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 September 30, 2019

OR

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

For the transition period from to

Commission File Number 001-35366

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 November 8, 2019
Common Stock, $0.001 par value	70,780,103
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock, $0.001 par value	1,039,292

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

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

($ in thousands except for share and per share amounts)

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 134,945	$ 65,508
Accounts receivable (net of allowance of $250 and $0 at September 30, 2019 and December 31, 2018, respectively)	5,137	5,498
Short-term investments (certificates of deposit)	5,000	17,604
Inventory	941	678
Other receivables - related party	1,243	2,095
Prepaid expenses and other current assets	4,117	6,735
Restricted cash, current	14,929	-
Current assets held for sale	-	13,089
Total current assets	166,312	111,207
Property and equipment, net	12,152	12,019
Operating lease right-of-use asset, net	21,876	-
Restricted cash	1,145	16,074
Long-term investment, at fair value	11,193	-
Intangible asset, net	7,731	1,417
Other assets	1,179	276
Total assets	**$ 221,588**	**$ 140,993**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 28,512	$ 34,067
Accounts payable and accrued expenses - related party	-	149
Interest payable	1,039	1,232
Interest payable - related party	89	97
Notes payable, short-term - related party (net of debt discount of $0 and $336 at September 30, 2019 and December 31, 2018, respectively)	15,472	9,164
Partner company convertible note, short-term, at fair value	-	9,914
Operating lease liabilities - short-term	1,741	-
Derivative warrant liability	-	991
Total current liabilities	46,853	55,614
Notes payable, long-term (net of debt discount of $5,728 and $4,567 at September 30, 2019 and December 31, 2018, respectively)	68,542	60,425
Operating lease liabilities - long-term	24,168	-
Other long-term liabilities	7,025	5,211
Total liabilities	**146,588**	**121,250**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 1,026,111 and 1,000,000 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively; liquidation value of $25.00 per share	1	1
Common stock, $.001 par value, 100,000,000 shares authorized, 70,335,534 and 57,845,447 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	70	58
Common stock issuable, 307,486 and 744,322 shares as of September 30, 2019 and December 31, 2018, respectively	500	659
Additional paid-in-capital	445,966	397,408
Accumulated deficit	(420,742)	(396,274)
Total stockholders' equity attributed to the Company	25,795	1,852
Non-controlling interests	49,205	17,891
Total stockholders' equity	75,000	19,743
Total liabilities and stockholders' equity	**$ 221,588**	**$ 140,993**

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue				
Product revenue, net	$ 9,492	$ 5,168	$ 23,816	$ 17,366
Revenue - from a related party	280	5	1,683	525
Net revenue	9,772	5,173	25,499	17,891
Operating expenses				
Cost of goods sold - product revenue	2,702	1,406	6,972	4,546
Research and development	14,571	16,082	56,355	58,528
Research and development – licenses acquired	700	3,706	1,350	3,804
General and administrative	14,339	12,184	41,260	38,788
Total operating expenses	32,312	33,378	105,937	105,666
Loss from operations	(22,540)	(28,205)	(80,438)	(87,775)
Other income (expenses)				
Interest income	738	269	1,955	841
Interest expense and financing fee	(3,168)	(2,657)	(8,743)	(7,650)
Change in fair value of derivative liability	-	12	-	114
Change in fair value of subsidiary convertible note	-	(84)	-	26
Change in fair value of investments	-	(565)	-	(1,390)
Other loss	-	-	-	(333)
Gain on deconsolidation of Caelum	-	-	18,521	-
Total other income (expenses)	(2,430)	(3,025)	11,733	(8,392)
Loss from continuing operations	(24,970)	(31,230)	(68,705)	(96,167)
Discontinued operations:				
Income (loss) from discontinued operations, net of tax	-	2,643	-	(6,354)
Total income (loss) from discontinued operations	-	2,643	-	(6,354)
Net loss	**(24,970)**	**(28,587)**	**(68,705)**	**(102,521)**
Less: net loss attributable to non-controlling interests	12,208	11,949	44,237	43,254
Net loss attributable to common stockholders	**$ (12,762)**	**$ (16,638)**	**$ (24,468)**	**$ (59,267)**
Loss from continuing operations per common share - basic and diluted	$ (0.44)	$ (0.70)	$ (1.29)	$ (2.21)
Income (loss) from discontinued operations per common share - basic and diluted	$ -	$ 0.06	$ -	$ (0.15)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.22)	$ (0.37)	$ (0.46)	$ (1.36)
Weighted average common shares outstanding - basic and diluted	56,856,821	44,818,186	53,060,565	43,578,763

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)

Three Months Ended September 30, 2019

	Series A Preferred Stock		Common Stock		Common Shares	Additional Paid-In	Accumulated	Non-Controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	Issuable	Capital	Deficit	Interests	Equity
Balance at June 30, 2019	**1,000,000**	**$ 1**	**68,138,203**	**$ 68**	**$ 490**	**$ 439,295**	**$ (407,980)**	**$ 57,946**	**$ 89,820**
Stock-based compensation expense	-	-	-	-	-	3,741	-	-	3,741
Issuance of restricted stock	-	-	177,292	-	-	-	-	-	-
Issuance of common stock for at-the-market offering, net	-	-	1,213,643	1	-	1,930	-	-	1,931
Issuance of preferred A for at-the-market offering, net	26,111	-	-	-	-	523	-	-	523
Preferred A dividends declared and paid	-	-	-	-	-	(601)	-	-	(601)
Partner company's offering, net	-	-	-	-	-	52	-	-	52
Partner company's at-the-market offering, net	-	-	-	-	-	3,341	-	-	3,341
Common shares issuable for 2017 Subordinated Note Financing interest expense	-	-	-	-	500	-	-	-	500
Common shares issued for 2017 Subordinated Note Financing interest expense	-	-	317,804	1	(490)	489	-	-	-
Common shares issued for Opus interest expense	-	-	91,767	-	-	165	-	-	165
Common shares issued for Opus debt	-	-	396,825	-	-	500	-	-	500
Non-controlling interest in subsidiaries	-	-	-	-	-	(3,467)	-	3,467	-
Write off of Partner company note receivable	-	-	-	-	-	(2)	-	-	(2)
Net loss attributable to non-controlling interest	-	-	-	-	-	-	-	(12,208)	(12,208)
Net loss attributable to common stockholders	-	-	-	-	-	-	(12,762)	-	(12,762)
Balance at September 30, 2019	**1,026,111**	**$ 1**	**70,335,534**	**$ 70**	**$ 500**	**$ 445,966**	**$ (420,742)**	**$ 49,205**	**$ 75,000**

Nine Months Ended September 30, 2019

	Series A Preferred Stock		Common Stock		Common Shares	Additional Paid-In	Accumulated	Non-Controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	Issuable	Capital	Deficit	Interests	Equity
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	-	-	-	-	-	10,423	-	-	10,423
Issuance of restricted stock	-	-	1,842,034	2	-	(2)	-	-	-
Issuance of common stock under ESPP	-	-	54,221	-	-	60	-	-	60
Issuance of subsidiaries' common shares for license expenses	-	-	-	-	(164)	164	-	-	-
Issuance of common stock for at-the-market offering, net	-	-	8,604,469	9	-	15,789	-	-	15,798
Issuance of Series A preferred stock for at-the-market offering, net	26,111	-	-	-	-	523	-	-	523
Preferred A dividends declared and paid	-	-	-	-	-	(1,773)	-	-	(1,773)
Partner company's offering, net	-	-	-	-	-	61,036	-	-	61,036
Partner company's at-the-market offering, net	-	-	-	-	-	29,680	-	-	29,680
Issuance of partner company warrants in conjunction with Horizon Notes	-	-	-	-	-	888	-	-	888
Common shares issuable for 2017 Subordinated Note Financing interest expense	-	-	-	-	500	-	-	-	500
Common shares issued for 2017 Subordinated Note Financing interest expense	-	-	1,330,450	1	(495)	1,468	-	-	974
Common shares issuable for Opus interest expense	-	-	-	-	281	-	-	-	281
Common shares issued for Opus interest expense	-	-	262,088	-	(281)	506	-	-	225
Common shares issued for Opus debt	-	-	396,825	-	-	500	-	-	500
Non-controlling interest in subsidiaries	-	-	-	-	-	(70,702)	-	70,702	-
Write off of Partner company note receivable	-	-	-	-	-	(2)	-	-	(2)
Deconsolidation of Caelum non-controlling interest	-	-	-	-	-	-	-	4,849	4,849
Net loss attributable to non-controlling interest	-	-	-	-	-	-	-	(44,237)	(44,237)
Net loss attributable to common stockholders	-	-	-	-	-	-	(24,468)	-	(24,468)
Balance at September 30, 2019	**1,026,111**	**$ 1**	**70,335,534**	**$ 70**	**$ 500**	**$ 445,966**	**$ (420,742)**	**$ 49,205**	**$ 75,000**

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)

Three Months Ended September 30, 2018

	Series A Preferred Stock		Common Stock		Common Shares	Additional Paid-In	Accumulated	Non-Controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	Issuable	Capital	Deficit	Interests	Equity
Balance at June 30, 2018	**1,000,000**	**$ 1**	**53,987,074**	**$ 54**	**$ 776**	**$ 397,858**	**$ (354,756)**	**$ 52,332**	**$ 96,265**
Stock-based compensation expense	-	-	-	-	-	4,096	-	-	4,096
Issuance of restricted stock	-	-	251,147	-	-	-	-	-	-
Issuance of subsidiaries' common shares for license expenses	-	-	-	-	-	206	-	-	206
Subsidiary's offering cost	-	-	-	-	-	11	-	-	11
Subsidiary's ATM offering, net	-	-	-	-	-	7,726	-	-	7,726
Issuance of common stock for at-the-market offering	-	-	1,537,921	2	-	2,887	-	-	2,889
At-the-market offering cost	-	-	-	-	-	(99)	-	-	(99)
Contribution of capital for 2017 bonuses	-	-	-	-	-	1,000	-	-	1,000
Common shares issued for Opus interest expense	-	-	234,030	-	(287)	574	-	-	287
Common shares issuable for 2017 Subordinated Note Financing interest expense	-	-	-	-	495	-	-	-	495
Common shares issued for2017 Subordinated Note Financing interest expense	-	-	173,308	-	(489)	489	-	-	-
Preferred A dividends declared and paid	-	-	-	-	-	(586)	-	-	(586)
Disposal of NHLD	-	-	-	-	-	934	-	-	934
Non-controlling interest in subsidiaries	-	-	-	-	-	(6,481)	-	6,481	-
Net loss attributable to non-controlling interest	-	-	-	-	-	-	-	(11,949)	(11,949)
Net loss attributable to common stockholders	-	-	-	-	-	-	(16,638)	-	(16,638)
Balance at September 30, 2018	**1,000,000**	**$ 1**	**56,183,480**	**$ 56**	**$ 495**	**$ 408,615**	**$ (371,394)**	**$ 46,864**	**$ 84,637**

Nine Months Ended September 30, 2018

	Series A Preferred Stock		Common Stock		Common Shares	Additional Paid-In	Accumulated	Non-Controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	Issuable	Capital	Deficit	Interests	Equity
Balance at December 31, 2017	**1,000,000**	**$ 1**	**50,991,285**	**$ 51**	**$ 500**	**$ 364,148**	**$ (312,127)**	**$ 67,929**	**$ 120,502**
Stock-based compensation expense	-	-	-	-	-	12,043	-	-	12,043
Issuance of restricted stock	-	-	1,809,421	2	-	(2)	-	-	-
Issuance of common stock under ESPP	-	-	43,707	-	-	128	-	-	128
Issuance of subsidiaries' common shares for license expenses	-	-	-	-	-	229	-	-	229
Subsidiary's offering, net	-	-	-	-	-	22,668	-	-	22,668
Subsidiary's ATM offering, net	-	-	-	-	-	7,726	-	-	7,726
Exercise of subsidiary's warrants for cash	-	-	-	-	-	181	-	-	181
Issuance of common stock for at-the-market offering	-	-	2,668,756	3	-	6,956	-	-	6,959
At-the-market offering cost	-	-	-	-	-	(240)	-	-	(240)
Contribution of capital for 2017 bonuses	-	-	-	-	-	1,000	-	-	1,000
Common shares issued for Opus interest expense	-	-	234,030	-	-	574	-	-	574
Common shares issuable for 2017 Subordinated Note Financing interest expense	-	-	-	-	495	-	-	-	495
Common shares issued for 2017 Subordinated Note Financing interest expense	-	-	436,281	-	(500)	1,478	-	-	978
Preferred A dividends declared and paid	-	-	-	-	-	(1,758)	-	-	(1,758)
2017 Preferred A offering cost adjustment	-	-	-	-	-	1,297	-	-	1,297
Disposal of NHLD	-	-	-	-	-	14,376	-	-	14,376
Non-controlling interest in subsidiaries	-	-	-	-	-	(22,189)	-	22,189	-
Net loss attributable to non-controlling interest	-	-	-	-	-	-	-	(43,254)	(43,254)
Net loss attributable to common stockholders	-	-	-	-	-	-	(59,267)	-	(59,267)
Balance at September 30, 2018	**1,000,000**	**$ 1**	**56,183,480**	**$ 56**	**$ 495**	**$ 408,615**	**$ (371,394)**	**$ 46,864**	**$ 84,637**

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)

