(7,813)**	**48%**
Less: net loss attributable to non-controlling interest	11,698	17,647	(5,949)	-34%
Net income (loss) attributable to common stockholders	**$ (12,370)**	**$ 1,392**	**$ (13,762)**	**-989%**

Net revenues increased $6.4 million or 99% from the three months ended March 31, 2019 to the three months ended March 31, 2020. The increase in net revenue is related to an increase in product revenue of $5.8 million associated with Journey's marketed products driven by the expansion of its product lines and overall sales growth, and an increase of $0.6 million in collaboration revenue between Checkpoint and TGTX due to the Cosibelimab clinical trial milestone achievement.

Cost of goods sold increased by $1.9 million or 102% from the three months ended March 31, 2019 to the three months ended March 31, 2020 due to the increase in Journey marketed products revenue in the current quarter as compared to the prior period.

Research and development expenses decreased $8.4 million or 36% from the three months ended March 31, 2019 to the three months ended March 31, 2020. The following table shows the change in research and development spending by Fortress and its partner companies:

($ in thousands)	Three Months Ended March 31, 2020	2019	Change $	Change %
Research & Development				
Stock-based compensation				
Fortress	$ 201	$ 167	$ 34	20%
Partner Companies:				
Avenue	85	182	(97)	-53%
Checkpoint	144	196	(52)	-27%
Mustang	453	96	357	372%
Other[1]	10	3	7	233%
Sub-total stock-based compensation	893	644	249	39%
Other Research & Development				
Fortress	477	544	(67)	-12%
Partner Companies:				
Avenue	612	10,060	(9,448)	-94%
Checkpoint	2,491	4,385	(1,894)	-43%
Mustang	8,798	6,801	1,997	29%
Other[1]	1,596	839	757	90%
Total Research & Development	**$ 14,867**	**$ 23,273**	**$ (8,406)**	**-36%**

Note 1: Includes the following partner companies: Aevitas, Baergic (2020 only), Cellvation, Cyprium, Helocyte and Tamid (2019 only).

The increase in stock-based compensation for the quarter ended March 31, 2020 is primarily due to additional equity grants to key employees and non-employees of Mustang.

The decrease in research and development expense of $9.4 million at Avenue is due to the completion of Avenue's abdominoplasty and safety studies; the decreased spending at Checkpoint of $1.9 million is attributable primarily to manufacturing costs related to Cosibelimab incurred in the three months ended March 31, 2019 and not replicated in the current quarter and a reduction in clinical costs for CK-101. Mustang's increase in research and development spending of $2.0 million is attributable to personnel costs due to increased headcount, laboratory supplies, as well as consulting and outside services. The increase in "Other" is attributable to increased spend in the quarter ended March 31, 2020 as compared to the quarter ended March 31, 2019 for Fortress' partner companies Helocyte and Cyprium.

General and administrative expenses increased $2.0 million, or 15%, from the three months ended March 31, 2019 to the three months ended March 31, 2020. The following table shows the change in general and administrative spending by Fortress and its partner companies:

	Three Months Ended March 31,		Change	
($ in thousands)	**2020**	**2019**	$	%
General & Administrative				
Stock-based compensation				
Fortress	$ 1,471	$ 1,118	$ 353	32%
Partner Companies:				
Avenue	130	569	(439)	-77%
Checkpoint	495	602	(107)	-18%
Mustang	352	336	16	5%
Other[2]	59	40	19	48%
Sub-total stock-based comp.	2,507	2,665	(158)	-6%
Other General & Administrative				
Fortress	4,192	3,477	715	21%
Partner Companies:				
Avenue	447	550	(103)	-19%
Checkpoint	1,058	967	91	9%
JMC[1]	5,689	3,885	1,804	46%
Mustang	1,417	1,550	(133)	-9%
Other[2]	209	384	(175)	-46%
Total General & Administrative	**$ 15,519**	**$ 13,478**	**2,041**	**15%**

Note 1: Includes cost of outsourced sales force for the three months ended March 31, 2020 and 2019 of $3.0 million and $2.3 million, respectively.
Note 2: Includes the following partner companies: Aevitas, Baergic (2020 only), Cellvation, Cyprium, Helocyte and Tamid (2019 only).

For the quarter ended March 31, 2020, the increase in general and administrative expenses of $2.0 million or 15% is primarily attributable to Journey's sales and marketing cost increases due to increased product portfolio as well as sales force headcount increase, and Fortress' increase due to increased professional fees for ongoing business development activities as well as legal and accounting fees.

Total other income (expense) fluctuated $18.9 million, or 116%, from a gain of $16.4 million for the three months ended March 31, 2019 to expense of $2.5 million for the three months ended March 31, 2020, primarily due to the gain on the deconsolidation of Caelum recognized in the quarter ended March 31, 2019, offset by the increase in interest expense and financing fees due to Mustang's debt financing with Horizon.

Net loss attributable to common stockholders increased $13.8 million, or 989%, from income of $1.4 million for the three months ended March 31, 2019 to a net loss of $12.4 million for the three months ended March 31, 2020. This fluctuation is primarily due to the gain on the deconsolidation of Caelum.

Liquidity and Capital Resources

We will require additional financing to fully develop and prepare regulatory filings and obtain regulatory approvals for our existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for our potential products, and sales and marketing capabilities. We have funded our operations to date primarily through the sale of equity and debt securities. We believe that our current cash and cash equivalents is sufficient to fund operations for at least the next twelve months. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We may seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, sales of stakes in partner companies, the contingent acquisitions of Avenue and Caelum, or through other sources of financing.

In addition to the foregoing, based on the Company's current assessment, the Company does not expect any material impact on its long-term development timeline and its liquidity due to the worldwide spread of the COVID-19 virus. However, the Company is continuing to assess the effect on its operations by monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world.

Cash Flows for the Three Months Ended March 31, 2020 and 2019

	Three Months Ended March 31,	
($ in thousands)	**2020**	**2019**
Statement of cash flows data:		
Total cash (used in)/provided by:		
Operating activities	$ (21,892)	$ (25,325)
Investing activities	(1,776)	24,148
Financing activities	22,753	52,113
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (915)	$ 50,936

Components of cash flows from publicly-traded partner companies are comprised of:

	For the Three Months Ended March 31, 2020				
($ in thousands)	**Fortress[1]**	**Avenue**	**Checkpoint**	**Mustang**	**Total**
Statement of cash flows data:					
Total cash (used in)/provided by:					
Operating activities	$ (6,029)	$ (1,171)	$ (4,540)	$ (10,152)	$ (21,892)
Investing activities	(250)	(1,000)	-	(526)	(1,776)
Financing activities	17,730	-	(56)	5,079	22,753
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 11,451	$ (2,171)	$ (4,596)	$ (5,599)	$ (915)

	For the Three Months Ended March 31, 2019					
($ in thousands)	**Fortress[1]**	**Avenue**	**Caelum**	**Checkpoint**	**Mustang**	**Total**
Statement of cash flows data:						
Total cash (used in)/provided by:						
Operating activities	$ 13,313	$ (5,568)	$ (18,384)	$ (8,203)	$ (6,483)	$ (25,325)
Investing activities	12,147	-	-	-	12,001	24,148
Financing activities	5,800	32,345	-	355	13,613	52,113
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 31,260	$ 26,777	$ (18,384)	$ (7,848)	$ 19,131	$ 50,936

Note 1: Includes Fortress and non-public partner companies, excluding Caelum.

Operating Activities

Net cash used in operating activities decreased $3.4 million from the three months ended March 31, 2019, compared to the three months ended March 31, 2020. The decrease is due to the decrease of $18.4 million in the gain recognized on the deconsolidation of Caelum, offset by the $7.8 million increase in net loss and the $7.4 million increase in cash used from the changes in operating assets and liabilities.

Investing Activities

Net cash provided by investing activities decreased $25.9 million from the three months ended March 31, 2019, compared to the three months ended March 31, 2020The decrease is primarily due to $13.1 million received from the sale of National in the quarter ended March 31, 2019, a decrease in the purchase of short-term investments of $12.6 million, an increase in the purchase of property and equipment of $0.2 million, and $1.2 million decrease in cash due to the deconsolidation of Caelum.

Financing Activities

Net cash provided by financing activities was $52.1 million for the three months ended March 31, 2019, compared to $22.8 million of net cash provided by financing activities for the three months ended March 31, 2020. During the three months ended March 31, 2020, net proceeds the issuance of Series A preferred stock was $13.2 million, net proceeds from at-the-market offerings for both the Company and its partners was $10.8 million, offset by $1.2 million paid in Series A Preferred dividends. During the three months ended March 31, 2019, proceeds from partner's offerings were $31.5 million, proceeds from the company's at-the-market offering was $6.1 million, and net proceeds from Mustang's Horizon Notes was $14.8 million, offset slightly by $0.6 million paid in Series A Preferred dividends.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

Market risk represents the risk of loss that may result from the change in value of financial instruments due to fluctuations in their market price. Market risk is inherent in all financial instruments. Market risk may be exacerbated in times of trading illiquidity when market participants refrain from transacting in normal quantities and/or at normal bid-offer spreads. Our exposure to market risk is directly related to derivatives, debt and equity linked instruments related to our financing activities.

Our assets and liabilities are denominated in U.S. dollars. Consequently, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. We do not know, nor do we plan to, use derivative financial instruments for speculative or trading purposes. However, these circumstances might change.

