Table of Contents

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, 2021

OR

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

For the transition period from to

Commission File Number 001-35366

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 11, 2021
Common Stock, $0.001 par value	99,629,396
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock, $0.001 par value	3,427,138

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

TABLE OF CONTENTS

SUMMARY RISK FACTORS

Our business is subject to risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risk factors, the risk factors described in Item 1A, and the other reports and documents that we have filed with the Securities and Exchange Commission ("SEC"). As used below and throughout this filing (including in the risk factors described in Item 1A), the words "we", "us" and "our" may refer to Fortress Biotech, Inc. individually or together with one or more partner companies, as dictated by context.

Risks Inherent in Drug Development

- Many of our and our partner companies' product candidates are in early development stages and are subject to time and cost intensive regulation and clinical testing. As a result, our product candidates may never be successfully developed or commercialized.
- Our competitors may develop treatments for our or our partner companies' products' target indications, which could limit our product candidates' commercial opportunity and profitability.

Risks Pertaining to the Need for and Impact of Existing and Additional Financing Activities

- We have a history of operating losses and we expect such losses to continue in the future.
- We have funded our operations in part through the assumption of debt, which lending agreements may restrict our operations. Further, the occurrence of any default event under any applicable loan document could adversely affect our business.
- Our research and development ("R&D") programs will require additional capital, which we may be unable to raise as needed and which may impede our R&D programs, commercialization efforts, or planned acquisitions.
- If we raise capital by issuing additional equity securities, our existing stockholders will be diluted.

Risks Pertaining to Our Existing Revenue Stream from Journey Medical Corporation ("Journey" or "JMC")

- Our operating income derives primarily from the sale of our partner company Journey's dermatology products, particularly Qbrexza, Ximino, Targadox, Accutane, and Exelderm. Any issues relating to the manufacture, sale, utilization, or reimbursement of Journey's products (including products liability claims) could significantly impact our operating results.
- The majority of Journey's sales derive from products that are without patent protection and/or are or may become subject to third party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse effect on our operating income. Two of Journey's marketed products, Qbrexza and Ximino, as well as DFD-29, a modified release oral minocycline for the treatment of rosacea licensed from Dr. Reddy's Laboratories, LTD, currently have patent protection. Three of Journey's marketed products, Accutane, Targadox, and Exelderm, do not have patent protection or otherwise are not eligible for patent protection. With respect to Journey products that are covered by valid claims of issued patents, such patents may be subject to invalidation, which would harm our operating income.
- Continued sales and coverage, including formulary inclusion without the need for a prior authorization or step edit therapy, of our products for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics.

Risks Pertaining to our Business Strategy, Structure and Organization

- We have entered, and will likely in the future enter, into certain collaborations or divestitures which may cause a reduction in our business' size and scope, market share and opportunities in certain markets, or our ability to compete in certain markets and therapeutic categories.
- We and our partner companies have also entered into several arrangements under which we and/or they have agreed to contingent dispositions of such partner companies and/or their assets. The failure to consummate any such transaction may impair the value of such companies and/or assets, and we may not be able to identify or execute alternative arrangements on favorable terms, if at all. The consummation of any such arrangements with respect to certain product candidates may also result in our eligibility to receive a lower portion of sales (if any) of resulting approved products than if we or our partner companies had developed and commercialized such product candidates ourselves.

- Our growth and success depend on our acquiring or in-licensing products or product candidates and integrating such products into our business.
- We act as guarantor and/or indemnitor of certain obligations of our subsidiaries and affiliates, which could require us to pay substantial amounts based on the actions or omissions of said subsidiaries or affiliates.

Risks Pertaining to Reliance on Third Parties

- We rely heavily on third parties for several aspects of our operations, including manufacturing and developing product candidates, conducting clinical trials, and producing commercial supplies for products. Such reliance on third-parties reduces our ability to control every aspect of the drug development process and may hinder our ability to develop and commercialize our products in a cost-effective and timely manner.

Risks Pertaining to Intellectual Property and Potential Disputes with Licensors Thereof

- If we are unable to obtain and maintain patent protection for our technologies and products, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technologies and products similar or identical to ours, and our ability to successfully commercialize our technologies and products may be impaired.
- We or our licensors may be subject to costly and time-consuming litigation for infringement of third-party intellectual property rights or to enforce our or our licensors' patents.
- Any dispute with our licensors may affect our ability to develop or commercialize our product candidates.

Risks Pertaining to Generic Competition and Paragraph IV Litigation

- Generic drug companies may submit applications seeking approval to market generic versions of our products.
- In connection with these applications, generic drug companies may seek to challenge the validity and enforceability of our patents through litigation and/or with the United States Patent and Trademark Office (PTO), such as the Paragraph IV certification made by Perrigo pertaining to the patents covering Qbrexza, a product being commercialized by our partner company Journey. Such challenges may subject us to costly and time-consuming litigation and/or PTO proceedings.
- As a result of the loss of any patent protection from such litigation or PTO proceedings, or the "at-risk" launch by a generic competitor of our products, our products could be sold at significantly lower prices, and we could lose a significant portion of sales of that product in a short period of time, which could adversely affect our business, financial condition, operating results and prospects.

Risks Pertaining to the Commercialization of Product Candidates

- If our products are not broadly accepted by the healthcare community, the revenues from any such products are likely to be limited.
- We may not obtain the desired product labels or intended uses for product promotion, or favorable scheduling classifications desirable to successfully promote our products.
- Even if a product candidate is approved, it may be subject to various post-marketing requirements, including studies or clinical trials, the results of which could cause such products to later be withdrawn from the market.
- Any successful products liability claim related to any of our current or future product candidates may cause us to incur substantial liability and limit the commercialization of such products.

Risks Pertaining to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries

- We operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations.

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 252,721	$ 233,351
Accounts receivable, net	31,738	23,928
Inventory	11,614	1,404
Other receivables - related party	947	744
Prepaid expenses and other current assets	4,167	6,723
Total current assets	301,187	266,150
Property and equipment, net	13,975	11,923
Operating lease right-of-use asset, net	19,415	20,487
Restricted cash	1,645	1,645
Long-term investment, at fair value	56,860	17,566
Intangible asset, net	13,043	14,629
Other assets	1,708	1,013
Total assets	**$ 407,833**	**$ 333,413**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 82,855	$ 45,389
Accounts payable - related party	74	—
Deferred revenue	3,354	—
Operating lease liabilities, short-term	2,047	1,849
Notes payable, short-term	10,450	—
Partner company installment payments - licenses, short-term (net of imputed interest of $ 567 and $778 as of September 30, 2021 and December 31, 2020, respectively)	4,433	4,522
Total current liabilities	103,213	51,760
Notes payable, long-term (net of debt discount of $ 7,431 and $8,323 as of September 30, 2021 and December 31, 2020, respectively)	42,569	51,677
Operating lease liabilities, long-term	21,522	22,891
Partner company installment payments - licenses, long-term (net of imputed interest of $ 461 and $863 as of September 30, 2021 and December 31, 2020, respectively)	3,539	8,137
Partner company convertible preferred shares, short-term (net of debt discount of $ 1,923 as of September 30, 2021)	18,078	—
Partner company derivative warrant liabilities	4,365	—
Other long-term liabilities	2,079	1,949
Total liabilities	**195,365**	**136,414**
Commitments and contingencies (Note 16)		
Stockholders' equity		
Cumulative redeemable perpetual preferred stock, $ .001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively, liquidation value of $25.00 per share	3	3
Common stock, $.001 par value, 170,000,000 shares authorized, 98,714,222 shares issued and outstanding as of September 30, 2021; 150,000,000 shares authorized, 94,877,492 shares issued and outstanding as of December 31, 2020, respectively	99	95
Common stock issuable, 116,866 and 0 shares as of September 30, 2021 and December 31, 2020, respectively	365	—
Additional paid-in-capital	608,089	583,000
Accumulated deficit	(515,898)	(482,760)
Total stockholders' equity attributed to the Company	92,658	100,338
Non-controlling interests	119,810	96,661
Total stockholders' equity	212,468	196,999
Total liabilities and stockholders' equity	**$ 407,833**	**$ 333,413**

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue				
Product revenue, net	$ 19,610	$ 9,447	$ 45,617	$ 30,808
Collaboration revenue	1,446	—	4,646	—
Revenue - related party	29	28	252	1,042
Net revenue	21,085	9,475	50,515	31,850
Operating expenses				
Cost of goods sold - product revenue	11,167	3,379	22,559	10,313
Research and development	27,367	13,298	70,226	43,868
Research and development - licenses acquired	713	458	15,585	2,278
Selling, general and administrative	22,221	15,383	59,145	45,358
Wire transfer fraud loss	9,540	—	9,540	—
Total operating expenses	71,008	32,518	177,055	101,817
Loss from operations	(49,923)	(23,043)	(126,540)	(69,967)
Other income (expense)				
Interest income	132	265	505	1,228
Interest expense and financing fee	(4,444)	(6,958)	(9,393)	(13,142)
Change in fair value of investments	8,376	575	39,294	575
Change in fair value of derivative liability	(2)	(803)	(184)	(1,189)
Total other income (expense)	4,062	(6,921)	30,222	(12,528)
Net loss	**(45,861)**	**(29,964)**	**(96,318)**	**(82,495)**
Net loss attributable to non-controlling interests	25,080	14,417	63,180	41,264
Net loss attributable to common stockholders	**$ (20,781)**	**$ (15,547)**	**$ (33,138)**	**$ (41,231)**
Net loss per common share - basic and diluted	$ (0.56)	$ (0.39)	$ (1.19)	$ (1.19)
Net loss per common share attributable to non - controlling interests - basic and diluted	$ (0.31)	$ (0.19)	$ (0.78)	$ (0.59)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.26)	$ (0.20)	$ (0.41)	$ (0.59)
Weighted average common shares outstanding - basic and diluted	81,348,243	76,093,211	81,056,165	69,404,499

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

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

For the Three Months Ended September 30, 2021

	Series A Perpetual Preferred Stock		Common Stock		Common Shares Issuable	Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance as of June 30, 2021	**3,427,138**	**$ 3**	**97,495,244**	**$ 97**	**$ 263**	**$ 603,035**	**$ (495,117)**	**$ 140,020**	**$ 248,301**
Stock-based compensation expense	—	—	—	—	—	4,326	—	—	4,326
Issuance of common stock related to equity plans	—	—	354,007	1	—	(1)	—	—	—
Issuance of common stock for at-the-market offering, net	—	—	786,300	1	—	2,747	—	—	2,748
Preferred A dividends declared and paid	—	—	—	—	—	(2,008)	—	—	(2,008)
Partner company's at-the-market offering, net	—	—	—	—	—	4,626	—	—	4,626
Issuance of common stock under partner company's ESPP	—	—	—	—	—	151	—	—	151
Partner company's dividends declared and paid	—	—	—	—	—	(187)	—	—	(187)
Issuance of partner company's common shares for research and development expenses	—	—	—	—	—	7	—	—	7
Common shares issued for dividend on partner company's convertible preferred shares	—	—	78,671	—	(263)	263	—	—	—
Common shares issuable for dividend on partner company's convertible preferred shares	—	—	—	—	365	—	—	—	365
Non-controlling interest in partner companies	—	—	—	—	—	(4,870)	—	4,870	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	(25,080)	(25,080)
Net loss attributable to common stockholders	—	—	—	—	—	—	(20,781)	—	(20,781)
Balance as of September 30, 2021	**3,427,138**	**$ 3**	**98,714,222**	**$ 99**	**$ 365**	**$ 608,089**	**$ (515,898)**	**$ 119,810**	**$ 212,468**

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

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

For the Three Months Ended September 30, 2020

	Series A Perpetual Preferred Stock		Common Stock		Common Shares Issuable	Treasury Stock	Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount						
Balance as of June 30, 2020	**2,693,806**	**$ 3**	**86,113,331**	**$ 86**	**$ 813**	**$ —**	**$ 521,493**	**$ (461,918)**	**$ 56,381**	**$ 116,858**
Stock-based compensation expense	—	—	—	—	—	—	3,171	—	—	3,171
Issuance of common stock related to equity plans	—	—	268,800	—	—	—	—	—	—	—
Issuance of common stock for at-the-market offering, net	—	—	7,064,214	7	—	—	21,110	—	—	21,117
Preferred A dividends declared and paid	—	—	—	—	—	—	(1,719)	—	—	(1,719)
Issuance of Series A preferred stock for cash, net	733,332	—	—	—	—	—	11,965	—	—	11,965
Partner company's offering, net	—	—	—	—	—	—	18,774	—	—	18,774
Partner company's at-the-market offering, net	—	—	—	—	—	—	23,053	—	—	23,053
Partner company's preferred stock offering, net	—	—	—	—	—	—	7,088	—	—	7,088
Issuance of common stock under partner company's ESPP	—	—	—	—	—	—	180	—	—	180
Partner company's dividends declared and paid	—	—	—	—	—	—	(50)	—	—	(50)
Reclass partner company's warrants from liability to equity	—	—	—	—	—	—	1,216	—	—	1,216
Issuance of partner company's common shares for research and development expenses	—	—	—	—	—	—	21	—	—	21
Common shares issued for 2017 Subordinated Note Financing interest expense	—	—	302,029	1	(500)	—	810	—	—	311
Write off common shares issuable for 2019 Notes interest expense	—	—	—	—	(313)	—	—	—	—	(313)
Common shares issuable for service	—	—	—	—	18	—	—	—	—	18
Issuance of warrants in conjunction with Oaktree Note	—	—	—	—	—	—	4,419	—	—	4,419
Non-controlling interest in partner companies	—	—	—	—	—	—	(37,070)	—	37,070	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	(14,417)	(14,417)
Net loss attributable to common stockholders	—	—	—	—	—	—	—	(15,547)	—	(15,547)
Balance as of September 30, 2020	**3,427,138**	**$ 3**	**93,748,374**	**$ 94**	**$ 18**	**$ —**	**$ 574,461**	**$ (477,465)**	**$ 79,034**	**$ 176,145**

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

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

For the Nine Months Ended September 30, 2021

	Series A Preferred Stock		Common Stock		Common Shares Issuable	Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance as of December 31, 2020	**3,427,138**	**$ 3**	**94,877,492**	**$ 95**	**$ —**	**$ 583,000**	**$ (482,760)**	**$ 96,661**	**$ 196,999**
Stock-based compensation expense	—	—	—	—	—	12,449	—	—	12,449
Issuance of common stock related to equity plans	—	—	2,912,652	3	—	(3)	—	—	—
Issuance of common stock under ESPP	—	—	59,107	—	—	137	—	—	137
Issuance of common stock for at-the-market offering, net	—	—	786,300	1	—	2,747	—	—	2,748
Preferred A dividends declared and paid	—	—	—	—	—	(6,023)	—	—	(6,023)
Partner companies' at-the-market offering, net	—	—	—	—	—	101,958	—	—	101,958
Partner company's exercise of options for cash	—	—	—	—	—	7	—	—	7
Issuance of common stock under partner company's ESPP	—	—	—	—	—	309	—	—	309
Partner company's dividends declared and paid	—	—	—	—	—	(562)	—	—	(562)
Issuance of partner company's common shares for research and development expenses	—	—	—	—	—	136	—	—	136
Common shares issued for dividend on partner company's convertible preferred shares	—	—	78,671	—	—	263	—	—	263
Common shares issuable for dividend on partner company's convertible preferred shares	—	—	—	—	365	—	—	—	365
Non-controlling interest in partner companies	—	—	—	—	—	(86,329)	—	86,329	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	(63,180)	(63,180)
Net loss attributable to common stockholders	—	—	—	—	—	—	(33,138)	—	(33,138)
Balance as of September 30, 2021	**3,427,138**	**$ 3**	**98,714,222**	**$ 99**	**$ 365**	**$ 608,089**	**$ (515,898)**	**$ 119,810**	**$ 212,468**

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

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

For the Nine Months Ended September 30, 2020

	Series A Preferred Stock		Common Stock		Common Shares Issuable	Treasury Stock	Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount						
Balance as of December 31, 2019	**1,341,167**	**$ 1**	**74,027,425**	**$ 74**	**$ 500**	**$ —**	**$ 461,874**	**$ (436,234)**	**$ 46,317**	**$ 72,532**
Stock-based compensation expense	—	—	—	—	—	—	10,319	—	—	10,319
Issuance of common stock related to equity plans	—	—	2,307,231	2	—	—	(2)	—	—	—
Issuance of common stock under ESPP	—	—	53,268	—	—	—	90	—	—	90
Issuance of common stock for at-the-market offering, net	—	—	16,378,234	17	—	—	43,183	—	—	43,200
Preferred A dividends declared and paid	—	—	—	—	—	—	(4,507)	—	—	(4,507)
Repurchase of Series A preferred stock, net	(5,000)	—	—	—	—	(70)	(2)	—	—	(72)
Retirement of Series A preferred stock	—	—	—	—	—	70	(70)	—	—	—
Issuance of Series A preferred stock for cash, net	2,090,971.0	2.0	—	—	—	—	35,466	—	—	35,468
Partner company's offering, net	—	—	—	—	—	—	53,698	—	—	53,698
Partner companies' at-the-market offering, net	—	—	—	—	—	—	33,500	—	—	33,500
Partner company's preferred stock offering, net	—	—	—	—	—	—	7,088	—	—	7,088
Issuance of common stock under partner company's ESPP	—	—	—	—	—	—	349	—	—	349
Partner company's dividends declared and paid	—	—	—	—	—	—	(50)	—	—	(50)
Partner company's exercise of warrants for cash	—	—	—	—	—	—	13	—	—	13
Reclass partner company's warrants from liability to equity	—	—	—	—	—	—	1,216	—	—	1,216
Issuance of partner company's common shares for research and development expenses	—	—	—	—	—	—	42	—	—	42
Common shares issued for 2017 Subordinated Note Financing interest expense	—	—	982,216	1	(500)	—	1,816	—	—	1,317
Common shares issuable for service	—	—	—	—	18	—	—	—	—	18
Issuance of warrants in conjunction with Oaktree Note	—	—	—	—	—	—	4,419	—	—	4,419
Non-controlling interest in partner companies	—	—	—	—	—	—	(73,981)	—	73,981	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	(41,264)	(41,264)
Net loss attributable to common stockholders	—	—	—	—	—	—	—	(41,231)	—	(41,231)
Balance as of September 30, 2020	**3,427,138**	**$ 3**	**93,748,374**	**$ 94**	**$ 18**	**$ —**	**$ 574,461**	**$ (477,465)**	**$ 79,034**	**$ 176,145**

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

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

	Nine Months Ended September 30,	
	2021	2020
Cash Flows from Operating Activities:		
Net loss	$ (96,318)	$ (82,495)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation expense	1,868	1,676
Bad debt (reserve) expense	(67)	47
Amortization of debt discount	1,623	5,319
Accretion of partner company convertible preferred shares	1,034	—
Non-cash interest	616	492
Prepayment penalty of Oaktree Note	450	—
Amortization of product revenue license fee	1,983	1,065
Amortization of operating lease right-of-use assets	1,259	1,214
Stock-based compensation expense	12,449	10,319
Issuance of partner company's common shares for research and development expenses	136	42
Common shares issued for dividend on partner company's convertible preferred shares	263	—
Common shares issuable for dividend on partner company's convertible preferred shares	365	—
Common shares issued for 2017 Subordinated Note Financing interest expense	—	1,317
Common shares issuable for service	—	18
Change in fair value of investment	(39,294)	(575)
Change in fair value of derivative liability	184	1,189
Research and development-licenses acquired, expense	15,449	2,236
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:		
Accounts receivable	(7,743)	(2,161)
Inventory	(10,210)	(195)
Other receivables - related party	(203)	(74)
Prepaid expenses and other current assets	2,854	2,429
Other assets	(695)	(198)
Accounts payable and accrued expenses	33,953	(2,686)
Accounts payable and accrued expenses - related party	74	19
Interest payable	—	(1,019)
Interest payable - related party	—	(92)
Deferred revenue	3,354	—
Partner company contract liability	—	—
Lease liabilities	(1,358)	(943)
Other long-term liabilities	130	(140)
Net cash used in operating activities	(77,844)	(63,196)
Cash Flows from Investing Activities:		
Purchase of research and development licenses	(9,830)	(3,369)
Purchase of property and equipment	(2,609)	(1,228)
Purchase of intangible asset	(400)	(1,000)
Net cash used in investing activities	(12,839)	(5,597)

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Unaudited Condensed Consolidated Statements of Cash Flows

($ in thousands)	Nine Months Ended September 30,	
	2021	2020
Cash Flows from Financing Activities:		
Payment of Series A perpetual preferred stock dividends	$ (6,023)	$ (4,507)
Purchase of treasury stock	—	(70)
Payment of costs related to purchase of treasury stock	—	(2)
Proceeds from issuance of Series A perpetual preferred stock	—	39,075
Payment of costs related to issuance of Series A perpetual preferred stock	—	(3,407)
Proceeds from issuance of common stock for at-the-market offering	2,833	44,796
Payment of costs related to issuance of common stock for at-the-market offering	(85)	(1,506)
Proceeds from issuance of common stock under ESPP	137	90
Proceeds from partner companies' ESPP	309	349
Partner company's dividends declared and paid	(562)	(50)
Proceeds from partner companies' sale of stock	—	57,729
Payment of costs related to partner companies' sale of stock	—	(3,642)
Proceeds from partner companies' at-the-market offering	104,097	34,254
Payment of costs related to partner companies' at-the-market offering	(2,223)	(754)
Proceeds from partner company's preferred stock offering	—	8,000
Payment of costs related to partner company's preferred stock offering	(13)	(912)
Proceeds from exercise of partner company's warrants	—	13
Proceeds from exercise of partner company's options	7	—
Payment of debt issuance costs associated with 2017 Subordinated Note Financing	—	(93)
Payment of debt issuance costs associated with 2018 Venture Notes	—	(58)
Proceeds from Oaktree Note	—	60,000
Payment of debt issuance costs associated with Oaktree Note	(95)	(4,239)
Repayment of 2017 Subordinated Note Financing	—	(28,356)
Repayment of 2018 Venture Notes	—	(21,707)
Repayment of 2019 Notes	—	(9,000)
Repayment of partner company's Horizon Notes	—	(15,750)
Repayment of IDB Note	—	(14,858)
Repayment of partner company installment payments - licenses	(5,300)	—
Proceeds from partner company convertible preferred shares	18,967	—
Payment of debt issuance costs associated with partner company convertible preferred shares	(1,996)	—
Net cash provided by financing activities	110,053	135,395
Net increase in cash and cash equivalents and restricted cash	19,370	66,602
Cash and cash equivalents and restricted cash at beginning of period	234,996	153,432
Cash and cash equivalents and restricted cash at end of period	$ 254,366	$ 220,034
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 5,025	$ 6,669
Cash paid for interest - related party	$ —	$ 463
Cash paid for tax	$ 661	$ —
Supplemental disclosure of non-cash financing and investing activities:		
Settlement of restricted stock units into common stock	$ 3	$ 2
Issuance of warrants in conjunction with Oaktree Note	$ —	$ 4,419
Common shares issued from 2017 Subordinated Note Financing interest expense	$ —	$ 500
Unpaid fixed assets	$ 1,376	$ 317
Partner company's unpaid intangible assets	$ —	$ 3,727
Reclass partner company's warrants from liability to equity	$ —	$ 1,216
Unpaid debt offering cost	$ —	$ 57
Unpaid partner company's debt offering cost	$ 214	$ —
Unpaid partner company's deferred offering cost	$ 264	$ —
Partner company derivative warrant liability associated with partner company convertible preferred shares	$ 362	$ —
Unpaid at-the-market offering cost	$ —	$ 96
Unpaid partner company's offering cost	$ —	$ 457
Unpaid Series A perpetual preferred stock offering cost	$ —	$ 203
Retirement of Series A perpetual preferred stock	$ —	$ 70
Unpaid research and development licenses acquired	$ 1,800	$ 117
Lease liabilities arising from obtaining right-of-use assets	$ 187	$ —

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to 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 at entities the Company founded and in which it maintains significant minority ownership positions. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who identify and evaluate promising products and product candidates for potential acquisition by new or existing partner companies. Fortress through its partner companies has executed such arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center, Fred Hutchinson Cancer Research Center, St. Jude Children's Research Hospital, Dana-Farber Cancer Institute, Nationwide Children's Hospital, Cincinnati Children's Hospital Medical Center, Columbia University, the University of Pennsylvania, AstraZeneca plc and Dr. Reddy's Laboratories, Ltd.