	Nine Months Ended September 30,	
	2019	**2018**
Cash Flows from Operating Activities:		
Net loss	$ (68,705)	$ (102,521)
Net loss on discontinued operations	-	(6,354)
Loss from continuing operations	(68,705)	(96,167)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation expense	1,414	892
Bad debt expense	250	-
Amortization of debt discount	2,459	1,819
Amortization of product revenue license fee	820	433
Amortization of operating lease right-of-use assets	1,150	-
Stock-based compensation expense	10,423	12,053
Common shares issuable for 2017 Subordinated Note Financing interest expense	500	495
Common shares issued for 2017 Subordinated Note Financing interest expense	974	978
Common shares issuable for Opus interest expense	281	-
Common shares issued for Opus interest expense	225	574
Change in fair value of investments	-	1,390
Change in fair value of derivative liability	-	(114)
Change in fair value of partner company convertible note	-	(26)
Gain on deconsolidation of Caelum	(18,521)	-
Research and development-licenses acquired, expense	1,350	3,804
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:		
Accounts receivable	111	2,327
Inventory	(263)	(503)
Other receivables - related party	852	204
Prepaid expenses and other current assets	1,812	(1,428)
Other assets	(903)	200
Current assets held for sale	-	(9,451)
Noncurrent assets held for sale	-	1,274
Current liabilities held for sale	-	12,561
Accounts payable and accrued expenses	(3,841)	(407)
Accounts payable and accrued expenses - related party	(149)	(19)
Interest payable	5	(274)
Interest payable - related party	(8)	(3)
Lease liabilities	(940)	-
Other long-term liabilities	795	222
Net cash used in continuing operating activities	(69,909)	(69,166)
Net cash used in discontinued operating activities	-	(7,522)
Net cash used in operating activities	(69,909)	(76,688)

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 (Continued)
($ in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2019	**2018**
Cash Flows from Investing Activities:		
Purchase of research and development licenses	(850)	(1,075)
Purchase of property and equipment	(1,455)	(6,743)
Purchase of intangible asset	(2,400)	-
Purchase of short-term investment (certificates of deposit)	(5,000)	(47,538)
Redemption of short-term investment (certificates of deposit)	17,604	61,002
Security deposits paid	-	(344)
Deconsolidation of Caelum	(1,201)	-
Net cash provided by continuing investing activities	6,698	5,302
Net cash provided by discontinued investing activities	13,089	-
Net cash provided by investing activities	19,787	5,302
Cash Flows from Financing Activities:		
Payment of Preferred A dividends	(1,773)	(1,758)
Inter-company costs related to the issuance of Series A preferred stock	-	1,297
Proceeds from issuance of common stock under ESPP	60	128
Proceeds from issuance of common stock for at-the-market offering	16,099	6,959
Payment of cost related to issuance of common stock for at-the-market offering	(301)	(240)
Proceeds from issuance of Series A preferred stock for at-the-market offering	539	-
Payment of cost related to issuance of Series A preferred stock for at-the-market offering	(16)	-
Proceeds from partner company's sale of stock	66,623	23,011
Payment of costs related to partner company's sale of stock	(4,754)	(343)
Proceeds from partner company's at-the-market offering	30,419	7,980
Payment of costs related to partner company's at-the-market offering	(739)	(234)
Proceeds from exercise of partner company's warrants	-	181
Payment of debt issuance costs associated with 2017 Subordinated Note Financing	(79)	(404)
Proceeds from 2018 Venture Notes	-	21,707
Payment of debt issuance costs associated with 2018 Venture Notes	(126)	(1,868)
Proceeds from partner company's Horizon Notes	15,000	-
Payment of debt issuance costs associated with partner company's Horizon Notes	(1,393)	-
Payment of partner company's Convertible Notes	-	(4,076)
Net cash provided by financing activities	119,559	52,340
Net increase (decrease) in cash and cash equivalents and restricted cash	69,437	(19,046)
Cash and cash equivalents and restricted cash at beginning of period	81,582	110,958
Cash and cash equivalents and restricted cash at end of period	$ 151,019	$ 91,912

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 (Continued)
($ in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2019	**2018**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,976	$ 3,767
Cash paid for interest - related party	$ 342	$ 281
Supplemental disclosure of non-cash financing and investing activities:		
Settlement of restricted stock units into common stock	$ 2	$ 2
Unpaid partner company's at-the-market offering cost	$ -	$ 20
Common shares issuable for license acquired	$ 164	$ -
Issuance of partner company warrants in conjunction with Horizon Notes	$ 888	$ -
Common shares issued for 2017 Subordinated Note Financing interest expense	$ -	$ 500
Common shares issued for Opus debt, a related party	$ 500	$ -
Unpaid fixed assets	$ 288	$ 125
Partner company's previous paid offering cost	$ 833	$ -
Partner company's unpaid intangible assets	$ 4,734	$ 1,200

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, and the University of Pennsylvania.

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).

As of September 30, 2019, several of the Fortress partner companies maintain licenses to product candidate intellectual property, including Aevitas Therapeutics, Inc. ("Aevitas"), Avenue Therapeutics, Inc. ("Avenue"), Caelum Biosciences, Inc. ("Caelum"), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. ("Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Journey Medical Corporation ("Journey" or "JMC"), Mustang Bio, Inc. ("Mustang"), and Tamid Bio, Inc. ("Tamid").

Liquidity and Capital Resources

Since inception, the Company's operations have been financed primarily through the sale of equity and debt securities and 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.

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 18, 2019, from which the Company derived the balance sheet data at December 31, 2018, as well as Checkpoint's Form 10-K, filed with the SEC on March 18, 2019, Mustang's Form 10-K, filed with the SEC on March 18, 2019, and Avenue's Form 10-K, filed with the SEC on March 12, 2019.

The Company's unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries: Avenue, Aevitas, CB Securities Corporation, Cellvation, Coronado SO Co., Checkpoint, Cyprium, Escala Therapeutics, Inc., GeneXion Oncology, Inc., Helocyte, Immune Limited, JMC, Mustang, Tamid, Fortress Biotech China, Inc., FBIO Acquisition Corp. IV, FBIO Acquisition Corps. VI - XIV, and JG Pharma, Inc., a subsidiary of JMC. All intercompany balances and transactions have been eliminated.

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 and intangible assets, fair value measurements, stock-based compensation, common stock issued to acquire licenses, investments, accrued expenses, derivative warrant liabilities, revenue with customers, provisions for income taxes and contingencies. Due to the uncertainty inherent in such estimates, actual results may differ from these estimates.

Discontinued Operations

At December 31, 2018, the Company determined that its National Holdings Corporation ("National") segment met the discontinued operations criteria set forth in Accounting Standards Codification (ASC) Subtopic 205-20-45, *Presentation of Financial Statements.* As such, the National segment results have been classified as discontinued operations in the accompanying Condensed Consolidated financial statements. See Note 3 for more information relating to the Company's discontinued operations.

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2018 Annual Report other than the adoption of the Financial Accounting Standards Board (FASB) Accounting Standard Updates (ASU) ASU 2016-02, *Leases,* and 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*.

Leases

Effective January 1, 2019, the Company accounts for its leases under ASC 842,*Leases*. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the condensed consolidated balance sheet as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line rent expense over the lease term. For finance leases, interest on the lease liability and the amortization of the right-of-use asset results in front-loaded expense over the lease term. Variable lease expenses are recorded when incurred.

In calculating the right-of-use asset and lease liability, the Company elects to combine lease and non-lease components. The Company continues to account for leases in the prior period financial statements under ASC Topic 840.

Stock-Based Compensation

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards and forfeiture rates.

For stock-based compensation awards to non-employees, prior to the adoption of ASU 2018-07 on January 1, 2019, the Company remeasured the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards were recognized as compensation expense in the period of change. Subsequent to the adoption of ASU 2018-07, the Company recognizes non-employees compensation costs over the requisite service period based on a measurement of fair value for each stock award.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model or independent appraisals, as applicable. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Recently Adopted Accounting Pronouncements

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, *Disclosure Update and Simplification*, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule became effective on November 5, 2018. The Company included the required presentation of changes in stockholders' equity in this Form 10-Q.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU No. 2018-07 as of January 1, 2019. As a result of the adoption of ASU 2018-07, the grant date fair value of non-employee awards will be fixed as of December 31, 2018, rather than the prior methodology that recognized a variable cost based on the fair value of such shares as of their vesting dates. The Company recorded non-employees' awards as of January 1, 2019 prospectively. The Company's implementation of this standard as of January 1, 2019 did not have a material impact on its condensed consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The adoption of this ASU on January 1, 2019 did not have a material impact on its condensed consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted Topic 842 on January 1, 2019, using the optional transition method by recording a right of use asset of $23.0 million, a lease liability of $26.8 million and eliminated deferred rent of approximately $3.8 million; there was no effect on opening retained earnings, and the Company continues to account for leases in the prior period financial statements under ASC Topic 840. In adopting the new standard, the Company elected to apply the practical expedients regarding the identification of leases, lease classification, indirect costs, and the combination of lease and non-lease components.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326)*: Measurement of Credit Losses on Financial Instruments. ASU 2016-13 requires that expected credit losses relating to financial assets are measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The new standard will be effective on January 1, 2020 and may be adopted earlier. The Company is currently evaluating the impact, if any, that ASU 2016-13 will have on its condensed consolidated financial statements and related disclosures.

In August 2018, the FASB issued 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. The Company does not expect the adoption of this guidance to have a material impact on its condensed consolidated financial statements.

3. Discontinued Operations

The following is a summary of revenue and expenses of National for the three and nine months ended September 30, 2018. The Company had no activity related to National in 2019.

($ in thousands)	**Three Months Ended September 30, 2018**	**Nine Months Ended September 30, 2018**
Revenue	$ 58,520	$ 165,061
Operating expenses		
Commissions, compensation and fees	48,556	141,462
Clearing fees	451	1,772
Communications	856	2,429
Occupancy	738	2,834
Licenses and registration	861	2,028
Professional fees	1,076	3,047
Interest	26	30
Underwriting costs	43	230
Depreciation and amortization	871	2,587
Other administrative expenses	1,726	5,839
Total operating expenses	55,204	162,258
Loss from operations	3,316	2,803
Other income (expenses)		
Interest income	-	6
Interest expense and financing fees	429	1,195
Change in fair value of derivative liabilities	(12)	(8,045)
Other income	(146)	69
Total other income (expenses)	271	(6,775)
Income (loss) from discontinued operations before income taxes	3,587	(3,972)
Income tax expense	944	2,382
Income (loss) from discontinued operations	2,643	(6,354)
Gain from disposal of National	-	-
Total income (loss) from discontinued operations, net of tax	$ 2,643	$ (6,354)

During the nine months ended September 30, 2019, the Company received $13.1 million or $3.25 per share, for its remaining ownership of National, as such as of September 30, 2019, the Company had no asset available for sale on its condensed consolidated balance sheets. In connection with this sale, the Company classified the assets and liabilities related to National, included on its condensed consolidated balance sheet as of December 31, 2018, as held for sale as presented in the table below:

($ in thousands)	December 31, 2018
ASSETS	
Current assets	
Current assets held for sale	$ 13,089
Total current assets held for sale	13,089
Total assets held for sale	$ 13,089

The table below depicts the cash flows from the transaction for the nine months ended September 30, 2019 and 2018, respectively:

	Nine Months Ended September 30,	
($ in thousands)	**2019**	**2018**
Operating activities		
Effect of elimination entry with discontinued operations presentation	$ -	$ (1,168)
Net loss on discontinued operations	-	(6,354)
Total cash used in discontinued operating activities	$ -	$ (7,522)
Investing activities		
Proceeds from sale of National	$ 13,089	$ -
Total cash provided by discontinued investing activities	$ 13,089	$ -

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 for pre-negotiated economics.

The Company deconsolidated its holdings in Caelum immediately prior to the execution of the DOSPA. Following the DOSPA execution, the Company owns approximately 40% of the issued and outstanding capital stock of Caelum. The following table provides a summary of the assets and liabilities of Caelum impacted by the deconsolidation:

($ in thousands)	January 2019
ASSETS	
Current assets	
Cash and cash equivalents	$ 1,201
Prepaid expenses and other current assets	6
Total current assets	$ 1,207
LIABILITIES	
Current liabilities	
Accounts payable and accrued expenses	$ 2,246
Interest payable	198
Interest payable - related party	106
Note payable - related party	929
Note payable	9,914
Warrant liability	991
Total current liabilities	14,384
Net liability impacted by deconsolidation	**$ 13,177**

In connection with this transaction the Company recorded a gain resulting from the deconsolidation of Caelum on its condensed consolidated financial statements for the nine months ended September 30, 2019:

($ in thousands)	**Gain on deconsolidation of Caelum**
Fair value of Caelum	$ 11,193
Net liabilities deconsolidated	13,177
Non-controlling interest share	(4,849)
Write off of MSA fees due Fortress	(1,000)
Gain on deconsolidation of Caelum	**$ 18,521**

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, 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)	September 30, 2019 (Unaudited)	December 31, 2018
Computer equipment	3	$ 648	$ 648
Furniture and fixtures	5	1,153	1,128
Machinery & equipment	5	3,960	3,143
Leasehold improvements	5-15	9,358	9,271
Construction in progress (1)	N/A	1,011	393
Total property and equipment		16,130	14,583
Less: Accumulated depreciation		(3,978)	(2,564)
Property and equipment, net		$ 12,152	$ 12,019

Note 1: Relates to the Mustang cell processing facility.