The primary quantifiable market risk associated with our financial instruments is sensitivity to changes in interest rates. Interest rate risk represents the potential loss from adverse changes in market interest rates. We use an interest rate sensitivity simulation to assess our interest rate risk exposure. For purposes of presenting the possible earnings effect of a hypothetical, adverse change in interest rates over the 12-month period from our reporting date, we assume that all interest rate sensitive financial instruments will be impacted by a hypothetical, immediate 100 basis point increase in interest rates as of the beginning of the period. The sensitivity is based upon the hypothetical assumption that all relevant types of interest rates that affect our results would increase instantaneously, simultaneously and to the same degree. We do not believe that our cash and equivalents have significant risk of default or illiquidity.

The sensitivity analyses of the interest rate sensitive financial instruments are hypothetical and should be used with caution. Changes in fair value based on a 1% or 2% variation in an estimate generally cannot be extrapolated because the relationship of the change in the estimate to the change in fair value may not be linear. Also, the effect of a variation in a particular estimate on the fair value of financial instruments is calculated independent of changes in any other estimate; in practice, changes in one factor may result in changes in another factor, which might magnify or counteract the sensitivities. In addition, the sensitivity analyses do not consider any action that we may take to mitigate the impact of any adverse changes in the key estimates.

Based on our analysis, for the years ended December 31, 2018 and December 31, 2019 and for the interim period through March 31, 2020, we determined the effect of a 100+1-basis point change in interest rates on the value of our financial instruments and the resultant effect on our net loss to be immaterial.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness, as of March 31, 2020, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

No change in internal control over financial reporting occurred during the most recent quarter with respect to our operations, which materially affected, or is reasonable likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Investing in our Common Stock, Series A Preferred Stock or any other type of equity or debt securities (together our "Securities") involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K including the consolidated financial statements and the related notes, as well as the risks, uncertainties and other information set forth in the reports and other materials filed or furnished by our partners and affiliates Checkpoint, Mustang, and Avenue with the SEC, before deciding to invest in our Securities. If any of the following risks or the risks included in the public filings of Checkpoint, Mustang or Avenue were to materialize, our business, financial condition, results of operations, and future growth prospects could be materially and adversely affected. In that event, the market price of our Securities could decline, and you could lose part of or all of your investment in our Securities. In addition, you should be aware that the below stated risks should be read as being applicable to our partners and affiliates such that, if any of the negative outcomes associated with any such risk is experienced by one of our partners or affiliates, the value of Fortress' holdings in such partner or affiliate (if any) may decline.

Major public health issues, and specifically the pandemic caused by the coronavirus COVID-19, could have an adverse effect on the clinical trials of our partner companies, and as a result, have an adverse impact on our financial condition and results of operations and other aspects of our business.

In December 2019, a novel strain of coronavirus which causes a disease referred to as COVID-19, was first detected in Wuhan, China, and has since spread worldwide. On March 11, 2020, the World Health Organization declared that the rapidly spreading COVID-19 outbreak had evolved into a pandemic. In response to the pandemic, many governments around the world are implementing a variety of control measures to reduce the spread of COVID-19, including travel restrictions and bans, instructions to residents to practice social distancing, quarantine advisories, shelter-in-place orders and required closures of non-essential businesses.

The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. The extent to which the COVID-19 pandemic impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the virus and the actions to contain it or treat its impact, among others.

Some factors from the COVID-19 outbreak that may delay or otherwise adversely affect our or our partner companies' clinical trial programs, as well as adversely impact our business generally, include:

- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical sites, and delays enrolling patients in our clinical trials or increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine, or not otherwise being able to complete study assessments, particularly for older patients or others with a higher risk of contracting COVID-19;
- missed study visits or study procedures which could lead to an abundance of protocol deviations that have the potential to interfere with the interpretability of trial results;
- impacts to clinical results, including an increased number of observed adverse events, as a result of participants enrolled in our clinical trials contracting COVID-19;
- diversion of healthcare resources, including clinical trial investigators and staff, away from the conduct of clinical trials to focus on pandemic concerns which could result in delays to our partner companies' clinical trials;

- limitations on travel, including limitations on domestic and international travel, and government-imposed quarantines or restrictions imposed by key third parties that could interrupt key trial activities, such as clinical trial site initiations and monitoring;

- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, or production slowdowns or stoppages;

- disruptions and delays caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home across the healthcare system; and

- disruptions in or delays to regulatory approvals, inspections, reviews or other regulatory activities, including review of NDAs and approvals of protocol changes or amendments to SPAs, as a result of the spread of COVID-19 affecting the operations of the FDA or other regulatory authorities.

The disruptions discussed above and other consequences of COVID-19 pandemic could result in missed study visits or study procedures in our clinical trials, which could lead to an abundance of protocol deviations that impact the interpretability of the trial results. A significant number of deviations may call into question whether the execution of a clinical trial was consistent with the protocol, which is of particular importance where study designs were agreed to as part of a Special Protocol Assessment (SPA). In extreme cases, significant deviations from the protocol may be considered a violation of an SPA and result in potential rescindment of an SPA agreement.

We and our partner companies currently rely on third parties for certain functions or services in support of our clinical trials and key areas of our operations. These third parties include contract research organizations (CROs), medical institutions and clinical investigators, contract manufacturing organizations, suppliers, and external business partners supporting our preparations for commercialization. If these third parties themselves are adversely impacted by restrictions resulting from the COVID-19 outbreak, we will likely experience delays and/or realize additional costs. As a result, our or our partner companies' efforts to obtain regulatory approvals for, and to commercialize, our or our partner companies' product candidates may be delayed or disrupted.

In addition, as a result of government directives on social distancing and to protect the health of our workforce, we have asked our office-based employees to work remotely and have restricted domestic and international travel indefinitely. While our remote work policy remains in place, we may experience reductions in productivity and disruptions to our business routines.

We closed our offices in response to the pandemic and requested that our personnel work remotely and restricted on-site staff to only those personnel and contractors who must perform essential activities that must be completed on-site. Third parties on which we rely may also increase their use of remote working arrangements in response to COVID-19. Our increased reliance on personnel working remotely may negatively impact productivity, including our ability to monitor clinical trials, prepare regulatory applications, and conduct data analysis, or disrupt, delay, or otherwise adversely impact our business. In addition, remote working could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors.

The ability of the Company's employees and consultants to work may be significantly impacted by the coronavirus.

The Company's employees and consultants are being affected by the COVID-19 pandemic. Substantially all of our office and management personnel are working remotely, and the Company may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the coronavirus. COVID-19 may also compromise the ability of independent contractors who perform consulting services for us to deliver services or deliverables in a satisfactory or timely manner. Further, our management team is focused on mitigating the adverse effects of the COVID-19 pandemic, which has required and will continue to require a large investment of time and resources, thereby diverting their attention from other priorities that existed prior to the outbreak of the pandemic. If these conditions worsen, or last for an extended period of time, the Company's ability to manage its business may be impaired, and operational risks, cybersecurity risks and other risks facing the Company even prior to the pandemic may be elevated.

Risks Related to our Growth Strategy

If we acquire, enter into joint ventures with or obtain a controlling interest in companies in the future, it could adversely affect our operating results and the value of our Securities, thereby diluting stockholder value, disrupting our business and/or diminishing the value of our holdings in our partner companies.

As part of our growth strategy, we might acquire, enter into joint ventures with, or obtain significant ownership stakes in other companies. Acquisitions of, joint ventures with and investments in other companies involve numerous risks, including, but not necessarily limited to:

- risk of entering new markets in which we have little to no experience;

- diversion of financial and managerial resources from existing operations;

- successfully negotiating a proposed acquisition or investment timely and at a price or on terms and conditions favorable to us;

- the impact of regulatory reviews on a proposed acquisition or investment;

- the outcome of any legal proceedings that may be instituted with respect to the proposed acquisitions or investment;

- with respect to an acquisition, difficulties in integrating operations, technologies, services and personnel; and

- potential inability to maintain relationships with customers of the companies we may acquire or invest in.

If we fail to properly evaluate potential acquisitions, joint ventures or other transaction opportunities, we might not achieve the anticipated benefits of any such transaction, we might incur higher costs than anticipated, and management resources and attention might be diverted from other necessary or valuable activities.

If we cannot innovate and develop products and services and/or commercialize biopharmaceutical products or grow our and their respective businesses, we may not be able to generate revenue.

Our growth strategy also depends on our ability to generate revenue. If we cannot innovate and develop products and services, or commercialize future biopharmaceutical products or grow their respective businesses, we may not be able to generate revenue growth as anticipated.

Our future growth depends in part on our ability to identify and acquire or in-license products and product candidates, and if we are unable to do so, or to integrate acquired products into our operations, we may have limited growth opportunities.

An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including, but not necessarily limited to:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed technologies in the current economic environment;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

We may not be able to generate returns for our investors if our partners, several of which have limited or no operating history, no commercialized revenue generating products, and are not yet profitable, cannot obtain additional third-party financing.

As part of our growth strategy, we have made and will likely continue to make substantial financial and operational commitments in our partners, which often have limited or no operating history, no commercialized revenue generating products, and require additional third-party financing to fund product and services development or acquisitions. Our business depends in large part on the ability of one or more of our partner companies to innovate, in-license, develop or acquire successful biopharmaceutical products and/or acquire companies in increasingly competitive and highly regulated markets. If certain of our partner companies do not successfully obtain additional third-party financing to commercialize products or successfully acquire companies, as applicable, the value of our businesses and our ownership stakes in our partner companies may be materially adversely affected.