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 financial expertise to help its partner companies achieve their goals. The partner companies then assess a broad range of potential 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 three have consummated strategic partnerships with industry leaders Alexion Pharmaceuticals, Inc. ("Alexion"), InvaGen Pharmaceuticals, Inc. ("InvaGen") (a subsidiary of Cipla Limited) and Sentynl Therapeutics, Inc. ("Sentynl"). On October 6, 2021, AstraZeneca plc (acquiror of Alexion) purchased 100% of our partner company Caelum Biosciences, Inc. ("Caelum") for approximately $150 million upfront and up to $350 million in contingent regulatory and sales milestone payments.

Several of our partner companies possess licenses to product candidate intellectual property, including Aevitas Therapeutics, Inc. ("Aevitas"), Avenue Therapeutics, Inc. ("Avenue"), Baergic Bio, Inc. ("Baergic"), Caelum, Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. ("Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), FBIO Acquisition Corp. VIII, Helocyte, Inc. ("Helocyte"), Journey, Mustang Bio, Inc. ("Mustang") and Oncogenuity, Inc. ("Oncogenuity").

Liquidity and Capital Resources

Since inception, the Company's operations have been financed primarily through the sale of equity and debt securities, from the sale of partner companies, and the proceeds from the exercise of warrants and stock options. The Company has incurred losses from operations and negative cash flows from operating activities since inception and expects to continue to incur substantial losses for the next several years as it continues to fully develop and prepare regulatory filings and obtain regulatory approvals for its existing and new product candidates. The Company's current cash and cash equivalents are sufficient to fund operations for at least the next 12 months. However, the Company will need to raise additional funding through strategic relationships, public or private equity or debt financings, sale of a partner companies, grants or other arrangements to 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 plans, and plans for expansion of its general and administrative infrastructure may be curtailed. The Company also has the ability, subject to limitations imposed by Rule 144 of the Securities Act of 1933 and other applicable laws and regulations, to raise money from the sale of common stock of the public companies in which it has ownership positions. In addition to the foregoing, the Company experienced minimal impact on its development timelines, revenue levels and its liquidity due to the worldwide spread of COVID-19.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying interim unaudited 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 interim unaudited 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 unaudited 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 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 SEC on March 31, 2021, from which the Company derived the balance sheet data at December 31, 2020, as well as Checkpoint's Form 10-K, filed with the SEC on March 12, 2021, Mustang's Form 10-K, filed with the SEC on March 24, 2021, Avenue's Form 10-K, filed with the SEC on March 31, 2021, and the public filing of the Journey Medical Corporation Form S-1 on October 22, 2021, as amended on November 8, 2021 and November 10, 2021.

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

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

Use of Estimates

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

Restricted Cash

The Company records cash held in trust or pledged to secure certain debt obligations as restricted cash. As of September 30, 2021 and December 31, 2020, the Company had $1.6 million of restricted cash representing pledges to secure letters of credit in connection with certain office leases.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

The following table provides a reconciliation of cash, cash equivalents, and restricted cash from the unaudited condensed consolidated balance sheets to the unaudited condensed consolidated statements of cash flows at September 30, 2021, and 2020:

	September 30,	
	2021	2020
Cash and cash equivalents	$ 252,721	$ 218,389
Restricted cash	1,645	1,645
Total cash and cash equivalents and restricted cash	$ 254,366	$ 220,034

Revenue Recognition

The Company records revenue in accordance with the provisions of Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The core principle of this revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company's revenues primarily result from contracts with customers, which are generally short-term and have a single performance obligation — the delivery of product. The Company's performance obligation to deliver products is satisfied when the goods are received by the customer, which is the point at which the customer obtains title to, and accepts the risks and rewards of ownership of, the products. The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both.

Many of the Company's products sold are subject to trade discounts, rebates, coupons and right of return. Revenues are recorded net of provisions for variable consideration, including discounts, rebates, governmental rebate programs, price adjustments, returns, chargebacks, promotional programs and other sales allowances. Accruals for these provisions are presented in the interim unaudited condensed consolidated financial statements as reductions in determining net sales and as a contra asset in accounts receivable, net (if settled via credit) and other current liabilities (if paid in cash). Amounts recorded for revenue deductions can result from a complex series of judgements about future events and uncertainties and can rely heavily on estimates and assumptions. The following section briefly describes the nature of the Company's provisions for variable consideration and how such provisions are estimated.

Trade Discounts and Other Sales Allowances — The Company provides trade discounts and allowances to its wholesale customers for sales order management, data, and distribution services. The Company also provides for prompt pay discounts if payment is received within the payment term days which generally range from 30 to 75 days. These discounts and allowances are recorded at the time of sale based on the customer's contracted rate and have been recorded as a reduction of revenue and a reduction to accounts receivables.

Product Returns — Consistent with industry practice, the Company offers customers a right to return any unused product. Such right of return commences six months prior to the product expiration date and ends one year after the product expiration date. Products returned for expiration are reimbursed at current or contracted price, less 5%. The Company estimates the amount of its product sales that may be returned by its customers and accrues this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return reserves using available industry data and its own sales information, including its visibility and estimates into the inventory remaining in the distribution channel.

The Company currently estimates product returns to be approximately 3% of gross sales to the wholesalers. The 3% return rate is estimated by using both historical and industry data. The Company monitors product returns on a quarterly basis, and will adjust the estimated return percentage if needed. The Company does not estimate returns for sales made to specialty pharmacies as their historical ordering pattern is approximately every two weeks and, as such, inventory turns every two weeks.

Government Chargebacks — Chargebacks for fees and discounts to indirect qualified government healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified U.S. Department of Veterans Affairs hospitals and 340B entities at prices lower than the list prices charged to customers who purchase product directly from the Company. Customers charge the Company for the difference between what they pay for the product and the statutory selling price to the qualified government entity. These allowances are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable, net. The chargeback amount from our direct customers is generally determined at the time of our direct customers' resale to the qualified government healthcare provider, and the Company generally issues credits for such amounts within a few weeks of our direct customer's notification to the Company of the resale. The allowance for chargebacks is based on expected sellthrough levels by our direct customers to indirect customers, as well as estimated wholesaler inventory levels.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

Government Rebates — The Company is subject to discount obligations under state Medicaid programs and Medicare. These accruals are recorded in the same period that the related revenue is recognized, resulting in a reduction of product revenue. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap, for whom the Company will owe an additional liability under the Medicare Part D program. For Medicaid programs, the Company estimates the portion of sales attributed to Medicaid patients and records a liability for the rebates to be paid to the respective state Medicaid programs. The Company's liability for these rebates consists of invoices received for: claims from prior quarters that have not been paid or for which an invoice has not yet been received; estimates of claims for the current quarter; and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Coupons — The Company offers coupons on products for qualified commercially-insured parties with prescription drug co-payments. Such product sales flow through both traditional wholesaler and specialty pharmacy channels. Approximately 85% of the Company's product revenues are sold through the specialty pharmacy channel, which has a shorter cycle from the Company's sales date to the fulfilment of the prescription by the specialty pharmacy customer, resulting in less inventory in this channel. Coupons are processed and redeemed at the time of prescription fulfilment by the pharmacy, and the Company is charged for the coupons redeemed monthly. The majority of coupon liability at the end of the period represents coupons that have been redeemed and for which the Company has been billed, and an accrual for expected redemptions for product in the distribution channel. This element of the liability requires the Company to estimate the distribution channel inventory at period end, the expected redemption rates, and the cost per coupon claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel at the end of each reporting period. The estimate of product remaining in the distribution channel is comprised of actual inventory at the wholesaler as well as an estimate of inventory at the specialty pharmacies, which the Company estimates based upon historical ordering patterns, which consist of reordering approximately every two weeks. The estimated redemption rate is based on historical redemptions as a percentage of units sold. The cost per coupon is based on the coupon rate.

Managed Care Rebates — The Company offers managed care rebates to certain providers. The Company calculates rebate payment amounts due under this program based on actual qualifying products and applies a contractual discount rate. The accrual is based on an estimate of claims that the Company expects to receive and inventory in the distribution channel. The accrual is recognized at the time of sale, resulting in a reduction of product revenue.

Collaboration Revenue

Our collaboration revenue includes service revenue, license fees and future contingent milestone based payments. We recognize collaboration revenue for contracted R&D services performed for our customers over time. We measure our progress using an input method based on the effort we expend or costs we incur toward the satisfaction of our performance obligation. We estimate the amount of effort we expend, including the time it will take us to complete the activities, or the costs we may incur in a given period, relative to the estimated total effort or costs to satisfy the performance obligation. This results in a percentage that we multiply by the transaction price to determine the amount of revenue we recognize each period. This approach requires us to make estimates and use judgement. If our estimates or judgements change over the course of the collaboration, they may affect the timing and amount of revenue that we recognize in the current and future periods.

Reclassifications

Certain comparative figures have been reclassified to conform to the current year presentation. The Company reclassified certain return reserves related to accounts receivable balances of $4.6 million from accounts receivable to current liabilities on the unaudited condensed consolidated balance sheet at December 31, 2020. This reclassification was deemed to be immaterial.

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2020 Annual Report, other than the accounting for inventory, partner company convertible preferred shares and sequencing.

Inventories

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

Inventories comprise raw materials and finished goods, which are valued at the lower of cost and net realizable value, on a first-in, first-out basis. The Company evaluates the carrying value of inventories on a regular basis, taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand. The acquired Qbrexza finished goods inventory includes a fair value step-up of $6.5 million, which will be expensed within cost of sales, as the inventory is sold to customers. All of the step-up finished goods inventory is expected to be sold in 2021.

Partner Company Convertible Preferred Shares

The Journey 8% Cumulative Convertible Class A Preferred Stock ("Journey Preferred Stock") includes settlement features that result in liability classification. The initial carrying value of the Journey Preferred Stock is accreted to the expected settlement value, a fixed monetary amount to be settled by issuing a variable number of Journey common shares. The discount to the settlement value is accreted to interest expense using the effective interest method.

Sequencing

On March 31, 2021, the Company adopted a sequencing policy under ASC 815-40-35 *Derivatives and Hedging* ("ASC 815") whereby in the event that reclassification of contracts from equity to assets or liabilities is necessary pursuant to ASC 815 due to the Company's inability to demonstrate it has sufficient authorized shares as a result of certain securities convertible or exchangeable for a potentially indeterminable number of shares, shares will be allocated on the basis of the earliest issuance date of potentially dilutive instruments, with the earliest grants receiving the first allocation of shares. Pursuant to ASC 815, grants or issuances of securities or options to the Company's non-employees, employees or directors are not subject to the sequencing policy.

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. On January 1, 2021, the Company's adoption of this guidance did not have a material impact on its financial statements.

Recently Issued Accounting Pronouncements

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)*. This ASU reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This ASU provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. This ASU will be effective for all entities for fiscal years beginning after December 15, 2021. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including adoption in an interim period. The adoption of ASU 2021-04 is not expected to have a material impact on the Company's financial statements or disclosures.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

In August 2020, the FASB issued ASU No. 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20)* and *Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption will be permitted. The Company is currently evaluating the impact of this standard on its financial statements.

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

3. Collaboration and Stock Purchase Agreements

Caelum

Agreement with AstraZeneca's Alexion

In January 2019, Caelum entered into a Development, Option and Stock Purchase Agreement (as amended, the "DOSPA") and related documents by and among Caelum, AstraZeneca (as successor-in-interest to Alexion, "AstraZeneca"), the Company and Caelum's other equity holders as parties thereto (such equity holders, including Fortress, the "Sellers"). Under the terms of the agreement, AstraZeneca obtained a minority interest in Caelum and a contingent exclusive option to acquire the remaining equity in Caelum.

On September 28, 2021 AstraZeneca notified Caelum of its intention to exercise its purchase option, and on October 6, 2021 AstraZeneca acquired Caelum for an upfront payment of approximately $150 million (see Note 21). The Sellers currently remain eligible to receive up to an additional $350 million in contingent regulatory and commercial milestone payments.

Cyprium

Agreement with Sentynl

On February 24, 2021, Cyprium entered into a development and contingent asset purchase agreement with Sentynl. Pursuant to the terms of the agreement, Sentynl paid Cyprium an upfront fee of $8.0 million specifically earmarked to complete the CUTX-101 development program for the treatment of Menkes disease, through the filing of Cyprium's New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"). Cyprium also remains eligible to receive up to an additional $12.0 million payable as follows: (i) $3.0 million upon acceptance by the FDA of the NDA for review; and (ii) $9.0 million upon FDA approval of the NDA and transfer of CUTX-101 to Sentynl. The Company will recognize revenue associated with these future milestones based upon achievement. At September 30, 2021, none of these future milestones was deemed probable.

Following the transfer of CUTX-101 to Sentynl (if any), Cyprium would remain eligible to receive up to $255.0 million in additional sales milestone payments (payable pursuant to five milestones), as well as royalties on CUTX-101 net sales ranging from mid-single digits up to the mid-twenties. Cyprium would retain 100% ownership over any FDA Priority Review Voucher that may be issued at NDA approval for CUTX-101.

The Company determined that this agreement falls within the scope of *ASC 606-10-15-3* and *ASC 808-10-15-5A Revenue from Collaborative Arrangements* ("ASC 808") and as such the Company will recognize revenue in connection with achievement of two future development milestone payments.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

In connection with the $8.0 million upfront payment to Sentynl, the Company is recognizing revenue using an input method based upon the costs incurred to date in relation to the total estimated costs to complete the development activities. Accordingly, revenue is being recognized over the period in which the development activities are expected to occur. For the three and nine months ended September 30, 2021, the Company recognized revenue of $1.4 million and $4.6 million, respectively. No revenue was recognized in connection with this agreement in 2020.

Avenue

Agreement with InvaGen

On November 12, 2018, Avenue entered into a Stock Purchase and Merger Agreement (the "Avenue SPMA") with InvaGen and Madison Pharmaceuticals Inc. (the "Merger Sub"), under which Avenue would be sold to InvaGen in a two-stage transaction. The first stage of the strategic transaction between InvaGen and Avenue closed in February 2019. InvaGen acquired approximately 5.8 million shares of Avenue's common stock at $6.00 per share for total gross consideration of $35.0 million, representing a 33.3% stake in Avenue's capital stock on a fully diluted basis (the "Stock Purchase Transaction"). At the second stage closing, InvaGen would acquire the remaining shares of Avenue's common stock, for $180 million, pursuant to a reverse triangular merger (the "Merger Transaction").

Consummation of the Merger Transaction was conditioned upon, among other things, FDA approval of IV Tramadol, its labeling and scheduling, and the absence of certain other restrictions in effect with respect to IV Tramadol. Pursuant to the Avenue SPMA, if FDA approval of IV Tramadol was not obtained on or before April 30, 2021, InvaGen would not be subject to the mandatory closing obligations set forth in the Avenue SPMA with respect to the Merger Transaction (but would instead retain an option to complete the Merger Transaction up until such time as the Avenue SPMA was terminated). Pursuant to the Avenue SPMA, the Company could choose to terminate the Avenue SPMA after October 31, 2021, if FDA approval of IV Tramadol had not occurred by such time. On November 1, 2021, the Company terminated the Avenue SPMA.

Even though the Avenue SPMA has been terminated, InvaGen retains certain rights pursuant to the Stockholders Agreement entered into on November 12, 2018 between the Company, Avenue and InvaGen, and other agreements entered into in connection therewith on such date. These rights exist as long as InvaGen maintains at least 75% of the common shares acquired in the Stock Purchase Transaction, and include, among other things, the right to restrict Avenue from certain equity issuances and changes to Avenue's capital stock without obtaining InvaGen's prior written consent.

Over the past year, Avenue has communicated with InvaGen relating to InvaGen's assertions that Material Adverse Effects (as defined in the Avenue SPMA) have occurred due to the impact of the COVID-19 pandemic on potential commercialization and projected sales of IV Tramadol. Additionally, in connection with the resubmission of Avenue's NDA in February 2021, InvaGen communicated to Avenue that it believes the proposed label for IV Tramadol would also constitute a Material Adverse Effect (as defined in the Avenue SPMA) on the purported basis that the proposed label under certain circumstances would make the product commercially unviable. Even though the Avenue SPMA has been terminated, it is still possible for InvaGen to pursue monetary claims against the Company and/or Avenue based on the foregoing or other potential causes of action.

Avenue is not yet generating revenue, has incurred substantial operating losses since its inception and expects to continue to incur significant operating losses for the foreseeable future as it executes on its product development plan and may never become profitable. As of September 30, 2021, Avenue had an accumulated deficit of $76.1 million.

On October 12, 2020, Avenue announced that it had received a Complete Response Letter ("the First CRL") from the FDA regarding Avenue's NDA for IV Tramadol. The First CRL cited deficiencies related to the terminal sterilization validation and stated that IV Tramadol, intended to treat patients in acute pain who require an opioid, is not safe for the intended patient population. On February 12, 2021, Avenue resubmitted its NDA to the FDA for IV Tramadol. The NDA resubmission followed the receipt of official minutes from a Type A meeting with the FDA. The resubmission included revised language relating to the proposed product label and a report relating to terminal sterilization validation. On June 14, 2021, Avenue announced that it had received a second Complete Response Letter (the "Second CRL") from the FDA regarding Avenue's NDA for IV tramadol. The Second CRL stated that the delayed and unpredictable onset of analgesia with IV tramadol does not support its benefit as a monotherapy to treat patients in acute pain and that there is insufficient information to support that IV tramadol in combination with other analgesics is safe and effective for the intended patient population. In particular, the Second CRL stated that, while the primary endpoint was met in two efficacy studies, meaningful pain relief was delayed (accounting for the use of rescue medication, e.g., ibuprofen), and some patients never achieved pain relief.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

Avenue continues to pursue regulatory approval for IV Tramadol and had a Type A meeting with the FDA in July 2021. The FDA did not deviate from any of the positions the FDA previously took in the First CRL and the Second CRL. Avenue submitted a formal dispute resolution request ("FDRR") with the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, Avenue received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to the FDRR submitted on July 27, 2021. On August 31, 2021, Avenue submitted a FDRR with the Office of New Drugs ("OND") of the FDA. On October 21, 2021, Avenue received a written response from the OND of the FDA stating that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR. Avenue's ability to potentially commercialize IV Tramadol, and the timing of any potential commercialization, are dependent on the FDA's review of the FDRR for IV Tramadol, the outcome of the aforementioned Advisory Committee meeting, whether or not the FDA ultimately approves IV Tramadol, and potentially on whether or not Avenue procures additional capital.

As of September 30, 2021, Avenue had cash and cash equivalents of $0.6 million. Avenue believes that its cash and cash equivalents are only sufficient to fund its operating expenses into the fourth quarter of 2021. Avenue will need to secure additional funds through equity or debt offerings, or other potential sources. Furthermore, under the Shareholders's Agreement between Avenue and InveGen, any equity funding must be approved by InvaGen. Avenue cannot be certain that additional funding will be available to it on acceptable terms, or at all. These factors individually and collectively raise substantial doubt about Avenue's ability to continue as a going concern within one year from the date of this report.

In light of the foregoing, it may be necessary at some point for Avenue to seek protection under Chapter 11 of the United States Bankruptcy Code, which could have a material adverse impact on Avenue's business, financial condition, operations and could place its shareholders at significant risk of losing all of their investment. In any such Chapter 11 proceeding, Avenue may seek to restructure its obligations or commence an orderly wind-down of its operations and sale of its assets, in either event, holders of equity interests could receive or retain little or no recovery. The Company also notes that the process of exploring refinancing or restructuring alternatives, including those under Chapter 11, may be disruptive to Avenue's business and operations.

On September 2, 2021, Avenue received a delinquency notification letter from the Listing Qualifications Staff of the Nasdaq Stock Market LLC ("Nasdaq") indicating that Avenue is not in compliance with Nasdaq rules requiring listed securities to maintain a minimum Market Value of Listed Securities ("MVLS") of $35 million (the "MVLS Requirement"). Avenue has 180 calendars days, expiring March 1, 2022, to regain compliance with the MVLS Requirement. If Avenue maintains a MVLS at or greater than $35 million or more for a minimum of ten consecutive business days, Avenue will regain compliance. If Avenue does not regain compliance within 180 calendar days, Avenue will receive a written notification from Nasdaq that its securities are subject to delisting. Avenue intends to monitor its MVLS and may, if appropriate, consider implementing available options to regain compliance with the MVLS Requirement. There can be no assurance that Avenue will be able to regain compliance with the MVLS Requirement, or maintain compliance if Avenue regains compliance.

4. Inventory

Inventory consisted of the following:

($ in thousands)	September 30, 2021	December 31, 2020
Raw materials	$ 5,453	$ —
Work-in-process	—	—
Finished goods	6,161	1,404
Total inventories	$ 11,614	$ 1,404

The acquired Qbrezxa finished goods inventory includes a fair value step-up of $6.5 million, which will be expensed within cost of sales as the inventory is sold to customers. All of the step-up finished goods inventory is expected to be sold in 2021. For additional information on Journey's acquisition of Qbrexza, please refer to Note 9.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

5. Property and Equipment

Fortress' property and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	September 30, 2021	December 31, 2020
Computer equipment	3	$ 739	$ 663
Furniture and fixtures	5	1,387	1,199
Machinery & equipment	5	6,330	5,748
Leasehold improvements	2-15	13,134	10,580
Construction in progress [1]	N/A	1,019	499
Total property and equipment		22,609	18,689
Less: Accumulated depreciation		(8,634)	(6,766)
Property and equipment, net		$ 13,975	$ 11,923

Note 1: Relates to the Mustang cell processing facility.

Fortress' depreciation expense for the three months ended September 30, 2021 and 2020 was approximately $0.7 million and $0.6 million, respectively. Fortress' depreciation expense for the nine months ended September 30, 2021 and 2020 was approximately $1.9 million and $1.7 million, respectively. Depreciation expense is recorded in both research and development expense and general and administrative expense in the unaudited condensed consolidated statement of operations.

6. Fair Value Measurements

The Company follows accounting guidance on fair value measurements for financial assets and liabilities measured at fair value on a recurring basis. Under the accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.
Level 2: Observable inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.
Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques,

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

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.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

Fair Value of Caelum

As of September 30, 2021, based on notification from AstraZeneca of their intent to exercise their exclusive option to purchase Caelum for the option price of $150 million (see Note 3), the Company wrote up the carrying value of its investment in Caelum to the 42.4% share of the net proceeds it expects to receive upon distribution of the option exercise price. Accordingly, the fair value of the Company's investment in Caelum at September 30, 2021 was deemed to be $56.9 million. This amount reflects deduction of the 10% escrow holdback, to be distributed in 24 months, as well as deductions for legal expenses and fees, approximating $1.1 million.