Fortress' depreciation expense for the three months ended September 30, 2019 and 2018, was approximately $0.5 million and $0.4 million, respectively, and was recorded in both research and development expense and general and administrative expense in the Condensed Consolidated Statements of Operations.

Fortress' depreciation expense for the nine months ended September 30, 2019 and 2018, was approximately $1.4 million and $0.9 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 $11.2 million based on a per share value of $1.549. The following inputs were utilized to derive the value: risk free rate of return of 2.24%, volatility of 70% and a discount for lack of marketability of 27.9%.

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.

Caelum Warrant Liability

The Caelum warrant liability and convertible notes did not exist as of September 30, 2019. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Caelum's warrant liability that are categorized within Level 3 of the fair value hierarchy as of December 31, 2018 is as follows:

	December 31, 2018
Risk-free interest rate	2.905% – 2.909%
Expected dividend yield	–%
Expected term in years	3.84 – 3.96
Expected volatility	70%

($ in thousands)	Fair Value of Derivative Warrant Liability
Beginning balance at January 1, 2019	$ 991
Issuance of warrant due to conversion of note	(991)
Ending balance at September 30, 2019	$ –

Caelum Convertible Notes

A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Caelum's convertible notes that are categorized within Level 3 of the fair value hierarchy as of December 31, 2018 is as follows:

	December 31, 2018
Risk-free interest rate	2.302%
Expected dividend yield	–%
Expected term in years	0.32
Expected volatility	67%

($ in thousands)	Caelum Convertible Notes, at fair value
Beginning balance at January 1, 2019	$ 9,914
Conversion of the convertible notes	(9,914)
Ending balance at September 30, 2019	$ –

The following tables classify into the fair value hierarchy of Fortress' financial instruments, measured at fair value as of September 30, 2019 and December 31, 2018:

	Fair Value Measurement as of September 30, 2019			
($ in thousands)	Level 1	Level 2	Level 3	Total
Assets				
Fair value of investment in Caelum	$ –	$ –	$ 11,193	$ 11,193
Total	$ –	$ –	$ 11,193	$ 11,193

	Fair Value Measurement as of December 31, 2018			
($ in thousands)	Level 1	Level 2	Level 3	Total
Liabilities				
Caelum warrant liability	$ –	$ –	$ 991	$ 991
Caelum convertible notes, at fair value	–	–	9,914	9,914
Total	$ –	$ –	$ 10,905	$ 10,905

The table below provides a roll-forward of the changes in fair value of Level 3 financial instruments as of September 30, 2019:

($ in thousands)	Investment in Caelum	Caelum Convertible Note	Warrant Liabilities	Total
Balance at December 31, 2018	$ -	$ 9,914	$ 991	$ 10,905
Conversion of convertible notes	-	(9,914)	-	(9,914)
Issuance of warrant	-	-	(991)	(991)
Fair value of investment	11,193	-	-	11,193
Balance at September 30, 2019	$ 11,193	$ -	$ -	$ 11,193

As of September 30, 2019, 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 Tamid require substantial completion of research and development, and regulatory and marketing approval efforts in order to reach technological feasibility. As such, for the three and nine months ended September 30, 2019 and 2018, 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2019	2018	2019	2018
Fortress Companies:				
Helocyte	$ -	$ 1,500	$ -	$ 1,521
Checkpoint	-	1,000	-	1,000
Caelum	-	201	-	201
Mustang	700	1,000	1,350	1,075
Aevitas	-	5	-	6
Cellvation	-	-	-	1
Total	$ 700	$ 3,706	$ 1,350	$ 3,804

Checkpoint

The table below provides a summary of Checkpoint's expense related to its licenses, for the three and nine months ended September 30, 2019 and 2018 by license as recorded in the Condensed Consolidated Statements of Operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2019	2018	2019	2018
Dana Farber License CK-301	$ -	$ 1,000	$ -	$ 1,000
Total	$ -	$ 1,000	$ -	$ 1,000

For the three and nine months ended September 30, 2018, Checkpoint recorded a $1.0 million milestone in connection with their license agreement with Dana-Farber, in connection with the achievement of dosing the 12th patient in the Phase 1 trial for CK-301.

Helocyte

For the three and nine months ended September 30, 2019 and 2018, Helocyte recorded expense of nil and $1.5 million, respectively in connection with Helocyte's amended and restated license agreement for Triplex with City of Hope ("COH"). The expense in 2018 relates to the achievement of a probable milestone.

Mustang

License with Calimmune

On August 23, 2019, Mustang entered into a Non-Exclusive License Agreement with Calimmune, Inc. ("Calimmune License") for the rights to the cellbank to be used in the manufacture of the XSCID vector that was separately licensed from St. Jude Children's Research Hospital, Inc. ("St. Jude") in August 2018 (the "Mustang XSCID License"). Pursuant to the term of the Calimmune License Mustang paid an upfront fee of $0.2 million. Three additional development milestones are due, upon achievement totaling $1.0 million. Royalty payments in the low-single digits are due on net sales of licensed products. Upon the execution of the Calimmune License Mustang recorded research and development expense of $0.2 million in the condensed consolidated statement of operations for the three and nine months ended September 30, 2019.

License with Nationwide

In February 2019, Mustang announced that it partnered and entered into an exclusive worldwide license agreement with Nationwide Children's Hospital ("Nationwide") to develop the C134 oncolytic virus (MB-108) for the treatment of glioblastoma multiforme ("GBM"). Mustang intends to combine MB-108 with MB-101 (IL13Rα2-specific CAR) to potentially enhance efficacy in treating GBM. Mustang paid $0.2 million in consideration for the license for exclusive, worldwide rights to develop and commercialize products that incorporate data, know-how and/or C134 virus that were developed at Nationwide. Additional payments are due to Nationwide upon achievement of development and commercialization milestones totaling $152.8 million. Royalty payments in the low-single digits are due on net sales of licensed products.

License with University of California

On March 17, 2017, Mustang entered into an exclusive license agreement with the Regents of the University of California ("UCLA License") to acquire intellectual property rights in patent applications related to the engineered anti-prostate stem cell antigen antibodies for cancer targeting and detection. In September 2019, COH commenced its Phase 1 clinical trial resulting in the achievement of a development milestone resulting in Mustang recording an expense of $0.3 million in the condensed consolidated statement of operations for the three and nine months ended September 30, 2019.

Licenses with City of Hope

PSCA License

On May 31, 2017, Mustang entered into an exclusive license a prostate stem cell antigen (PSCA) chimeric antigen receptor ("CAR") T technology or MB-105 with COH, for the treatment of prostate cancer. In September 2019, the first patient in a Phase 1 clinical trial in treating patients with prostate stem cell antigen positive (PSCA+) castration resistant prostate cancer was dosed with MB-105, and Mustang recorded an expense of $0.2 million marking the achievement of this milestone in the condensed consolidated statement of operations for the three and nine months ended September 30, 2019.

CD123 License

In February 2017, Mustang entered into an Amended and Restated License Agreement with COH for the development of CD123 or MB-102, ("CD123 License"). In March 2019, COH dosed the 12th patient in its Phase 1 trial treating patients with relapsed/refractory Acute Myeloid Leukemia ("AML") and recorded expense of nil and $0.3 million in the condensed consolidated statement of operations for the three and nine months ended September 30, 2019, respectively.

CS1 License

In February 2017, Mustang entered into an exclusive license agreement with the COH for the use of CS1-specific CAR T or MB-104. In May 2019 Mustang expensed a non-refundable milestone payment of $0.2 million upon the first patient dosed in a Phase 1 clinical study of CS1 treating patients with relapsed or treatment-resistant multiple myeloma. For the three and nine months ended September 30, 2019, Mustang recorded nil and $0.2 million in the condensed consolidated statement of operations related to the CS1 milestone payment.

For the three and nine months ended September 30, 2019 and 2018, Mustang recorded the following expenses in research and development for licenses acquired on the condensed consolidated statement of operations:

	For the three months ended September 30,		For the nine months ended September 30,	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
City of Hope				
CD123	$ -	$ -	$ 250	$ -
CSI	-	-	200	-
Manufacturing	-	-	-	75
PSCA	200	-	200	-
Calimmune	200	-	200	-
UCLA	300	-	300	-
St. Jude - X-SCID	-	1,000	-	1,000
Nationwide Children's Hospital - C134	-	-	200	-
Total	$ 700	$ 1,000	$ 1,350	$ 1,075

8. Sponsored Research and Clinical Trial Agreements

Aevitas

Duke SRA

On September 1, 2019, Aevitas entered into a Sponsored Research Arrangement ("SRA") with Duke University School of Medicine ("Duke") for the purpose of conducting a study to identify a dose range for AAV8 vectors in Dry Age-related Macular Degeneration ("Dry AMD"). The cost of the SRA is approximately $0.1 million. The study is expected to be completed in four months. For the three and nine months ended September 30, 2019, Aevitas recorded approximately $17,000 in research and development expense on the condensed consolidated statement of operations. No expense related to this SRA was recorded in 2018.

UMass/UPenn SRA

In 2018, Aevitas entered into a Sponsored Research Agreement ("SRA") with the University of Massachusetts ("UMass SRA") for certain continued research and development activities related to the development of adeno-associated virus ("AAV") gene therapies in complement-mediated diseases and with the Trustees of the University of Pennsylvania ("UPenn SRA") for certain continued research and development activities related to the development of AAV gene therapies in complement-mediated diseases.

For the three and nine months ended September 30, 2019 and 2018, Aevitas recorded the following expense in research and development for sponsored research and clinical trial agreements:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
UMass - AAV	$ –	$ 188	$ –	$ 564
UPenn - AAV	255	250	755	250
Duke - AAV	17	-	17	-
Total	$ 272	$ 438	$ 772	$ 814

Cellvation

For the three and nine months ended September 30, 2019 and 2018, respectively, Cellvation recorded expense of nil million and $0.1 million and $0.1 million and $0.2 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 Condensed Consolidated Statements of Operations.

Mustang

For the three and nine months ended September 30, 2019 and 2018, Mustang recorded the following expense in research and development for sponsored research and clinical trial agreements:

	For the three months ended September 30,		For the nine months ended September 30,	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
City of Hope	$ 500	$ 500	$ 1,500	$ 1,500
City of Hope - CD123	269	123	1,028	387
City of Hope - IL13Rα2	244	346	811	849
City of Hope - Manufacturing	114	114	343	344
Fred Hutch - CD20	49	255	690	938
BIDMC - CRISPR	-	69	69	69
Total	$ 1,176	$ 1,407	$ 4,441	$ 4,087

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 of $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, single digits 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 September 30, 2019, 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 September 30, 2019 and December 31, 2018, respectively:

($ in thousands)	**Estimated Useful Lives (Years)**	**September 30, 2019**	**December 31, 2018**
		(Unaudited)	
Intangible assets – asset purchases	3 to 7	$ 9,934	$ 2,800
Total		9,934	2,800
Accumulated amortization		(2,203)	(1,383)
Net intangible assets		$ 7,731	$ 1,417

The table below provides a summary for the nine months ended September 30, 2019, of JMC 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**
Beginning balance at January 1, 2019	$ 1,417
Additions:	
Purchase of Ximino[(1)]	7,134
Amortization expense	(820)
Ending balance at September 30, 2019	$ 7,731

Note 1: Includes four payments of $7.0 million due in consecutive years commencing on the second anniversary of the execution of the APA. Such payments were discounted by $2.3 million as a result of the long-term nature of such payments.

The future amortization of these intangible assets is as follows:

($ in thousands)	Exelderm®	Ximino®	Total Amortization
For the three-months ending December 31, 2019	$ 100	$ 255	$ 355
Year Ended December 31, 2020	400	1,019	1,419
Year Ended December 31, 2021	267	1,019	1,286
Year Ended December 31, 2022	-	1,019	1,019
Year Ended December 31, 2023	-	1,019	1,019
Thereafter	-	2,633	2,633
Total	$ 767	$ 6,964	$ 7,731

10. Debt and Interest

Debt

Total debt consists of the following as of September 30, 2019 and December 31, 2018:

($ in thousands)	September 30, 2019 (Unaudited)	December 31, 2018	Interest rate	Maturity
IDB Note[4]	$ 14,929	$ 14,929	2.25%	Aug - 2020
2017 Subordinated Note Financing	3,254	3,254	8.00%[3]	March - 2021
2017 Subordinated Note Financing	13,893	13,893	8.00%[3]	May - 2021
2017 Subordinated Note Financing	1,820	1,820	8.00%[3]	June - 2021
2017 Subordinated Note Financing	3,018	3,018	8.00%[3]	August - 2021
2017 Subordinated Note Financing	6,371	6,371	8.00%[3]	September - 2021
2018 Venture Notes	6,517	6,517	8.00%	August - 2021
2018 Venture Notes	15,190	15,190	8.00%	September - 2021
Opus Credit Facility[1]	9,000	9,500	12.00%	September - 2021
Mustang Horizon Notes[2]	15,750	-	9.00%	October - 2022
Caelum Convertible Note, at fair value	-	1,000	8.00%	January - 2019
Caelum Convertible Note, at fair value	-	6,800	8.00%	February - 2019
Caelum Convertible Note, at fair value	-	2,114	8.00%	March - 2019
Total notes payable	89,742	84,406		
Less: Discount on notes payable	5,728	4,903		
Total notes payable	$ 84,014	$ 79,503		

Note 1: Classified as short-term on the Company's Consolidated Balance Sheet as of December 31, 2018.
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, the interest rate of 9% takes effect in year 4 of the note.
Note 4: Classified as short-term on the Company's Consolidated Balance Sheet as of September 30, 2019.