If we cannot continue to fund our research and development programs, we may be required to reduce product development, which will adversely impact our growth strategy.

Our research and development ("R&D") programs will require substantial additional capital to conduct research, preclinical testing and clinical trials, establish pilot scale and commercial scale manufacturing processes and facilities, and establish and develop quality control, regulatory, marketing, sales, and administrative capabilities to support these programs. We expect to fund our R&D activities from a combination of cash generated from royalties and milestones from our partners in various past, ongoing, and future collaborations, and through additional equity or debt financings from third parties. These financings could depress the stock prices of our securities. If additional funds are required to support our operations and such funds cannot be obtained on favorable terms, we may not be able to develop products, which will adversely impact our growth strategy.

Collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.

We anticipate substantial reliance upon strategic collaborations for marketing and commercializing our existing product candidates and we may rely even more on strategic collaborations for R&D of other product candidates. We may sell product offerings through strategic partnerships with pharmaceutical and biotechnology companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited.

If we enter into R&D collaborations during the early phases of drug development, success will, in part, depend on the performance of research collaborators. We may not directly control the amount or timing of resources devoted by research collaborators to activities related to product candidates. Research collaborators may not commit sufficient resources to our R&D programs. If any research collaborator fails to commit sufficient resources, the preclinical or clinical development programs related to the collaboration could be delayed or terminated. Also, collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to collaborators or to observe other obligations in agreements with them, the collaborators may have the right to terminate or stop performance of those agreements.

Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property positions. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of product candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, the related product revenues that might follow are likely to be lower than if we directly marketed and sold products. Such collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on, and such collaborations could be more attractive than the one with us for any future product candidate.

Management of our relationships with collaborators will require:

- significant time and effort from our management team;
- coordination of our marketing and R&D programs with the respective marketing and R&D priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

As we continue to execute our growth strategy, we may be subject to further government regulation which could adversely affect our financial results.

If we engage in business combinations and other transactions that result in holding minority or non-control investment interests in a number of entities, we may become subject to regulation under the Investment Company Act of 1940, as amended (the "Investment Company Act"). If we do become subject to the Investment Company Act, we would be required to register as an investment company and could be expected to incur significant registration and compliance costs in the future.

We may not be able to manage our anticipated growth, which may in turn adversely impact our business.

We will need to continue to expend capital on improving our infrastructure to address our anticipated growth. Acquisitions of companies or products could place a strain on our management, and administrative, operational and financial systems. In addition, we may need to hire, train, and manage more employees, focusing on their integration with us and corporate culture. Integration and management issues associated with increased acquisitions may require a disproportionate amount of our management's time and attention and distract our management from other activities related to running our business.

We may not be able to hire or retain key officers or employees needed to implement our business strategy and develop products and businesses.

Our success depends on the continued contributions of our executive officers, financial, scientific, and technical personnel and consultants, and on our ability to attract additional personnel as we continue to implement growth strategies and acquire and invest in companies with varied businesses. During our operating history, many essential responsibilities have been assigned to a relatively small number of individuals. However, as we continue to implement our growth strategy, the demands on our key employees will expand, and we will need to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel, or our inability to attract additional personnel to fill critical positions, could adversely affect our business.

We currently depend heavily upon the efforts and abilities of our management team and the management teams of our partners. The loss or unavailability of the services of any of these individuals could have a material adverse effect on our business, prospects, financial condition and results. In addition, we have not obtained, do not own, and are not the beneficiary of key-person life insurance for any of our key personnel. We only maintain a limited amount of directors' and officers' liability insurance coverage. There can be no assurance that this coverage will be sufficient to cover the costs of the events that may occur, in which case, there could be a substantial impact on our ability to continue operations.

Our employees, consultants, or third-party partners may engage in misconduct or other improper activities, including but not necessarily limited to noncompliance with regulatory standards and requirements or internal procedures, policies or agreements to which such employees, consultants and partners are subject, any of which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, consultants, or third-party partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with current good manufacturing practices ("cGMPs"), comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, comply with internal procedures, policies or agreements to which such employees, consultants or partners are subject, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee, consultant, or third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation, as well as civil and criminal liability. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other civil and/or criminal sanctions.

We receive a large amount of proprietary information from potential or existing licensors of intellectual property and potential acquisition target companies, all pursuant to confidentiality agreements. The confidentiality and proprietary invention assignment agreements that we have in place with each of our employees and consultants prohibit the unauthorized disclosure of such information, but such employees or consultants may nonetheless disclose such information through negligence or willful misconduct. Any such unauthorized disclosures could subject us to monetary damages and/or injunctive or equitable relief. The notes, analyses and memoranda that we have generated based on such information are also valuable to our businesses, and the unauthorized disclosure or misappropriation of such materials by our employees and consultants could significantly harm our strategic initiatives – especially if such disclosures are made to our competitor companies.

Certain of our officers and directors serve in similar roles at our partners, affiliates, related parties and/or other entities with which we transact business or in which we hold significant minority ownership positions; ongoing and future relationships and transactions between these parties could result in conflicts of interest.

We share directors and/or officers with certain of our partners, and other entities with which we transact business or in which we hold significant minority ownership positions, and such arrangements could create conflicts of interest in the future, including with respect to the allocation of corporate opportunities. While we believe that we have put in place policies and procedures to identify and mitigate such conflicts, and that any existing agreements that may give rise to such conflicts and any such policies or procedures were negotiated at arm's length in conformity with fiduciary duties, such conflicts of interest may nonetheless arise. The existence and consequences of such potential conflicts could expose us to lost profits, claims by our investors and creditors, and harm to our results of operations.

Risks Related to Our Biopharmaceutical Business and Industry

We are an early-stage company with limited operating history on which stockholders can base an investment decision, and we rely heavily on third parties for the development and manufacturing of products and product candidates.

We are primarily an early-stage biopharmaceutical company and certain of our partners, on whose successes we largely rely, are also early-stage biopharmaceutical companies with limited operating histories. To date, we have engaged primarily in acquisition, evaluative and R&D activities and have not generated any revenues from product sales (except through Journey). We have incurred significant net losses since our inception. As of March 31, 2020, we had an accumulated deficit of approximately $448.6 million. We may need to rely on third parties for activities critical to the product candidate development process, including but not necessarily limited to:

- identifying and evaluating product candidates;
- negotiating, drafting and entering into licensing and other arrangements with product development partners; and
- continuing to undertake pre-clinical development and designing and executing clinical trials.

We have also not demonstrated the ability to perform the functions necessary for the successful commercialization of any of our pre-market product candidates, should any of them be approved for marketing. If we were to have any such product candidates approved, the successful commercialization of such products would require us to perform or contract with third parties for performance of a variety of critical functions, including, but not necessarily limited to:

- advising and participating in regulatory approval processes;
- formulating and manufacturing products for clinical development programs and commercial sale; and
- conducting sales and marketing activities.

Our operations have been limited to acquiring, developing and securing the proprietary rights for, and undertaking pre-clinical development and clinical trials of, product candidates, both at the Fortress level and via our partner companies. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to develop and commercialize potential product candidates, as well as for you to assess the advisability of investing in our securities.

If we are unable to establish or maintain sales and marketing capabilities or fail to enter into agreements with third parties to market, distribute and sell products that may be successfully developed, we may not be able to effectively market and sell products and generate product revenue.

We do not currently have the infrastructure for the sales, marketing and distribution of any of our product candidates (except for that which exists through Journey), and we must build and maintain such infrastructures or make arrangements with third parties to perform these functions in order to commercialize any products that we may successfully develop. The establishment and development of a sales force, either by us or certain of our partners, or the establishment of a contract sales force, to market any products for which we may receive marketing approval is expensive and time-consuming and could delay any such product launch or compromise the successful commercialization of such products. If we are unable to establish and maintain sales and marketing capabilities or any other non-technical capabilities necessary to commercialize any products that may be successfully developed, we will need to contract with third parties to market and sell such products. We may not be able to establish arrangements with third parties on commercially reasonable terms, or at all. Notwithstanding the foregoing, Journey's sales force has been and is expected to continue to be an important contributor to its commercial success; any disruptions to Journey's relationship with such sales force could materially adversely affect Journey's product sales.

If any of our product candidates that may be successfully developed do not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that any such product candidates generate from sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally would also be necessary for commercial success. The degree of market acceptance of any approved products would depend on a number of factors, including, but not necessarily limited to:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates in a broader patient group (i.e., based on actual use);
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;

- changes in regulatory requirements by government authorities for our product candidates;
- relative convenience and ease of administration;
- the prevalence and severity of side effects and adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and in turn we may not become or remain profitable.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

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

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which pharmaceuticals they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- experimental or investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require that we provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability. Additionally, while we may seek approval of our products in combination with each other, there can be no guarantee that we will obtain coverage and reimbursement for any of our products together, or that such reimbursement will incentivize the use of our products in combination with each other as opposed to in combination with other agents which may be priced more favorably to the medical community.

In both the United States and certain foreign countries, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products reimbursed by Medicare, resulting in lower rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. Since 2003, there have been a number of other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "Affordable Care Act" or "ACA," was enacted in 2010 and made significant changes to the United States' healthcare system. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business.

Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Pricing Program;
- new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new regulatory pathway for the approval of biosimilar biological products, all of which will impact existing government healthcare programs and will result in the development of new programs; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015.

President Trump ran for office on a platform that supported the repeal of the ACA, and one of his first actions after his inauguration was to sign an Executive Order instructing federal agencies to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law. However, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In March 2017, following the passage of the budget resolution for fiscal year 2017, the United States House of Representatives passed legislation known as the American Health Care Act of 2017, which, if enacted, would amend or repeal significant portions of the ACA. Attempts in the Senate in 2017 to pass ACA repeal legislation, including the Better Care Reconciliation Act of 2017, were unsuccessful.

At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court's prior decision. On December 14, 2018, a Texas federal district court judge issued a ruling declaring that the ACA in its entirety is unconstitutional. Upon appeal, the Fifth Circuit upheld the district court's ruling that the individual mandate is unconstitutional. However, the Fifth Circuit remanded the case back to the district court to conduct a more thorough assessment of the constitutionality of the entire ACA despite the individual mandate being unconstitutional. While this decision has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome may have a significant impact on our business.

The Bipartisan Budget Act of 2018, the "BBA," which set government spending levels for Fiscal Years 2018 and 2019, revised certain provisions of the ACA. Specifically, beginning in 2019, the BBA increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70%, ultimately increasing the liability for brand drug manufacturers. Further, this mandatory manufacturer discount applies to biosimilars beginning in 2019.

The 116th Congress has explored legislation intended to address the cost of prescription drugs. Notably, the major committees of jurisdiction in the Senate (Finance Committee, Health, Education, Labor and Pensions Committee, and Judiciary Committee), have marked up legislation intended to address various elements of the prescription drug supply chain. Proposals include a significant overhaul of the Medicare Part D benefit design, addressing patent "loopholes", and efforts to cap the increase in drug prices. The House Energy and Commerce Committee approved drug-related legislation intended to increase transparency of drug prices and also curb anti-competitive behavior in the pharmaceutical supply chain. In addition, the House Ways & Means Committee approved legislation intended to improve drug price transparency, including for drug manufacturers to justify certain price increases. While we cannot predict what proposals may ultimately become law, the elements under consideration could significantly change the landscape in which the pharmaceutical market operates.

The Senate Committee on Health, Education, Labor, and Pensions (HELP) advanced the Lower Health Care Costs Act of 2019. Among other things, the bill is intended to reduce costs in the United States health sector. The bill revises certain requirements to expedite the approval of generics and biosimilars. It also limits prices that pharmacy benefit managers may charge health insurers or enrollees for prescription drugs. Although this bill still needs to pass the full Senate and House of Representatives, it is worth noting the wide-ranging effects it could have on the health care sector.

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The Trump Administration has also taken several regulatory steps to redirect ACA implementation. The Department of Health and Human Services, the HHS, finalized a Medicare hospital payment reduction for Part B drugs acquired through the 340B Drug Pricing Program. The courts have since overturned this payment reduction, but the lawsuit is ongoing on appeal and HHS continues to implement the payment cuts. HHS also has signaled its intent to continue to pursue reimbursement policy changes for all Medicare Part B drugs that likely would reduce hospital and physician reimbursement for these drugs.

HHS has made numerous other proposals aimed at lowering drug prices for Medicare beneficiaries and increasing price transparency. While many of the proposals have been withdrawn or struck down by the courts, it appears the Trump Administration will continue to explore its authority to make regulatory changes to the pharmaceutical industry. For example, the Trump Administration released an Advance Notice of Proposed Rulemaking related to an international price index model. It is unclear what eventually will be proposed, but the President has alluded to the concept of most favored nation pricing with regard to U.S. drug purchasing. In addition, HHS, in conjunction with the FDA, released two pharmaceutical importation models in December 2019: (1) a Notice of Proposed Rulemaking to permit importation of pharmaceuticals from Canada, and (2) draft FDA guidance permitting manufacturers to import their own pharmaceuticals that were originally intended for marketing in other countries.

HHS also has taken steps to increase the availability of cheaper health insurance options, typically with fewer benefits and less generous coverage. The Administration has also signaled its intention to address drug prices and to increase competition, including by increasing the availability of biosimilars and generic drugs. As these are regulatory actions, a new administration could undo or modify these efforts.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In addition, governments may impose price controls, which may adversely affect our future profitability In January 2020, President Trump signed into law the U.S.-Mexico-Canada (USMCA) trade deal into law. As enacted, there are no commitments with respect to biologic product intellectual property rights or data protection, which may create an unfavorable environment across these three countries.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the US and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, which requires manufacturers of certain drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to "covered recipients," which include physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals) and applicable manufacturers. Applicable group purchasing organizations also are required to report annually to CMS the ownership and investment interests held by the physicians and their immediate family members. The SUPPORT for Patients and Communities Act added to the definition of covered recipient practitioners including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse-midwives effective in 2022. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end of each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our businesses. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our businesses.

Failure to be included in formularies developed by managed care organizations and coverage by other organizations may negatively impact the utilization of our products, which could harm our market shares and could have a material adverse effect on our business and financial condition.

Managed care organizations and other third-party payors try to negotiate the pricing of medical services and products to control their costs. Managed care organizations and pharmacy benefit managers typically develop formularies to reduce their cost for medications. Formularies can be based on the prices and therapeutic benefits of the available products. Due to their lower costs, generic products are often favored. The breadth of the products covered by formularies varies considerably from one managed care organization to another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of our products. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic products, this could have a material adverse effect on our business and financial condition.

Most of our product candidates are at early stages of development and may not be successfully developed or commercialized.

Most of our existing product candidates remain in the early stages of development and will require substantial further capital expenditures, development, testing and regulatory clearances/approvals prior to commercialization. The development and regulatory approval processes take several years, and it is not likely that our product candidates, even if successfully developed and approved by the FDA and/or foreign equivalent regulatory bodies, would be commercially available for several years. Of the large number of drugs in development, only a small percentage successfully obtain regulatory approval and are commercialized. Accordingly, even if we are able to obtain the requisite financing to fund development programs, we cannot assure you that any of our product candidates will be successfully developed or commercialized, which could result in the failure of our business and a loss of your investment in our Company.

Because we in-license the intellectual property needed to develop and commercialize products and product candidates from third parties, any dispute with the licensors or the non-performance of such license agreements may adversely affect our ability to develop and commercialize the applicable product candidates.

The patents, patent applications and other intellectual property rights underpinning all of our existing product candidates were in-licensed from third parties. Under the terms of such license agreements, the licensors generally have the right to terminate such agreements in the event of a material breach. The licenses require us to make annual, milestone or other payments prior to commercialization of any product and our ability to make these payments depends on the ability to generate cash in the future. These license agreements also generally require the use of diligent and reasonable efforts to develop and commercialize product candidates.

If there is any conflict, dispute, disagreement or issue of non-performance between us or one of our partners, on the one hand, and the respective licensing partner, on the other hand, regarding the rights or obligations under the license agreements, including any conflict, dispute or disagreement arising from a failure to satisfy payment obligations under such agreements, the ability to develop and commercialize the affected product candidate may be adversely affected.

The types of disputes that may arise between us and the third parties from whom we license intellectual property include, but are not necessarily limited to:

- the scope of rights granted under such license agreements and other interpretation-related issues;
- the extent to which our technologies and processes infringe on intellectual property of the licensor that is not subject to such license agreements;
- the scope and interpretation of the representations and warranties made to us by our licensors, including those pertaining to the licensors' right title and interest in the licensed technology and the licensors' right to grant the licenses contemplated by such agreements;
- the sublicensing of patent and other rights under our license agreements and/or collaborative development relationships, and the rights and obligations associated with such sublicensing, including whether or not a given transaction constitutes a sublicense under such license agreement;
- the diligence and development obligations under license agreements (which may include specific diligence milestones) and what activities or achievements satisfy those diligence obligations;
- whether or not the milestones associated with certain milestone payment obligations have been achieved or satisfied;
- the applicability or scope of indemnification claims or obligations under such license agreements;
- the permissibility and advisability of, and strategy regarding, the pursuit of potential third-party infringers of the intellectual property that is the subject of such license agreements;
- the calculation of royalty, milestone, sublicense revenue and other payment obligations under such license agreements;
- the extent to which rights, if any, are retained by licensors under such license agreements;
- whether or not a material breach has occurred under such license agreements and the extent to which such breach, if deemed to have occurred, is or can be cured within applicable cure periods, if any;
- disputes regarding patent filing and prosecution decisions, as well as payment obligations regarding past and ongoing patent expenses;

- intellectual property rights resulting from the joint creation or use of intellectual property (including improvements made to licensed intellectual property) by our and our partners' licensors and us and our partners; and

- the priority of invention of patented technology.

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

Product candidates that we advance into clinical trials may not receive regulatory approval.

Pharmaceutical development has inherent risks. We will be required to demonstrate through well-controlled clinical trials that product candidates are effective with a favorable benefit-risk profile for use in their target indications before seeking regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful, as product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Also, we may need to conduct additional clinical trials that are not currently anticipated. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. As a result, product candidates that we advance into clinical trials may not receive regulatory approval.