As of December 31, 2020, 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 $17.6 million based on a per share value of $2.43. As of December 31, 2020, the following inputs were utilized to derive the value: risk free rate of return of 0.36%, volatility of 70% and a discount for lack of marketability ranging from 21% to 31% based on the maturity date assumptions of various scenarios. Further, the Company considered the impact of the acquisition of Alexion by AstraZeneca, which shortened the timeframe in which the option could be exercised in accordance with the A&R DOSPA.

Journey Warrant Liabilities

Placement Agent Warrants

In connection with Journey's Preferred Stock offering (see Note 11), upon a Qualified Financing (defined as an external financing of $25.0 million or greater), Journey will issue warrants to the placement agent (the "Placement Agent Warrants") to purchase 5% of the shares of common stock into which the Preferred Stock converts. The Placement Agent Warrants have a term of five years and are exercisable at a 15% discount to the Qualified Financing price. The Company valued the Placement Agent Warrants using a Monte Carlo simulation valuation methodology. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Journey's warrant liability that are categorized within Level 3 of the fair value hierarchy as of September 30, 2021 was as follows:

	September 30, 2021
Risk-free interest rate	0.98 %
Expected dividend yield	—
Expected term in years	1.0
Expected volatility	50 %

At September 30, 2021, the value of the placement agent warrants was deemed to be $0.5 million.

Contingent Payment Derivative

In connection with the license, collaboration, and assignment agreement (the "DFD Agreement") (see Note 7), between Journey and Dr. Reddy's Laboratories, LTD ("DRL") for a modified release oral minocycline for the treatment of rosacea (DFD-29"), Journey agreed to pay DRL additional consideration upon either an initial public offering of Journey's common stock ("Journey IPO") or an acquisition of Journey, with the agreement specifying that only one payment can be made. The contingent payment associated with a Journey IPO, is deemed to be achieved if, upon the completion of a Journey IPO, Journey's market capitalization on a fully diluted basis is $150 million or greater at the close of business on the date of the Journey IPO. The payment due for the achievement of the Journey IPO criteria is as follows: (a) issue DRL a number of shares of Journey's common stock equal to $5.0 million as calculated using a fifteen (15) day volume weighted average price of Journey's closing price, measured fifteen (15) days following the Journey IPO/up-listing, without any additional consideration (financial or otherwise) from DRL; or (b) make a cash payment to DRL equal to $5.0 million.

In the event the Journey IPO contingency is not satisfied, and Journey or its affiliate executes a definitive agreement for an acquisition event during the period beginning on June 29, 2021 and ending twenty-four (24) months after the regulatory approval of DFD-29, Journey shall pay to DRL: (a) 20% of the value of DFD-29 attributable to the acquisition event, if such acquisition event occurs between closing and NDA approval; or (b) 12% of the value of DFD-29 attributable to the acquisition event, if such acquisition event occurs within 24 months after NDA approval.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

The Company valued this contingent payment utilizing a Probability Weighted Expected Return Method (PWERM) model. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Journey's derivative liability that are categorized within Level 3 of the fair value hierarchy as of September 30, 2021 was as follows:

	September 30, 2021
Discount rate	30 %
Expected dividend yield	—
Expected term	3 months to 5 years
Probability of outcomes	3% to 70 %

At September 30, 2021 the value of the contingent payment warrant is $3.8 million, and was recorded on the unaudited condensed consolidated balance sheet. No liability was recorded at December 31, 2020.

The following tables classify into the fair value hierarchy of Fortress' financial instruments, measured at fair value as of September 30, 2021 and December 31, 2020:

	Fair Value Measurement as of September 30, 2021			
($ in thousands)	Level 1	Level 2	Level 3	Total
Assets				
Fair value of investment in Caelum	$ —	$ —	$ 56,860	$ 56,860
Total	$ —	$ —	$ 56,860	$ 56,860

	Fair Value Measurement as of September 30, 2021			
($ in thousands)	Level 1	Level 2	Level 3	Total
Liabilities				
Journey derivative warrant liabilities	$ —	$ —	$ 4,365	$ 4,365
Total	$ —	$ —	$ 4,365	$ 4,365

	Fair Value Measurement as of December 31, 2020			
($ in thousands)	Level 1	Level 2	Level 3	Total
Assets				
Fair value of investment in Caelum	$ —	$ —	$ 17,566	$ 17,566
Total	$ —	$ —	$ 17,566	$ 17,566

The tables below provide a roll-forward of the changes in fair value of Level 3 financial instruments as of September 30, 2021:

($ in thousands)	Investment in Caelum
Balance at December 31, 2020	$ 17,566
Change in fair value of investments	39,294
Balance at September 30, 2021	$ 56,860

($ in thousands)	Warrants liabilities
Balance at December 31, 2020	$ —
Additions:	
Journey contingent payment warrant	3,820
Journey placement agent warrant	545
Balance at September 30, 2021	$ 4,365

During the nine month period ended September 30, 2021, no transfers occurred between Level 1, Level 2, and Level 3 instruments.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

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 and its partner companies 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, 2021 and 2020, the purchase price of licenses acquired were classified as research and development-licenses acquired in the unaudited condensed consolidated statement of operations as reflected in the following table:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2021	2020	2021	2020
Partner companies:				
JMC	$ 76	$ —	$ 13,819	$ —
Mustang	630	287	1,630	1,837
Aevitas	7	162	34	162
Baergic	—	8	—	8
Oncogenuity	—	1	1	271
FBIO Acquisition Corp VIII	—	—	101	—
Total	$ 713	$ 458	$ 15,585	$ 2,278

Journey

On June 29, 2021, Journey entered into the DFD Agreement to obtain the global rightsfor the development and commercialization of DFD-29 with DRL. Pursuant to the terms and conditions of the DFD-29 Agreement, Journey agreed to pay $10.0 million, of which $2.0 million (the "First Installment") was paid upon execution and $8.0 million (the "Second Installment") which was paid on September 29, 2021. Additional contingent regulatory and commercial milestone payments totaling up to $163.0 million are also payable. Royalties ranging from approximately 10% to approximately 15% are payable on net sales of the DFD-29 product.

Additionally, Journey is required to fund and oversee the Phase III clinical trials at a cost approximating $24.0 million, based upon the current development plan and budget.

The DFD Agreement also includes contingent payments to be made to DRL in the event of a Journey IPO or the sale of Journey, See Note 6. The fair value of the contingent payment as of September 30, 2021 was deemed to be $3.8 million, and was recorded in research and development, licenses acquired expense for the nine months ended September 30, 2021.

Mustang

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
($ in thousands)	2021	2020	2021	2020
City of Hope National Medical Center				
CD123 (MB-102)	$ —	$ —	$ 250	$ 334
IL13Rα2 (MB-101)	—	—	—	333
HER2 (MB-103)	—	—	—	250
PSCA (MB-105)	250	—	250	—
Spacer	—	—	—	333
Mayo Clinic	—	—	750	—
Fred Hutchinson Cancer Research Center - CD20 (MB-106)	—	—	—	300
Leiden University Medical Centre	350	—	350	—
CSL Behring (Calimmune)	30	170	30	170
SIRION Biotech LentiBOOST™	—	117	—	117
Total	$ 630	$ 287	$ 1,630	$ 1,837

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

City of Hope National Medical Center

CD123 License (MB-102)

In February 2017, Mustang entered into an Amended and Restated Exclusive License Agreement with the City of Hope National Medical Center ("COH") to acquire intellectual property rights pertaining to CD123-specific chimeric antigen receptor ("CAR") engineered T cell ("CAR T") technology. Pursuant to this agreement, payments are due for the achievement of eight development milestones totaling $14.5 million; additional payments are due upon the occurrence of certain one-time events, and royalty payments as a percentage of revenue in the mid-single digits are due on net sales of licensed products.

For the nine months ended September 30, 2021, Mustang expensed a non-refundable milestone payment of $0.3 million for the 24th patient treated in the Phase 1 clinical study for MB-102 at COH. For the nine months ended September 30, 2020, Mustang expensed a non-refundable payment of $0.3 million in connection with Mustang's public underwritten offerings.

IL13Rα2 License (MB-101)

In February 2017, Mustang entered into an Amended and Restated Exclusive License Agreement with COH to acquire intellectual property rights pertaining to IL13Rα2-specific CAR T technology. Pursuant to this agreement, payments are due for the achievement of eight development milestones totaling $14.5 million; additional payments are due upon the occurrence of certain one-time events, and royalty payments as a percentage of revenue in the mid-single digits are due on net sales of licensed products.

For the nine months ended, September 30, 2020, Mustang expensed a non-refundable payment of $0.3 million in connection with Mustang's public underwritten offerings.

Spacer License

In February 2017, Mustang entered into an Amended and Restated Exclusive License Agreement with COH to acquire intellectual property rights pertaining to Spacer patent rights. Pursuant to this agreement, payments are due upon the occurrence of certain one-time events, and royalty payments as a percentage of revenue in the low single digits are due on net sales of licensed products.

For the nine months ended, September 30, 2020, Mustang expensed a non-refundable payment of $0.3 million in connection with Mustang's public underwritten offerings.

PSCA License (MB-105)

In May 2017, Mustang entered into an exclusive license agreement with COH for the use of prostate stem cell antigen ("PSCA") CAR T technology to be used in the treatment of prostate cancer, pancreatic cancer and other solid tumors. Pursuant to this agreement, Mustang paid an upfront fee of $0.3 million and pays an annual maintenance fee of $50,000. Additional payments are due for the achievement of ten development milestones totaling $14.9 million, and royalty payments in the mid-single digits are due on net sales of licensed products.

For the three and nine months ended, September 30, 2021, Mustang expensed a non-refundable milestone payment of $0.3 million for the twelfth patient treated in the Phase 1 clinical study of MB-105 at COH.

HER2 License (MB-103)

On May 31, 2017, Mustang entered into an exclusive license agreement with COH for the use of human epidermal growth factor receptor 2 ("HER2") CAR T technology, which will initially be applied in the treatment of glioblastoma multiforme and brain metastases from HER2+ malignancies. Pursuant to this agreement, Mustang paid an upfront fee of $0.6 million and pays an annual maintenance fee of $50,000 (which began in 2019). Additional payments are due for the achievement of ten development milestones totaling $14.9 million, and royalty payments as a percentage of revenue in the mid-single digits are due on net sales of licensed products.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

For the nine months ended, September 30, 2020, Mustang expensed a non-refundable milestone payment of $0.3 million for the twelfth patient treated in the Phase 1 clinical study of MB-103 at COH.

CSL Behring (Calimmune) License

On August 23, 2019, Mustang entered into a non-exclusive license agreement with CSL Behring (Calimmune, Inc.) ("Calimmune License") for the rights to the Cytegrity™ stable producer cell line for the production of viral vector for our lentiviral gene therapy program for the treatment of XSCID (MB-107 and MB-207). Mustang previously licensed the XSCID gene therapy program from St. Jude Children's Research Hospital, Inc. ("St. Jude") in August 2018. Pursuant to the terms of the Calimmune License, Mustang paid an upfront fee of $0.2 million. CSL Behring is eligible to receive additional payments totaling $1.2 million upon the achievement of three development and commercialization milestones. Royalty payments as a percentage of revenue in the low-single digits are due on net sales of licensed products.

For the three and nine months ended September 30, 2021 and 2020, Mustang expensed non-refundable milestone payments of $30,000 and $0.2 million, respectively, in connection with the Calimmune License.

Leiden University Medical Centre License

On September 8, 2021, Mustang entered into an exclusive, worldwide licensing agreement with Leiden University Medical Centre ("Leiden") for the use of a gene therapy under development for the treatment of severe immunodeficiency caused by RAG1 deficiency (the "Leiden License"). Pursuant to the Leiden License, Mustang expensed an upfront fee of $0.4 million. Additional payments are due for the achievement of certain development milestones totaling up to $31 million and royalty payments in the low to mid-single digits are due on net sales of licensed products.

For the three and nine months ended September 30, 2021, Mustang expensed an upfront payment of $0.4 million in connection with the Leiden License.

Fred Hutchinson Cancer Research Center - CD20 License (MB-106)

On July 3, 2017, Mustang entered into an exclusive, worldwide licensing agreement with Fred Hutchinson Cancer Research Center ("Fred Hutch") for the use of a CAR T therapy related to autologous T cells engineered to express a CD20-specific chimeric antigen receptor ("CD20 Technology License"). Pursuant to the CD20 Technology License, Mustang paid Fred Hutch an upfront fee of $0.3 million and will owe an annual maintenance fee of $50,000 on each anniversary of the license until the achievement by Mustang of regulatory approval of a licensed product using CD20 Technology. Additional payments are due for the achievement of eleven development milestones totaling $39.1 million, and royalty payments in the mid-single digits are due on net sales of licensed products.

For the nine months ended, September 30, 2020, Mustang expensed a non-refundable milestone payment of $0.3 million in connection with the Phase 1 clinical study of MB-106 at Fred Hutch.

Mayo Clinic – CAR T Technology License

On April 1, 2021, Mustang entered into an exclusive license agreement with the Mayo Foundation for Medical Education and Research (the "Mayo Clinic") for a novel technology that may be able to transform the administration of CAR T therapies and has the potential to be used as an off-the-shelf therapy. Pursuant to this agreement, Mustang paid an upfront fee of $0.8 million and will pay an annual maintenance fee of $25,000. Additional payments are due for each of two licensed products for the achievement of eleven development and commercial milestones totaling up to $92.6 million per product, and royalty payments in the mid-single digits are due on net sales of licensed products.

For the nine months ended September 30, 2021, Mustang expensed an upfront payment of $0.8 million pursuant to the terms of the license agreement.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

SIRION Biotech GmbH - LentiBOOST™

In October 2020, Mustang entered into a licensing agreement with SIRION Biotech ("SIRION") for the rights to SIRION's LentiBOOST™ technology for the development of MB-207, a lentiviral gene therapy for the treatment of previously transplanted XSCID patients (the "SIRION Technology License"). Pursuant to the SIRION Technology License, Mustang paid SIRION a one-time upfront fee of $0.1 million (€0.1 million). In addition, five future development milestone payments totaling up to approximately $5.6 million (€4.7 million) in the aggregate are due upon achievement of certain milestones. Additional milestone payments totaling up to $4.1 million (€3.5 million) in the aggregate are due in connection with the achievement of three commercial milestones and low- to mid-single digit royalties as a percentage of revenue are due on aggregate cumulative worldwide net sales of licensed products.

For the three and nine months ended September 30, 2020, Mustang expensed an upfront payment of $0.1 million pursuant to the terms of the SIRION Technology License.

8. Sponsored Research and Clinical Trial Agreements

Aevitas

In 2018, Aevitas entered into a Sponsored Research Agreement ("SRA") with the Trustees of the University of Pennsylvania ("UPenn SRA"), as amended in July 2019, for certain continued research and development activities related to the development of adeno-associated virus ("AAV") gene therapies in complement-mediated diseases. Also in 2018, Aevitas entered into an SRA with the University of Massachusetts ("UMass SRA"), as amended in January 2020, for certain continued research and development activities related to the development of AAV. For the three and nine months ended September 30, 2021 and 2020, Aevitas recorded the following expense in connection with its sponsored research and clinical trial agreements:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
($ in thousands)	**2021**	**2020**	**2021**	**2020**
UMass SRA	$ 17	163	$ 289	$ 218
UPenn SRA	—	—	—	567
Total	$ 17	$ 163	$ 289	$ 785

Mustang

For the three and nine months ended September 30, 2021 and 2020, 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)	**2021**	**2020**	**2021**	**2020**
City of Hope National Medical Center	$ —	$ —	$ —	$ 500
IL13Rα2 (MB-101)	199	96	992	422
CD123 (MB-102)	24	48	250	344
CS1 (MB-104)	138	65	510	835
HER2 (MB-103)	319	—	473	—
PSCA (MB-105)	23	—	69	—
Fred Hutchinson Cancer Research Center - CD20 (MB-106)	492	418	1,490	1,134
St. Jude Children's Research Hospital - XSCID (MB-107)	330	107	610	1,665
Mayo Clinic	231	—	464	—
Total	$ 1,756	$ 734	$ 4,858	$ 4,900

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

City of Hope Sponsored Research Agreement

In March 2015, in connection with Mustang's license with COH for the development of chimeric antigen receptor ("CAR") engineered T cell ("CAR T") technology, Mustang entered into a SRA in which Mustang was to fund continued research in the amount of $2.0 million per year, payable in four equal annual installments, through the first quarter of 2020. The research covered under this arrangement is for the IL13Rα2-directed CAR T program (MB-101), the CD123-directed CAR T program (MB-102), and the Spacer technology. For the nine months ended September 30, 2021 and 2020, Mustang recorded expense of nil and $0.5 million, respectively, in research and development expense in the Company's unaudited condensed consolidated statement of operations.

IL13Rα2 (MB-101) Clinical Research Support Agreements

In February 2017, Mustang entered into a clinical research support agreement for the IL13Rα2-directed CAR T program (the "IL13Rα2 CRA"). Pursuant to the terms of the IL13Rα2 CRA, Mustang made an upfront payment of approximately $9,300 and will contribute an additional $0.1 million related to patient costs in connection with the on-going investigator-initiated study. Further, Mustang agreed to fund approximately $0.2 million over three years pertaining to the clinical development of the IL13Rα2-directed CAR T program.

In October 2020, Mustang entered into a clinical research support agreement for the IL13Rα2-directed CAR T program for adult patients with leptomeningeal glioblastoma, ependymoma or medulloblastoma (the "IL13Rα2 Leptomeningeal CRA"). Pursuant to the terms of the IL13Rα2 Leptomeningeal CRA, Mustang made an upfront payment of approximately $29,000 and will contribute an additional $0.1 million per patient in connection with the on-going investigator-initiated study. Further, Mustang agreed to fund approximately $0.2 million annually pertaining to the clinical development of the IL13Rα2-directed CAR T program.

In March 2021, Mustang entered into a clinical research support agreement for an Institutional Review Board-approved, investigator-initiated protocol entitled: "Single Patient Treatment with Intraventricular Infusions of IL13Rα2-targeting and HER2-targeting Chimeric Antigen Receptor (CAR)-T cells for a Single Patient (UPN 181) with Recurrent Multifocal Malignant Glioma". Pursuant to the terms of this agreement, Mustang will contribute up to $0.2 million in connection with the on-going investigator-initiated study.

For the three months ended September 30, 2021 and 2020, Mustang recorded $0.2 million and $0.1 million, respectively, pursuant to the terms of these agreements. For the nine months ended September 30, 2021 and 2020, Mustang recorded $1.0 million and $0.4 million, respectively, pursuant to the terms of these agreements.

CD123 (MB-102) Clinical Research Support Agreement

In February 2017, Mustang entered into a clinical research support agreement for the CD123-directed CAR T program (the "CD123 CRA"). Pursuant to the terms of the CD123 CRA, Mustang made an upfront payment of $19,450 and will contribute an additional $97,490 per patient in connection with the on-going investigator-initiated study. Further, Mustang agreed to fund approximately $0.2 million over three years pertaining to the clinical development of the CD123-directed CAR T program. For the three months ended September 30, 2021 and 2020, Mustang recorded $24,000 and $48,000, respectively, pursuant to the terms of this agreement. For the nine months ended September 30, 2021 and 2020, Mustang recorded $0.3 million and $0.3 million, respectively, pursuant to the terms of this agreement.

CS1 (MB-104) Clinical Research and Support Agreement

In June 2020, Mustang entered into a clinical research and support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: "Phase I Study to Evaluate Cellular Immunotherapy Using Memory-Enriched T Cells Lentivirally Transduced to Express a CS1-Targeting, Hinge-Optimized, 41BB-Costimulatory Chimeric Antigen Receptor and a Truncated EGFR Following Lymphodepleting Chemotherapy in Adult Patients with CS1+ Multiple Myeloma." Under the terms of the agreement Mustang paid COH $0.8 million for costs incurred and will reimburse COH for costs associated with this trial, when incurred, not to exceed $2.4 million. The agreement will expire upon the delivery of a final study report or earlier. For the three months ended September 30, 2021 and 2020, Mustang recorded $0.1 million and $0.1 million, respectively, pursuant to the terms of this agreement. For the nine months ended September 30, 2021 and 2020, Mustang recorded $0.5 million and $0.8 million, respectively, pursuant to the terms of this agreement.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

HER2 (MB-103) Clinical Research Support Agreement

In September 2020, Mustang entered into a clinical research support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: "Phase I Study of Cellular Immunotherapy using Memory-Enriched T Cells Lentivirally Transduced to Express a HER2-Specific, Hinge-Optimized, 41BB-Costimulatory Chimeric Receptor and a Truncated CD19 for Patients with Recurrent/Refractory Malignant Glioma." Under the terms of the agreement Mustang paid COH $29,375 upon execution and will reimburse COH for costs associated with this trial not to exceed $3.0 million. The agreement will expire upon the delivery of a final study report or earlier. For the three and nine months ended September 30, 2021, Mustang recorded $0.3 million and $0.5 million, respectively, pursuant to the terms of this agreement.

PSCA (MB-105) Clinical Research Support Agreement

In October 2020, Mustang entered into a clinical research support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: "A Phase 1b study to evaluate PSCA-specific chimeric antigen receptor (CAR)-T cells for patients with metastatic castration resistant prostate cancer." Under the terms of the agreement Mustang paid COH $33,000 upon execution and will reimburse COH for costs associated with this trial not to exceed $2.3 million. The agreement will expire upon the delivery of a final study report or earlier. For the three months ended September 30, 2021 and 2020, Mustang recorded approximately $23,000 and nil, respectively, pursuant to the terms of this agreement. For the nine months ended September 30, 2021 and 2020, Mustang recorded $0.1 million and nil, respectively, pursuant to the terms of this agreement.

CD20 (MB-106) Clinical Trial Agreement with Fred Hutchinson Cancer Research Center

On July 3, 2017, in conjunction with the CD20 Technology License from Fred Hutchinson Cancer Research Center ("Fred Hutch"), Mustang entered into an investigator-initiated clinical trial agreement (the "CD20 CTA") to provide partial funding for a Phase 1/2 clinical trial at Fred Hutch evaluating the safety and efficacy of the CD20 Technology in patients with relapsed or refractory B-cell non-Hodgkin lymphomas. In connection with the CD20 CTA, Mustang agreed to fund up to $5.3 million of costs associated with the clinical trial, which commenced during the fourth quarter of 2017. In November 2020, the CD20 CTA was amended to include additional funding of approximately $0.8 million for the treatment of five patients with chronic lymphocytic leukemia. For the three months ended September 30, 2021 and 2020, Mustang recorded $0.5 million and $0.4 million, respectively, pursuant to the terms of this agreement. For the nine months ended September 30, 2021 and 2020, Mustang recorded $1.5 million and $1.1 million, respectively, pursuant to the terms of this agreement.

XSCID (MB-107) Data Transfer Agreement with St. Jude Children's Research Hospital

In June 2020, Mustang entered into a Data Transfer Agreement with St. Jude Children's Research Hospital ("St. Jude") under which Mustang will reimburse St. Jude for costs associated with St. Jude's clinical trial for the treatment of infants with X-linked severe combined immunodeficiency ("XSCID"). Pursuant to the terms of this agreement Mustang paid an upfront fee of $1.1 million on July 1, 2020, and will continue to reimburse St. Jude for costs incurred in connection with this trial. For the three months ended September 30, 2021 and 2020, Mustang recorded $0.3 million and $0.1 million, respectively, pursuant to the terms of this agreement. For the nine months ended September 30, 2021 and 2020, Mustang recorded $0.6 million and $1.7 million, respectively, pursuant to the terms of this agreement.