2017 Subordinated Note Financing

On August 6, 2019, the Company provided notice to NAM Biotech Fund II, LLC ("NAMBF") and NAM Special Situations Fund I QP, LLC ("NAMSS") of extension by one year of the maturity dates under the 2017 Subordinated Note Financing totaling $28.4 million, of which $12.3 million in the aggregate pertains to NAMBF and $16.1 million in the aggregate pertains to NAMSS.

On August 6, 2019, the Company provided notice to NSC Biotech Opportunities Fund, LLC ("NSCBOF") and NSC Biotech Opportunities QP Fund, LLC ("NSCBOQPF") of extension by six months of the maturity dates of the 2018 Venture Notes totaling $21.7 million of which $5.1 million in the aggregate pertains to NSCBOF and $16.6 million in the aggregate pertains to NSCBOQPF.

Opus Credit Facility

On July 18, 2019, Fortress issued 396,825 common shares of Fortress at $1.26 per share to Dr. Rosenwald. The shares were issued as a prepayment by Fortress of $500,000 of debt owed to Dr. Rosenwald that was held in the name of Opus Point Healthcare Innovations Fund, LP ("Opus"), an investment fund co-owned by Dr. Rosenwald. The prepayment was made in the form of Fortress common stock, measured at the closing price on July 18, 2019, under that certain Amended & Restated Credit Facility Agreement, dated as of March 12, 2018, by and between Fortress and Opus (the "Opus Credit Agreement").

On August 6, 2019, the Company and Opus executed an amendment to the Opus Credit Agreement, extending the maturity date of amounts owing thereunder by one year.

Mustang Horizon Notes

On March 29, 2019, Mustang entered into a $20.0 million venture debt financing agreement (the "Loan Agreement") with Horizon Technology Finance Corporation ("Horizon"), the proceeds of which will provide Mustang with additional working capital to continue development of its gene and cell therapies. In accordance with the Loan Agreement, $15.0 million of the $20.0 million loan was funded on the Closing Date, with the remaining $5.0 million fundable upon Mustang achieving certain predetermined milestones.

Each advance under the Horizon Loan Agreement will mature 42 months from the first day of the month following the funding of the advance. The first three advances will mature on October 1, 2022 (the "Loan Maturity Date"). Each advance accrues interest at a per annum rate of interest equal to 9.00% plus the amount by which the one-month LIBOR Rate, as reported in the Wall Street Journal, exceeds 2.5%. The Loan Agreement provides for interest-only payments commencing May 1, 2019 through and including October 1, 2020. The interest-only period may be extended to April 1, 2021 if Mustang satisfies the Interest Only Extension Milestone (as defined in the Loan Agreement). Thereafter, commencing May 1, 2021, amortization payments will be payable monthly in eighteen installments of principal and interest. At its option, upon ten business days' prior written notice to Horizon, Mustang may prepay all or any portion greater than or equal to $500,000 of each of the outstanding advances by paying the entire principal balance (or portion thereof) and all accrued and unpaid interest, subject to a prepayment charge of 4.0% of the then outstanding principal balance of each advance if such advance is prepaid on or before the Loan Amortization Date (as defined in the Loan Agreement), 3% if such advance is prepaid after the Loan Amortization Date applicable to such Loan, but on or prior to twelve months following the Loan Amortization Date, and 2% thereafter. In addition, a final payment equal to $0.3 million for each advance (i.e., $0.8 million in aggregate with respect to the initial $15.0 million) is due on the maturity date or other date of payment in full. Amounts outstanding during an event of default shall be payable on demand and shall accrue interest at an additional rate of 5.0% per annum of the past due amount outstanding.

Each advance of the loan is secured by a lien on substantially all of the assets of Mustang, other than Intellectual Property and Excluded Collateral (in each case as defined in the Loan Agreement), and contains customary covenants and representations, including a liquidity covenant, financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries.

The events of default under the Loan Agreement include, among other things, without limitation, and subject to customary grace periods, (1) Mustang's failure to make any payments of principal or interest under the Loan Agreement, promissory notes or other loan documents, (2) Mustang's breach or default in the performance of any covenant under the Loan Agreement, (3) the occurrence of a material adverse change, (4) Mustang making a false or misleading representation or warranty in any material respect, (5) Mustang's insolvency or bankruptcy, (6) certain attachments or judgments on the Mustang's assets, (7) the occurrence of any material default under certain agreements or obligations of Mustang involving indebtedness in excess of $0.3 million or (8) failing to maintain minimum monthly cash balances which range from approximately $8.0 million to $13.0 million over the term of the loan ($9.4 million as of September 30, 2019). If an event of default occurs, Horizon is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

The Loan Agreement also contains warrant coverage of 5% of the total amount of the facility. Four warrants (the "Warrants") were issued by Mustang to Horizon to purchase a combined 288,184 shares of Mustang's common stock with an exercise price of $3.47 and a fair value of $0.9 million. The Warrant is exercisable for ten years from the date of issuance. Horizon may exercise the Warrant either by (a) cash or check or (b) through a net issuance conversion. The shares of Mustang's common stock will, upon request by Horizon, be registered and freely tradeable following a period of six months after issuance.

Mustang paid Horizon an initial commitment fee of $0.2 million and reimbursed Horizon for $30,000 of legal fees in connection with the Loan Agreement. Mustang incurred approximately $1.2 million of legal and other direct costs incurred in connection with the Loan Agreement.

All fees, warrants, and costs paid to Horizon and all direct costs incurred by Mustang are recognized as a debt discount to the funded loans and are amortized to interest expense using the effective interest method over the term of the Loan Agreement.

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 September 30,					
	2019			2018		
($ in thousands)	*Interest*	*Fees [1]*	Total	*Interest*	*Fees [1]*	Total
IDB Note	$ 86	$ -	$ 86	$ 85	$ -	$ 85
2017 Subordinated Note Financing	1,072	326	1,398	1,060	331	1,391
Opus Credit Facility	275	104	379	288	105	393
2018 Venture Notes	438	166	604	438	136	574
LOC Fees	14	-	14	7	-	7
Helocyte Convertible Note	-	-	-	6	-	6
Caelum Convertible Note	-	-	-	198	-	198
Mustang Horizon Notes	345	234	579	-	-	-
Ximino Note	-	108	108	-	-	-
Other	-	-	-	3	-	3
Total Interest Expense and Financing Fee	$ 2,230	$ 938	$ 3,168	$ 2,085	$ 572	$ 2,657

Note 1: Amortization of fees

	Nine Months Ended September 30,					
	2019			2018		
($ in thousands)	*Interest*	*Fees [1]*	Total	*Interest*	*Fees [1]*	Total
IDB Note	$ 254	$ -	$ 254	$ 254	$ -	$ 254
2017 Subordinated Note Financing	3,148	1,081	4,229	3,157	1,013	4,170
Opus Credit Facility	840	336	1,176	853	525	1,378
2018 Venture Notes	1,299	468	1,767	923	281	1,204
LOC Fees	45	-	45	23	-	23
Helocyte Convertible Note	-	-	-	93	-	93
Caelum Convertible Note	-	-	-	589	-	589
Mustang Horizon Notes	698	466	1,164	-	-	-
Ximino Note	-	108	108	-	-	-
Other	-	-	-	(61)	-	(61)
Total Interest Expense and Financing Fee	$ 6,284	$ 2,459	$ 8,743	$ 5,831	$ 1,819	$ 7,650

Note 1: Amortization of fees

11. Leases

On October 3, 2014, the Company entered into a 15-year lease for office space at 2 Gansevoort Street, New York, NY 10014, at an average annual rent of $2.7 million. The Company took possession of this space, which serves as its principal executive offices, in December 2015, and took occupancy in April 2016. Total rent expense, over the full term of the lease for this space will approximate $40.7 million. In conjunction with the lease, the Company entered into Desk Space Agreements with two related parties: OPPM and TGTX, to occupy 10% and 45%, respectively, of the office space that requires them to pay their share of the average annual rent of $0.3 million and $1.1 million, respectively. The total net rent expense will approximate $16.0 million over the lease term. These initial rent allocations will be adjusted periodically for each party based upon actual percentage of the office space occupied. Additionally, the Company has reserved the right to execute desk space agreements with other third parties and those arrangements will also affect the cost of the lease actually borne by us.

In October 2015, the Company entered into a 5-year lease for approximately 6,100 square feet of office space in Waltham, MA at an average annual rent of approximately $0.2 million. The Company took occupancy of this space in January 2016.

Journey

In June 2017, Journey extended its lease for 2,295 square feet of office space in Scottsdale, AZ by one year, at an average annual rent of approximately $55,000. Journey originally took occupancy of this space in November 2014. In August 2018, Journey amended their lease and entered into a new two-year extension for 3,681 square feet of office space in the same location in Scottsdale, AZ at an annual rate of approximately $94,000. The term of this amended lease commenced on December 1, 2018 and will expire on November 30, 2020.

Mustang

On October 27, 2017, Mustang entered into a lease agreement with WCS - 377 Plantation Street, Inc., a Massachusetts nonprofit corporation ("Landlord"). Pursuant to the terms of the lease agreement, Mustang agreed to lease 27,043 square feet from the Landlord, located at 377 Plantation Street in Worcester, MA (the "Facility"), through November 2026, subject to additional extensions at Mustang's option. Base rent, net of abatements of $0.6 million over the lease term, totals approximately $3.6 million, on a triple-net basis.

The terms of the lease also require that Mustang post an initial security deposit of $0.8 million, in the form of $0.5 million letter of credit and $0.3 million in cash, which increased to $1.3 million ($1.0 million letter of credit, $0.3 million in cash) on November 1, 2019. After the fifth lease year, the letter of credit obligation is subject to reduction.

The Facility began operations for the production of personalized CAR T and gene therapies in 2018.

The Company leases copiers under agreements classified as operating leases that expire on various dates through 2021.

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. At September 30, 2019, the Company had operating lease liabilities of $25.9 million and right of use assets of $21.9 million, which were included in the condensed consolidated balance sheet.

During the three and nine months ended September 30, 2019, the Company recorded $0.8 million and $2.4 million, respectively, as lease expense to current period operations.

($ in thousands)	**Three Months Ended September 30, 2019**	**Nine Months Ended September 30, 2019**
Lease cost		
Operating lease cost	$ 798	$ 2,397
Shared lease costs	(479)	(1,408)
Variable lease cost	160	575
Total lease cost	$ 479	$ 1,564

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

($ in thousands)	Nine Months Ended September 30,
Operating cash flows from operating leases	$ (2,185)
Weighted-average remaining lease term – operating leases	6.4
Weighted-average discount rate – operating leases	6.2%

($ in thousands)	Future Lease Liability
Three months ended December 31, 2019	$ 776
Year Ended December 31, 2020	2,966
Year Ended December 31, 2021	3,114
Year Ended December 31, 2022	3,084
Year Ended December 31, 2023	3,137
Other	23,463
Total	36,540
Less: present value discount	(10,631)
Operating lease liabilities	$ 25,909

At December 31, 2018, the total future minimum lease payments under all leases were:

($ in thousands)	
2019	$ 3,070
2020	3,289
2021	3,084
2022	3,084
2023	3,137
Beyond	23,466
Total minimum lease payments	$ 39,130

12. Accrued Liabilities and other Long-Term Liabilities

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

($ in thousands)	September 30, 2019 (Unaudited)	December 31, 2018
Accrued expenses:		
Professional fees	$ 1,577	$ 1,434
Salaries, bonuses and related benefits	5,863	5,843
Research and development	3,285	3,805
Research and development - manufacturing	919	826
Research and development - clinical supplies	159	160
Research and development - license maintenance fees	689	519
Research and development - milestones	500	200
Dr. Falk Pharma milestone	-	300
Accrued royalties payable	1,833	1,108
Accrued coupon expense	1,994	838
Other	2,586	1,327
Total accrued expenses	$ 19,405	$ 16,360
Other long-term liabilities:		
Deferred rent and long-term lease abandonment charge[(1)]	$ 2,183	$ 5,211
Long-term note payable [(2)]	4,842	-
Total other long-term liabilities	$ 7,025	$ 5,211

Note 1: As of September 30, 2019, balance consists of deferred charges related to build-out of the New York facility, and as of December 31, 2018, balance consists of deferred rent and deferred build out charges.

Note 2: As of September 30, 2019, Journey recorded a note payable, net of an imputed interest discount of $2.3 million, of $4.7 million in connection with its acquisition of Ximino, see Note 9. The imputed interest discount was calculating 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 nine months ended September 30, 2019.