In addition, even if our product candidates were to obtain approval, regulatory authorities may approve any such product candidates or any future product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of the product. In addition, the Drug Enforcement Agency (or foreign equivalent) may classify one or more of our product candidates in scheduling under the Controlled Substances Act (or its foreign equivalent) that could impede such product's commercial viability. Any of these scenarios could compromise the commercial prospects for one or more of our current or future product candidates.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the US generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, corrective advertising, injunctions or criminal prosecution, any of which could harm our business.

Any product candidates we advance into clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of any product candidate, including our product candidates, is subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market a product candidate until such product candidate's Biologics License Application ("BLA") or New Drug Application ("NDA") is approved by the FDA. The process of obtaining approval is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the products involved. In addition to significant clinical testing requirements, our ability to obtain marketing approval for product candidates depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our product manufacturing processes, testing procedures or facilities are inadequate to justify approval. Approval policies or regulations may change, and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in the clinical development of product candidates, regulatory approval is never guaranteed.

The FDA and other regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

- our inability to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for an indication;

- the FDA may not accept clinical data from trials conducted by individual investigators or in countries where the standard of care is potentially different from that of the United States;

- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;

- the FDA may disagree with the interpretation of data from preclinical studies or clinical trials;

- the FDA may not approve the manufacturing processes or facilities or those of third-party manufacturers with which we or our respective collaborators currently contract for clinical supplies and plan to contract for commercial supplies; or

- the approval policies or regulations of the FDA may significantly change in a manner rendering the clinical data insufficient for approval or the product characteristics or benefit-risk profile unfavorable for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, recent events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.

Unacceptable adverse events caused by any of our product candidates that we advance into clinical trials could cause regulatory authorities to interrupt, delay or stop clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale.

We have not completed testing for any of our product candidates for the indications for which we intend to seek product approval in humans, and we currently do not know the extent of the adverse events, if any, that will be observed in patients who receive any of our product candidates. If any of our product candidates causes unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such products, or, if such product candidates are approved for marketing, future adverse events could cause us to withdraw such products from the market.

Delays in the commencement or resumption of our clinical trials could result in increased costs and delay our ability to pursue regulatory approval.

The commencement or resumption of clinical trials can be delayed for a variety of reasons, including, but not necessarily limited to, delays in:

- obtaining regulatory clearance/approval to commence a clinical trial;

- identifying, recruiting and training suitable clinical investigators;
- reaching and preserving agreements on acceptable terms with prospective clinical research organizations ("CROs") and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining Institutional Review Board ("IRB") or ethics committee approval to conduct a clinical trial at a prospective site;
- developing and validating companion diagnostics on a timely basis, if required;
- adding new clinical sites once a trial has begun;
- the death, disability, departure or other change to the principal investigator or other staff overseeing the clinical trial at a given site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; or
- retaining (or replacing) patients who have initiated a clinical trial but who may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process, personal issues, or other reasons.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Suspensions or delays in the completion of clinical testing could result in increased costs and delay or prevent our ability to complete development of that product or generate product revenues.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements and on a timely basis. Further, a clinical trial may be modified, suspended or terminated by us, an IRB, an ethics committee or a data safety monitoring committee overseeing the clinical trial, any clinical trial site with respect to that site, or the FDA or other regulatory authorities, due to a number of factors, including, but not necessarily limited to:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- stopping rules contained in the protocol;
- unforeseen safety issues or any determination that the clinical trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements and guidance also may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may in turn impact the costs and timing of, and the likelihood of successfully completing, a clinical trial. If we experience delays in the completion of, or if we must suspend or terminate, any clinical trial of any product candidate, our ability to obtain regulatory approval for that product candidate will be delayed, and the commercial prospects, if any, for the product candidate may suffer as a result. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate.

Even if approved, any product candidates that we may develop and market may be later withdrawn from the market or subject to promotional limitations.

We may not be able to obtain the labeling claims or scheduling classifications necessary or desirable for the promotion of our marketed products (or our product candidates if approved). We may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory or if adverse events or other safety issues arise after approval, the FDA or a comparable regulatory authority in another jurisdiction may withdraw marketing authorization or may condition continued marketing on commitments from us that may be expensive and/or time consuming to complete. In addition, if we or others identify adverse side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of such products if approved.

We currently rely predominantly on third parties to manufacture our preclinical and clinical pharmaceutical supplies and expect to continue to rely heavily on them and other contractors to produce commercial supplies of our products, and our dependence on third-party suppliers could adversely impact our businesses. We also rely solely on third parties to manufacture Journey's commercialized products, which dependence may also adversely impact our businesses.

We depend heavily on third party manufacturers for product supply. If our contract manufacturers cannot successfully manufacture material that conforms to applicable specifications and with FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for those products. Our third-party suppliers will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA and comparable agencies and authorities in other jurisdictions to confirm such compliance. In the event that the FDA or such other authorities determine that our third-party suppliers have not complied with cGMPs or comparable regulations, the relevant clinical trials could be terminated or subjected to a clinical hold until such time as we are able to obtain appropriate replacement material and/or applicable compliance, and commercial product could be unfit for sale, or if distributed, could be recalled from the market. Any delay, interruption or other issues that arise in the manufacture, testing, packaging, labeling, storage, or distribution of our products as a result of a failure of the facilities or operations of our third-party suppliers to comply with regulatory requirements or pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products and product candidates. In addition, several of our currently commercialized products, sold through our partner company Journey, are produced by a single manufacturer, and, although we closely monitor inventory prophylactically, disruptions to such supply arrangements could adversely affect our ability to meet product demand and therefore diminish revenues.

We also rely on third-party manufacturers to purchase from third-party suppliers the materials necessary to produce product candidates for anticipated clinical trials. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture those products. We do not have any control over the process or timing of the acquisition of these raw materials by our third-party manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of raw material components related to an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval.

We do not expect to have the resources or capacity to commercially manufacture our product candidates internally, if approved, and would likely continue to be heavily dependent upon third-party manufacturers. Our dependence on third parties to manufacture and supply clinical trial materials, as well as our planned dependence on third party manufacturers for any products that may be approved, may adversely affect our ability to develop and commercialize products in a timely or cost-effective manner, or at all.

We rely on third parties to conduct clinical trials. If these third parties do not meet agreed-upon deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful, and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We rely on third-party contract research organizations and site management organizations to conduct most of our preclinical studies and all of our clinical trials for our product candidates. We expect to continue to rely on third parties, such as contract research organizations, site management organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct some of our preclinical studies and all of our clinical trials. These CROs, investigators, and other third parties will and do play a significant role in the conduct of our trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators and other third parties upon which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fails to meet expected deadlines, or fails to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of the clinical trial sites terminates for any reason, we may lose follow-up information on patients enrolled in our ongoing clinical trials unless the care of those patients is transferred to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisers or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site, or the FDA's willingness to accept such data, may be jeopardized.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with good laboratory practice ("GLP") as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices ("GCPs") for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If any of our relationships with these third-party contract research organizations or site management organizations terminates, we may not be able to enter into arrangements with alternative contract research organizations or site management organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization or site management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or site management organizations, there can be no assurance that we will not encounter similar challenges or delays in the future.

We rely on clinical and pre-clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

As part of the strategy we implement to mitigate development risk, we seek to develop product candidates with well-studied mechanisms of action, and we intend to utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical and pre-clinical data and other results produced or obtained by third parties, which may ultimately prove to be inaccurate or unreliable. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidates, we could make inaccurate assumptions and conclusions about our product candidates, and our research and development efforts could be compromised or called into question during the review of any marketing applications that we submit.

If our competitors develop treatments for any of the target indications for which our product candidates are being developed and those competitor products are approved more quickly, marketed more successfully or demonstrated to be more effective, the commercial opportunity with respect to that product candidate will be reduced or eliminated.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render one or more of our product candidates obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render one or more of our product candidates obsolete or noncompetitive.

Competitors may seek to develop alternative formulations that do not directly infringe on our in-licensed patent rights. The commercial opportunity for one or more of our product candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize one or more of our product candidates. Our competitors may also develop drugs that are more effective, safe, useful and less costly than ours and may be more successful than us in manufacturing and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We will also face competition from these third parties in establishing clinical trial sites, in patient registration for clinical trials, and in identifying and in-licensing new product candidates.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for one or more of our product candidates or a future product candidate we may license or acquire and may have to limit their commercialization.

The use of one or more of our product candidates and any future product candidate we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- suspension or termination of clinical trial sites or entire trial programs;
- decreased demand for any product candidates or products that we may develop;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our product candidate or future product candidates.

We will obtain limited product liability insurance coverage for any and all of our upcoming clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. When needed we intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for one or more of our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Additionally, we have entered into various agreements under which we indemnify third parties for certain claims relating to product candidates. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We, and/or third parties on our behalf, may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations may also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our respective resources, and clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted in connection with the storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

Our success depends, in large part, on our ability to obtain patent protection for product candidates and their formulations and uses. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in obtaining patents or what the scope of an issued patent may ultimately be. These risks and uncertainties include, but are not necessarily limited to, the following:

- patent applications may not result in any patents being issued, or the scope of issued patents may not extend to competitive product candidates and their formulations and uses developed or produced by others;
- our competitors, many of which have substantially greater resources than us or our partners, and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that may limit or interfere with our abilities to make, use, and sell potential product candidates, file new patent applications, or may affect any pending patent applications that we may have;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

In addition, patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the US Patent and Trademark Office ("PTO"), or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our US patent positions. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technologies or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Third parties are often responsible for maintaining patent protection for our product candidates, at our and their expense. If that party fails to appropriately prosecute and maintain patent protection for a product candidate, our abilities to develop and commercialize products may be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. Such a failure to properly protect intellectual property rights relating to any of our product candidates could have a material adverse effect on our financial condition and results of operations. In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents.