Sponsored Research Support Agreement with Mayo Clinic

In June 2021, Mustang entered into an SRA with the Mayo Clinic in which Mustang will fund research in the amount of $2.1 million over a period of two years. The research performed pursuant to this agreement will support technology Mustang has licensed from Mayo Clinic for a novel technology that may be able to transform the administration of CAR T therapies and has the potential to be used as an off-the-shelf therapy. For the three and nine months ended September 30, 2021, Mustang recorded $0.2 million and $0.5 million, respectively, in research and development expenses pursuant to the terms of this agreement.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

Oncogenuity

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
($ in thousands)	**2021**	**2020**	**2021**	**2020**
Columbia	$ 187	$ 125	$ 562	$ 250
Oxford	91	—	265	—
McCormick Labs	56	—	178	—
Total	$ 334	$ 125	$ 1,005	$ 250

Columbia Sponsored Research Agreement

Pursuant to the terms of a SRA entered into with the Trustees of Columbia University in the City of New York ("Columbia") in May 2020, to develop novel oligonucleotides for the treatment of genetically driven cancers (the "Columbia SRA"), Oncogenuity will make semi-annual research payments to Columbia semiannually for five years ending in November 2024, such payments not to exceed $4.8 million. For the three months ended September 30, 2021 and 2020, Oncogenuity recorded expense of $0.2 million and $0.1 million, respectively; and $0.6 million and $0.3 million, respectively, for the nine months ended September 30, 2021 and 2020.

The Chancellor Masters and Scholars of the University of Oxford Sponsored Research Agreement

In December 2020, Oncogenuity entered into a Sponsored Research Agreement with The Chancellor Masters and Scholars of the University of Oxford, (the "Oxford SRA"). For the three and nine months ended September 30, 2021, Oncogenuity recorded expense of $0.1 million and $0.3 million, respectively, in research and development in the Company's unaudited condensed consolidated statement of operations. No expense was recorded in 2020.

The Regents of the University of California Sponsored Research Agreement

In December 2020, Oncogenuity entered into a SRA with The Regents of the University of California, with Frank McCormick PhD, FRS as principal investigator ("McCormick SRA"). For the three and nine months ended September 30, 2021Oncogenuity recorded expense of $0.1 million and $0.2 million, respectively, in research and development in the Company's unaudited condensed consolidated statement of operations. No expense was recorded in 2020.

9. Intangibles, net

On March 31, 2021 Journey executed an Asset Purchase Agreement (the "Qbrexza APA") with Dermira, Inc. a subsidiary of Eli Lilly and Company ("Dermira"). Pursuant to the terms of the agreement Journey acquired the rights to Qbrexza® (glycopyrronium), a prescription cloth towelette to treat primary axillary hyperhidrosis in patients nine years of age or older.

Upon Hart-Scott-Rodino clearance, which was received on May 13, 2021, Journey paid the upfront fee of $12.5 million to Dermira. In addition, Dermira is eligible to receive up to $144 million in the aggregate upon the achievement of certain milestones. Royalties ranging from the lower teen digits to the upper teen digits will be payable on net sales of Qbrexza® products, of which royalty amounts are subject to 50% diminution in the event of loss of exclusivity due to the introduction of an authorized generic.

Upon closing of the Qbrexza® purchase, Journey became substituted for Dermira as the plaintiff in U.S. patent litigation commenced by Dermira on October 21, 2020 in the U.S. District Court of Delaware (the "Patent Litigation") against Perrigo Pharma International DAC ("Perrigo") alleging infringement of certain patents covering Qbrexza® (the "Qbrexza® Patents"), which are included among the proprietary rights to Qbrexza® to be acquired pursuant to the Qbrexza APA. The Patent Litigation was initiated following the submission by Perrigo, in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), of an Abbreviated New Drug Application ("ANDA"). The ANDA seeks approval to market a generic version of Qbrexza® prior to the expiration of the Qbrexza® Patents and alleges that the Qbrexza® Patents are invalid. Perrigo is subject to a 30-month stay preventing it from selling a generic version, but that stay is set to expire on March 9, 2023. Trial in the Patent Litigation is scheduled for September 19, 2022. The Company cannot make any predictions about the final outcome of this matter or the timing thereof.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

The purchase price of $12.5 million included the asset Qbrexza as well as finished goods and raw material inventory. Journey also has the obligation to accept all product returns related to sales made by Dermira, which is estimated to be approximately $1.4 million. The Company allocated the upfront payment to inventory, since the fair value of the inventory and Qbrexza rights exceed the purchase price. The future contingent milestone payments, if achieved, will be recorded to intangible asset and amortized over the seven year life of the asset commencing on the closing date.

The table below provides a summary of the Journey intangible assets as of September 30, 2021 and December 31, 2020, respectively:

($ in thousands)	Estimated Useful Lives (Years)	September 30, 2021 (Unaudited)	December 31, 2020
Total intangible assets – asset purchases	3 to 7	$ 19,003	$ 18,606
Accumulated amortization		(5,960)	(3,977)
Net intangible assets		$ 13,043	$ 14,629

The table below provides a summary for the nine months ended September 30, 2021, of Journey's recognized expense related to its product licenses, which was recorded in costs of goods sold on the unaudited condensed consolidated statement of operations:

($ in thousands)	Intangible Assets, Net
Beginning balance at January 1, 2021	$ 14,629
Additions:	
Exelderm milestone	397
Amortization expense	(1,983)
Ending balance at September 30, 2021	$ 13,043

The future amortization of these intangible assets is as follows:

($ in thousands)	Ximino®	Accutane®	Total Amortization
Three months ending December 31, 2021	$ 255	$ 236	$ 491
Year ended December 31, 2022	1,019	946	1,965
Year ended December 31, 2023	1,019	945	1,964
Year ended December 31, 2024	1,019	946	1,965
Year ended December 31, 2025	1,019	945	1,964
Thereafter	595	157	752
Sub-total	$ 4,926	$ 4,175	$ 9,101
Assets not yet placed in service:			
Anti-itch product license acquisition	—	—	3,942
Total	$ 4,926	$ 4,175	$ 13,043

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

10. Debt and Interest

Debt

Total debt consists of the following as of September 30, 2021 and December 31, 2020:

($ in thousands)	September 30, 2021	December 31, 2020	Interest rate	Maturity
	(Unaudited)			
Total notes payable - Oaktree Note	$ 60,450	$ 60,000	11.00 %	August - 2025
Less: Discount on notes payable	(7,431)	(8,323)		
Total notes payable	$ 53,019	$ 51,677		

Oaktree Note

On August 27, 2020 (the "Closing Date"), Fortress, as borrower, entered into a $60.0 million senior secured credit agreement with Oaktree (the "Oaktree Agreement" and the debt thereunder, the "Oaktree Note"). The Oaktree Note bears interest at a fixed annual rate of 11.0%, payable quarterly and maturing on the fifth anniversary of the Closing Date, August 27, 2025, (the "Maturity Date"). The Company is required to make quarterly interest-only payments until the Maturity Date, at which point the outstanding principal amount is due. The Company may voluntarily prepay the Oaktree Note at any time subject to a Prepayment Fee, the mechanics of which are set forth therein. The Company is required to make mandatory prepayments of the Oaktree Note under various circumstances set forth in the Oaktree Agreement. No amounts paid or prepaid may be reborrowed without Oaktree consent.

Pursuant to the terms of the Oaktree Agreement on the Closing Date the Company paid Oaktree an upfront commitment fee equal to 3% of the $60.0 million, or $1.8 million. In addition, the Company paid a $35,000 agency fee to the Oaktree administrative agent entity, which was due on the Closing Date and will be due annually, together with $2.5 million, in fees that were due to third parties involved in the transaction.

In connection with the Oaktree Note, the Company issued warrants to Oaktree and certain of its affiliates to purchase up to 1,749,450 shares of common stock (see Note 15) with a relative fair value of $4.4 million.

The Company recorded the fees totaling $8.7 million ($1.8 million to Oaktree, $2.5 million of expenses paid to third-parties and $4.4 million representing the relative fair value of the Oaktree Warrants) to debt discount. These costs are being amortized over the term of the Oaktree Note.

AstraZeneca's notification of its intent to acquire Caelum, received on September 28, 2021, is defined in the Oaktree Agreement as a monetization event and as such, triggered a $10 million prepayment and an applicable prepayment fee of $0.5 million. Accordingly, as of September 30, 2021, the prepayment amount and the fee were classified as short-term on the Company's unaudited condensed consolidated balance sheet. The prepayment fee of $0.5 million was included in interest expense for the three months ended September 30, 2021. The Company paid the $10.5 million on October 12, 2021.

Partner Company Installment Payments – Licenses

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

The following tables show the details of partner company installment payments – licenses for the periods presented.

	September 30, 2021			
($ in thousands)	Ximino [1]	Accutane [2]	Anti-Itch Product [3]	Total
Partner company installment payments - licenses, short-term	$ 2,000	$ 2,000	$ 1,000	$ 5,000
Less: imputed interest	(472)	(84)	(11)	(567)
Sub-total partner company installment payments - licenses, short-term	$ 1,528	$ 1,916	$ 989	$ 4,433
Partner company installment payments - licenses, long-term	$ 3,000	$ 1,000	$ —	$ 4,000
Less: imputed interest	(428)	(33)	—	(461)
Sub-total partner company installment payments - licenses, long-term	$ 2,572	$ 967	$ —	$ 3,539
Total partner company installment payments - licenses	$ 4,100	$ 2,883	$ 989	$ 7,972

	December 31, 2020			
($ in thousands)	Ximino [1]	Accutane [2]	Anti-Itch Product [3]	Total
Partner company installment payments - licenses, short-term	$ 2,000	$ 500	$ 2,800	$ 5,300
Less: imputed interest	(602)	(122)	(54)	(778)
Sub-total partner company installment payments - licenses, short-term	$ 1,398	$ 378	$ 2,746	$ 4,522
Partner company installment payments - licenses, long-term	$ 5,000	$ 3,000	$ 1,000	$ 9,000
Less: imputed interest	(775)	(88)	—	(863)
Sub-total partner company installment payments - licenses, long-term	$ 4,225	$ 2,912	$ 1,000	$ 8,137
Total partner company installment payments - licenses	$ 5,623	$ 3,290	$ 3,746	$ 12,659

Note 1: Imputed interest rate of 11.96% and maturity date of July 22, 2024.
Note 2: Imputed interest rate of 4.03% and maturity date of July 29, 2023.
Note 3: Imputed interest rate of 4.25% and maturity date of January 1, 2022.

Interest Expense

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

	Three Months Ended September 30,					
	2021			2020		
($ in thousands)	*Interest*	*Fees[1]*	Total	*Interest*	*Fees[1]*	Total
IDB Note	$ —	$ —	$ —	$ 77	—	$ 77
2017 Subordinated Note Financing	—	—	—	694	1,374	2,068
2019 Notes	—	—	—	172	—	172
2018 Venture Notes	—	—	—	387	638	1,025
LOC Fees	14	—	14	14	—	14
Mustang Horizon Notes	—	—	—	895	1,792	2,687
Oaktree Note	2,136	342	2,478	624	108	732
Partner company convertible preferred shares	1,034	378	1,412	—	—	—
Partner company dividend payable	365	—	365	—	—	—
Partner company installment payments - licenses [2]	175	—	175	187	—	187
Other	—	—	—	(4)	—	(4)
Total Interest Expense and Financing Fee	$ 3,724	$ 720	$ 4,444	$ 3,046	$ 3,912	$ 6,958

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

	Nine Months Ended September 30,					
	2021			2020		
($ in thousands)	*Interest*	*Fees[1]*	Total	*Interest*	*Fees[1]*	Total
IDB Note	$ —	$ —	$ —	$ 246	$ -	$ 246
2017 Subordinated Note Financing	—	—	—	2,870	1,890	4,760
2019 Notes	—	—	—	710	—	710
2018 Venture Notes	—	—	—	1,253	1,000	2,253
LOC Fees	37	—	37	45	—	45
Mustang Horizon Notes	—	—	—	1,585	2,321	3,906
Oaktree Note	5,455	975	6,430	624	108	732
Partner company convertible preferred shares	1,034	648	1,682		—	—
Partner company dividend payable	628	—	628	—	—	—
Partner company installment payments - licenses [2]	616	—	616	492	—	492
Other	—	—	—	(2)	—	(2)
Total Interest Expense and Financing Fee	$ 7,770	$ 1,623	$ 9,393	$ 7,823	$ 5,319	$ 13,142

Note 1: Amortization of fees in connection with debt raises.
Note 2: Imputed interest expense related to Ximino, Accutane and inti-itch cream acquisitions.

Journey Working Capital Line of Credit

On March 31, 2021, Journey entered into an agreement with East West Bank ("EWB") in which EWB agreed to provide a $7.5 million working capital line of credit. eredit is secured by Jounrey's receivables and cash. Interest on the line is the greater of 4.25% or the Prime Rate plus 1%. The agreement matures in 36 months. There have been no amounts drawn upon this line of credit during the three or nine months ended September 30, 2021.

Journey paid an origination fee of $56,250 in connection with the issuance of the working capital line of credit. In addition, Journey agreed to pay certain third party fees incurred by EWB, as well as legal fees incurred by Journey in connection with the EWB Loan totaling approximately $0.1 million. As of September 30, 2021 fees totaling approximately $0.1 million were recorded as a deferred asset on the unaudited condensed consolidated balance sheet.

11. Journey 8% Cumulative Convertible Class A Preferred Offering

In March 2021, Journey commenced an offering of 8% Cumulative Convertible Class A Preferred Stock ("Journey Preferred Offering") in an aggregate minimum amount of $12.5 million and an aggregate maximum amount of $30.0 million. The Journey Preferred Offering terminated on July 18, 2021. The Journey Preferred Stock automatically converts into Journey's Common Stock upon a sale of Journey or a financing in an amount of at least $25.0 million within a year of the closing date of the Journey Preferred Offering (extendable by another six months at Journey's option) at a discount of 15% to the per share qualified stock price. In the event that neither a sale of Journey nor a $25.0 million financing is completed, the Journey Preferred Stock will be exchanged for shares of Fortress common stock, at a 7.5% discount to the average Fortress common stock trading price over the 10-day period preceding such exchange.

The Company evaluated the terms of the Journey Preferred Offering under ASC 480, *Distinguishing Liabilities from Equity*, and determined the instrument met the criteria to be recorded as a liability. The value at conversion does not vary with the value of Journey's common shares, therefore the settlement provision would not be considered a conversion feature. Accordingly, the Company determined liability classification is appropriate and as such, this instrument is accounted for as a liability on the Company's unaudited condensed consolidated balance sheet.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

Dividends on the Journey Preferred Stock will be paid quarterly in shares of Fortress common stock based upon a 7.5% discount to the average trading price over the 10-day period preceding the dividend payment date As consideration for the foregoing, Journey will issue to Fortress additional shares of common stock, debt securities, or a combination of the two for the amount of such dividend. At September 30, 2021 the Company recorded Shares Issuable of $0.4 million representing the dividend payable on September 30, 2021 to the Journey Preferred Stock shareholders, the payment of which was contingent upon an effective registration statement, which was declared effective on November 4, 2021. Dividends paid on the Journey Preferred Stock are recorded as interest expense on the unaudited condensed consolidated statements of operations. For the three and nine months ended September 30, 2021, interest expense was $0.4 million and $0.6 million, respectively, associated with the Journey Preferred Stock.

Journey has completed five closings in connection with the Journey Preferred Offering (" Journey Closings"). In connection with the Journey Closings, Journey issued an aggregate of 758,680 Class A Preferred shares at a price of $25.00 per share, for gross proceeds of $19.0 million. Following the payment of placement agent fees of $1.9 million, and other expenses of $0.1 million, Journey received $17.0 million of net proceeds. Non-cash fees were the initial fair value of the contingent placement agent warrant of $0.4 million (see Note 6). The fees were recorded to debt discount on the unaudited interim condensed consolidated balance sheet at September 30, 2021.

12. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

($ in thousands)	September 30, 2021 (Unaudited)	December 31, 2020
Accounts Payable	$ 42,707	$ 11,412
Accrued expenses:		
Professional fees	1,320	1,236
Salaries, bonus and related benefits	7,100	6,701
Research and development	6,541	5,007
Research and development - manufacturing	—	518
Research and development - license maintenance fees	645	461
Research and development - milestones	1,332	600
Accrued royalties payable	4,496	2,682
Accrued coupon expense	12,449	12,869
Income taxes payable	—	136
Return reserve	3,652	2,580
Other	2,613	1,187
Total accounts payable and accrued expenses	$ 82,855	$ 45,389

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

13. Non-Controlling Interests

Non-controlling interests in consolidated entities are as follows:

($ in thousands)	As of September 30, 2021 NCI equity share	For the Nine Months Ended September 30, 2021 Net loss attributable to non-controlling interests	As of September 30, 2021 Non-controlling interests in consolidated entities	Non-controlling ownership
FBIO Acquisition Corp VIII	$ (247)	$ (131)	$ (378)	32.0 %
Aevitas	(4,049)	(751)	(4,800)	45.9 %
Avenue [2]	2,058	(2,182)	(124)	77.5 %
Baergic	(1,995)	(29)	(2,024)	39.5 %
Cellvation	(1,400)	(100)	(1,500)	22.1 %
Checkpoint [1]	59,574	(20,618)	38,956	81.2 %
Coronado SO	(290)	—	(290)	13.0 %
Cyprium	(1,276)	(623)	(1,899)	29.8 %
Helocyte	(5,401)	(65)	(5,466)	18.3 %
JMC	886	(2,339)	(1,453)	7.2 %
Mustang [2]	136,441	(35,787)	100,654	82.4 %
Oncogenuity	(581)	(555)	(1,136)	24.9 %
Tamid	(730)	—	(730)	22.8 %
Total	$ 182,990	$ (63,180)	$ 119,810	

($ in thousands)	As of December 31, 2020 NCI equity share	For the twelve months ended December 31, 2020 Net loss attributable to non-controlling interests	As of December 31, 2020 Non-controlling interests in consolidated entities	Non-controlling ownership
FBIO Acquisition Corp VIII	$ (7)	(27)	$ (34)	10.0 %
Aevitas	(2,370)	(823)	(3,193)	39.0 %
Avenue [2]	5,800	(3,974)	1,826	77.4 %
Baergic	(1,662)	(97)	(1,759)	39.5 %
Cellvation	(1,089)	(182)	(1,271)	22.1 %
Checkpoint [1]	41,704	(13,265)	28,439	80.4 %
Coronado SO	(290)	—	(290)	13.0 %
Cyprium	567	(1,478)	(911)	30.5 %
Helocyte	(4,986)	(259)	(5,245)	18.8 %
JMC	138	491	629	7.1 %
Mustang [2]	116,060	(36,429)	79,631	80.9 %
Oncogenuity	(82)	(376)	(458)	25.3 %
Tamid	(663)	(40)	(703)	22.8 %
Total	$ 153,120	$ (56,459)	$ 96,661	

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.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

14. Net Loss per Common Share

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

The following shares of potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding, as the effect of including such securities would be anti-dilutive for the nine months ended September 30, 2021:

	Nine Months Ended September 30,	
	2021	2020
Warrants to purchase Common Stock	4,535,804	3,026,693
Options to purchase Common Stock	836,732	1,187,600
Unvested Restricted Stock	16,372,752	14,305,949
Unvested Restricted Stock Units	209,595	434,215
Total	21,954,883	18,954,457

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 months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2021	2020	2021	2020
Employee and non-employee awards	$ 2,185	$ 1,231	$ 6,236	$ 3,868
Executive awards of Fortress Companies' stock	377	369	1,070	1,136
Warrants	—	32	—	97
Partner Companies:				
Avenue	69	161	299	592
Checkpoint	779	725	2,319	2,095
Mustang	884	606	2,427	2,368
Other	32	47	98	163
Total stock-based compensation expense	$ 4,326	$ 3,171	$ 12,449	$ 10,319

For the three months ended September 30, 2021 and 2020, approximately $1.1 million and $0.7 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 $3.2 million and $2.5 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, 2021 and 2020, approximately $3.1 million and $2.5 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 $9.4 million and $7.8 million, respectively, was included in general and administrative expenses in connection with grants made to employees, members of the board of directors and consultants.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

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, 2020	1,053,490	$ 5.02	$ 647,482	2.63
Forfeited	(35,000)	4.33	—	—
Options vested and expected to vest at September 30, 2021	1,018,490	$ 5.04	$ 666,957	1.93
Options vested and exercisable at September 30, 2021	1,018,490	$ 5.04	$ 666,957	1.93

As of September 30, 2021, 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, 2020	15,507,504	$ 2.49
Restricted stock granted	2,330,678	3.17
Restricted stock vested	(301,492)	2.75
Restricted stock units granted	1,130,842	4.13
Restricted stock units forfeited	(96,750)	3.49
Restricted stock units vested	(493,027)	3.51
Unvested balance at September 30, 2021	18,077,755	$ 2.64

As of September 30, 2021 and 2020, the Company had unrecognized stock-based compensation expense related to restricted stock and restricted stock unit awards of approximately $21.1 million and $17.5 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 3.1 years and 3.9 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, 2020	4,590,621	$ 3.17	$ 607,848	4.85
Expired	(60,000)	1.37	—	
Forfeited	(25,000)	3.00	—	
Outstanding as of September 30, 2021	4,505,621	$ 3.20	$ 632,587	4.19
Exercisable as of September 30, 2021	4,370,621	$ 3.23	$ 475,087	4.11

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

In connection with the Oaktree Note (see Note 10), the Company issued warrants to Oaktree and certain of its affiliates to purchase up to 1,749,450 shares of common stock at a purchase price of $3.20 per share (the "Oaktree Warrants"). Oaktree is entitled to additional warrants if at any time prior to the expiration of the Oaktree Warrants in event the Company issues equity, warrants or convertible notes (collectively known as "Security Instruments") at a price that is less than 95% of the market price of the Company's Common Stock on the trading day prior to the issuance of the Security Instruments.

The Oaktree Warrants expire on August 27, 2030 and may be net exercised at the holder's election. The Company also agreed to file a registration statement on Form S-3 to register for resale the shares of common stock issuable upon exercise of the Warrants.

The Company evaluated the accounting treatment of the Oaktree Warrants and determined that the Oaktree Warrants met the scope exception of *ASC 815-10-15-74(a) Derivatives and Hedging* and therefore should be classified in stockholders' equity. As such the Company used a Black-Scholes model to value the Oaktree Warrants, utilizing the following inputs: term of 10 years, volatility of 86.8%, and risk-free rate of return of 0.74%, yielding a value of $4.8 million. *ASC 470-20-25-2 Debt – Debt with Conversion and Other Options* dictates that debt or stock issued with detachable warrants requires the proceeds to be allocated to the two instruments based on their relative fair values. The relative fair value of the warrants was determined to be $4.4 million and was recorded as a component of Stockholders' Equity in the Company's unaudited condensed consolidated balance sheet.

Employee Stock Purchase Plan ("ESPP")

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, 2021, 636,408 shares have been purchased and 363,592 shares are available for future sale under the Company's ESPP. Share-based compensation expense recorded was approximately $31,000 and $38,000, respectively, for the three months ended September 30, 2021 and 2020 and approximately $0.1 million and $0.1 million, respectively, for the nine months ended September 30, 2021 and 2020.

Capital Raises

Journey 8% Cumulative Convertible Class A Preferred Offering

See Note 11.