13. Non-Controlling Interests

Non-controlling interests in consolidated entities are as follows:

	As of September 30, 2019			
($ in thousands)	NCI equity share	Net loss attributable to non-controlling interests	Non-controlling interests in consolidated entities	Non-controlling ownership
Aevitas	$ (1,160)	$ (491)	$ (1,651)	35.8%
Avenue [2]	24,114	(14,869)	9,245	77.3%
Cellvation	(726)	(129)	(855)	21.1%
Checkpoint [1]	14,907	(10,525)	4,382	69.9%
Coronado SO	(290)	-	(290)	13.0%
Cyprium	(306)	(106)	(412)	10.6%
Helocyte	(4,229)	(181)	(4,410)	19.3%
JMC	(216)	197	(19)	6.9%
Mustang [2]	61,899	(18,053)	43,846	70.2%
Tamid	(551)	(80)	(631)	23.4%
Total	$ 93,442	$ (44,237)	$ 49,205	

	As of December 31, 2018			
($ in thousands)	NCI equity share	Net loss attributable to non-controlling interests	Non-controlling interests in consolidated entities	Non-controlling ownership
Aevitas	$ (474)	$ (606)	$ (1,080)	36.1%
Avenue [2]	13,326	(13,735)	(409)	64.8%
Caelum [3]	(2,436)	(2,413)	(4,849)	36.8%
Cellvation	(457)	(185)	(642)	21.1%
Checkpoint [1]	31,648	(23,470)	8,178	69.3%
Coronado SO	(290)	-	(290)	13.0%
Cyprium	(210)	(62)	(272)	10.8%
Helocyte	(3,372)	(684)	(4,056)	19.8%
JMC	(475)	245	(230)	6.9%
Mustang [2]	38,631	(16,628)	22,003	60.5%
Tamid	(211)	(251)	(462)	23.4%
Total	$ 75,680	$ (57,789)	$ 17,891	

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.

Note 3: Effective January 30, 2019, Caelum ceased to be a controlled Fortress entity and as such is no longer consolidated.

14. Net Loss per Common Share

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

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

The following shares of potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding, as the effect of including such securities would be anti-dilutive at the end of the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	**2018**
Warrants to purchase Common Stock	865,364	890,892
Opus warrants to purchase Common Stock	1,880,000	1,880,000
Options to purchase Common Stock	1,169,293	1,085,502
Convertible preferred stock	1,002,087	1,000,000
Unvested Restricted Stock	12,622,881	11,014,596
Unvested Restricted Stock Units	791,610	1,796,134
Total	18,331,235	17,667,124

15. 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 and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
Employee awards	$ 936	$ 1,012	$ 2,791	$ 3,075
Executive awards of Fortress Companies' stock	358	446	1,065	1,408
Non-employee awards	15	24	84	70
Warrants	97	-	97	-
Fortress Companies:				
Avenue	298	371	1,585	1,043
Checkpoint	833	1,128	2,444	2,336
Mustang	1,120	903	2,174	3,869
Other	84	222	183	252
Total stock-based compensation expense	$ 3,741	$ 4,106	$ 10,423	$ 12,053

For the three months ended September 30, 2019 and 2018, approximately $1.2 million and $1.8 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 $2.3 million, respectively, was included in general and administrative expenses in connection with grants made to employees, members of the board of directors and consultants.

For the nine months ended September 30, 2019 and 2018, approximately $2.6 million and $4.9 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 $7.8 million and $7.1 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, 2018	1,285,501	$ 3.75	$ -	2.93
Granted	125,000	1.18	28,750	
Options vested and expected to vest at September 30, 2019	1,410,501	$ 4.30	$ 43,903	2.58
Options vested and exercisable	1,285,501	$ 4.60	$ 15,153	2.41

As of September 30, 2019, 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, 2018	12,645,982	$ 2.72
Restricted stock granted	1,516,408	0.86
Restricted stock vested	(220,000)	3.16
Restricted stock units granted	40,000	1.63
Restricted stock units forfeited	(244,272)	4.45
Restricted stock units vested	(250,209)	3.59
Unvested balance at September 30, 2019	13,487,909	$ 2.46

As of September 30, 2019, the Company had unrecognized stock-based compensation expense related to restricted stock and restricted stock unit awards of approximately $12.7 million and $1.8 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 5.0 years and 2.0 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, 2018	2,754,189	$ 3.28	$ 7,800	3.49
Granted	60,000	1.92	-	
Forfeited	(73,009)	5.65	-	
Outstanding as of September 30, 2019	2,741,180	$ 3.19	$ 2,400	2.98
Exercisable as of September 30, 2019	776,180	$ 3.76	$ 2,400	2.62

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 September 30, 2019, 410,728 shares have been purchased and 589,272 shares are available for future sale under the Company's ESPP. Share-based compensation expense recorded was approximately $18,000 and $52,000, respectively for the three months ended September 30, 2019 and 2018, and was approximately $0.1 million and $0.1 million, respectively, for the nine months ended September 30, 2019 and 2018.

Capital Raises

2016 Common Stock At-the-Market Offering

On August 17, 2016, the Company entered into an Amended and Restated At Market Issuance Sales Agreement (the "2016 Common ATM"), with B. Riley FBR, Inc. ("B. Riley," f/k/a MLV & Co. LLC and FBR Capital Markets & Co.) as selling agents, governing potential sales of the Company's common stock. For the three and nine months ended September 30, 2019, the Company issued approximately 0.6 million and 8.0 million shares of common stock at an average price of $1.48 and $1.88 per share for gross proceeds of $0.9 million and $15.1 million, respectively. Under the 2016 Common ATM, the Company pays the agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock, and in connection with these sales, with respect to the nine months ended September 30, 2019, the Company paid aggregate fees of approximately $0.3 million. The 2016 Common ATM expired on August 17, 2019.

The above-mentioned shares of common stock were sold under the Company's shelf registration statement on Form S-3 originally filed on August 8, 2016 and declared effective December 1, 2016 (the "2016 Shelf"). The 2016 Shelf expires on December 1, 2019, and approximately $5.1 million of securities remain available for sale under the 2016 Shelf at September 30, 2019.

2018 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock At Market Offering

On April 5, 2018, the Company entered into an At Market Sales Agreement (the "2018 Preferred ATM"), with B. Riley, National Securities Corporation, LifeSci Capital LLC, Maxim Group LLC and Noble Capital Markets, Inc. as selling agents, governing the issuance of the Company's 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock ("Perpetual Preferred Stock"). For the three and nine months ended September 30, 2019, the Company issued approximately 26,000 shares of Perpetual Preferred Stock for gross proceeds $0.5 million at an average selling price of $20.66. No shares of Perpetual Preferred Stock were issued in 2018. Under the 2018 Preferred ATM, the Company pays the agents a commission rate of up to 7.0% of the gross proceeds from the sale of any shares of Perpetual Preferred Stock, and in connection with these sales, with respect to the nine months ended September 30, 2019, the Company paid aggregate fees of approximately $16,000.

The above-mentioned shares of Perpetual Preferred Stock were sold under the 2016 Shelf. The 2016 Shelf expires on December 1, 2019, and approximately $5.1 million of securities remain available for sale under the 2016 Shelf at September 30, 2019.

2019 Common Stock At-the-Market Offering

On June 28, 2019, the Company entered into an At Market Issuance Sales Agreement ("2019 Common ATM"), with Cantor Fitzgerald & Co., Oppenheimer & Co., Inc., H.C. Wainwright & Co. Inc., Jones Trading Institutional Services LLC and B. Riley, as selling agents, governing potential sales of the Company's common stock. For the three and nine months ended September 30, 2019, the Company issued approximately 0.6 million shares of common stock for gross proceeds of $1.0 million at an average selling price of $1.79. Under the 2019 Common ATM, the Company pays the agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock, and in connection with these sales, with respect to the nine months ended September 30, 2019, the Company paid aggregate fees of approximately $32,000.

The above-mentioned shares of common 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 $48.9 million of securities remain available for sale under the 2019 Shelf at September 30, 2019.

Checkpoint Therapeutics, Inc.

Checkpoint At-the-Market Offering

In November 2017, Checkpoint filed a shelf registration statement on Form S-3 (the "Checkpoint S-3"), which was declared effective in December 2017. Under the Checkpoint S-3, Checkpoint may sell up to a total of $100 million of its securities. In connection with the Checkpoint S-3, Checkpoint entered into an At-the-Market Issuance Sales Agreement (the "Checkpoint ATM") with Cantor Fitzgerald & Co., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock. Under the Checkpoint ATM, Checkpoint 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 and nine months ended September 30, 2019, Checkpoint sold a total of 1.1 million and 2.2 million of its common stock, respectively, under the Checkpoint ATM for aggregate total gross proceeds of approximately $3.4 million and $7.9 million at an average selling price of $3.00 and $3.54 per share, respectively. Pursuant to the Founders Agreement, Checkpoint issued 28,555 and 55,750 shares of common stock to Fortress during the three and nine months ended September 30, 2019, respectively, for the ATM offering noted above. During the three and nine months ended September 30, 2018, Checkpoint sold a total of 1,841,774 shares of its common stock under the Checkpoint ATM for aggregate total gross proceeds of approximately $8.0 million at an average selling price of $4.33 per share, resulting in net proceeds of approximately $7.7 million after deducting commissions and other transactions costs. Pursuant to the Founders Agreement, Checkpoint issued 178,292 shares of common stock to Fortress during the three and nine months ended September 30, 2018, respectively.

Approximately $ 61.1 million of the shelf remains available for sale under the Checkpoint S-3, following the offerings noted above. Checkpoint may offer the securities under the Checkpoint 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.

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 and nine months ended September 30, 2019, Mustang issued approximately 3.5 million shares of common stock at an average price of $6.42 per share for gross proceeds of $22.5 million. In connection with these sales, Mustang paid aggregate fees of approximately $0.5 million, for net proceeds of approximately $22.0 million. No sales were made under the Mustang ATM in 2018.

Mustang Public Offering of Common Stock

On April 30, 2019, Mustang announced the pricing of an underwritten public offering, whereby it sold 6,875,000 shares of its common stock, (plus a 30-day option to purchase up to an additional 1,031,250 shares of common stock, which was exercised in May 2019) at a price of $4.00 per share for gross proceeds of approximately $31.6 million, before deducting underwriting discounts and commissions and offering expenses. The shares were sold under the 2018 Mustang S-3. Mustang paid aggregate fees of approximately $2.1 million and received approximately $29.5 million of net proceeds.

On August 16, 2019, Mustang filed a shelf registration statement No. 333-233350 on Form S-3 (the “2019 Mustang S-3”), which was declared effective on September 30, 2019. Under the 2019 Mustang S-3, Mustang may sell up to a total of $75.0 million of its securities. As of September 30, 2019, no sales were made under Mustang’s 2019 S-3 and approximately $20.9 million of the 2018 Mustang S-3 remains available for sale.

16. Commitments and Contingencies

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

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.

17. 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 11.7% of the Company's issued and outstanding Common Stock as of September 30, 2019. The Company's Executive Vice Chairman, Strategic Development owns approximately 13.4% of the Company's issued and outstanding Common Stock at September 30, 2019.

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 September 30, 2019 and 2018, the Company invoiced TGTX $0.1 million and $0.2 million, respectively. For the nine months ended September 30, 2019 and 2018, the Company invoiced TGTX $0.3 million and $1.2 million, respectively. At September 30, 2019, the amount receivable from TGTX related to this arrangement approximated $0.1 million.

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"), for the three months ended September 30, 2019, the Company had paid $0.7 million in rent under the Desk Space Agreements, and invoiced TGTX and OPPM approximately $0.4 million and $24,000, respectively, for their prorated share of the rent base. At September 30, 2019, the amount due related to this arrangement from TGTX approximated $0.2 million and the amount due from OPPM approximated $0.4 million.

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 extends the maturity date of the notes issued under the Opus Credit Facility from September 14, 2018 by one year to September 14, 2019. On August 6, 2019, the Company and Opus executed a second amendment to the Opus Credit Agreement, extending the maturity date of amounts owing thereunder by one year, to September 12, 2020.

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. Fortress retains the ability to prepay the Notes at any time without penalty.

On July 18, 2019, the Company prepaid $500,000 of debt owed under the A&R Opus Credit Facility by issuing 396,825 shares of Fortress common stock at $1.26 per share (the closing price on July 18, 2019) to Dr. Rosenwald.

The notes payable under the A&R Opus Credit Facility continue to bear interest at 12% per annum. For the nine months ended September 30, 2019 and 2018, the Company paid $0.3 million and $0.3 million, respectively.

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 18, 2019. 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

Fortress Partner Company	Effective Date [1]	PIK Dividend as a % of fully diluted outstanding capitalization	Class of Stock Issued
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
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, 2018, filed with the SEC on March 18, 2019. 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
Caelum[2]	January 1, 2017	-
Cyprium	March 13, 2017	500
Aevitas	July 28, 2017	500
Tamid	November 30, 2017	500
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: Effective January 31, 2019 the Caelum Founders Agreement and MSA with Fortress were terminated in conjunction with the execution of a DOSPA between Caelum and Alexion Therapeutics, Inc. and $1.0 million of fees accrued under the MSA were written off (See Note 4).