We and our licensors also rely on trade secrets and proprietary know-how to protect product candidates. Although we have taken steps to protect our and their trade secrets and unpatented know-how, including entering into confidentiality and non-use agreements with third parties, and proprietary information and invention assignment agreements with employees, consultants and advisers, third parties may still come upon this same or similar information independently. Despite these efforts, any of these parties may also breach the agreements and may unintentionally or willfully disclose our or our licensors' proprietary information, including our trade secrets, and we may not be able to identify such breaches or obtain adequate remedies. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our or our licensors' trade secrets were to be lawfully obtained or independently developed by a competitor, we and our licensors would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our or our licensors' trade secrets were to be disclosed to or independently developed by a competitor, our competitive positions would be harmed.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify any patentable aspects of our research and development output and methodology, and, even if we do, an opportunity to obtain patent protection may have passed. Given the uncertain and time-consuming process of filing patent applications and prosecuting them, it is possible that our product(s) or process(es) originally covered by the scope of the patent application may have changed or been modified, leaving our product(s) or process(es) without patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for one or more product candidates or any future product candidate we may license or acquire, third parties may be able to leverage our proprietary information and products without risk of infringement, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of licensed patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the US. The patent situation outside the US is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the US, and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than US law does. We might also become involved in derivation proceedings in an event that a third party misappropriates one or more of our inventions and files their own patent application directed to such one or more inventions. The costs of these proceedings could be substantial and it is possible that our efforts to establish priority of invention (or that a third party derived an invention from us) would be unsuccessful, resulting in a material adverse effect on our US patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the US and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the US have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first instance for protection under the patent laws of the US. Accordingly, we cannot predict the breadth of claims that may be allowed and remain enforceable in our patents or in those licensed from a third party.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include changes to transition from a "first-to-invent" system to a "first inventor-to-file" system and to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a less burdensome, quicker and less expensive process for challenging issued patents. The PTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

We also may rely on the regulatory period of market exclusivity for any of our biologic product candidates that are successfully developed and approved for commercialization. Although this period in the United States is generally 12 years from the date of marketing approval (depending on the nature of the specific product), there is a risk that the U.S. Congress could amend laws to significantly shorten this exclusivity period. Once any regulatory period of exclusivity expires, depending on the status of our patent coverage and the nature of the product, we may not be able to prevent others from marketing products that are biosimilar to or interchangeable with our products, which would materially adversely affect our business.

If we or our licensors are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our success also depends on our ability, and the abilities of any of our respective current or future collaborators, to develop, manufacture, market and sell product candidates without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our or our licensors' intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we or our licensors are not aware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the US and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or such licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we and our licensors were the first to file for patent protection of such inventions. In the event that a third party has also filed a US patent application relating to our product candidates or a similar invention, depending upon the priority dates claimed by the competing parties, we may have to participate in interference proceedings declared by the PTO to determine priority of invention in the US. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our licensors' patent rights are highly uncertain.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or any of our licensors, suppliers or collaborators infringe the third party's intellectual property rights, we may have to, among other things:

- obtain additional licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign products or processes to avoid infringement, which may demand substantial funds, time and resources and which may result in inferior or less desirable processes and/or products;
- pay substantial damages, including the possibility of treble damages and attorneys' fees, if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross-licenses to our product candidates; and/or
- defend litigation or administrative proceedings which may be costly regardless of outcome, and which could result in a substantial diversion of financial and management resources.

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

Competitors may infringe our or our licensors' patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging invalidity of our or our licensors' patents or that we infringe their patents; or provoke those parties to petition the PTO to institute *inter partes* review against the asserted patents, which may lead to a finding that all or some of the claims of the patent are invalid. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensor's is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found to be unenforceable, or interpreted narrowly and could likewise put pending patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

We may be subject to claims that our employees and/or consultants have wrongfully used or disclosed to us alleged trade secrets of their former employers or other clients.

As is common in the biopharmaceutical industry, we rely on employees and consultants to assist in the development of product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biopharmaceutical companies, including our competitors or potential competitors. We may become subject to claims related to whether these individuals have inadvertently or otherwise used, disclosed or misappropriated trade secrets or other proprietary information of their former employers or their former or current clients. Litigation may be necessary to defend against these claims. Even if we are successful in defending these claims, litigation could result in substantial costs and be a distraction to management and/or the employees or consultants that are implicated.

Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with products, when and if any of them are approved.

Any product for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of, and review by, the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping, and requirements regarding company presentations and interactions with healthcare professionals. Even if we obtain regulatory approval for a product, the approval may be subject to limitations on the indicated uses for which the product may be marketed or subject to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. We also may be subject to state laws and registration requirements covering the distribution of drug products. Later discovery of previously unknown problems with products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on product manufacturing, distribution or use;
- restrictions on the labeling or marketing of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls;
- fines;
- suspension or withdrawal of marketing or regulatory approvals;
- refusal to permit the import or export of products;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

If we or our suppliers, third-party contractors, clinical investigators or collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we or our collaborators may be subject to the actions listed above, including losing marketing approval for products when and if any of them are approved, resulting in decreased revenue from milestones, product sales or royalties.

We rely on information technology, and any internet or internal computer system failures, inadequacies, interruptions or compromises of our systems or the security of confidential information could damage our reputation and harm our business.

Although a significant portion of our business is conducted using traditional methods of contact and communications such as face-to-face meetings, our business is increasingly dependent on critical, complex and interdependent information technology systems, including internet-based systems, to support business processes as well as internal and external communications. We could experience system failures and degradations in the future. We cannot assure you that we will be able to prevent an extended and/or material system failure if any of the following or similar events occurs:

- human error;
- subsystem, component, or software failure;
- a power or telecommunications failure;
- hacker attacks, cyber-attacks, software viruses, security breaches, unauthorized access or intentional acts of vandalism; or
- terrorist acts or war.

If any of the foregoing events were to occur, our business operations could be disrupted in ways that would require the incurrence of substantial expenditures to remedy. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed clinical trials for one or more of our product conducts could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data and applications, or inappropriate/unauthorized disclosure of confidential or proprietary information (including trade secrets), we could incur liability and our business and financial condition could be harmed.

The occurrence of a catastrophic disaster could damage our facilities beyond insurance limits or we could lose key data which could cause us to curtail or cease operations.

We are vulnerable to damage and/or loss of vital data from natural disasters, such as earthquakes, tornadoes, power loss, fire, health epidemics and pandemics, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our businesses could be seriously impaired. We have property, liability and business interruption insurance that may not be adequate to cover losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and prospects. Any of the aforementioned circumstances, including without limitation the emerging COVID-19 virus, may also impede our employees' and consultants' abilities to provide services in-person and/or in a timely manner; hinder our ability to raise funds to finance our operations on favorable terms or at all; and trigger effectiveness of "force majeure" clauses under agreements with respect to which we receive goods and services, or under which we are obligated to achieve developmental milestones on certain timeframes. Disputes with third parties over the applicability of such "force majeure" clauses, or the enforceability of developmental milestones and related extension mechanisms in light of such business interruptions, may arise and may become expensive and time-consuming.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

We cannot predict the likelihood, nature or extent of how government regulation that may arise from future legislation or administrative or executive action taken by the U.S. presidential administration may impact our business and industry. In particular, the U.S. President has taken several executive actions, specifically through rulemaking and guidance, that could impact the pharmaceutical business and industry. A few of the major administrative actions include:

1. On October 9, 2019, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule entitled, *Modernizing and Clarifying the Physician Self-Referral Regulations* and on the same day the HHS Office of Inspector General issued a similar rule, entitled *Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary penalty Rules Regarding Beneficiary Inducements*. The proposed rules are an effort to reform regulations dealing with anti-kickback and self-referral laws. The proposals are attempting to allow certain financial arrangements that would otherwise violate anti-kickback and self-referral laws for providers that are participating in value-based payment arrangements. The proposed rule could impact drug purchasing behavior to ensure providers are within their budget and/or restructure existing payment structures between providers and manufacturers.

2. On October 30, 2019, the Administration issued an advanced notice of proposed rulemaking ("ANPRM") entitled, *International Pricing Index Model for Medicare Part B Drugs*. This ANPRM is soliciting feedback on a potential proposal to align United States drug prices in the Medicare Part B program with international prices. It also solicits public feedback on a policy that would allowing private-sector vendors to negotiate prices, take title to drugs, and improve competition for hospital and physician business. Although this is only a notice for a potential rule, it signals the Administration's desire to regulatorily influence the United States drug pricing system that could adversely affect the industry.

3. On November 15, 2019, CMS issued a proposed rule entitled, *Transparency in Coverage* and finalized the *Calendar Year ("CY") 2020 Outpatient Prospective Payment System ("OPPS") & Ambulatory Surgical Center Price Transparency Requirements for Hospitals to Make Standard Charges Rule*. Together the rules would increase price transparency through health plans and in hospitals. The affects may influence consumer purchasing habits in the health care sector as a whole. Although the transparency provisions are not yet in effect and the hospital price transparency requirements are subject to litigation, there could be implications for the industry related to drug pricing if or when it is enacted.