At-the-Market Offering

For the nine-month period ended September 30, 2021, the Company issued 786,300 shares pursuant to the terms of the Company's Amended and Restated At Market Issuance Sales Agreement, or Sales Agreement (the "ATM"), with B. Riley FBR, Inc. at an average price of $ 3.60 for gross proceeds of $2.8 million, before fees of approximately $0.1 million. For the nine month period ended September 30, 2020, the Company issued approximately 16.4 million shares of common stock under the ATM at an average price of $ 2.74 per share for gross proceeds of $44.8 million. In connection with these sales, the Company paid aggregate fees of approximately $1.6 million.

Mustang At-the-Market Offering

During the nine months ended September 30, 2021, Mustang issued approximately 17.3 million shares of common stock at an average price of $3.87 per share for gross proceeds of $66.9 million under the Mustang ATM. In connection with these sales, Mustang paid aggregate fees of approximately $1.3 million. During the nine months ended September 30, 2020, Mustang issued approximately 7.2 million shares of common stock at an average price of $3.56 per share for gross proceeds of $25.6 million under the Mustang ATM. In connection with these sales, Mustang paid aggregate fees of approximately $0.5 million.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

Pursuant to the Founders Agreement, Mustang issued 517,304 shares of common stock to Fortress at a weighted average price of $3.84 per share and recorded 52,019 shares issuable to Fortress for the nine months ended September 30, 2021 in connection with the shares issued under the Mustang ATM. During the nine months ended September 30, 2020, Mustang issued 117,405 shares of common stock to Fortress at a weighted average price of $3.56 per share in connection with the Mustang ATM.

On October 23, 2020, Mustang filed a shelf registration statement No. 333-249657 on Form S-3 (the "Mustang 2020 S-3"), which was declared effective on December 4, 2020. Under the Mustang 2020 S-3, Mustang may sell up to a total of $100.0 million of its securities. As of September 30, 2021, approximately $19.3 million of the Mustang 2020 S-3 remains available for sales of securities.

On April 23, 2021, Mustang filed a shelf registration statement on Form S-3 (the "Mustang 2021 S-3"), which was declared effective on May 24, 2021. Under the Mustang 2021 S-3, Mustang may sell up to a total of $200.0 million of its securities upon being declared effective. As of September 30, 2021, there have been no sales of securities under the Mustang 2021 S-3.

Checkpoint At-the-Market Offering

During the nine months ended September 30, 2021, Checkpoint issued a total of 10,860,983 shares of common stock under the Checkpoint ATM for aggregate total gross proceeds of approximately $37.2 million at an average selling price of $3.42 per share, resulting in net proceeds of approximately $36.3 million after deducting commissions and other transaction costs. Pursuant to the Founders Agreement, Checkpoint issued 271,515 shares of common stock to Fortress at a weighted average price of $3.41 per share.

During the nine months ended September 30, 2020, Checkpoint sold a total of 3,614,344 shares of common stock under the Checkpoint ATM for aggregate total gross proceeds of approximately $8.7 million at an average selling price of $2.40 per share, resulting in net proceeds of approximately $8.4 million after deducting commissions and other transaction costs.

Checkpoint Underwritten Offering

In September 2020, Checkpoint completed an underwritten public offering in which it sold 7,321,429 shares of its common stock at a price of $2.80 per share for gross proceeds of approximately $20.5 million. Total net proceeds from the offering were approximately $18.9 million, net of underwriting discounts and offering expenses of approximately $1.6 million. The shares were sold under a shelf registration statement on Form S-3 that Checkpoint filed in November 2017 and was declared effective in December 2017 ("the Checkpoint S-3").

Pursuant to the Founders Agreement, Checkpoint issued 273,379 shares of common stock to Fortress at a weighted average price of $2.92 per share for the Checkpoint ATM offerings and the Checkpoint Underwritten offering.

At September 30, 2021, approximately $58.7 million of the Checkpoint shelf remains available for sale under the Checkpoint S-3.

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. The Company has director and officer insurance to address such claims. The Company and its partner companies also provide indemnification of contractual counterparties in certain situations, including without limitation to clinical sites, service providers and licensors.

In addition, we act, and are likely to continue acting, as indemnitor of potential losses or liabilities that may be experienced by one or more of our affiliated companies and/or their partners or investors. For instance, under that certain Indemnification Agreement, dated as of November 12, 2018 (the "Indemnification Agreement"), we agreed to indemnify InvaGen and its affiliates for losses they may sustain in connection with inaccuracies that may appear in the representations and warranties that Avenue made to InvaGen in the Avenue SPMA, as such representations and warranties were given as of the dates of signing and first closing, and as may be required to be given as of the second stage closing under the Avenue SPMA as well.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

The maximum amount of indemnification we may have to provide under the Indemnification Agreement is $35.0 million, and such obligation terminates upon the consummation of the Merger Transaction (as defined in the Avenue SPMA). In the event of payment by us of any such indemnification amount, we would be able to recoup such amounts (other than our pro rata share of the indemnification as a shareholder in Avenue) from the Merger Transaction proceeds, but if the Merger Transaction never occurs, we would have no means of recouping such previously-paid indemnification amounts. If we become obligated to pay all or a portion of such indemnification amounts (regardless of whether or not we are partially reimbursed out of the proceeds of the Merger Transaction), our business and the market value of our common stock and/or debt securities may be materially adversely impacted.

Legal Proceedings

On March 31, 2021 Journey executed an Asset Purchase Agreement (the "Qbrexza APA") with Dermira, Inc. a subsidiary of Eli Lilly and Company ("Dermira"). Pursuant to the terms of the agreement Journey acquired the rights to Qbrexza® (glycopyrronium), a prescription cloth towelette to treat primary axillary hyperhidrosis in patients nine years of age or older. Upon closing of the Qbrexza® purchase, Journey became substituted for Dermira as the plaintiff in U.S. patent litigation commenced by Dermira on October 21, 2020 in the U.S. District Court of Delaware (the "Patent Litigation") against Perrigo Pharma International DAC ("Perrigo") alleging infringement of certain patents covering Qbrexza® (the "Qbrexza® Patents"), which are included among the proprietary rights to Qbrexza® to be acquired pursuant to the Qbrexza APA. The Patent Litigation was initiated following the submission by Perrigo, in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), of an Abbreviated New Drug Application, or ANDA. The ANDA seeks approval to market a generic version of Qbrexza® prior to the expiration of the Qbrexza® Patents and alleges that the Qbrexza® Patents are invalid. Perrigo is subject to a 30-month stay preventing it from selling a generic version, but that stay is set to expire on March 9, 2023. Trial in the Patent Litigation is scheduled for September 19, 2022. The Company cannot make any predictions about the final outcome of this matter or the timing thereof.

To our knowledge, there are no other legal proceedings pending against us, other than routine actions and administrative proceedings, and other actions not deemed material are not expected to have a material adverse effect on our financial condition, results of operations, or cash flows. In the ordinary course of business, however, the Company 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

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 10.6% of the Company's issued and outstanding Common Stock as of September 30, 2021. The Company's Executive Vice Chairman, Strategic Development owns approximately 11.4% of the Company's issued and outstanding Common Stock as of September 30, 2021.

Shared Services Agreement with TG Therapeutics, Inc ("TGTX")

In July 2015, 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, 2021 and 2020, the Company invoiced TGTX $0.1 million and 0.1 million, respectively. For the nine months ended September 30, 2021 and 2020, the Company invoiced TGTX $0.3 million and $0.3 million, respectively. On September 30, 2021, the amount due from TGTX related to this arrangement approximated $69,000.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

Shared Services Agreement with Journey

On November 12, 2021, Journey and the Company entered into an arrangement to share the cost of certain legal, finance, regulatory, and research and development employees. The Company's Executive Chairman and Chief Executive Officer is the Executive Chairman of Journey. Under the terms of the Agreement, Journey will reimburse the Company for the salary and benefit costs associated with these employees based upon actual hours worked on Journey related projects following the completion of their initial public offering. To date, the Company's employees have provided services to Journey totaling approximately $0.4 million. Upon completion of Journey's initial public offering the amount due will be converted into Journey common stock at the initial public offering price.

Desk Space Agreements with TGTX and Opus Point Partners Management, LLC ("OPPM")

In connection with the Company's Desk Space Agreements for the New York, NY office space, for the three months ended September 30, 2021 and 2020, the Company had paid $0.7 million and $0.7 million in rent, respectively, and invoiced TGTX and OPPM approximately $0.4 million and $0.4 million and nil and nil respectively, for their prorated share of the rent base. At September 30, 2021, there were no material amounts due related to this arrangement from TGTX or OPPM.

As of July 1, 2018, TGTX employees began to occupy desks in the Waltham, MA office under the Desk Share Agreement. TGTX began to pay their share of the rent based on actual percentage of the office space occupied on a month by month basis. For the three months ended September 30, 2021 and 2020, the Company had paid approximately $0.1 million and $0.1 million in rent for the Waltham, MA office, and invoiced TGTX approximately $21,000 and $29,000, respectively.

Avenue Secondment with Journey

Effective June 1, 2021, the Company, InvaGen, Avenue and Journey entered into a secondment agreement for a certain Avenue employee to be seconded to Journey. During the secondment, Journey will have the authority to supervise the Avenue employee and will reimburse Avenue for the employee's salary and salary-related costs. The term of this agreement lasts until the approval of IV tramadol by the FDA or until the employee's services are needed again by the Company. The amount reimbursable to Avenue is $0.1 million for the three and nine months ended September 30, 2021.

Avenue Key Employee Retention

Effective June 24, 2021, the Company and certain of Avenue's key employees entered into retention agreements (the "Avenue Retention Agreements") pursuant to which retention bonuses are payable only if the Merger Transaction (as defined in the Avenue SPMA) occurs and the applicable employee remains employed by Avenue immediately prior to the closing of such Merger Transaction. These Avenue Retention Agreements are effective until the earlier of the consummation of the Merger Transaction or the termination of the Avenue SPMA. Amounts potentially payable to these Avenue key employees were $2.9 million as of September 30, 2021. Effective upon termination of the Avenue SPMA, which was terminated on November 1, 2021, the amounts payable under the Fortress Retention Agreements no longer have any force or effect.

Journey Promissory Note:

On September 30, 2021, the Company increased the Journey promissory note by $9.5 million in response to a cyber incident that occurred at Journey and resulted in $9.5 million of fraudulent payments. The $9.5 million contribution was approved by the boards of directors of both the Company and Journey, and will ensure that Journey's accounts payable function will continue to operate smoothly. This contribution, along with $ 5.2 million already outstanding under the Journey Promissory Note, will convert into Journey common stock upon the consummation of the Journey IPO at the Journey IPO price. The amounts associated with the Journey Promissory Note are eliminated in the unaudited condensed consolidated balance sheets.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

Founders Agreement

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, 2020, filed with the SEC on March 31, 2021. The following table summarizes, by partner company, the effective date of the Founders Agreements and PIK dividend or equity fee payable to the Company in accordance with the terms of the Founders Agreements, Exchange Agreements, and the subsidiaries' certificates of incorporation:

Fortress Partner Company	Effective Date [1]	PIK Dividend as a % of fully diluted outstanding capitalization	Class of Stock Issued
Helocyte	March 20, 2015	2.5 %	Common Stock
Avenue	February 17, 2015	0.0 %[2]	Common Stock
Mustang	March 13, 2015	2.5 %	Common Stock
Checkpoint	March 17, 2015	0.0 %[3]	Common Stock
Cellvation	October 31, 2016	2.5 %	Common Stock
Caelum	January 1, 2017	0.0 %[4]	Common Stock
Baergic	December 17, 2019 [4]	2.5 %	Common Stock
Cyprium	March 13, 2017	2.5 %	Common Stock
Aevitas	July 28, 2017	2.5 %	Common Stock
Oncogenuity	April 22, 2020 [4]	2.5 %	Common Stock
FBIO Acquisition Corp. VIII	November 7, 2017 [4]	0.0 %	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 Avenue SPMA entered into between, Avenue, the Company and InvaGen (together, the " SPMA Parties"), the SPMA Parties entered into a waiver and termination 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 until such time as InvaGen beneficially owns less than 75% of the shares of Avenue common stock it acquired under the first closing of the Avenue SPMA.

Note 3: Instead of a PIK dividend, Checkpoint pays the Company an annual equity fee in shares of Checkpoint's common stock equal to2.5% of Checkpoint's fully diluted outstanding capitalization.

Note 4: Represents the Trigger Date, the date that the Fortress partner company first acquires, whether by license or otherwise, ownership rights in a product.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

Management Services Agreements

The Company has entered in Management Services Agreements (the "MSAs") with certain of its partner companies as described in the Company's Form 10-K for the year ended December 31, 2020, filed with the SEC on March 31, 2021. The following table summarizes the effective date of the MSA and the annual consulting fee payable by the partner company to the Company in quarterly installments:

Fortress partner company	Effective Date	Annual MSA Fee (Income)/Expense
Helocyte	March 20, 2015	$ 500
Avenue [1]	February 17, 2015	—
Mustang	March 13, 2015	500
Checkpoint	March 17, 2015	500
Cellvation	October 31, 2016	500
Baergic	March 9, 2017	500
Cyprium	March 13, 2017	500
Aevitas	July 28, 2017	500
Oncogenuity	February 10, 2017	500
FBIO Acquisition Corp. VIII	November 7, 2017	500
Fortress		(4,500)
Consolidated (Income)/Expense		$ —

Note 1: Concurrently with the execution and delivery of the Avenue SPMA entered into among, Avenue, the Company and InvaGen (together, the "SPMA Parties"), the SPMA Parties entered into a waiver and termination 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 until such time as InvaGen beneficially owns less than 75% of the shares of Avenue common stock it acquired under the first closing of the Avenue SPMA.

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. The following tables summarize, for the periods indicated, operating results from continued operations by reportable segment (Certain reclass adjustments were made in the quarter ended September 30, 2021 to conform with the filing of the Journey Medical Corporation Form S-1 on October 22, 2021, as amended on November 8, 2021):

($ in thousands) Three Months Ended September 30, 2021	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net revenue	$ 19,610	$ 1,475	$ 21,085
Direct cost of goods	(11,167)	—	(11,167)
Research and development	(794)	(27,286)	(28,080)
General and administrative[1]	(10,755)	(11,466)	(22,221)
Wire transfer fraud loss	(9,540)	—	(9,540)
Other expense	(1,375)	5,437	4,062
Segment loss	$ (14,021)	(31,841)	$ (45,861)

Note 1: Includes $9.2 million in sales and marketing costs for the quarter ended September 30, 2021.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

($ in thousands) **Three Months Ended September 30, 2020**	**Dermatology Products Sales**	**Pharmaceutical and Biotechnology Product Development**	**Consolidated**
Net revenue	$ 9,447	$ 28	$ 9,475
Direct cost of goods	(3,379)	—	(3,379)
Research and development	—	(13,756)	(13,756)
General and administrative[1]	(5,829)	(9,554)	(15,383)
Other expense	(187)	(6,734)	(6,921)
Segment income (loss)	$ 52	$ (30,016)	$ (29,964)

Note 1: Includes $4.6 million in sales and marketing costs for the quarter ended September 30, 2020.

Nine Months Ended September 30, 2021	**Dermatology Products Sales**	**Pharmaceutical and Biotechnology Product Development**	**Consolidated**
Net revenue	$ 45,617	$ 4,898	$ 50,515
Direct cost of goods	(22,559)	—	(22,559)
Research and development	(14,566)	(71,245)	(85,811)
General and administrative[1]	(24,776)	(34,369)	(59,145)
Wire transfer fraud loss	(9,540)	—	(9,540)
Other Expenses	(3,120)	33,342	30,222
Segment loss	$ (28,944)	$ (67,374)	$ (96,318)

Note 1: Includes $20.8 million in sales and marketing costs for the nine months ended September 30, 2021.

Nine Months Ended September 30, 2020	**Dermatology Products Sales**	**Pharmaceutical and Biotechnology Product Development**	**Consolidated**
Net revenue	$ 30,808	$ 1,042	$ 31,850
Direct cost of goods	(10,313)	—	(10,313)
Research and development	—	(46,146)	(46,146)
General and administrative[1]	(16,284)	(29,074)	(45,358)
Other expense	(492)	(12,036)	(12,528)
Segment income (loss)	$ 3,719	$ (86,214)	$ (82,495)

Note 1: Includes $12.7 million in sales and marketing costs for the nine months ended September 30, 2020.

The following tables summarize, for the periods indicated, total assets by reportable segment:

($ in thousands) **September 30, 2021**	**Dermatology Products Sales**	**Pharmaceutical and Biotechnology Product Development**	**Total Assets**
Intangible assets, net	$ 13,043	$ —	$ 13,043
Tangible assets	67,597	327,193	394,790
Total segment assets	$ 80,640	$ 327,193	$ 407,833

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

($ in thousands) December 31, 2020	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Total Assets
Intangible assets, net	$ 14,629	$ —	$ 14,629
Tangible assets	35,422	283,362	318,784
Total segment assets	$ 50,051	$ 283,362	$ 333,413

19. Revenues from Contracts and Significant Customers

Disaggregation of Total Revenue

Product revenue comprises Journey's seven marketed products: Targadox®, Luxamend®, Ceracade®, Exelderm®, Ximino®, Accutane® and Qbrexza®. Substantially all of the product revenue is recorded in the U.S. The Company's collaboration revenue is from Cyprium's agreement with Sentynl (see Note 3). The Company's related party revenue is from Checkpoint's collaborations with TGTX. The table below summarizes the Company's revenue for the three and nine months ending September 30, 2021 and 2020:

	Three months ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue				
Product revenue, net	$ 19,610	$ 9,447	$ 45,617	$ 30,808
Collaboration revenue	1,446	—	4,646	—
Revenue – related party	29	28	252	1,042
Net revenue	$ 21,085	$ 9,475	$ 50,515	$ 31,850

Significant Customers

For the three months ended September 30, 2021, one of the Company's dermatology products customers accounted for more than 10% of its total gross product revenue at 10.1%. For the nine months ended September 30, 2021, none of the Company's dermatology products customers accounted for more than 10% of its total gross product revenue.

For the three months ended September 30, 2020, none of the Company's dermatology products customers accounted for more than 10% of its total gross product revenue. For the nine months ended September 30, 2020, one of the Company's dermatology products customers accounted for more than 10% of its total gross product revenue.

At September 30, 2021, two of the Company's dermatology products customers accounted for more than 10% of its total accounts receivable balance at 20.7% and 14.9%. At December 31, 2020, one of the Company's dermatology products customers accounted for more than 10% of its total accounts balance at 14.5%.

20. Income taxes

On March 11, 2021, the President of the United States signed the American Rescue Plan Act, also called the COVID-19 Stimulus Package or American Rescue Plan into law. The American Rescue Plan includes many non-tax and tax provisions to help address the continuing pandemic, including extending the Employee Retention Credit to December 31, 2021. The Company will continue to evaluate the impact of the American Rescue Plan on its financial positions, results of operations and cash flows.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

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 does not expect to realize the net deferred tax asset and as such has recorded a full valuation allowance.

The Company files a consolidated income tax return with subsidiaries for which the Company has an80% or greater ownership interest. Subsidiaries for which the Company does not have an 80% or more ownership are not included in the Company's consolidated income tax group and file their own separate income tax return. As a result, certain corporate entities included in these financial statements are not able to combine or offset their taxable income or losses with other entities' tax attributes.

Income tax expense for the three and nine months ended September 30, 2021 and 2020 is based on the estimated annual effective tax rate. Based on the Company's effective tax rate and full valuation allocation, tax expense is expected to be $0 for 2021.

21. Subsequent Events

Caelum Acquisition

On September 28, 2021, AstraZeneca notified the Company of its intention to exercise its option to purchase all of the equity of Caelum. The transaction closed on October 5, 2021. The Company received 42.4% of the distribution of proceeds from the option exercise price of $150 million, approximately $56.9 million, which is net of the 10%, 24-month escrow holdback and other miscellaneous transaction expenses. On September 30, 2021, the Company fair valued its investment in Caelum at $56.9 million, an increase of $8.4 million and $39.3 million for the three and nine months ended September 30, 2021, respectively.

Journey Initial Public Offering (the "Journey IPO")

The Journey IPO is expected to close on November 16, 2021, subject to customary closing conditions, resulting in the issuance of3,520,000 shares of Journey's common stock. The shares are issued at $ 10.00 per share, resulting in net proceeds of approximately $31.4 million, after deducting underwriting discounts and other offering costs. In addition, Journey granted the underwriters a 30-day option to purchase up to an additional 528,000 additional shares of common stock, at the public offering price, less the underwriting discount, to cover over-allotments, if any. Journey's common stock began trading on the Nasdaq Capital Market on November 12, 2021 under the ticker symbol "DERM."

Avenue Underwritten Public Offering of Common Stock

On November 12, 2021, pursuant to an underwritten public offering, Avenue sold1,946,787 shares of its common stock at a price of $1.34 per share for gross proceeds of approximately $2.6 million before deducting underwriting discounts and commissions and other estimated expenses. In addition, Avenue granted the underwriters a 45-day option to purchase additional shares of common stock, representing up to 15% of the number of total shares, solely to cover over-allotments, if any, which would increase the total gross proceeds of the offering to approximately $3.0 million, if the over-allotment option is exercised in full.

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 unaudited condensed consolidated financial statements and the related notes included elsewhere in this Form 10-Q. Our unaudited condensed 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. For such forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. 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, 2020. As used below, the words "we," "us" and "our" may refer to Fortress Biotech, Inc. individually or together with one or more partner companies, as dictated by context.

Overview

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

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

Recent Events

Marketed Dermatology Products

- Our seven dermatology products are marketed by our partner company, Journey Medical Corporation ("Journey" or "JMC").
- During the three months ended September 30, 2021 and 2020, JMC's marketed products generated net revenue of $19.6 million and $9.4 million, respectively.
- During the nine months ended September 30, 2021 and 2020, JMC's marketed products generated net revenue of $ 45.6 million and $30.8 million, respectively.

Late Stage Product Candidates

Intravenous (IV) Tramadol

- In July 2021, Avenue Therapeutics ("Avenue") submitted a Formal Dispute Resolution Request ("FDRR") to the U.S. Food and Drug Administration ("FDA") with respect to the Complete Response Letters ("CRLs") previously issued by the FDA to Avenue related to its intravenous ("IV") tramadol New Drug Application ("NDA"). The submission followed a Post-Action Type A meeting with the FDA that did not resolve the issues identified in the CRLs.
- On August 26, 2021, Avenue received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to its FDRR submitted in July 2021 with respect to the CRLs.
- On August 31, 2021, Avenue filed an FDRR with the Office of New Drugs ("OND") for review, which office communicated to Avenue on October 21, 2021 that it needs additional input from an Advisory Committee in order to reach a decision on the FDRR. Accordingly, the FDA will convene an Advisory Committee meeting and seek advice from the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee.
- On November 1, 2021, Avenue terminated the Stock Purchase and Merger Agreement, dated as of November 12, 2018, by and among Avenue, InvaGen Pharmaceuticals Inc. ("InvaGen") and Madison Pharmaceuticals Inc. (the "Avenue SPMA").
- IV tramadol is currently in development at our partner company, Avenue.

CUTX-101 (Copper Histidinate for Menkes disease)

- We intend to begin the rolling submission of the NDA for CUTX-101 to the FDA in the fourth quarter of 2021.
- In October 2021, we announced positive results from an efficacy and safety analysis of data integrated from two completed pivotal studies in patients with Menkes disease treated with CUTX-101, copper histidinate (CuHis). In both pre-specified primary and secondary efficacy analyses, treatment with CUTX-101 demonstrated a significantly greater median overall survival compared to untreated historical control patients.
- CUTX-101 is currently in development at our partner company, Cyprium Therapeutics, Inc.