18. 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. Prior to the sale of National the Company operated in three segments, one of which included National, see Note 3. The following tables summarize, for the periods indicated, operating results, from continuing operations by reportable segment:

Three Months Ended September 30, 2019	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net Revenue	$ 9,492	$ 280	$ 9,772
Direct cost of goods	(2,702)	-	(2,702)
Sales and marketing costs	(4,370)	-	(4,370)
Research and development[1]	-	(15,271)	(15,271)
General and administrative	(669)	(9,300)	(9,969)
Segment income (loss) from operations	$ 1,751	$ (24,291)	$ (22,540)
Segment assets	$ 18,697	$ 202,891	$ 221,588

Three Months Ended September 30, 2018	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net Revenue	$ 5,168	$ 5	$ 5,173
Direct cost of goods	(1,406)	-	$ (1,406)
Sales and marketing costs	(2,754)	-	$ (2,754)
Research and development[(1)]	-	(19,788)	$ (19,788)
General and administrative	(505)	(8,925)	$ (9,430)
Segment income (loss) from operations	$ 503	$ (28,708)	$ (28,205)
Segment assets	$ 10,765	$ 157,781	$ 168,546
Assets held for sale			56,373
Total consolidated			$ 224,919

Nine Months Ended September 30, 2019	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net Revenue	$ 23,816	$ 1,683	$ 25,499
Direct cost of goods	(6,972)	-	(6,972)
Sales and marketing costs	(12,064)	-	(12,064)
Research and development[(1)]	-	(57,705)	(57,705)
General and administrative	(1,808)	(27,388)	(29,196)
Segment income (loss) from operations	$ 2,972	$ (83,410)	$ (80,438)
Segment assets	$ 18,697	$ 202,891	$ 221,588

Nine Months Ended September 30, 2018	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net Revenue	$ 17,366	$ 525	$ 17,891
Direct cost of goods	(4,546)	-	$ (4,546)
Sales and marketing costs	(8,443)	-	$ (8,443)
Research and development[(1)]	-	(62,332)	$ (62,332)
General and administrative	(1,270)	(29,075)	$ (30,345)
Segment income (loss) from operations	$ 3,107	$ (90,882)	$ (87,775)
Segment assets	$ 10,765	$ 157,781	$ 168,546
Assets held for sale			56,373
Total consolidated			$ 224,919

Note 1: Research and development includes the cost of licenses acquired.

19. Revenues from Contracts and Significant Customers

Disaggregation of Total Revenues

The Company's portfolio of marketed products, with the majority of sales from Targadox®, Ximino® and Exelderm®. Substantially all of the Company's product revenues are recorded in the U.S. Substantially all of the Company's collaboration revenues are from its collaboration with TGTX. Revenues by product and collaborator are summarized as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2019	2018	2019	2018
Targadox®	$ 6,608	$ 4,322	$ 19,538	$ 16,183
Ximino®	2,194	-	2,194	-
Exelderm®	668	625	1,712	626
Other branded revenue	22	221	372	557
Total product revenues	9,492	5,168	23,816	17,366
TGTX	280	5	1,683	525
Total Revenue	$ 9,772	$ 5,173	$ 25,499	$ 17,891

Significant Customers

Commencing in the second quarter of 2018, the majority of our dermatology products are sold under a third-party logistics ("3PL") Title Model, and as such, one customer consistently accounts for a significant portion of gross product revenue and AR. Under a 3PL Title Model, the company sells product to a 3PL, who in turn, manages distribution and collections.

For the three and nine months ended September 30, 2019, gross product revenue under the 3PL Title Model accounted for approximately 60.0% and 76.0%, respectively.

For the three months ended September 30, 2018, one of the Company's Dermatology Products customers each accounted for more than 10.0% of its total gross product revenue in the amount of $10.9 million.

For the nine months ended September 30, 2018, two of the Company's Dermatology Products customers each accounted for more than 10.0% of its total gross product revenue in the amount of $22.5 million and $7.3 million, respectively.

At September 30, 2019, two of the Company's Dermatology Products customers accounted for more than 10.0% of its total accounts receivable balance in the amounts of $3.5 million and $2.8 million.

At September 30, 2018, two of the Company's Dermatology Products customers each accounted for more than 10.0% of its total accounts receivable balance in the amount of $9.0 million and $1.4 million, respectively.

20. Incomes taxes

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 nine months ended September 30, 2019 and 2018 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, 2018.

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. We have 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. We have executed such arrangements in collaboration 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, and the University of Pennsylvania.

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).

Recent Events

Marketed Dermatology Products

During the three and nine months ended September 30, 2019, through our partner company Journey Medical Corporation ("Journey" or "JMC"), our marketed products generated net revenue of $9.5 million and $23.8 million, respectively.

IV Tramadol

IV Tramadol is currently in development with our partner company, Avenue Therapeutics, Inc. ("Avenue"). Avenue plans to submit a new drug application, or an 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) by the end of 2019.

MB-101 (IL13Rα2 CAR T)

In October 2019, our partner company Mustang Bio, Inc. ("Mustang") announced that City of Hope ("COH") had received grant awards totaling $4.1 million for a clinical trial of MB-101 in combination with nivolumab (commercial name: Opdivo®) and ipilimumab (commercial name: Yervoy®) in patients with recurrent malignant glioma. Additional information on the trial can be found on www.CinicalTrials.gov using identifier NCT04003649.

MB-105 (PSCA CAR T)

In September 2019, Mustang announced that COH opened and has initiated patient treatments in a Phase 1 clinical trial of MB-105, a prostate stem cell antigen ("PSCA") chimeric antigen receptor ("CAR") engineered T cell ("CAR T") technology for the treatment of prostate cancer. Additional information on the Phase 1 trial can be found on www.CinicalTrials.gov using identifier NCT03873805.

MB-103 (HER2 CAR T)

In August 2019, Mustang announced that COH had received a $9.3 million grant from the California Institute for Regenerative Medicine ("CIRM") to fund an ongoing Phase 1 trial of MB-103 for the treatment of HER2-positive breast cancer with brain metastases. COH patents covering the HER2 CAR were licensed to Mustang in 2017. Additional information on the Phase 1 trial can be found on www.CinicalTrials.gov using identifier NCT03696030.

MB-107 (XSCID gene therapy)

In August 2019, Mustang, together with St. Jude, announced that MB-107 was granted Regenerative Medicine Advanced Therapy ("RMAT") designation by the U.S. Food and Drug Administration ("FDA"). Under the RMAT designation, the FDA will help facilitate the program's expedited development and review and provide guidance on generating the evidence needed to support the approval of MB-107 for XSCID.

Also announced in August 2019 was the license agreement with Calimmune, Inc. ("Calimmune License") for the Cytegrity™ stable producer cell line developed and used by St. Jude Cytegrity™ cell line will be used to produce the viral vector for MB-107.

MB-108 (Oncolytic Virus C134)

In October 2019, Mustang announced that the first participant was dosed in a Phase 1 clinical trial to determine the safety and efficacy of MB-108, an attenuated herpes simplex virus type 1, in recurrent glioblastoma multiforme. Additional information on the Phase 1 trial can be found on www.CinicalTrials.gov using identifier NCT03657576.

MB-102 (CD123 CAR T)

In July 2019, Mustang announced that the FDA had granted Orphan Drug Designation to MB-102 for the treatment of acute myeloid leukemia.

In August 2019, Mustang announced that the FDA had approved its Investigational New Drug ("IND") application to initiate a multi-center Phase 1/2 clinical trial of MB-102 in acute myeloid leukemia ("AML"), blastic plasmacytoid dendritic cell neoplasm ("BPDCN") and high-risk myelodysplastic syndrome ("MDS").

Cosibelimab (formerly CK-301, an anti-PD-L1 antibody)

In September 2019, our partner company, Checkpoint Therapeutics, Inc. ("Checkpoint"), announced updated interim results from its ongoing multicenter Phase 1 clinical trial of Cosibelimab. The data were presented in a poster presentation at the European Society for Medical Oncology (ESMO) Congress 2019 in Barcelona, Spain. Checkpoint continues to enroll cutaneous squamous cell carcinoma ("CSCC") patients to support an initial BLA submission for Cosibelimab based on this ongoing clinical trial. Additional information on the Phase 1 trial can be found on www.CinicalTrials.gov using identifier NCT03212404.

In July 2019, Checkpoint was added to the Russell 2000® Index.

Reportable Business Segments

For presentation purposes, Results of Operations is presented on a detailed revenue and expense basis rather than on a reportable business segment basis. Our operations are subject to wide fluctuations due to our early stage of development. The following provides a summary of revenues and expenses for the periods presented.

Results of Operations

General

For the three and nine months ended September 30, 2019, we generated $9.8 million and $25.5 million, respectively, of net revenue, of which $0.3 million and $1.7 million, respectively, of revenue relates to Checkpoint's collaborative agreements with TG Therapeutics Inc. ("TGTX") and $9.5 million and $23.8 million, respectively, of revenue relates primarily to the sale of Journey branded products. At September 30, 2019, we had an accumulated deficit of $420.7 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 and nine months ended September 30, 2019, we had $2.7 million and $7.0 million, respectively, of costs of goods sold in connection with the sale of Journey's marketed products, compared to $1.4 million and $4.5 million, respectively, for the three and nine months ended September 30, 2018. The increase can be attributed to the increase in sales as well as the expansion of the branded product portfolio.

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 September 30, 2019 and 2018, research and development expenses were approximately $14.6 million and $16.1 million, respectively. Additionally, during the three months ended September 30, 2019 and 2018, we expensed approximately $0.7 million and $3.7 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 September 30, 2019 and 2018, was $1.2 million and $1.8 million, respectively.

Research and development costs associated with the development of our licenses, exclusive of noncash stock-based compensation expenses ("SBC"), for the three months ended September 30, 2019 and 2018, by entity, are as follows:

	Three Months Ended September 30,		% of total	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
Research & Development				
Fortress	$ 549	$ 771	4%	5%
Partner Companies:				
Avenue	1,566	1,547	12%	11%
Checkpoint	3,715	6,143	28%	43%
Mustang	6,516	4,532	49%	32%
Other[(1)]	1,014	1,267	7%	9%
Research & Development exclusive of SBC	**$ 13,360**	**$ 14,260**	**100%**	**100%**

Note 1: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Helocyte and Tamid

Noncash stock-based compensation expense recorded in research and development for the three months ended September 30, 2019 and 2018, by entity is as follows:

	Three Months Ended September 30,		% of total	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
Research & Development				
Noncash stock-based compensation				
Fortress	$ 158	$ 235	13%	13%
Partner Companies:				
Avenue	140	127	12%	7%
Checkpoint	179	642	15%	35%
Mustang	731	702	60%	39%
Other[(1)]	3	116	-	6%
Total stock-based compensation in Research & Development	**$ 1,211**	**$ 1,822**	**100%**	**100%**

Note 1: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Helocyte and Tamid

Research and development costs associated with the development of our licenses, exclusive of noncash stock-based compensation expenses, for the nine months ended September 30, 2019 and 2018, by entity, are as follows:

	Nine Months Ended September 30,		% of total	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
Research & Development				
Fortress	$ 1,454	$ 4,702	3%	9%
Partner Companies:				
Avenue	17,834	14,280	33%	27%
Checkpoint	12,036	18,115	22%	34%
Mustang	19,789	10,226	37%	19%
Other[(1)]	2,607	6,265	5%	11%
Research & Development exclusive of SBC	**$ 53,720**	**$ 53,588**	**100%**	**100%**

Note 1: Includes the following subsidiaries: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Helocyte and Tamid

Noncash stock-based compensation expense for the nine months ended September 30, 2019 and 2018, by entity is as follows:

	Nine Months Ended September 30,		% of total	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
Research & Development				
Noncash stock-based compensation				
Fortress	$ 447	$ 878	18%	18%
Partner Companies:				
Avenue	505	363	19%	7%
Checkpoint	559	930	21%	19%
Mustang	1,116	2,732	42%	55%
Other[(1)]	8	37	-	1%
Total stock-based compensation in Research & Development	**$ 2,635**	**$ 4,940**	**100%**	**100%**

Note 1: Includes the following subsidiaries: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Helocyte and Tamid

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 September 30, 2019 and 2018, general and administrative expenses were approximately $14.3 million and $12.2 million, respectively. Noncash, stock-based compensation expense included in general and administrative expenses for the three months September 30, 2019 and 2018, was $2.5 million and $2.3 million, respectively.

Included in the remaining $11.8 million and $9.9 million figures for the three months ended September 30, 2019 and 2018, respectively are the following partner company expenses:

	Three Months Ended September 30,		% of Total	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
General & Administrative				
Fortress	$ 3,746	$ 3,530	32%	36%
Partner Companies:				
Avenue	459	564	4%	6%
Checkpoint	749	823	6%	8%
JMC[1]	5,038	3,211	43%	32%
Mustang	1,535	1,078	13%	11%
Other[2]	282	694	2%	7%
General & Administrative exclusive of SBC	**$ 11,809**	**$ 9,900**	**100%**	**100%**

Note 1: Includes cost of outsourced sales force

Note 2: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

Noncash stock-based compensation expense included in general and administrative expense for the three months ended September 30, 2019 and 2018, by entity is as follows:

	Three Months Ended September 30,		% of Total	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
General & Administrative				
Non cash stock-based compensation				
Fortress	$ 1,248	$ 1,246	50%	55%
Partner Companies:				
Avenue	158	244	6%	11%
Checkpoint	654	486	26%	21%
Mustang	389	201	15%	9%
Other[1]	81	107	3%	4%
Total stock-based compensation in General & Administrative	**$ 2,530**	**$ 2,284**	**100%**	**100%**

Note 1: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

For the nine months ended September 30, 2019 and 2018, general and administrative expenses were approximately $41.3 million and $38.8 million, respectively. Noncash stock-based compensation expense included in general and administrative expenses for the nine months ended September 30, 2019 and 2018, was $7.8 million and $7.1 million, respectively.