4. On November 18, 2019, CMS issued a proposed rule entitled, *Medicaid Fiscal Accountability Regulation ("MFAR")*. The proposed rule would significantly impact states' ability to finance their Medicaid programs. If finalized, the MFAR could force states to restructure their Medicaid financing that could disincentivize or change state prescription drug purchasing behavior that would adversely impact the industry.

5. On December 18, 2019, the FDA issued a proposed rule entitled, *Importation of Prescription Drugs.* The proposed rule would allow the importation of certain prescription drugs from Canada. If finalized, states or other non-federal government entities would be able to submit importation program proposals to FDA for review and authorization. This proposed rule could also influence pricing practices in the United States.

6. On January 30, 2020, CMS issued a state waiver option entitled, *Health Adult Opportunity ("HAO").* The HAO would allow states to restructure benefits and coverage policies for their Medicaid programs. The HAO will provide states administrative flexibilities in exchange for a capped federal share. The cap on the federal share is commonly referred to as a "block grant." Importantly, the HAO allows states to set formularies that align with Essential Health Benefit requirements while still requiring manufacturers to participate in the Medicaid Rebate Program. Depending on utilization of the HAO by states, it could impact the industry – especially if states elect to use a formulary.

It is also possible that the Trump Administration will include drug pricing proposals in annual rulemaking throughout the year. As noted above, it is impossible to predict whether these policies will be included in future rulemaking; however, it is possible and worth noting.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business or the business of our partners. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough nonessential FDA employees and stop routine activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If the timing of FDA's review and approval of new products is delayed, the timing of our or our partners' development process may be delayed, which could result in delayed milestone revenues and materially harm our operations or business.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product cannot be marketed in the US or other countries until it has completed a rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Negative public opinion and increased regulatory scrutiny of the therapies that underpin many of our product candidates may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Public perception may be influenced by claims that one or more of the therapies underpinning our product candidates, including without limitation gene therapy, is unsafe, and such therapy may not gain the acceptance of the public or the medical community. In particular, the success of our gene therapy platforms will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity, could lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that do obtain approval and/or a decrease in demand for any such product candidates. Concern about environmental spread of our products, whether real or anticipated, may also hinder the commercialization of our products.

Risks Relating to our Finances, Capital Requirements and Other Financial Matters

We are an early-stage company with a history of operating losses that is expected to continue, and we are unable to predict the extent of future losses, whether we will generate significant or any revenues or whether we will achieve or sustain profitability.

We are an early-stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We continue to generate operating losses in all periods including losses from continuing operations of approximately $101.7 million and $130.8 million for the years ended December 31, 2019 and 2018, respectively, and a loss from continuing operations of $24.1 million for the three months ended March 31, 2020. At March 31, 2020, we had an accumulated deficit of approximately $448.6 million. We expect to make substantial expenditures and incur increasing operating costs and interest expense in the future, and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates and finance investments in certain of our existing and new partners and affiliates in accordance with our growth strategy. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity.

Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if:

- one or more of our product candidates is approved for commercial sale, due to our ability to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;
- we are required by the FDA or foreign regulatory authorities, to perform studies in addition to those currently expected;
- there are any delays in completing our clinical trials or the development of any of our product candidates;

- we execute other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- there are variations in the level of expenses related to our future development programs;
- there are any product liability or intellectual property infringement lawsuits in which we may become involved;
- there are any regulatory developments affecting product candidates of our competitors; and
- one or more of our product candidates receives regulatory approval.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage products, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain regulatory approval for one or more of our product candidates, or any future product candidate that we may license or acquire;
- manufacture commercial quantities of one or more of our product candidates or any future product candidate, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell one or more of our product candidates or any future product candidate, if approved.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have also historically financed a significant portion of our growth and operations in part through the assumption of debt; should an event of default occur under any applicable loan documents, our business would be materially adversely affected.

At March 31, 2020, the total amount of debt outstanding, net of the debt discount was $85.4 million. If we default on our obligations, the holders of our debt may declare the outstanding amounts immediately payable together with accrued interest, and/or take possession of pledged collateral, if any. If an event of default occurs, we may not be able to cure it within any applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. In addition, current or future debt obligations may limit our ability to finance future operations or satisfy capital needs or to engage in, expand or pursue our business activities. Such restrictive covenants may also prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding debt, which may not be desirable or possible.

To service our debt securities, which may be deemed to include our Series A Preferred Stock, we will be required to generate a significant amount of cash. Our ability to generate cash depends on a number of factors, some of which are beyond our control, and any failure to meet our debt obligations would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock and/or preferred stock to decline.

Prevailing economic conditions and financial, business and other factors, many of which are beyond our control, may affect our ability to make payments on our debt. If we do not generate sufficient cash flow to satisfy our debt obligations, we may have to undertake alternative financing plans, such as refinancing or restructuring our debt, selling assets, reducing or delaying capital investments or seeking to raise additional capital. Alternatively, as we have done in the past, we may also elect to refinance certain of our debt, for example, to extend maturities. Our ability to restructure or refinance our debt will depend on the capital markets and our financial condition at such time. If we are unable to access the capital markets, whether because of the condition of those capital markets or our own financial condition or reputation within such capital markets, we may be unable to refinance our debt. In addition, any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. Our inability to generate sufficient cash flow to satisfy our debt obligations or to refinance our obligations on commercially reasonable terms, or at all, could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock and/or debt securities to decline.

Repayment of our indebtedness is dependent in part on the generation of cash flow by Journey and its ability to make such cash available to us, by dividend, debt repayment or otherwise. Journey may not be able to, or may not be permitted to, make distributions to enable us to make payments in respect of our indebtedness. Each of our subsidiaries, including Journey, is a distinct legal entity and, under certain circumstances, legal and contractual restrictions may limit our ability to obtain cash from our subsidiaries.

Our ability to continue to reduce our indebtedness will depend upon factors including our future operating performance, our ability to access the capital markets to refinance existing debt and prevailing economic conditions and financial, business and other factors, many of which are beyond our control. We can provide no assurance of the amount by which we will reduce our debt, if at all. In addition, servicing our debt will result in a reduction in the amount of our cash flow available for other purposes, including operating costs and capital expenditures that could improve our competitive position and results of operations.

We have in the past acted, do currently act, and are likely to continue in the future to act as guarantor and/or indemnitor of the obligations, actions or inactions of certain of our subsidiaries and affiliated companies; depending on the terms of such arrangements, we may be contractually obligated to pay substantial amounts to third parties based on the actions or inactions of our subsidiaries and/or affiliates.

We have in the past acted, do currently act, and are likely to continue in the future to act as guarantor of the debt obligations of several of our subsidiaries and/or affiliates, including Aevitas, Baergic, Cellvation and Cyprium. Depending on the terms of such guaranty arrangements, we may be contractually obligated to pay substantial amounts to third party lenders based on the actions or inactions of such subsidiaries and/or affiliates, which would result in a reduction of the amount of our cash available for other purposes and may have a material adverse effect on the price of our Securities.

We also have in the past acted, do currently act, and are likely to continue in the future to act as indemnitor of potential losses that may be experienced by one or more of our affiliated companies and/or their partners or investors. In particular, under that certain Indemnification Agreement, dated as of November 12, 2018 (the "Indemnification Agreement"), we indemnify InvaGen Pharmaceuticals Inc. ("InvaGen") and its affiliates for any losses they may sustain in connection with inaccuracies that may appear in the representations and warranties that our partner company Avenue made to InvaGen in that certain Stock Purchase and Merger Agreement, dated as of November 12, 2018 (the "Avenue SPMA"). The maximum amount of indemnification we may have to provide under the Indemnification Agreement is $35.0 million, and such obligation terminates upon the consummation of the Merger Transaction (as defined in the Avenue SPMA). In the event of payment by us of any such indemnification amount, we would be able to recoup such amounts (other than our pro rata share of the indemnification as a shareholder in Avenue) from the Merger Transaction proceeds, but if the Merger Transaction never occurs, we would have no means of recouping such previously-paid indemnification amounts. If we become obligated to pay all or a portion of such indemnification amounts (regardless of whether or not we are partially reimbursed out of the proceeds of the Merger Transaction), our business and the market value of our common stock and/or debt securities may be materially adversely impacted.

We have in the past and are likely in the future to undergo collaborations and/or divestitures with respect to certain of our assets and subsidiaries, some of which may be material and/or transformative, which could adversely affect our business, prospects and opportunities for growth.

We have in the past completed a number of partnerships and/or contingent sales of our assets and subsidiaries, including an equity investment and contingent sale between Avenue and InvaGen and an equity investment and contingent option transaction between Caelum and Alexion Pharmaceuticals, Inc. Each of these transactions has been time-consuming and has diverted management's attention. As a result of these contingent sales (and other similar transactions we may in the future complete), we may experience a reduction in the size or scope of our business, our market share in particular markets, our opportunities with respect to certain markets, products or therapeutic categories or our ability to compete in certain markets and therapeutic categories. For example, in connection with execution of the Avenue SPMA, we signed a Restrictive Covenant Agreement, which prohibits us from, directly or indirectly, engaging in the business of hospital administered pain management anywhere in the world other than Canada, Central America or South America for a period of five years after the earlier of the termination of the Avenue SPMA or consummation of the Merger Transaction (as defined in the SPMA).