MB-107/MB-207 (Ex vivo Lentiviral Therapies for X-linked Severe Combined Immunodeficiency (XSCID))

- In August 2021, Mustang announced that the European Medicines Agency ("EMA") granted Priority Medicines ("PRIME") designation to MB-107, a lentiviral gene therapy for the treatment of XSCID in newly diagnosed infants. In addition to PRIME designation, the EMA granted Advanced Therapy Medicinal Product ("ATMP") classification to MB-107 in April 2020 and Orphan Drug designation in November 2020. MB-107 has also received Orphan Drug, Rare Pediatric Disease and Regenerative Medicine Advanced Therapy ("RMAT") designations from the FDA.
- Mustang is proceeding with its plans to initiate the pivotal Phase 2 trial in newly diagnosed XSCID patients and to file an Investigational New Drug application to conduct a pivotal Phase 2 trial in previously transplanted XSCID patients.
- MB-107 and MB-207 are currently in development at our partner company, Mustang Bio, Inc. ("Mustang").

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

- Checkpoint Therapeutics, Inc. ("Checkpoint")'s registration-enabling study in metastatic cutaneous squamous cell carcinoma ("mCSCC") is fully enrolled, and we anticipate reporting top-line results around year-end 2021. With a potentially favorable safety profile versus anti-PD-L1 therapy and a plan to commercialize at a substantially lower price, we believe cosibelimab has the potential to be a market disruptive product in the $25 billion and growing PD-(L)1 class.
- A Phase 3 registration-enabling trial is planned to begin in first-line metastatic non-small cell lung cancer ("NSCLC") in the fourth quarter of 2021.
- Cosibelimab is currently in development at our partner company, Checkpoint.

CAEL-101 (light chain fibril-reactive monoclonal antibody for AL amyloidosis)

- On October 5, 2021, AstraZeneca's Alexion acquired Caelum Biosciences, Inc. ("Caelum") a company founded by Fortress, for an upfront payment of approximately $150 million to Caelum shareholders, of which approximately $56.9 million was paid to Fortress Biotech. The agreement also provides for additional potential payments to Caelum stockholders totaling up to $350 million, payable upon the achievement of regulatory and commercial milestones.
- Caelum has two ongoing Phase 3 studies of CAEL-101 for AL amyloidosis.

- CAEL-101 was sourced by Fortress in 2017.

Early Stage Product Candidates

Ex Vivo Lentiviral Gene Therapy for the Treatment of RAG1 Severe Combined Immunodeficiency ("RAG1-SCID")

- In November, 2021, Mustang announced that it had executed an exclusive license agreement with Leiden University Medical Centre ("LUMC") for a first-in-class *ex vivo* lentiviral gene therapy for the treatment of RAG1-SCID. The therapy, which includes low-dose conditioning prior to reinfusion of the patients' own gene-modified blood stem cells, is currently being evaluated in a Phase 1/2 multicenter clinical trial in Europe. This therapy was developed in the laboratory of Frank J. Staal, Ph.D., professor of Molecular Stem Cell biology and co-director of the LUMC Flow Cytometry Core Facility. The ongoing clinical trial recently enrolled its first patient, and additional clinical sites plan to onboard in the near future. The RAG1-SCID program has been granted Orphan Drug Designation by the European Medicines Agency.
- RAG1-SCID is currently in development at our partner company, Mustang.

Platform to Administer CAR T Therapy

- In August, Mustang entered into an exclusive license with Mayo Foundation for Medical Education and Research ("Mayo Clinic") for a novel technology that may be able to transform the administration of chimeric antigen receptor engineered T cell ("CAR T") therapies and has the potential to be used as an off-the-shelf therapy. Successful implementation may lead to an off-the-shelf product with no need to isolate and expand patient T cells *ex vivo*.
- Preclinical proof-of-concept has been established, and the ongoing development of this technology will take place at Mayo Clinic. Mustang plans to file an Investigational New Drug ("IND") application for a multicenter Phase 1 clinical trial once a lead construct has been identified.
- This technology is in development at our partner company, Mustang.

MB-106 (CD20-targeted CAR T Cell Therapy)

- On November 1, 2021, Mustang announced that it had been awarded awarded a grant of approximately $2 million from the National Cancer Institute. This two-year grant will partially fund the Mustang-sponsored phase 1/2 trial of MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-cell non-Hodgkin lymphomas ("NHL") or chronic lymphocytic leukemia ("CLL").
- MB-106 is currently in development at our partner company, Mustang.

General Corporate

- In November 2021, Avenue announced the pricing of an underwritten public offering of 1,946,787 shares of its common stock at a price of $1.34 per share for gross proceeds of approximately $2.6 million before deducting underwriting discounts and commissions and other estimated expenses. In addition, Avneue granted the underwriters a 45-day option to purchase additional shares of common stock, representing up to 15% of the number of total shares, solely to cover over-allotments, if any, which would increase the total gross proceeds of the offering to approximately $3.0 million, if the over-allotment option is exercised in full.
- In October 2021, Journey filed a registration statement with the Securities and Exchange Commission for an initial public offering of $40 million.
- In September 2021, Journey was the victim of a business e-mail compromise cybersecurity incident affecting its accounts payable function, which led to to the misdirection of approximately $9.5 million in wire transfers to apparently fraudulent accounts. The details of the incident and its origin are under investigation with the assistance of third-party cybersecurity experts, working at the direction of legal counsel. The incident does not appear to have compromised any personally identifiable information or protected health information. The matter has been reported to the Federal Bureau of Investigation. As the controlling stockholder of Journey and as its supporting partner in its back-office functions, Fortress is providing Journey with $9.5 million to ensure Journey's accounts payable operations continue to function smoothly.

- In July 2021, Journey completed its final close in connection with its 8% Cumulative Convertible Class A Preferred Stock Offering (the "Journey Offering"). In connection with the Journey Offering, Journey issued an aggregate of 758,680 Journey 8% Cumulative Convertible Class A Preferred shares at a price of $25.00 per share for gross proceeds of $19.0 million.

Critical Accounting Policies and Use of Estimates

There were no material changes to our critical accounting policies that are disclosed in our audited consolidated financial statements for the year ended December 31, 2020 filed with the SEC on March 31, 2021.

Recent Accounting Pronouncements

See Note 2 to our unaudited condensed consolidated financial statements located in "Part I – Financial Information, Item 1.Financial Statements" in this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our unaudited condensed consolidated financial statements.

Smaller Reporting Company Status

We are a "smaller reporting company," meaning that the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K , have reduced disclosure obligations regarding executive compensation, and smaller reporting companies are permitted to delay adoption of certain recent accounting pronouncements discussed in Note 2 to our unaudited condensed consolidated financial statements located in "Part I – Financial Information, Item 1.Financial Statements" in this Quarterly Report on Form 10-Q.

Results of Operations

General

For the three months ended September 30, 2021 and 2020, we generated $21.1 million and $9.5 million, respectively, of net revenue, of which $19.6 million and $9.4 million, respectively, relates primarily to the sale of Journey branded and generic products. Collaboration revenue of $1.4 million recognized in the quarter ended September 30, 2021 is a result of Cyprium's agreement with Sentynl. Approximately $29,000 and $28,000, respectively, relates to Checkpoint's collaborative agreements with TG Therapeutics Inc. ("TGTX").

For the nine months ended September 30, 2021 and 2020, we generated $50.5 million and $31.9 million, respectively, of net revenue, of which $45.6 million and $30.8 million, respectively, relates primarily to the sale of Journey branded and generic products. Cyprium's collaboration revenue with Sentynl was $4.6 million for the nine months ended September 30, 2021. Approximately $0.3 million and $1.0 million, respectively, relates to Checkpoint's collaborative agreements with TGTX.

As of September 30, 2021, we had an accumulated deficit of $515.9 million. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our and our subsidiaries' current product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenues.

For the three months ended September 30, 2021 and 2020, we had $11.2 million or 56.9% of product revenue, net and $3.4 million or 35.8% of product revenue, net, respectively, of costs of goods sold in connection with the sale of Journey's marketed products, compared to $22.6 million or 49.5% of product revenue, net and $10.3 million or 33.5% of product revenue, net, respectively, for the nine months ended September 30, 2021 and 2020. The increase in cost of goods sold in the current fiscal year is related to the step-up charge of $3.0 million and $4.2 million, respectively, for the Qbrexza inventory sold in the three and nine months ended September 30, 2021.

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 and nine months ended September 30, 2021, research and development expenses were approximately $27.4 million and $13.3 million, respectively. Additionally, during the three months ended September 30, 2021 and 2020, we expensed approximately $0.7 million and $0.5 million, respectively, in costs related to the acquisition of licenses. Noncash, stock-based compensation expense included in research and development for the three months ended September 30, 2021 and 2020 was $1.1 million and $0.7 million, respectively.

The table below provides a summary of research and development costs associated with the development of our licenses by entity, for the quarter ended September 30, 2021 and 2020, by entity:

	Three Months Ended September 30,		% of total	
($ in thousands)	2021	2020	2021	2020
Research & Development				
Fortress	$ 651	$ 364	2 %	3 %
Partner Companies:				
Avenue	278	466	1 %	3 %
Checkpoint	9,384	2,543	34 %	19 %
JMC	718	—	2 %	— %
Mustang	14,028	7,925	50 %	60 %
Other[1]	2,308	2,000	9 %	15 %
Total Research & Development Expense	**$ 27,367**	**$ 13,298**	**98 %**	**100 %**

Note 1: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and FBIO Acquisition Corp VIII.

Selling, General and Administrative Expenses

Selling, 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, 2021 and 2020, selling, general and administrative expenses were approximately $22.2 million and $15.4 million, respectively. Noncash, stock-based compensation expense included in selling, general and administrative expenses for the three months September 30, 2021 and 2020 was $3.2 million and $2.5 million, respectively.

The table below provides a summary of selling, general and administrative costs for the quarter ended September 30, 2021 and 2020, by entity:

	Three Months Ended September 30,		% of Total	
($ in thousands)	2021	2020	2021	2020
Selling, General & Administrative				
Fortress	$ 5,989	$ 5,289	27 %	34 %
Partner Companies:				
Avenue	594	571	3 %	4 %
Checkpoint	1,760	1,573	8 %	10 %
JMC[1]	11,003	5,829	49 %	38 %
Mustang	2,219	1,640	10 %	11 %
Other[2]	656	481	3 %	3 %
Total Selling, General & Administrative Expense	**$ 22,221**	**$ 15,383**	**100 %**	**100 %**

Note 1: Includes cost of outsourced sales force for the three months ended September 30, 2021 and 2020 of $5.1 million and $2.9 million, respectively.

Note 2: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and FBIO Acquisition Corp VIII.

Comparison of three months ended September 30, 2021 and 2020

	Three Months Ended September 30,		Change	
($ in thousands)	2021	2020	$	%
Revenue				
Product revenue, net	$ 19,610	$ 9,447	$ 10,163	108 %
Collaboration revenue	1,446	—	1,446	100 %
Revenue – related party	29	28	1	4 %
Net revenue	21,085	9,475	11,610	122.5 %
Operating expenses				
Cost of goods sold – product revenue	11,167	3,379	7,788	230 %
Research and development	27,367	13,298	14,069	106 %
Research and development – licenses acquired	713	458	255	56 %
Selling, general and administrative	22,221	15,383	6,838	44 %
Wire transfer fraud loss	9,540	—	9,540	100 %
Total operating expenses	71,008	32,518	38,490	118 %
Loss from operations	(49,923)	(23,043)	(26,880)	117 %
Other income (expense)				
Interest income	132	265	(133)	(50)%
Interest expense and financing fee	(4,444)	(6,958)	2,514	(36)%
Change in fair value of investments	8,376	575	7,801	1,357 %
Change in fair value of derivative liability	(2)	(803)	801	(100)%
Total other income (expense)	4,062	(6,921)	10,983	(159)%
Net Loss	**(45,861)**	**(29,964)**	**(15,897)**	**53 %**
Less: net loss attributable to non-controlling interest	25,080	14,417	10,663	74 %
Net loss attributable to common stockholders	**$ (20,781)**	**$ (15,547)**	**$ (5,234)**	**34 %**

Net revenues increased $11.6 million, or 123%, from the three months ended September 30, 2020 to the three months ended September 30, 2021 primarily due to revenues associated with newly launched products as well as increases in legacy products Excelderm and Ximino. Journey launched Accutane in the first quarter of 2021 and Qbrexza during the second quarter of 2021. The increase in collaboration revenue is due to the Cyprium agreement with Sentnyl, signed in the first quarter of 2021.

Cost of goods sold increased by $7.8 million, or 230%, from the three months ended September 30, 2020 to the three months ended September 30, 2021 related primarily to the step-up in inventory cost of $3.8 million related to Qbrexza, as well as the increase in royalty expense related to Qbrexza and Accutane of $3.1 million and the expansion of Journey's product portfolio.

Research and development expenses increased $14.1 million or 106% from the three months ended September 30, 2020 to the three months ended September 30, 2021. The following table shows the change in research and development spending by Fortress and its partner companies:

($ in thousands)	Three Months Ended September 30, 2021	2020	Change $	Change %
Research & Development				
Stock-based compensation				
Fortress	$ 275	$ 207	$ 68	33 %
Partner Companies:				
Avenue	25	62	(37)	(59)%
Checkpoint	161	156	5	3 %
Mustang	655	258	397	154 %
Other[1]	2	15	(13)	(85)%
Sub-total stock-based compensation expense	1,118	698	420	60 %
Other Research & Development				
Fortress	376	157	219	140 %
Partner Companies:				
Avenue	253	404	(151)	(37)%
Checkpoint	9,223	2,388	6,835	286 %
JMC	718	—	718	100 %
Mustang	13,373	7,667	5,706	74 %
Other[1]	2,306	1,984	322	16 %
Total Research & Development Expense	**$ 27,367**	**$ 13,298**	**$ 14,069**	**106 %**

Note 1: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and FBIO Acquisition Corp VIII.

The increase in stock-based compensation for the quarter ended September 30, 2021 is primarily due to the effect of new equity grants to key employees and non-employees at both Mustang and Fortress.

The increased spending at Checkpoint of $6.8 million is attributable primarily to increased clinical and manufacturing costs related to cosibelimab. Mustang's increase in research and development spending of $5.7 million is attributable to increased costs associated with personnel related expenses, third party clinical trial costs, sponsored research and clinical trial agreements, laboratory supplies, and consulting and professional fees. Avenue's decrease of $0.2 million is primarily due to a decrease in expenses associated with NDA review related costs. Journey's increase in research and development expense of $0.7 million is attributable to the costs incurred related to the development of DFD-29, a potential rosacea treatment. The increase in "Other" of $0.3 million is attributable to increased spend in the three months ended September 30, 2021 as compared to the three months ended September 30, 2020 for Cyprium, as Cyprium prepares to file for its rolling NDA.

The increase in research and development – licenses acquired of $0.3 million or 56% from the three months ended September 30, 2020, as compared to the three months ended September 30, 2021, is due to the expense recorded in the third quarter of 2021 for Mustang's new license with Leiden University Medical Centre for $0.4 million, and $0.3 million for a milestone payment related to a PSCA milestone, offset by Mustang's CSL Behring milestone of $0.2 million and $0.1 million of expense Mustang's LentiBOOST™ license with SIRION recorded in the three-month period ended September 30, 2020, at Mustang.

Selling, general and administrative expenses increased $6.8 million, or 44%, from the three months ended September 30, 2020 to the three months ended September 30, 2021. The following table shows the change in selling, general and administrative spending by Fortress and its partner companies:

($ in thousands)	Three Months Ended September 30, 2021	2020	Change $	Change %
Selling, General & Administrative				
Stock-based compensation				
Fortress	$ 2,287	$ 1,425	$ 862	61 %
Partner Companies:				
Avenue	44	99	(55)	(56)%
Checkpoint	618	569	49	9 %
JMC	7	32	(25)	(77)%
Mustang	229	348	(119)	(34)%
Other[2]	23	—	23	100 %
Sub-total stock-based compensation expense	3,208	2,473	735	30 %
Other Selling, General & Administrative				
Fortress	3,702	3,864	(162)	(4)%
Partner Companies:				
Avenue	550	472	78	17 %
Checkpoint	1,142	1,004	138	14 %
JMC[1]	10,996	5,797	5,199	90 %
Mustang	1,990	1,292	698	54 %
Other[2]	633	481	152	32 %
Total Selling, General & Administrative Expense	**$ 22,221**	**$ 15,383**	**$ 6,838**	**44 %**

Note 1: Includes cost of outsourced sales force for the three months ended September 30, 2021 and 2020 of $5.1 million and $2.9 million, respectively.

Note 2: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and FBIO Acquisition Corp VIII.

For the quarter ended September 30, 2021, the increase in selling, general and administrative expenses of $6.8 million, or 44%, is primarily attributable to Journey's increased sales and marketing costs associated with the expansion of the outside sales headcount related to the expanded product portfolio, as well as Mustang's increase in consulting, professional fees and personnel related costs. Checkpoint's increase is due to increases in personnel-related costs. The increase in "Other" of $0.2 million is attributed to Cyprium's increase in personnel-related expenses.

In September 2021, wire fraud related costs totaled approximately $9.5 million. These costs were attributable to funds erroneously wired to fraudulent accounts as a result of a sophisticated business email compromise fraud scheme. Any insurance proceeds will be recorded when considered probable.

Total other expense changed $11.0 million, or 159%, from expense of $6.9 million for the three months ended September 30, 2020 to income of $4.1 million for the three months ended September 30, 2021, primarily due to the change in fair value of the Company's investment in Caelum of $7.8 million and the decrease in interest expense and financing fees of $2.5 million recorded in the three months ended September 30, 2021.

Net loss attributable to common stockholders increased $5.2 million, or 34%, from a net loss of $15.5 million for the three months ended September 30, 2020 to a net loss of $20.8 million for the three months ended September 30, 2021.

Comparison of nine months ended September 30, 2021 and 2020

(Sin thousands)	Nine Months Ended September 30, 2021	2020	Change $	Change %
Revenue				
Product revenue, net	$ 45,617	$ 30,808	$ 14,809	48 %
Collaboration revenue	4,646	—	4,646	100 %
Revenue – related party	252	1,042	(790)	(76)%
Net revenue	50,515	31,850	18,665	59 %
Operating expenses				
Cost of goods sold – product revenue	22,559	10,313	12,246	119 %
Research and development	70,226	43,868	26,358	60 %
Research and development – licenses acquired	15,585	2,278	13,307	584 %
General and administrative	59,145	45,358	13,787	30 %
Wire transfer fraud loss	9,540	—	9,540	100 %
Total operating expenses	177,055	101,817	75,238	74 %
Loss from operations	(126,540)	(69,967)	(56,573)	81 %
Other income (expense)				
Interest income	505	1,228	(723)	(59)%
Interest expense and financing fee	(9,393)	(13,142)	3,749	(29)%
Change in fair value of investments	39,294	575	38,719	6734 %
Change in fair value of derivative liability	(184)	(1,189)	1,005	(85)%
Total other income (expense)	30,222	(12,528)	42,750	(341)%
Net loss	**(96,318)**	**(82,495)**	**(13,823)**	**17 %**
Less: net loss attributable to non-controlling interest	63,180	41,264	21,916	53 %
Net loss attributable to common stockholders	**$ (33,138)**	**$ (41,231)**	**$ 8,093**	**(20)%**

Net revenues increased $18.7 million, or 59%, from the nine months ended September 30, 2020 to the nine months ended September 30, 2021 primarily due to revenues associated with newly launched products as well as increases in legacy products Excelderm and Ximino. Journey launched Accutane in the first quarter of 2021 and Qbrexza during the second quarter of 2021. The increase in collaboration revenue is due to the Cyprium agreement with Sentnyl, signed in the first quarter of 2021.

Cost of goods sold increased by $12.2 million, or 119%, from the nine months ended September 30, 2020 to the nine months ended September 30, 2021 due to the step-up in inventory value related to units sold of Qbrexza of $4.2 million for the nine months ended September 30, 2021, as well as the increase in royalty expense related to Qbrexza and Accutane of $4.9 million related to the expansion of Journey's marketed product portfolio. Journey expects the total step-up in inventory value related to Qbrexza units sold of $6.5 million to be incurred in 2021. However this amount is based upon the Company forecast and may be higher or lower depending on actual units sold.

Research and development expenses increased $26.4 million or 60% from the nine months ended September 30, 2020 to the nine months ended September 30, 2021. The following table shows the change in research and development spending by Fortress and its partner companies:

($ in thousands)	Nine Months Ended September 30, 2021	2020	Change $	Change %
Research & Development				
Stock-based compensation				
Fortress	$ 869	$ 611	$ 258	42 %
Partner Companies:				
Avenue	108	231	(123)	(53)%
Checkpoint	480	462	18	4 %
Mustang	1,633	1,156	477	41 %
Other[1]	7	26	(19)	(74)%
Sub-total stock-based compensation expense	3,097	2,486	611	25 %
Other Research & Development				
Fortress	1,110	775	335	43 %
Partner Companies:				
Avenue	756	2,151	(1,395)	(65)%
Checkpoint	20,315	7,745	12,570	162 %
JMC	747	—	747	100 %
Mustang	34,797	25,788	9,009	35 %
Other[1]	9,404	4,923	4,481	91 %
Total Research & Development Expense	**$ 70,226**	**$ 43,868**	**$ 26,358**	**60 %**

Note 1: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and FBIO Acquisition Corp VIII.

The increase in stock-based compensation for the nine months ended September 30, 2021, is primarily due to the effect of new equity grants to key employees and non-employees at both Mustang and Fortress.

The increased spending at Checkpoint of $12.6 million is attributable primarily to increased clinical and manufacturing costs related to cosibelimab. Mustang's increase in research and development spending of $9.0 million is attributable to increased costs associated with lab supplies, personnel related expenses, and consulting and professional fees. Avenue's decrease of $1.4 million is primarily due to decreases in expenses associated with NDA related and advisory committee preparation costs as well as commercial validation manufacturing activities and personnel costs. The increase in "Other" of $4.5 million is attributable to increased spend in the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020 for Cyprium, as Cyprium prepares to file for its rolling NDA.

The increase in research and development – licenses acquired of $13.3M or 584% from the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2021 is due to the expense recorded in the second quarter of 2021 for Journey's $10 million license, collaboration, and assignment agreement with Dr. Reddy's Laboratories, Ltd. for a potential rosacea treatment, referred to as the DFD-29 Agreement, and the contingent warrant liability related to the DFD-29 Agreement of $3.8 million.

Selling, general and administrative expenses increased $13.8 million, or 30%, from the nine months ended September 30, 2020 to the nine months ended September 30, 2021. The following table shows the change in selling, general and administrative spending by Fortress and its partner companies:

($ in thousands)	Nine Months Ended September 30, 2021	2020	Change $	Change %
Selling, General & Administrative				
Stock-based compensation				
Fortress	$ 6,437	$ 4,490	$ 1,947	43 %
Partner Companies:				
Avenue	191	361	(170)	(47)%
Checkpoint	1,839	1,633	206	13 %
JMC	40	—	40	100 %
Mustang	794	1,212	(418)	(35)%
Other[2]	51	137	(86)	(63)%
Sub-total stock-based compensation expense	9,352	7,833	1,519	19 %
Other Selling, General & Administrative				
Fortress	11,988	11,639	349	3 %
Partner Companies:				
Avenue	1,769	1,471	298	20 %
Checkpoint	3,271	2,989	282	9 %
JMC[1]	24,808	16,284	8,524	52 %
Mustang	5,714	4,119	1,595	39 %
Other[2]	2,243	1,023	1,220	119 %
Total Selling, General & Administrative Expense	**$ 59,145**	**$ 45,358**	**$ 13,787**	**30 %**

Note 1: Includes cost of outsourced sales force for the nine months ended September 30, 2021 and 2020 of $11.1 million and $7.5 million, respectively.