Included in the remaining $33.5 million and $31.7 million figures for the nine months ended September 30, 2019 and 2018, respectively are the following subsidiary level expenses:

	Nine Months Ended September 30,		% of Total	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
General & Administrative				
Fortress	$ 10,165	$ 11,599	30%	37%
Partner Companies:				
Avenue	1,373	2,016	4%	6%
Checkpoint	2,623	2,682	8%	8%
JMC[1]	13,872	9,613	41%	30%
Mustang	4,613	3,809	14%	12%
Other[2]	826	1,955	3%	7%
General & Administrative exclusive of SBC	**$ 33,472**	**$ 31,674**	**100%**	**100%**

Note 1: Includes cost of outsourced sales force

Note 2: Includes the following subsidiaries: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

Noncash stock-based compensation expense included in general and administrative expense for the nine months ended September 30, 2019 and 2018, by entity is as follows:

	Nine Months Ended September 30,		% of Total	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
General & Administrative				
Non cash stock-based compensation				
Fortress	$ 3,590	$ 3,674	46%	52%
Partner Companies:				
Avenue	1,079	679	14%	10%
Checkpoint	1,885	1,406	24%	20%
Mustang	1,058	1,137	14%	16%
Other[1]	176	218	2%	2%
Total stock-based compensation in General & Administrative	**$ 7,788**	**$ 7,114**	**100%**	**100%**

Note 1: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

Comparison of three months ended September 30, 2019 and 2018

	Three Months Ended September 30,		Change	
($ in thousands)	**2019**	**2018**	$	%
Revenue				
Product revenue, net	$ 9,492	$ 5,168	$ 4,324	84%
Revenue – from a related party	280	5	275	5500%
Net revenue	9,772	5,173	4,599	89%
Operating expenses				
Cost of goods sold – product revenue	2,702	1,406	1,296	92%
Research and development	14,571	16,082	(1,511)	-9%
Research and development – licenses acquired	700	3,706	(3,006)	-81%
General and administrative	14,339	12,184	2,155	18%
Total operating expenses	32,312	33,378	(1,066)	-3%
Loss from operations	(22,540)	(28,205)	5,665	-20%
Other expense				
Interest income	738	269	469	174%
Interest expense and financing fee	(3,168)	(2,657)	(511)	19%
Change in fair value of derivative liabilities	-	12	(12)	-100%
Change in fair value of subsidiary convertible note	-	(84)	84	-100%
Change in fair value of investments	-	(565)	565	-100%
Total other expense	(2,430)	(3,025)	595	20%
Loss from continuing operations	(24,970)	(31,230)	6,260	20%
Discontinued operations:				
Income from discontinued operations, net of tax	-	2,643	(2,643)	-100%
Total income from discontinued operations	-	2,643	(2,643)	-100%
Net loss	**(24,970)**	**(28,587)**	**3,617**	**-13%**
Less: net loss attributable to non-controlling interest	12,208	11,949	259	2%
Net loss attributable to common stockholders	**$ (12,762)**	**$ (16,638)**	**$ 3,876**	**-23%**

Net revenues increased $4.6 million or 89% from the three months ended September 30, 2018 to the three months ended September 30, 2019. The increase in net revenue is related to an increase in product revenue of $4.3 million associated with Journey's marketed products driven by the expansion of its product lines during the quarter, and an increase of $0.3 million in collaboration revenue between Checkpoint and TGTX.

Cost of goods sold increased by $1.3 million or 92% from the three months ended September 30, 2018 to the three months ended September 30, 2019 due to the increase in Journey marketed products revenue in the 2019 period as compared to the 2018 period.

Research and development expenses decreased $1.5 million or 9% from the three months ended September 30, 2018 to the three months ended September 30, 2019. The following table shows the change in research and development spending by Fortress and its partner companies:

	Three Months Ended September 30,		Change	
($ in thousands)	**2019**	**2018**	$	%
Research & Development				
Stock-based compensation				
Fortress	$ 158	$ 235	$ (77)	-33%
Partner Companies:				
Avenue	140	127	13	10%
Checkpoint	179	642	(463)	-72%
Mustang	731	702	29	4%
Other[(1)]	3	116	(113)	-97%
Sub-total stock-based compensation	1,211	1,822	(611)	-34%
Other Research & Development				
Fortress	549	771	(222)	-29%
Partner Companies:				
Avenue	1,566	1,547	19	1%
Checkpoint	3,715	6,143	(2,428)	-40%
Mustang	6,516	4,532	1,984	44%
Other[(1)]	1,014	1,267	(253)	-20%
Total Research & Development	**$ 14,571**	**$ 16,082**	**$ (1,511)**	**-9%**

Note 1: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

The decrease in stock-based compensation is due to the adoption of ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting,* of which no longer requires marking to market grants held by non-employees. For the quarter ended September 30, 2018, stock value increase led to Checkpoint's increased stock compensation expense due to marking to market grants held by non-employees.

The decrease in Fortress research and development spending is due to the lower research and development headcount subsequent to the transfer of Fortress research and development employees to TGTX, a related party, in the quarter ended September 30, 2018. Checkpoint's decrease in research and development spending is attributable to the manufacturing costs related to the PD-L1 or Cosibelimab GMP batch incurred in the three months ended September 30, 2018 and not replicated in the current quarter. Mustang's increase in research and development spending is attributable to increased headcount, and the purchase of lab supplies and computer equipment and software. The decrease in "Other" is attributable to Caelum's deconsolidation in 2019.

The decrease in research and development – licenses acquired of $3.0M or 81% from the three months ended September 30, 2019 as compared to the three months ended September 30, 2018 is due to the expense recorded in the third quarter of 2018 for milestones achieved by Helocyte ($1.5 million) and Checkpoint ($1.0 million), Mustang's acquisition of the X-SCID license from St. Jude ($1.0 million upfront payment), and Caelum's recognition of expense associated with anti-dilution shares issued to Columbia University ($0.2 million). This was offset by $0.7M of expense associated with Mustang's new Calimmune license and several milestones associated with Mustang's PSCA licenses totaling $0.5 million that were recognized in the third quarter of 2019.

General and administrative expenses increased $2.2 million, or 18%, from the three months ended September 30, 2018 to the three months ended September 30, 2019. The following table shows the change in general and administrative spending by Fortress and its partner companies:

($ in thousands)	Three Months Ended September 30, 2019	2018	Change $	Change %
General & Administrative				
Stock-based compensation				
Fortress	$ 1,248	$ 1,246	$ 2	-%
Partner Companies:				
Avenue	158	244	(86)	-35%
Checkpoint	654	486	168	35%
Mustang	389	201	188	-94%
Other[2]	81	107	(26)	-24%
Sub-total stock-based comp.	2,530	2,284	246	11%
Other General & Administrative				
Fortress	3,746	3,530	216	6%
Partner Companies:				
Avenue	459	564	(105)	-19%
Checkpoint	749	823	(74)	-9%
JMC[1]	5,038	3,211	1,827	57%
Mustang	1,535	1,078	457	42%
Other[2]	282	694	(412)	-59%
Total General & Administrative	**$ 14,339**	**$ 12,184**	**2,155**	**18%**

Note 1: Includes cost of outsourced sales force

Note 2: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

For the quarter ended September 30, 2019, the increase in general and administrative expenses of $2.2 million or 18% is primarily attributable to Journey's sales and marketing cost increases due to increased product portfolio as well as sales force headcount increase, and Mustang's increase due to increased headcount as well as increased professional fees.

Total other expense decreased $0.6 million, or 20%, from a loss of $3.0 million for the three months ended September 30, 2018 to $2.4 million for the three months ended September 30, 2019, primarily due to the increase in interest income and the positive change in fair value of investments, offset by the increase in interest expense and financing fees due to Mustang's new debt financing with Horizon.

Net loss attributable to common stockholders decreased $3.9 million, or 23%, from the three months ended September 30, 2018 to the three months ended September 30, 2019. This decrease is primarily due to the loss from discontinued operations, net of tax, of $2.6 million from the three months ended September 30, 2018 related to the sale of National.

Comparison of nine months ended September 30, 2019 and 2018

($ in thousands)	Nine Months Ended September 30, 2019	2018	Change $	Change %
Revenue				
Product revenue, net	$ 23,816	$ 17,366	$ 6,450	37%
Revenue – from a related party	1,683	525	1,158	221%
Net revenue	25,499	17,891	7,608	43%
Operating expenses				
Cost of goods sold – product revenue	6,972	4,546	2,426	53%
Research and development	56,355	58,528	(2,173)	-4%
Research and development – licenses acquired	1,350	3,804	(2,454)	-65%
General and administrative	41,260	38,788	2,472	6%
Total operating expenses	105,937	105,666	271	0%
Loss from operations	(80,438)	(87,775)	7,337	-8%
Other income (expense)				
Interest income	1,955	841	1,114	132%
Interest expense and financing fee	(8,743)	(7,650)	(1,093)	14%
Change in fair value of derivative liabilities	-	114	(114)	-100%
Change in fair value of subsidiary convertible note	-	26	(26)	-100%
Change in fair value of investments	-	(1,390)	1,390	-100%
Other loss	-	(333)	333	-100%
Gain from deconsolidation of Caelum	18,521	-	18,521	100%
Total other income (expense)	11,733	(8,392)	20,125	-240%
Loss from continuing operations	(68,705)	(96,167)	27,462	-29%
Discontinued operations:				
Loss from discontinued operations, net of tax	-	(6,354)	6,354	-100%
Total loss from discontinued operations	-	(6,354)	6,354	-100%
Net loss	**(68,705)**	**(102,521)**	**33,816**	**-33%**
Less: net loss attributable to non-controlling interest	44,237	43,254	983	2%
Net loss attributable to common stockholders	**$ (24,468)**	**$ (59,267)**	**$ 34,799**	**-59%**

Net revenues increased $7.6 million or 43% from the nine months ended September 30, 2018 to the nine months ended September 30, 2019. The increase in net revenue is related to an increase in product revenue of $6.5 million associated with Journey's marketed products, and an increase of $1.2 million in collaboration revenue between Checkpoint and TGTX.

Cost of goods sold increased by $2.4 million or 53% from the nine months ended September 30, 2018 to the nine months ended September 30, 2019 due to the increase in Journey marketed products revenue in the 2019 period as compared to the 2018 period.

Research and development expenses decreased $2.2 million or 4% from the nine months ended September 30, 2018 to the nine months ended September 30, 2019. The following table shows the change in research and development spending by Fortress and its partner companies:

	Nine Months Ended September 30,		Change	
($ in thousands)	**2019**	**2018**	$	%
Research & Development				
Stock-based compensation				
Fortress	$ 447	$ 878	$ (431)	-49%
Partner Companies:				
Avenue	505	363	142	39%
Checkpoint	559	930	(371)	-40%
Mustang	1,116	2,732	(1,616)	-59%
Other[(1)]	8	37	(29)	-78%
Sub-total stock-based compensation	2,635	4,940	(2,305)	-47%
Other R&D				
Fortress	1,454	4,702	(3,248)	-69%
Partner Companies:				
Avenue	17,834	14,280	3,554	25%
Checkpoint	12,036	18,115	(6,079)	-34%
Mustang	19,789	10,226	9,563	94%
Other[(1)]	2,607	6,265	(3,658)	-58%
Total Research & Development	**$ 56,355**	**$ 58,528**	**(2,173)**	**-4%**

Note 1: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

The decrease in stock-based compensation is due to the adoption of ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting,* which no longer requires marking to market grants held by non-employees. For the nine months ended September 30, 2018, stock value increase led to Checkpoint's increased stock compensation expense due to marking to market grants held by non-employees. The decrease in stock-based compensation is also due to overall vesting of grants for both Mustang and Checkpoint.

The decrease in Fortress research and development spending is due to the lower research and development headcount subsequent to the transfer of Fortress research and development employees to TGTX, a related party, in the quarter ended September 30, 2018. Checkpoint's decrease in research and development spending is attributable to the manufacturing costs related to the PD-L1 GMP batches incurred in the nine months ended September 30, 2018 and not replicated in the current period. Mustang's increase in research and development spending is attributable to the fitting out of the cell processing facility, the purchase of lab supplies, increased headcount, and increased costs incurred under sponsored research agreements with City of Hope. The decrease in "Other" is attributable to Caelum's deconsolidation and Helocyte's sponsored research activities with City of Hope not replicated in 2019.

The decrease in research and development – licenses acquired of $2.5M or 65% from the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018 is due to the expense recorded in the first nine months of 2018 for milestones achieved by Helocyte ($1.5 million) and Checkpoint ($1.0 million), Mustang's acquisition of the X-SCID license from St. Jude ($1.0 million upfront payment) and manufacturing license from COH ($0.1 million), and Caelum's recognition of expense associated with anti-dilution shares issued to Columbia University ($0.2 million) as compared to $1.0 million expense recorded in the nine months ended September 30, 2019 for Mustang's achievement of milestones ($0.3 million related to CD123, $0.2 million related to CS1, $0.5 million related to various PSCA licenses), and $0.4 million expense recorded by Mustang for the acquisition of licenses ($0.2 million for the Calimmune license and $0.2 million to Nationwide for the C134 license).