In addition, in connection with any such transaction that involves a (contingent or non-contingent) sale of one of our assets or subsidiaries, we may surrender our ability to realize long-term value from such asset or subsidiary, in the form of foregone royalties, milestone payments, sublicensing revenue or otherwise, in exchange for upfront and/or other payments. In the event, for instance, that a product candidate underpinning any such asset or subsidiary is granted FDA approval for commercialization following the execution of documentation governing the sale by us of such asset or subsidiary, the transferee of such asset or subsidiary may realize tremendous value from commercializing such product, which we would have realized for ourselves had we not executed such sale transaction and been able to achieve applicable approvals independently.

Should we seek to enter into collaborations or divestitures with respect to other assets or subsidiaries, we may be unable to consummate such arrangements on satisfactory or commercially reasonable terms within our anticipated timelines. In addition, our ability to identify, enter into and/or consummate collaborations and/or divestitures may be limited by competition we face from other companies in pursuing similar transactions in the biotechnology and pharmaceutical industries. Any collaboration or divestiture we pursue, whether we are able to complete it or not, may be complex, time consuming and expensive, may divert the management's attention, have a negative impact on our customer relationships, cause us to incur costs associated with maintaining the business of the targeted collaboration or divestiture during the transaction process and also to incur costs of closing and disposing the affected business or transferring the operations of the business to other facilities. In addition, if such transactions are not completed for any reason, the market price of our common stock may reflect a market assumption that such transactions will occur, and a failure to complete such transactions could result in a negative perception by the market of us generally and a decline in the market price of our common stock. For example, consummation of the Avenue-InvaGen merger contemplated by the Avenue SPMA is conditioned on, *inter alia*: (i) final FDA approval of IV tramadol (Avenue's lead product candidate); (ii) labeling for IV tramadol containing an indication as moderate to moderately severe (post-operative) pain, not restricted to any specific type of surgery; (iii) classification of IV tramadol by the DEA as a Schedule IV drug; and (iv) there being no Risk Evaluation and Mitigation Strategy from the FDA applicable to IV tramadol. If one or more of these conditions is not satisfied, InvaGen will not be obligated to consummate the Avenue-InvaGen merger, which could materially adversely affect our business.

As a result of these factors, any collaboration or divestiture (whether or not completed) could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock and/or preferred stock to decline.

We may need substantial additional funding and may be unable to raise capital when needed, which may force us to delay, curtail or eliminate one or more of our R&D programs, commercialization efforts or planned acquisitions and potentially change our growth strategy.

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2019 and 2018 we incurred R&D expenses of approximately $75.2 million and $83.3 million, respectively and $14.9 million for the three months ended March 31, 2020. We expect to continue to spend significant amounts on our growth strategy. We believe that our current cash and cash equivalents will enable us to continue to fund operations in the normal course of business for at least the next 12 months. Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance potential cash needs. Our ability to obtain additional funding when needed, changes to our operating plans, our existing and anticipated working capital needs, the acceleration or modification of our planned R&D activities, expenditures, acquisitions and growth strategy, increased expenses or other events may affect our need for additional capital in the future and require us to seek additional funding sooner or on different terms than anticipated. In addition, if we are unable to raise additional capital when needed, we might have to delay, curtail or eliminate one or more of our R&D programs and commercialization efforts and potentially change our growth strategy.

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing common stock (or preferred stock that is convertible into common stock), the share ownership of existing stockholders will be diluted. Any future debt financings may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain financial commitments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing or sublicensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Future revenue based on sales of our dermatology products, especially Ximino, Targadox and Exelderm, may be lower than expected or lower than in previous periods.

The vast majority of our operating income for the foreseeable future is expected to come from the sale of dermatology products through our partner company Journey Medical Corporation. Any setback that may occur with respect to such products, in particular Ximino, Targadox and Exelderm, could significantly impair our operating results and/or reduce our revenue and the market prices of our Securities. Setbacks for such products could include, but are not necessarily limited to, problems with shipping, distribution, demand, manufacturing, product safety, marketing, government regulation or reimbursement, licenses and approvals, intellectual property rights, competition with existing or new products, physician or patient acceptance of the products, as well as higher than expected total rebates, returns or recalls. These products also are or may become subject to third party generic competition.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. Also, if we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our Securities.

As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act ("SOX"), as well as rules subsequently implemented by the SEC, and the rules of the Nasdaq Stock Exchange. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

SOX requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of SOX. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

Our ability to use our pre-change NOLs and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

We may, from time to time, carry net operating loss carryforwards ("NOLs") as deferred tax assets on our balance sheet. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage- point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership, some of which changes are outside our control. As a result, our ability to use our pre-change NOLs and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

Risks Associated with our Capital Stock

Some of our executives, directors and principal stockholders can control our direction and policies, and their interests may be adverse to the interests of our other stockholders.

At March 31, 2020, Lindsay A. Rosenwald, M.D. our Chairman, President and Chief Executive Officer, beneficially owned 12.0% of our issued and outstanding capital stock. At March 31, 2020, Michael S. Weiss, our Executive Vice Chairman, Strategic Development, beneficially owned 13.0% of our issued and outstanding capital stock. By virtue of their holdings and membership on our Board of Directors, Dr. Rosenwald and Mr. Weiss may individually influence our management and our affairs and may make it difficult for us to consummate corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders.

The market price of our securities may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

The stock prices of our securities may experience substantial volatility as a result of a number of factors, including, but not necessarily limited to:

- announcements we make regarding our current product candidates, acquisition of potential new product candidates and companies and/or in-licensing through multiple partners/affiliates;
- sales or potential sales of substantial amounts of our Common Stock;
- issuance of debt or other securities;
- our delay or failure in initiating or completing pre-clinical or clinical trials or unsatisfactory results of any of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;

- developments concerning our licensors and/or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- unstable regional political and economic conditions;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market prices of our securities, regardless of our actual operating performance.

Sales of a substantial number of shares of our Common Stock, or the perception that such sales may occur, may adversely impact the price of our Common Stock.

Almost all of the 83.5 million outstanding shares of our Common Stock, inclusive of outstanding equity awards, as of March 31, 2020 are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), or an effective registration statement. In addition, pursuant to our current shelf registration statement on Form S-3, from time to time we may issue and sell shares of our Common Stock or Preferred Stock having an aggregate offering price of up to $17.9 million as of March 31, 2020. Any sale of a substantial number of shares of our Common Stock or our Preferred Stock could cause a drop in the trading price of our Common Stock or Preferred Stock on the Nasdaq Stock Market.

We have never paid and currently do not intend to pay cash dividends in the near future, except for the dividend we pay on our Preferred A shares. As a result, capital appreciation, if any, will be the sole source of gain for our Common Stockholders.

We have never paid cash dividends on our Common Stock, or made stock dividends, except for the dividend we pay on shares of our Series A Preferred Stock, and we currently intend to retain future earnings, if any, to fund the development and growth of our businesses, and retain our stock positions. In addition, the terms of existing and future debt agreements may preclude us from paying cash or stock dividends. Equally, each of our partners is governed by its own board of directors with individual governance and decision-making regimes and mandates to oversee such entities in accordance with their respective fiduciary duties. As a result, we alone cannot determine the acts that could maximize value to you of such partners in which we maintain ownership positions, such as declaring cash or stock dividends. As a result, capital appreciation, if any, of our Common Stock will be the sole source of gain for our Common Stockholders for the foreseeable future.

Provisions in our certificate of incorporation, our bylaws and Delaware law might discourage, delay or prevent a change in control of our Company or changes in our management and, therefore, depress the trading price of our Common Stock or other Securities.

Provisions of our certificate of incorporation, our bylaws and Delaware law may have the effect of deterring unsolicited takeovers and/or delaying or preventing a change in control of our Company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then-current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

In addition, the Delaware General Corporation Law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our Common Stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood that you would receive a premium for your ownership of our Securities through an acquisition.

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

None.

Item 3. **Defaults Upon Senior Securities**

None.

Item 4. **Mine Safety Disclosures**

None.

Item 5. **Other Information**

None.

Item 6. **Exhibits**

Exhibit Index

Exhibit Number	Exhibit Title
31.1	Certification of Chairman, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chairman, President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief 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	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

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.

May 11, 2020

FORTRESS BIOTECH, INC.

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D., Chairman, President and Chief Executive Officer (Principal Executive Officer)

May 11, 2020

By: /s/ Robyn M. Hunter
Robyn M. Hunter Chief Financial Officer (Principal Financial Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lindsay A. Rosenwald, M.D., certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Fortress Biotech, Inc. (the "Registrant");

(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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the Registrant and have:

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

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth 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 controls over financial reporting.

Dated: May 11, 2020

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D.
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robyn M. Hunter, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Fortress Biotech, Inc. (the "Registrant");

(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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the Registrant and have:

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

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth 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 controls over financial reporting.

Dated: May 11, 2020

By: /s/ Robyn M. Hunter
Robyn M. Hunter
Chief Financial Officer
(Principal Financial 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 Fortress Biotech, Inc. (the "Company") for the quarterly period ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lindsay A. Rosenwald, M.D., Chairman, President, and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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.

Dated: May 11, 2020

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D.
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 Fortress Biotech, Inc. (the "Company") for the quarterly period ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robyn M. Hunter, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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.

Dated: May 11, 2020

By: /s/ Robyn M. Hunter
Robyn M. Hunter
Chief Financial Officer
(Principal Financial Officer)