Note 2: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and FBIO Acquisition Corp VIII.

For the nine months ended September 30, 2021, the increase in selling, general and administrative expenses of $13.8 million, or 30%, is primarily attributable to Journey's increased sales and marketing costs associated with the expansion of the outside sales headcount related to the expanded product portfolio, as well as Mustang's increase in consulting and professional fees,and state tax expense. Avenue's increase is due to increased legal costs, and Checkpoint's increase is due to increases in personnel-related costs. The increase in "Other" of $1.2 million is attributed to Cyprium's increase in personnel-related expenses.

In September 2021, wire fraud related costs totaled approximately $9.5 million. These costs were attributable to funds erroneously wired to fraudulent accounts as a result of a sophisticated business email compromise fraud scheme. Any insurance proceeds will be recorded when considered probable.

Total other income (expense) increased $42.8 million, or 341%, from expense of $12.5 million for the nine months ended September 30, 2020 to income of $30.2 million for the nine months ended September 30, 2021, primarily due to the change in fair value of the Company's investment in Caelum of $38.7 million and the decrease in interest expense and financing fees of $3.7 million for the nine months ended September 30, 2021.

Net loss attributable to common stockholders decreased $8.1 million, or 20%, from a net loss of $41.2 million for the nine months ended September 30, 2020 to a net loss of $33.1 million for the nine months ended September 30, 2021.

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, from the sale of partner companies, and the proceeds from the exercise of warrants and stock options. 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, or through other sources of financing.

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

Cash Flows for the Nine Months Ended September 30, 2021 and 2020

($ in thousands)	Nine Months Ended September 30, 2021	2020
Statement of cash flows data:		
Total cash (used in)/provided by:		
Operating activities	$ (77,844)	$ (63,196)
Investing activities	(12,839)	(5,597)
Financing activities	110,053	135,395
Net increase in cash and cash equivalents and restricted cash	$ 19,370	$ 66,602

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

($ in thousands)	For the Nine Months Ended September 30, 2021				
	Fortress[1]	Avenue	Checkpoint	Mustang	Total
Statement of cash flows data:					
Total cash (used in)/provided by:					
Operating activities	$ (19,505)	$ (2,547)	$ (16,828)	$ (38,964)	$ (77,844)
Investing activities	(8,950)	—	—	(3,889)	(12,839)
Financing activities	7,866	—	36,259	65,928	110,053
Net increase in cash and cash equivalents and restricted cash	$ (20,589)	$ (2,547)	$ 19,431	$ 23,075	$ 19,370

($ in thousands)	For the Nine Months Ended September 30, 2020				
	Fortress[1]	Avenue	Checkpoint	Mustang	Total
Statement of cash flows data:					
Total cash (used in)/provided by:					
Operating activities	$ (20,315)	$ (3,420)	$ (11,617)	$ (27,844)	$ (63,196)
Investing activities	(1,649)	(1,000)	—	(2,948)	(5,597)
Financing activities	63,196	—	27,569	44,630	135,395
Net increase in cash and cash equivalents and restricted cash	$ 41,232	$ (4,420)	$ 15,952	$ 13,838	$ 66,602

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

Operating Activities

Net cash used in operating activities increased $14.7 million from the nine months ended September 30, 2020, compared to the nine months ended September 30, 2021. The increase is primarily due to the increase of $38.7 million in the fair value of the Company's investment in Caelum, the $13.8 million increase in year-to-date net loss, and $10.0 million in inventory related to the Qbrexza acquisition, offset by the increase in accounts payable and accrued expenses of $36.6 million, the increase in research and development – licenses acquired expense of 13.2 million, and the change in deferred revenue of $3.4 million.

Investing Activities

Net cash used by investing activities increased $7.2 million from the nine months ended September 30, 2020, compared to the nine months ended September 30, 2021. The increase is due to a $6.5 million increase in the purchase of research and development licenses, a $1.4 million increase in the purchase of property and equipment offset by $0.6 million decrease in the purchase of intangible assets.

Financing Activities

Net cash provided by financing activities was $135.4 million for the nine months ended September 30, 2020, compared to $110.1 million of net cash provided by financing activities for the nine months ended September 30, 2021, a decrease of $25.3 million. During the nine months ended September 30, 2021, net proceeds from at-the-market offerings for the partner companies increased $68.4 million, and cash used to repay debt decreased $84.4 million, net proceeds from partner company convertible preferred shares increased $17.0 million, offset by the decrease in proceeds from partner companies' sale of stock of $54.1 million, the decrease in proceeds from Series A perpetual preferred stock of $39.1 million, the decrease in proceeds from the issuance of common stock for at-the-market offering of $42.0 million, and the decrease in net proceeds from the Oaktree Note of $55.9 million.

Off-Balance Sheet Arrangements

We did not have during the periods presented, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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, 2019 and December 31, 2020, and for the interim period through September 30, 2021, 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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded,

processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

In September 2021, a partner company email account was compromised by a third-party impersonator and payments intended for a vendor, approximating $9.5 million, were fraudulently re-directed into an individual bank account controlled by this third-party impersonator. The impersonator had taken a number of steps to deceive our employees and reduce the likelihood of detection. As a result of the foregoing, we identified a material weakness due to our internal controls having not been adequately designed to prevent or timely detect unauthorized cash disbursements.

In light of the above incident, our management took immediate action to remediate the material weakness, including enhancing and formalizing cash disbursement controls to prevent and timely detect unauthorized cash disbursements and significantly enhancing our information technology infrastructure and security measures. However, given the identification of the material weakness during September 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2021, our disclosure controls and procedures were not effective at the reasonable assurance level. As of the date of this filing we believe this material weakness has been remediated.

Changes in Internal Control over Financial Reporting

Except for the remediation efforts described above taken to address the material weakness, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the most recent quarter with respect to our operations, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On March 31, 2021 Journey executed an Asset Purchase Agreement (the "Qbrexza APA") with Dermira, Inc. a subsidiary of Eli Lilly and Company ("Dermira"). Pursuant to the terms of the agreement Journey acquired the rights to Qbrexza® (glycoprronium), a prescription cloth towelette to treat primary axillary hyperhidrosis in patients nine years of age or older. Upon closing of the Qbrexza® purchase, Journey became substituted for Dermira as the plaintiff in U.S. patent litigation commenced by Dermira on October 21, 2020 in the U.S. District Court of Delaware (the "Patent Litigation") against Perrigo Pharma International DAC ("Perrigo") alleging infringement of certain patents covering Qbrexza® (the "Qbrexza® Patents"), which are included among the proprietary rights to Qbrexza® to be acquired pursuant to the APA. The Patent Litigation was initiated following the submission by Perrigo, in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), of an Abbreviated New Drug Application, or ANDA. The ANDA seeks approval to market a generic version of Qbrexza® prior to the expiration of the Qbrexza® Patents and alleges that the Qbrexza® Patents are invalid. Perrigo is subject to a 30-month stay preventing it from selling a generic version, but that stay is set to expire on March 9, 2023. Trial in the Patent Litigation is scheduled for September 19, 2022. The Company cannot make any predictions about the final outcome of this matter or the timing thereof.

To our knowledge, there are no other legal proceedings pending against us, other than routine actions and administrative proceedings, and other actions not deemed material are not expected to have a material adverse effect on our financial condition, results of operations, or cash flows. In the ordinary course of business, however, the Company 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.

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 Inherent in Drug Development

Most of our or our partner companies' product candidates are in the early stages of development and may not be successfully developed or commercialized, and the product candidates that do advance into clinical trials may not receive regulatory approval.

Most of our existing product candidates remain in the early stages of development and will require substantial further capital expenditures, development, testing and regulatory approvals prior to commercialization. The development and regulatory approval processes take several years, and it is unlikely that our product candidates, even if successfully developed and approved by the FDA and/or foreign equivalent regulatory bodies, would be commercially available for several years. Only a small percentage of drugs under development successfully obtain regulatory approval and are successfully commercialized. Accordingly, even if we are able to obtain the requisite financing to fund development programs, we cannot be sure 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.

Pharmaceutical development has inherent risks. Before we may seek regulatory approval for the commercial sale of any of our products, we will be required to demonstrate, through well-controlled clinical trials, that our product candidates are effective and have a favorable benefit-risk profile for their target indications. Success in early clinical trials is not necessarily indicative of success in later stage clinical trials, during which product candidates may fail to demonstrate sufficient safety or efficacy, despite having progressed through initial clinical testing, which may cause significant setbacks. Further, we may need to conduct additional clinical trials that are not currently anticipated. As a result, product candidates that we advance into clinical trials may never receive regulatory approval.

Even if any of our product candidates are approved, regulatory authorities may approve any such product candidates for fewer or more limited indications than we request, may place limitations on our ability to commercialize products at the intended price points, may grant approval contingent on the product's performance in costly post-marketing clinical trials, or may approve a label that does not include the claims necessary or desirable for the successful commercialization of that product candidate. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of the product. In addition, the Drug Enforcement Agency ("DEA"), or foreign equivalent, may schedule one or more of our product candidates under the Controlled Substances Act, or its foreign equivalent, which could impede such product's commercial viability. Any of these scenarios could impact the commercial prospects for one or more of our current or future product candidates.

The extensive regulation to which our product candidates are subject may be costly and time consuming, cause anticipated delays, and/or prevent the receipt of the required approvals for commercialization.

The research and clinical development, testing, 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 the FDA approves such product candidate's Biologics License Application ("BLA") or New Drug Application ("NDA"). The approval process is uncertain, expensive, often spans many years, and can vary substantially based upon the type, complexity and novelty of the products involved. In addition to significant and expansive clinical testing requirements, our ability to obtain marketing approval for product candidates depends on the results of required non-clinical testing, including the characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our manufacturing processes, testing procedures or equipment and facilities are inadequate to support approval. Further, the FDA has substantial discretion in the pharmaceutical approval process and may change approval policies or interpretations of regulations at any time, which could delay, limit or preclude a product candidate's approval.

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

- disagreement with the trial design or implementation of our clinical trials, including proper use of clinical trial methods and methods of data analysis;
- an inability to establish sufficient data and information to demonstrate that a product candidate is safe and/or effective for an indication;
- the FDA's rejection of 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 FDA's determination that clinical trial results do not meet the statistical significance levels required for approval;
- a disagreement by the applicable regulator regarding the interpretation of preclinical study or trial data;
- determination by the FDA that our manufacturing processes or facilities or those of third-party manufacturers with which we or our collaborators contract for clinical supplies or plan to contract for commercial supplies, do not satisfactorily comply with CGMPs; or
- a change to the FDA's approval policies or interpretation of regulations rendering our clinical data, product characteristics, or benefit-risk profile insufficient or unfavorable for approval.

Foreign approval procedures vary by country and may, in addition to the aforementioned risks, involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, rapid drug and biological development during the COVID-19 pandemic has raised questions about the safety and efficacy of certain marketed pharmaceuticals and 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.

Delays in the commencement of our clinical trials, or suspensions or terminations of such trials, could result in increased costs and/or delay our ability to pursue regulatory approvals.

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

- obtaining regulatory approval to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching and maintaining agreements on acceptable terms with prospective clinical research organizations ("CROs") and trial sites, the terms of which may be subject to extensive negotiation and 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 IRB or ethics committee approval to conduct a clinical trial at a prospective site;
- developing and validating companion diagnostics on a timely basis, if required;
- adding new clinical sites once a trial has begun;
- the death, disability, departure or other change to the principal investigator or other staff overseeing the clinical trial at a given site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; or
- retaining patients who participate in a clinical trial and replacing those 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.

If any of our product candidates causes unacceptable adverse safety events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product, preventing us from generating revenue from such products' sale. Alternatively, even if a product candidate is approved for marketing, future adverse events could lead to the withdrawal of such product from the market.

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 due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors. 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.

Regulatory requirements and guidance may change, and we may need to amend clinical trial protocols to reflect these changes. Any such change may require us to resubmit clinical trial protocols to IRBs, which may in turn impact a clinical trial's cost, timing, and likelihood of success. If any clinical trial is delayed, suspended, or terminated, 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. In addition, many of these factors may ultimately lead to the denial of regulatory approval of a product candidate.

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

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. Any of these developments may render one or more of our product candidates obsolete or noncompetitive.

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

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

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

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

If any of the technologies underpinning our product candidates, including gene therapy, is claimed to be unsafe, such product candidate may not gain the acceptance of the public or the medical community. The success of our gene therapy platforms in particular depends upon physicians who specialize in treating the diseases targeted by our product candidates prescribing treatments involving our product candidates in lieu of, or in addition to, treatments with which they are already familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity, could lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that do obtain approval and/or a decrease in demand for any such product candidates. Concern about environmental spread of our products, whether real or anticipated, may also hinder the commercialization of our products.

The FDA limits regulatory approval for our product candidates to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

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

While physicians may prescribe drugs for uses that are not described in the product's label or that differ from those tested in clinical studies and approved by the regulatory authorities ("off label uses"), our ability to promote the products is limited to those indications that are specifically approved by the FDA. Such off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the practice of medicine or behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies regarding the promotion of off-label use.

If our promotional activities fail to comply with these regulations or guidelines, we may be subject to compliance or enforcement actions, including Warning Letters, by, these authorities. In addition, our failure to follow FDA laws, regulations and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, request a recall, institute fines, or could result in disgorgement of money, operating restrictions, corrective advertising, injunctions or criminal prosecution, any of which could harm our business.

Risks Pertaining to the Need for and Impact of Existing and Additional Financing Activities

We have historically financed a significant portion of our growth and operations in part through the assumption of debt. Should an event of default occur under any applicable loan documents, our business would be materially adversely affected. Further, our current credit arrangement with Oaktree Capital restricts our and certain of our partner companies' abilities to take certain actions.

At December 31, 2020, the total amount of debt outstanding, net of the debt discount was $51.7 million. If we default on our obligations, the holders of our debt may declare the outstanding amounts immediately payable together with accrued interest, and/or take possession of any pledged collateral. If an event of default occurs, we may be unable to cure it within the applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment and we may be unable 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, satisfy capital needs, or to engage in, expand or pursue our business activities. Such restrictions 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.

On August 27, 2020, we entered into a $60.0 million senior secured credit agreement with Oaktree Fund Administration, LLC and the lenders from time-to-time party thereto (collectively, "Oaktree"). The Oaktree credit agreement contains certain affirmative and negative covenants restricting our and certain of our partner companies' abilities to take certain actions, especially as pertains indebtedness, liens, investments, affiliate transactions, acquisitions, mergers, dispositions, prepayment of other indebtedness, dividends and other distributions (subject in each case to exceptions). The Oaktree credit agreement also contains financial covenants obligating us to maintain a minimum liquidity amount and a minimum amount of revenue, in both cases subject to exceptions. The breach of any such provisions (even, potentially, in an immaterial manner) could result in an event of default under the Oaktree credit agreement, the announcement and impact of which could have a negative impact on the trading prices of our securities. The restrictions imposed by such provisions may also inhibit our and certain of our partner companies' ability to enter into certain transactions or arrangements that management otherwise believes would be in our or such partner companies' best interests, such as dispositions that would result in cash inflows to Fortress and/or our partner companies, or acquisitions or financings that would promote future growth.

We have a history of operating losses that is expected to continue, and we are unable to predict the extent of future losses, whether we will be able to sustain current revenues or whether we will ever achieve or sustain profitability.

We continue to generate operating losses in all periods including losses from continuing operations of approximately $103.0 million and $101.7 million for the years ended December 31, 2020 and 2019, respectively. At December 31, 2020, we had an accumulated deficit of approximately $482.8 million. We expect to make substantial expenditures and incur increasing operating costs and interest expense in the future, and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates and finance investments in certain of our existing and new partners and affiliates in accordance with our growth strategy. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity.

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

- one or more of our development-stage product candidates is approved for commercial sale and we decide to commercialize such product(s) ourselves, due to the need to establish the necessary commercial infrastructure to launch and commercialize this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for manufacturing, testing, warehousing, distribution, cash collection and related commercial activities;
- we are required by the FDA or a foreign regulatory authority to perform studies in addition to those currently expected;
- there are any delays in completing our clinical trials or the development of any of our product candidates;
- we execute other collaborative, licensing or similar arrangements, depending on the timing of payments we may make or receive under these arrangements;
- there are variations in the level of expenses related to our future development programs;
- we become involved in any product liability or intellectual property infringement lawsuits; and
- there are any regulatory developments affecting our competitors' product candidates.

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

- obtain regulatory approval for one or more of our product candidates, or any future product candidate that we may license or acquire in the future;
- manufacture commercial quantities of one or more of our product candidates or any future product candidate, if approved, at acceptable cost levels; and

- develop a commercial organization and the supporting infrastructure required to successfully market and sell one or more of our product candidates or any future product candidate, if approved.

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

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

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

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

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

We 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 R&D programs will require substantial additional capital for research, preclinical testing and clinical trials, establishing pilot scale and commercial scale manufacturing processes and facilities, and establishing and developing 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.

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2020 and 2019 we incurred R&D expenses of approximately $61.3 million and $75.2 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 from the filing of this 10-K. Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, however, 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. The terms of our existing debt arrangements, including that with Oaktree, have and will continue to inhibit our and our subsidiaries' abilities to raise capital.

In particular, as of September 30, 2021, Avenue had cash and cash equivalents of $0.6 million. In the event that IV Tramadol is approved by the FDA, this triggers an obligation by Avenue to make $5.0 million in contractual milestone payments, for which Avenue currently does not have sufficient funding. Avenue will need to secure additional funds through equity or debt offerings, or other potential sources, in order to complete the Advisory Committee process. Avenue cannot be certain that such additional funding will be available on acceptable terms, or at all. These factors individually and collectively raise substantial doubt about Avenue's ability to continue as a going concern within one year from the date of this report. In light of the foregoing, it may be necessary at some point for Avenue to seek protection under Chapter 11 of the United States Bankruptcy Code, which could have a material adverse impact on Avenue's business, financial condition, operations and could place its shareholders at significant risk of losing all of their investment. In any such Chapter 11 proceeding, Avenue may seek to restructure its obligations or commence an orderly wind-down of its operations and sale of its assets, in either event, holders of equity interests could receive or retain little or no recovery. We also note that the process of exploring refinancing or restructuring alternatives, including those under Chapter 11, may be disruptive to Avenue's business and operations.

On September 2, 2021, Avenue received a delinquency notification letter from the Listing Qualifications Staff of the Nasdaq Stock Market LLC ("Nasdaq") indicating that Avenue is not in compliance with Nasdaq rules requiring listed securities to maintain a minimum Market Value of Listed Securities ("MVLS") of $35 million (the "MVLS Requirement"). Avenue has 180 calendars days, expiring March 1, 2022, to regain compliance with the MVLS Requirement. If Avenue maintains a MVLS at or greater than $35 million or more for a minimum of ten consecutive business days, Avenue will regain compliance. If Avenue does not regain compliance within 180 calendar days, Avenue will receive a written notification from Nasdaq that its securities are subject to delisting. Avenue intends to monitor its MVLS and may, if appropriate, consider implementing available options to regain compliance with the MVLS Requirement. There can be no assurance that Avenue will be able to regain compliance with the MVLS Requirement, or maintain compliance if Avenue regains compliance.

We may be unable to generate returns for our investors if our partner companies and subsidiaries, several of which have limited or no operating history, have no commercialized revenue generating products, or 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 subsidiaries, which often have limited or no operating history, no commercialized revenue generating products, and require additional third-party financing to fund product and services development or acquisitions. Our business depends in large part on the ability of one or more of our subsidiaries and/or partner companies to innovate, in-license, develop or acquire successful biopharmaceutical products and/or acquire companies in increasingly competitive and highly regulated markets. If certain of our subsidiaries and/or partner companies do not successfully obtain additional third-party financing to commercialize products, or are not acquired in change-of-control transactions that result in cash distributions, as applicable, the value of our businesses and our ownership stakes in our partner companies may be materially adversely affected.

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

To the extent that we raise additional capital by issuing common stock (or preferred stock that is convertible into common stock), the share ownership of existing stockholders will be diluted. We have also entered into financing arrangements to raise capital for our subsidiaries under which Fortress common stock is or may be issuable to investors in lieu of cash, upon certain conditions being met; in the event such issuances take place, they will also be dilutive of the stakes of existing stockholders. 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.

Risks Pertaining to Our Existing Revenue Stream from Journey Medical Corporation

Future revenue based on sales of our dermatology products, especially Qbrexza, Ximino, Targadox, Accutane, 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 our dermatology products through our partner company Journey. Any setback that may occur with respect to such products could significantly impair our operating results and/or reduce our revenue and the value of our Securities. Setbacks for such products could include, but are not limited to, issues related to: supply chain, shipping; distribution; demand; manufacturing; product safety; product quality; marketing; government regulation, including but not limited to pricing or reimbursement; licensing and approval; intellectual property rights; competition with existing or new products, including third-party generic competition; product acceptance by physicians, other licensed medical professionals, and patients; and higher than expected total rebates, returns or recalls.Also, the majority of Journey's sales derive from products that are without patent protection and/or are or may become subject to third party generic competition; the introduction of new competitor products, or increased market share of existing competitor products, could have a significant adverse effect on our operating income.

We face challenges as our products face generic competition and/or losses of exclusivity.

Journey's products do and may compete with well-established products, both branded and generic, with similar or the same indications. We face increased competition from manufacturers of generic pharmaceutical products, who may submit applications to FDA seeking to market generic versions of our products. In connection with these applications, the generic drug companies may seek to challenge the validity and enforceability of our patents through litigation. When patents covering certain of our products (if applicable) expire or are successfully challenged through litigation or in USPTO proceedings, if a generic company launches a competing product "at risk," or when the regulatory or licensed exclusivity for our products (if applicable) expires or is otherwise lost, we may face generic competition as a result.

The majority of our sales derive from products that are without patent protection and/or are or may become subject to third-party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse impact on our operating income. Two of our marketed products, Qbrexza and Ximino, as well as DFD-29, currently have patent protection. Three of our marketed products, Accutane, Targadox, and Exelderm, do not have patent protection or otherwise are not eligible for patent protection. Accutane currently competes in the Isotretinoin market with five other AB rated products. Targadox will likely face additional AB rated generic entrants over the next six months. Exelderm may face AB rated generic competition in the future.

Generic versions are generally significantly less expensive than branded versions, and, where available, may be required to be utilized before or in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care.

Any disruptions to the capabilities, composition, size or existence of Journey's field sales force may have a significant adverse impact on our existing revenue stream. Further, our ability to effectively market and sell any future products that we may develop will depend our ability to establish and maintain sales and marketing capabilities or to enter into agreements with third parties to market, distribute and sell any such products.

Journey's field sales force has been and is expected to continue to be an important contributor to our commercial success. Any disruptions to our relationship with such field sales force or the professional employer organization that employs our field sales force, could materially adversely affect our product sales. We currently rely, and may continue to rely, on professional employer organizations and staffing organizations for the employment of our field sales force.

The establishment, development, and/or expansion of a field sales force, either by us or certain of our partners or vendors, or the establishment of a contract field sales force to market any products for which we may have or 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 or maintain arrangements with third parties on commercially reasonable terms, or at all.

If our products are not included in managed care organizations' formularies or coverage by other organizations, our products' utilization and market shares may be negatively impacted, which could have a material adverse effect on our business and financial condition.