General and administrative expenses increased $2.5 million, or 6%, from the nine months ended September 30, 2018 to the nine months ended September 30, 2019. The following table shows the change in general and administrative spending by Fortress and its partner companies:

	Nine Months Ended September 30,		Change	
($ in thousands)	**2019**	**2018**	$	%
General & Administrative				
Stock-based compensation				
Fortress	$ 3,590	$ 3,674	$ (84)	-2%
Partner Companies:				
Avenue	1,079	679	400	59%
Checkpoint	1,885	1,406	479	34%
Mustang	1,058	1,137	(79)	-7%
Other[(2)]	176	218	(42)	-20%
Sub-total stock-based compensation	7,788	7,114	674	9%
Other General & Administrative				
Fortress	10,165	11,599	(1,434)	-12%
Partner Companies:				
Avenue	1,373	2,016	(643)	-32%
Checkpoint	2,623	2,682	(59)	-2%
JMC[(1)]	13,872	9,613	4,259	44%
Mustang	4,613	3,809	804	21%
Other[(2)]	826	1,955	(1,129)	-58%
Total General & Administrative	**$ 41,260**	**$ 38,788**	**2,472**	**6%**

Note 1: Includes cost of outsourced sales force

Note 2: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

For the nine months ended September 30, 2019, the increase in general and administrative expenses of $2.5 million or 6% is primarily attributable to Journey's sales and marketing cost increases and Mustang's increased headcount and professional fees offset by Fortress' decreased headcount and travel costs and Avenue's decrease in investor relations and marketing costs.

Total other income or expense increased $20.1 million, or 240%, from a loss of $8.4 million for the nine months ended September 30, 2018 to income of $11.8 million for the nine months ended September 30, 2019, primarily due to the gain on the deconsolidation of Caelum of $18.5 million, offset by an increase in interest expense and financing fees due to Mustang's new Horizon debt.

Net loss attributable to common stockholders decreased $34.8 million, or 59%, from the nine months ended September 30, 2018 to the nine months ended September 30, 2019. This decrease is primarily due to the loss from discontinued operations of $6.4 million related to the sale of National and the gain on the deconsolidation of Caelum of $18.5 million.

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.

Cash Flows for the Nine Months Ended September 30, 2019 and 2018

($ in thousands)	Nine Months Ended September 30, 2019	2018
Statement of cash flows data:		
Total cash (used in)/provided by:		
Operating activities	$ (69,909)	$ (76,688)
Investing activities	19,787	5,302
Financing activities	119,559	52,340
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 69,437	$ (19,046)

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

	For the Nine Months Ended September 30, 2019				
($ in thousands)	Fortress[1]	Avenue	Checkpoint	Mustang	Total
Statement of cash flows data:					
Total cash (used in)/provided by:					
Operating activities	$ (7,911)	$ (21,263)	$ (16,644)	$ (24,091)	$ (69,909)
Investing activities	9,487	(5,000)	-	15,300	19,787
Financing activities	14,401	32,333	7,709	65,116	119,559
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 15,977	$ 6,070	$ (8,935)	$ 56,325	$ 69,437

	For the Nine Months Ended September 30, 2018				
($ in thousands)	Fortress[1]	Avenue	Checkpoint	Mustang	Total
Statement of cash flows data:					
Total cash (used in)/provided by:					
Operating activities	$ (28,789)	$ (16,978)	$ (18,200)	$ (12,721)	$ (76,688)
Investing activities	(559)	10,000	-	(4,139)	5,302
Financing activities	23,584	-	28,575	181	52,340
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (5,764)	$ (6,978)	$ 10,375	$ (16,679)	$ (19,046)

Note 1: Includes Fortress and non-public subsidiaries

Operating Activities

Net cash used in operating activities decreased $6.8 million from the nine months ended September 30, 2018, compared to the nine months ended September 30, 2019. The decrease is due to the decrease of $27.5 million in net loss from continuing operations, primarily offset by the gain from the deconsolidation of Caelum of $18.5 million and a decrease in the fair value of investments of $1.4 million.

Investing Activities

Net cash provided by investing activities increased $14.5 million from the nine months ended September 30, 2018, compared to the nine months ended September 30, 2019. The increase is primarily due to $13.1 million received from the sale of National, a decrease in the purchase of short-term investments of $42.5 million, and a decrease in the purchase of property and equipment of $5.3 million offset by the $43.4 million redemption of certificates of deposit held by Mustang, $1.2 million decrease in cash due to deconsolidation of Caelum, as well as an increase of $2.4 million in funds used to purchase intangible assets.

Financing Activities

Net cash provided by financing activities was $52.3 million for the nine months ended September 30, 2018, compared to $119.6 million of net cash provided by financing activities for the nine months ended September 30, 2019. During the nine months ended September 30, 2019, net proceeds from partners' offerings were $61.0 million, and net proceeds from Mustang's Horizon Notes was $13.6 million. Additionally, $1.8 million was paid in Preferred A dividends, and $15.8 million was received in net proceeds from the Company's at-the-market offering and $29.7 million was received in net proceeds from partner companies' at-the-market offerings.

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, 2017, December 31, 2018 and for the interim period through September 30, 2019, 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 September 30, 2019, 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.

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 investments, 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 or certain of our partner companies 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.

We may not be able to generate returns for our investors if certain of our partners or affiliates, 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 affiliated partners, which at the time of investment 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, acquire or invest in successful biopharmaceutical products, develop financial services 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, 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. In addition, there has been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. 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 would adversely affect our operations.

If we engage in business combinations and other transactions that result in holding passive 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 off 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, affiliates, related parties and/or 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 their products and product candidates.

We are primarily an early-stage biopharmaceutical company and certain of our partners and affiliates, 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 Medical Corporation). We have incurred significant net losses since our inception. As of September 30, 2019, we had an accumulated deficit of approximately $420.7 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-commercial 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. Each of these requirements will require substantial time, effort and financial resources.

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 Medical Corporation), 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.

If any of our product candidates that are 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, which may not occur, 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 is also 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 seen in a broader patient group, including its use outside the approved indication;
- 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 "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;
- the 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. Modifications to or repeal of all or certain provisions of the ACA have been attempted in Congress as a result of the outcome of the recent presidential and congressional elections, consistent with statements made by the incoming administration and members of Congress during the presidential and congressional campaigns and following the election.

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, so far have been 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, Texas federal district court judge Reed O'Connor issued a ruling declaring that the ACA in it is entirety is unconstitutional. While this decision has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome through the appeals process may have a significant impact on our business.

Most recently, 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 Trump Administration has also taken several regulatory steps to redirect ACA implementation. The Department of Health and Human Services ("HHS") finalized Medicare fee-for-service hospital payment reductions for Part B drugs acquired through the 340B Drug Pricing Program. HHS also has signaled its intent to pursue reimbursement policy changes for Medicare Part B drugs as a whole 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. These proposals include giving Medicare Advantage and Part D plans flexibility in the availability of drugs in "protected classes," more transparency in the cost of drugs, including the beneficiary's financial liability, and less costly alternatives and permitting the use of step therapy as a means of prior authorization. HHS has also proposed requiring pharmaceutical manufacturers disclose the prices of certain drugs in direct-to-consumer television advertisements. The proposal related to protected classes has been withdrawn and the disclosure requirements have been rejected by the courts. In addition, a proposed rule that would have passed drug rebates to consumers at the point of sale also has been withdrawn. However, 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 regards to U.S. drug purchasing. In addition, HHS, in conjunction with the FDA, announced that it will be exploring a reimportation pathway in certain instances and for certain drugs.

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.

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 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, would be commercially available for several years. Of the large number of drugs in development, only a small percentage successfully completes the FDA regulatory approval process and is 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. Any of these scenarios could compromise the commercial prospects for one or more of our current or future product candidates. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of the product.

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 insufficient 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. For example, in Phase 1/2 oncology trials, dose limiting toxicity ("DLT") stopping rules are commonly applied.

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 of our clinical trials could result in increased costs and delay our ability to pursue regulatory approval.

The commencement 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 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;
- 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 necessary or desirable for the promotion of 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 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 abilities to develop and commercialize our products and product candidates.

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 products 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 abilities 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 do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We intend to, and do, use CROs to conduct planned clinical trials and will, and do, rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with specified clinical protocols. 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, 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.

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.

We operate in highly competitive segments of the biopharmaceutical market and face competition from many different sources, including commercial pharmaceutical enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies, as well as new treatments that may be introduced by our competitors. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than we do. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in clinical and pre-clinical research, some in direct competition with us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. New developments, including the development of other biological and pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. 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 may incur substantial product liability or indemnification claims relating to the clinical testing of product candidates.

We face an inherent risk of product liability exposure related to the testing of product candidates in human clinical trials, and claims could be brought against us if use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. While we have and/or intend to maintain product liability insurance relating to clinical trials, that coverage may not be sufficient to cover potential claims, and we may be unable to maintain such insurance. Any claims against us, regardless of their merit, could severely harm our financial condition, strain management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. We are unable to predict if we will be able to obtain or maintain product liability insurance for any products that may be approved for marketing. 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.

We may use biological materials and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

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.

Our success depends upon our abilities to obtain and maintain intellectual property rights and take advantage of certain regulatory market exclusivity periods.

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 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. For example, on September 16, 2011, the Leahy-Smith America Invents Act (the “Leahy-Smith Act”), was signed into law, and includes a number of significant changes to U.S. patent law. These include changes to transition from a “first-to-invent” system to a “first-to-file” system and to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a quicker and less expensive process for challenging issued patents. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The USPTO implemented the America Invents Act on March 16, 2013.

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 licensor' 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.

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, as initially proposed by President Obama. 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/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;
- 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 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 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 consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their other clients or former employers.

As is common in the biopharmaceutical industry, we engage the services of consultants to assist in the development of product candidates. Many of these consultants were previously employed at, or may have previously been or are currently providing consulting services to, other pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims related to whether these consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. 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.

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 is 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 of a product, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the 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 lose 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 also rely on space and office-sharing arrangements that impose additional burdens on our ability to maintain the security of confidential information. We cannot assure you that we will be able to prevent an extended and/or material system failure or the unintentional disclosure of confidential information 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. 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, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our business could be seriously impaired. We have property, liability and business interruption insurance which 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.

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, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a civilian hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze was to remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget ("OMB") in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance or implement or enforce regulatory requirements in a timely fashion or at all. This hiring freeze was lifted later in 2017. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In addition on October 12, 2017, the President released an Executive Order intended to promote health care choices and competition and on June 24, 2019, the President released an Executive Order intended to improve price transparency and quality transparency. These may push HHS, FDA, and other relevant agencies to engage in rulemaking that may impact the pharmaceutical industry.

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 and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed 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 critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. 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 would result in delayed milestone revenues and materially harm our operations of business.

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 have also historically financed 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.

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 $130.8 million and $97.5 million for the years ended December 31, 2018 and 2017, respectively. At September 30, 2019, we had an accumulated deficit of approximately $420.7 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 risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant or any revenues or if we will ever achieve or sustain profitability.

At September 30, 2019, the total amount of debt outstanding was $84.0 million. If we default on our obligations, the holders of our debt may declare the outstanding amounts immediately payable together with accrued interest. 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 includes series of 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 debt securities 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, Cellvation, Cyprium and Tamid. Depending on the terms of such guaranty arrangements, we may be contractually obligated to pay substantial amounts to third parties 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 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 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 Avenue 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.

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 shares and/or debt securities to decline.

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 and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed 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 critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. 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 would result in delayed milestone revenues and materially harm our operations of business.

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, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our business could be seriously impaired. We have property, liability and business interruption insurance which 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.

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, 2018 and 2017 we incurred R&D expenses of approximately $83.3 million and $48.3 million, respectively. 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 equity securities, 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.

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.

Pursuant to Section 404 of the Sarbanes Oxley Act of 2002 and related rules, our management is required to report on, and our independent registered public accounting firm is required to attest to, the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to further upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. If material weaknesses or deficiencies in our internal controls exist and go undetected, our financial statements could contain material misstatements that, when discovered in the future could cause us to fail to meet our future reporting obligations and cause the price of our Securities to decline.

Future revenue based on sales of our dermatology products, especially Targadox®**,** Ximino® **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 Targadox®, Ximino® 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 rebates. These products also are or may become subject to third party generic competition.

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 September 30, 2019, Lindsay A. Rosenwald, M.D. our Chairman, President and Chief Executive Officer, beneficially owned 11.7% of our issued and outstanding common stock. At September 30, 2019, Michael S. Weiss, our Executive Vice Chairman, Strategic Development, beneficially owned 13.4% of our issued and outstanding common 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, such as those caused by the U.S. presidential administration change;
- 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 73.5 million outstanding shares of our Common Stock, inclusive of outstanding equity awards, as of September 30, 2019 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 having an aggregate offering price of up to $5.1 million as of September 30, 2019. A second amendment to a new registration statement was filed in June 2019. Common shares may also be sold under this shelf registration and we may issue and sell shares of our Common Stock having an aggregate offering price of up to $48.9 million as of September 30, 2019. Any sale of a substantial number of shares of our Common Stock could cause a drop in the trading price of our Common 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 shares of our Series A Preferred Stock. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on any of our or their 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 of stock dividends. Equally, each of our affiliates and 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 affiliates/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 your sole source of gain 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 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.

November 12, 2019

FORTRESS BIOTECH, INC.

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

November 12, 2019

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: November 12, 2019

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: November 12, 2019

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 September 30, 2019, 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: November 12, 2019

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 September 30, 2019, 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: November 12, 2019

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