In the United States, continued sales and coverage, including formulary inclusion without the need for a prior authorization or step edit therapy, of our products for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third party reimbursement may not be available for our products to enable us to realize an appropriate return on our investment of our currently marketed products or those which we may acquire or develop in the future.

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 are based on the prices and therapeutic benefits of 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.

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

We have obtained approval for some products, and intend to seek approval for other product candidates, to commercialize 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 regarding whether 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.

Legislative and regulatory changes to the healthcare systems of the United States and certain foreign countries could impact our ability to sell our products profitably. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the way Medicare covers and pays for pharmaceutical products by revising 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. In addition, this law provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this law and future laws could decrease the coverage and price that we will receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Therefore, any limitations in reimbursement that results from the MMA may result in reductions in payments from private payors.

Since 2003, there have been several other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "Affordable Care Act" or "ACA," was enacted in 2010 and made significant changes to the United States' healthcare system. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business.

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

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

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

At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court's prior decision. On December 14, 2018, a Texas federal district court judge issued a ruling declaring that the ACA in its entirety is unconstitutional. Upon appeal, the Fifth Circuit upheld the district court's ruling that the individual mandate is unconstitutional. However, the Fifth Circuit remanded the case back to the district court to conduct a more thorough assessment of the constitutionality of the entire ACA despite the individual mandate being unconstitutional. The Supreme Court agreed to hear the case on appeal from the Fifth Circuit on March 2, 2020 and held oral arguments on November 10, 2020. While this lawsuit has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome may have a significant impact on our business.

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

The 116th Congress 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), 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. The 117th Congress convened on January 3, 2021 and could reintroduce many of the bills targeting drug prices. While we cannot predict what proposals may ultimately become law, the elements under consideration could significantly change the landscape in which the pharmaceutical market operates.

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

On December 12, 2019, the House of Representatives passed broad legislation (H.R. 3, the *Elijah E. Cummings Lower Drug Costs Now Act*) that would, among other provisions, require HHS to negotiate drug prices and impose price caps and restructure the Medicare Part D benefit, imposing more financial responsibility on certain drug manufacturers. Failure by a manufacturer to reach an agreement with HHS on the negotiated price could result in significant penalties for prescription drug manufacturers. In addition, S. 2543, *the Prescription Drug Pricing Reduction Act* would also, among other provisions, restructure the Medicare Part D benefit, but it would not authorize direct negotiation by the federal government. 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 took several regulatory steps to redirect ACA implementation. The HHS finalized a Medicare hospital payment reduction for Part B drugs acquired through the 340B Drug Pricing Program.

Under the Trump Administration, HHS finalized several proposals aimed at lowering drug prices for Medicare beneficiaries and increasing price transparency. For example, the Trump Administration issued an interim final rule on November 27, 2020 implementing a "Most Favored Nation" payment model for Part B drugs that applies international reference pricing to determine reimbursement for certain drugs paid by Medicare Part B. The interim final rule was enjoined by federal courts prior to its implementation date of January 1, 2021, and the lawsuit is ongoing. In addition, HHS, in conjunction with the FDA, finalized four pharmaceutical importation pathways in September 2020: (1) regulations establishing importation of pharmaceuticals from Canada by wholesalers and pharmacists; (2) FDA guidance permitting manufacturers to import their own pharmaceuticals that were originally intended for marketing in other countries; (3) a request for proposals from private sector entities to import prescription drugs for personal use under existing statutory authority; and (4) a request for proposals from private sector entities to reimport insulin under existing statutory authority.

Further, on November 11, 2020, the Trump Administration issued a final rule that changes the permissible structure of drug rebates and discounts between drug manufacturers and third-party payors (including pharmacy benefit managers that negotiate drug prices on behalf of such third-party payors). This final rule, often referred to as the "Rebate Rule," could have significant direct and indirect impacts on drug pricing in both government and commercial markets. With respect to price transparency, the Trump Administration promulgated regulations that require hospitals and third-party payors to disclose prices of items and services, which may impact negotiated rates in the commercial market.

On January 20, 2021, Joe Biden was inaugurated as the 46th president of the United States. As a presidential candidate, Mr. Biden indicated support for several policies aimed at lowering drug prices, including government price negotiation, drug importation, international reference pricing, and price increase controls. The Biden Administration may continue, modify, or repeal many of the drug pricing policies proposed and finalized by the Trump Administration. While we cannot predict which policies the Biden Administration may support and enforce, the policies finalized in the months prior to the beginning of Mr. Biden's term, if continued, could significantly change the landscape in which the pharmaceutical market operates and significantly impact our ability to effectively market and sell our products.

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

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

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

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the payment that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidate, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

Risks Pertaining to our Business Strategy, Structure and Organization

We have entered, and will likely in the future enter, into certain collaborations or divestitures which may cause a reduction in our business' size and scope, market share and opportunities in certain markets, or our ability to compete in certain markets and therapeutic categories. We have also entered into several arrangements under which we have agreed to contingent dispositions of partner companies and/or their assets. The failure to consummate any such transaction may impair the value of such companies and/or assets, and we may not be able to identify or execute alternative arrangements on favorable terms, if at all.

We have entered into several partnerships and/or contingent sales of our assets and subsidiaries, including an equity investment and contingent sale between Avenue and InvaGen (the transaction agreement for which was terminated), an equity investment and contingent option transaction between Caelum and Alexion Pharmaceuticals, Inc. (which transaction has consummated) and a development funding and contingent asset purchase between Cyprium and Sentynl Therapeutics, Inc. Each of these transactions has been time-consuming and has diverted management's attention. As a result of these contingent sales, as with other similar transactions that we may 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 Stock Purchase and Merger Agreement between Avenue and InvaGen, dated as of November 12, 2018 (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 transaction involving 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 from management's attention, may 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.

We act, and are likely to continue acting, as guarantor and/or indemnitor of the obligations, actions or inactions of certain of our subsidiaries and affiliated companies. We have also entered into certain arrangements with our subsidiaries and third parties pursuant to which a substantial number of shares of our common stock may be issued. Depending on the terms of such arrangements, we may be contractually obligated to pay substantial amounts to third parties, or issue a substantially dilutive number of shares of our common stock, based on the actions or inactions of our subsidiaries and/or affiliates.

We act, and are likely to continue acting, as indemnitor of potential losses or liabilities that may be experienced by one or more of our affiliated companies and/or their partners or investors. For instance, under that certain Indemnification Agreement, dated as of November 12, 2018 (the "Indemnification Agreement"), we agreed to indemnify InvaGen and its affiliates for losses they may sustain in connection with inaccuracies that may appear in the representations and warranties that Avenue made to InvaGen in the Avenue SPMA, as such representations and warranties were given as of the dates of signing and first closing, and as may be required to be given as of the second stage closing under the Avenue SPMA as well. The maximum amount of indemnification we may have to provide under the Indemnification Agreement is $35.0 million, and such obligation terminates upon the consummation of the Merger Transaction (as defined in the Avenue SPMA).

In the event of payment by us of any such indemnification amount, we would be able to recoup such amounts (other than our pro rata share of the indemnification as a shareholder in Avenue) from the Merger Transaction proceeds, but if the Merger Transaction never occurs, we would have no means of recouping such previously-paid indemnification amounts. If we become obligated to pay all or a portion of such indemnification amounts (regardless of whether or not we are partially reimbursed out of the proceeds of the Merger Transaction), our business and the market value of our common stock and/or debt securities may be materially adversely impacted.

While not an indemnification obligation, we have agreed, in connection with a convertible preferred financing by our partner company Journey, to a contingent issuance of what could be a significant number of shares of Fortress common stock. Such issuance would occur only if Journey has neither been sold nor consummated a qualified financing (in one transaction or a series of related transactions) under which Journey has received an aggregate gross amount of $25 million from the sale of Journey's common stock, in each case by March 31, 2022 (extendible by up to an additional six months at Journey's option). Substantial dilution to Fortress stockholders may result if neither such event occurs and we are thereby obligated to issue the aforementioned Fortress common stock.

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

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

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

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

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, which could result in conflicts of interests relating to ongoing and future relationships and transactions with these parties.

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

Certain of our executives, directors and principal stockholders, whose interests may be adverse to those of our other stockholders, can control our direction and policies.

Certain of our executive officers, directors and stockholders own nearly or more than 10% of our outstanding common stock and, together with their affiliates and related persons, beneficially own a significant percentage of our capital stock. If these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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

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

- risk of entering new markets in which we have little to no experience;
- diversion of financial and managerial resources from existing operations;
- successfully negotiating a proposed acquisition or investment timely and at a price or on terms and conditions favorable to us;
- the impact of regulatory reviews on a proposed acquisition or investment;
- the outcome of any legal proceedings that may be instituted with respect to the proposed acquisitions or investment;
- with respect to an acquisition, difficulties in integrating operations, technologies, services and personnel; and
- potential inability to maintain relationships with customers of the companies we may acquire or invest in.

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

Risks Pertaining to Reliance on Third Parties

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

We also rely on third-party manufacturers to purchase from third-party suppliers the raw materials and equipment 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 direct 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 since such agreements are entered into by our third-party manufacturers and their qualified suppliers. 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 engage in our own commercial manufacturing of our product candidates, if they received marketing approval, and would likely continue to be heavily dependent upon third-party manufacturers. Our dependence on third parties to manufacture and supply clinical trial materials, as well as our planned dependence on third party manufacturers for any products that may be approved, may adversely affect our ability to develop and commercialize products in a timely or cost-effective manner, or at all.

In addition, because of the sometimes-limited number of third parties who specialize in the development, manufacture and/or supply of our clinical and preclinical materials, we are often compelled to accept contractual terms that we deem less than desirable, including without limitation as pertains representations and warranties, supply disruptions/failures, covenants and liability/indemnification. Especially as pertains liability and indemnification provisions, because of the frequent disparities in negotiating leverage, we are often compelled to agree to low caps on counterparty liability and/or indemnification language that could result in outsized liability to us in situations where we have zero or relatively little culpability.

We rely heavily on third parties for the development and manufacturing of products and product candidates.

Certain of our partner companies, on whose successes we largely rely, are early-stage biopharmaceutical companies with limited operating histories. To date, we have engaged primarily in intellectual property acquisitions, and evaluative and R&D activities and have not generated any revenues from product sales (except through Journey). We have incurred significant net losses since our inception. As of December 31, 2020, we had an accumulated deficit of approximately $482.8 million. We may need to rely on third parties for activities critical to the product candidate development process, including but not necessarily limited to:

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

We have also not demonstrated the ability to perform the functions necessary for the successful commercialization of any of our pre-market product candidates, should any of them be approved for marketing. If we were to have any such product candidates approved, the successful commercialization of such products would be dependent on us performing or contracting 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.

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

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

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

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities or potential liability. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with good laboratory practice ("GLP") as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices ("GCPs") for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may refuse to accept such data, or require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with products produced under CGMP in strict conformity to CGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

We rely on clinical and pre-clinical data and results obtained from and 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/or 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.

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

We anticipate substantial reliance on 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 collaboration proposals based upon their assessment of our financial, regulatory or intellectual property positions. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of product candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, the related product revenues that might follow are likely to be lower than if we directly marketed and sold products. Such collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on, and such collaborations could be more attractive than the one with us for any future product candidate.

Management of our relationships with collaborators will require:

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

Risks Pertaining to Intellectual Property and Potential Disputes with Licensors Thereof

If we are unable to obtain and maintain sufficient patent protection for our technology and products, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

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

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

In addition, patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the US Patent and Trademark Office ("PTO"), or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our US patent positions. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technologies or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Third parties are often responsible for maintaining patent protection for our product candidates, at our and their expense. If that party fails to appropriately prosecute and maintain patent protection for a product candidate, our abilities to develop and commercialize products may be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. Such a failure to properly protect intellectual property rights relating to any of our product candidates could have a material adverse effect on our financial condition and results of operations.

In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents.

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

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

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

Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first instance for protection under the patent laws of the US. Accordingly, we cannot predict the breadth of claims that may be allowed and remain enforceable in our patents or in those licensed from a third party.

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

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

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

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

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

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

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

- defend litigation or administrative proceedings which may be costly regardless of outcome, and which could result in a substantial diversion of financial and management resources.

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

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

We in-license from third parties the intellectual property needed to develop and commercialize products and product candidates. As such, any dispute with the licensors or 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 the vast majority 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.

Risks Pertaining to the Commercialization of Product Candidates

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

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

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates in a broader patient group (i.e., based on actual use);
- the availability, cost and benefits 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;
- the product labeling or product insert required by the FDA or regulatory authority in other countries, including any contradictions, warnings, drug interactions, or other precautions;
- changes in the standard of care for the targeted indications for our product candidate or future product candidates, which could reduce the marketing impact of any labeling or marketing claims that we could make following FDA approval;
- 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. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

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 desired labeling claims or scheduling classifications necessary or desirable for the promotion of our marketed products (or our product candidates if approved). We may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory or if adverse events or other safety issues arise after approval while our products are on the market, 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 manufacturing problems occur, regulatory approval may be impacted or 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 face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for one or more of our product candidates or a future product candidate we may license or acquire and may have to limit their commercialization.

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

- withdrawal of clinical trial participants;
- suspension or termination of clinical trial sites or entire trial programs;
- decreased demand for any product candidates or products that we may develop;
- initiation of investigations by regulators;

- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our product candidate or future product candidates.

Our partner company Journey acquired an isotretinoin product and began marketing that product under the Accutane® brand name in Q2 2021. Isotretinoin has a black box warning for use in pregnant women. Isotretinoin also has warnings for side effects related to psychiatric disorders and inflammatory bowel disease, among others. Historically, isotretinoin has been the subject of significant product liability claims, mainly related to irritable bowel disease . Currently, there is no significant isotretinoin product liability litigation. The federal multi-district litigation ("MDL") court dismissed all remaining federal isotretinoin cases in 2014 after ruling that the warning label on the drug was adequate. The MDL dissolved in 2015, which effectively put an end to federal lawsuits. Cases continued in New Jersey state court until 2017, when the trial court judge dismissed the remaining the isotretinoin product liability cases. Thus, should a product liability claim against Journey be brought related to its isotretinoin product, we have substantial defenses. However, it is not feasible to predict the ultimate outcome of any litigation and the Company could in the future be required to pay significant amounts as a result of settlement or judgments should such new product liability claims be brought.

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

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

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

Any product for which we obtain marketing approval, along with the authorized manufacturing facilities, processes and equipment, post-approval clinical data, labeling, advertising and promotional activities for such product, will remain subject to ongoing regulatory requirements governing drug or biological products, as well as review by the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, CGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping, and requirements regarding company presentations and interactions with healthcare professionals. Even if we obtain regulatory approval for a product, the approval may be subject to limitations on the indicated uses for which the product may be marketed or subject to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

We also may be subject to state laws and registration requirements covering the distribution of drug products. Later discovery of previously unknown problems with products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on product manufacturing, distribution or use;

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

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

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

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

Risks Pertaining to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries

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 former U.S. President took several executive actions, specifically through rulemaking and guidance, that could impact the pharmaceutical business and industry. Shortly after taking office in January 2021, President Biden announced that his Administration would be freezing a number of the prior Administration's drug pricing reforms, while others remain subject to both executive orders or regulatory changes issued by the Department of Health and Human Services. A few of the major administrative actions include:

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

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

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

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

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

- On December 2, 2020, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule entitled, *Modernizing and Clarifying the Physician Self-Referral Regulations* and on the same day the HHS Office of Inspector General finalized a similar rule, entitled *Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary penalty Rules Regarding Beneficiary Inducements.* The rules are an effort to reform regulations dealing with anti-kickback and self-referral laws. These rules allow certain financial arrangements that would otherwise violate anti-kickback and self-referral laws for providers that are participating in value-based payment arrangements. The rule could impact drug purchasing behavior to ensure providers are within their budget and/or restructure existing payment structures between providers and manufacturers.

As with any change in the Executive Office, and particularly with respect to changes from a Republican Administration under former President Trump to a Democratic Administration under President Biden, we expect there to be significant changes to existing rules, regulations and policies, the enactment of new Executive Orders and other immediate or iterative political, legislative and administrative changes, affecting the pharmaceutical industry. 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 based on similar governmental changes in other countries.

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

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

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

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

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

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

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

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

As we continue to execute our growth strategy, we may be subject to further government regulation which could adversely affect our financial results, including without limitation the Investment Company Act of 1940.

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

General Risks

Our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or third parties' cybersecurity.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information, including, but not limited to, information related to our intellectual property and proprietary business information, personal information, and other confidential information. It is critical that we maintain such confidential information in a manner that preserves its confidentiality and integrity. Furthermore, we have outsourced elements of our operations to third party vendors, who each have access to our confidential information, which increases our disclosure risk.

We are in the process of implementing our internal security and business continuity measures and developing our information technology infrastructure. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, data center facilities, lab equipment, and connection to the internet, face the risk of breakdown or other damage or interruption from service interruptions, system malfunctions, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), each of which could compromise our system infrastructure or lead to the loss, destruction, alteration, disclosure, or dissemination of, or damage or unauthorized access to, our data or data that is processed or maintained on our behalf, or other assets.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, and could result in financial, legal, business, and reputational harm to us. For example, in 2021, our partner company Journey was the victim of a cybersecurity incident that affected its accounts payable function and led to approximately $9.5 million in wire transfers being misdirected to fraudulent accounts. The details of the incident and its origin are under investigation with the assistance of third-party cybersecurity experts working at the direction of legal counsel. The matter was reported to the Federal Bureau of Investigation and does not appear to have compromised any personally identifiable information or protected health information. As Journey's controlling stockholder and supporting partner in back-office functions, Fortress provided Journey with $9.5 million to ensure its accounts payable operations continue to function smoothly. Fortress and Journey may incur additional expenses and losses as a result of this cybersecurity incident, including those related to investigation fees and remediation costs.

In addition, the loss or corruption of, or other damage to, clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our drug candidates or any future drug candidates and to conduct clinical trials, and similar events relating to their systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Sophisticated cyber attackers (including foreign adversaries engaged in industrial espionage) are skilled at adapting to existing security technology and developing new methods of gaining access to organizations' sensitive business data, which could result in the loss of proprietary information, including trade secrets. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies.

Any security breach or other event leading to the loss or damage to, or unauthorized access, use, alteration, disclosure, or dissemination of, personal information, including personal information regarding clinical trial subjects, contractors, directors, or employees, our intellectual property, proprietary business information, or other confidential or proprietary information, could directly harm our reputation, enable competitors to compete with us more effectively, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, or otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Each of the foregoing could result in significant legal and financial exposure and reputational damage that could adversely affect our business. Notifications and follow-up actions related to a security incident could impact our reputation or cause us to incur substantial costs, including legal and remediation costs, in connection with these measures and otherwise in connection with any actual or suspected security breach. We expect to incur significant costs in an effort to detect and prevent security incidents and otherwise implement our internal security and business continuity measures, and actual, potential, or anticipated attacks may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants. We may face increased costs and find it necessary or appropriate to expend substantial resources in the event of an actual or perceived security breach.

The costs related to significant security breaches or disruptions could be material, and our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Furthermore, if the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

The COVID-19 pandemic may continue to impact Journey's product revenues, future clinical trials, and as a result, our financial condition and results of operations and other aspects of our business.

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

To protect the health of our workforce, we asked our office-based employees to work remotely, have restricted domestic and international travel indefinitely, and restricted on-site staff to only those personnel and contractors who perform essential activities that must be conducted on-site. We intend to keep these precautionary measures in effect for the foreseeable future and may need to enact further measures to help minimize the risk of our employees being exposed to COVID-19. Although the impact of a remote working environment to our operations has been minimal, our continued reliance on remote work may negatively impact productivity, including our ability to generate revenues and product demand, prepare regulatory applications, and conduct data analysis, and may disrupt, delay, or otherwise adversely impact our business. In addition, continued remote working could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruption. COVID-19 may also compromise the ability of independent contractors who perform consulting services for us to deliver services or deliverables in a satisfactory or timely manner.

Some factors from the COVID-19 outbreak that may delay or otherwise adversely affect Journey's product revenues, as well as adversely impact Journey's business generally, include:

- the changes in buying patterns throughout Journey's supply chain caused by lack of normal access by patients to the healthcare system and concern about the continued supply of medications, which may increase or decrease demand for Journey's products;

- adverse effects on our manufacturing operations, supply chain and distribution systems, which may impact Journey's ability to produce and distribute products, as well as the ability of third parties to fulfill their obligations to us and could increase our expenses;

- the risk of shutdown in countries where Journey relies, or may rely, on CMOs to provide commercial manufacture of our products, clinical batch manufacturing of our product candidates, including DFD-29, or the procurement of active pharmaceutical ingredients or other manufacturing components for Journey's products or product candidates, which may cause delays or shortages in Journey's product supply and/or the timing of any our clinical trials;

- the risk that the COVID-19 pandemic may intensify other risks inherent in our business; and

- the possibility that third parties on which we rely for certain functions and services, including CMOs, suppliers, distributors, logistics providers, and external business partners, may be adversely impacted by restrictions resulting from COVID-19, which could cause us to experience delays or incur additional costs.

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

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

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

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

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

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

- announcements we make regarding our current product candidates, acquisition of potential new product candidates and companies and/or in-licensing through multiple partners/affiliates;
- sales or potential sales of substantial amounts of our Common Stock;

- issuance of debt or other securities;
- our delay or failure in initiating or completing pre-clinical or clinical trials or unsatisfactory results of any of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors and/or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- unstable regional political and economic conditions;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

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

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

Almost all of the 100.8 million outstanding shares of our Common Stock, inclusive of outstanding equity awards, as of December 31, 2020 are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), or an effective registration statement. In addition, pursuant to our current shelf registration statement on Form S-3, from time to time we may issue and sell shares of our Common Stock or Preferred Stock having an aggregate offering price of up to $26.7 million as of December 31, 2020. Any sale of a substantial number of shares of our Common Stock or our Preferred Stock could cause a drop in the trading price of our Common Stock or Preferred Stock on the Nasdaq Stock Market.

We 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.

A catastrophic disaster could damage our facilities beyond insurance limits or cause us to lose key data, which could cause us to curtail or cease operations.

We are vulnerable to damage and/or loss of vital data from natural disasters, such as earthquakes, tornadoes, power loss, fire, health epidemics and pandemics, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our businesses could be seriously impaired. We have property, liability and business interruption insurance that may not be adequate to cover losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and prospects.

Any of the aforementioned circumstances, including without limitation the COVID-19 virus, may also impede our employees' and consultants' abilities to provide services in-person and/or in a timely manner; hinder our ability to raise funds to finance our operations on favorable terms or at all; and trigger effectiveness of "force majeure" clauses under agreements with respect to which we receive goods and services, or under which we are obligated to achieve developmental milestones on certain timeframes. Disputes with third parties over the applicability of such "force majeure" clauses, or the enforceability of developmental milestones and related extension mechanisms in light of such business interruptions, may arise and may become expensive and time-consuming.

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

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

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

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

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

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

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

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

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

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

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

If the timing of FDA's review and approval of new products is delayed, the timing of our or our partners' development process may be delayed, which could result in delayed milestone revenues and materially harm our operations or business.

The COVID-19 pandemic has caused considerable disruptions at FDA, namely with respect to diverting FDA's attention and resources to facilitate vaccine development and ensure rapid review and emergency use authorization of vaccines intended to prevent COVID-19. Back in March, Dr. Janet Woodcock, the Director of FDA's Center for Drug Evaluation and Research, temporarily stepped away from her role to focus on the therapeutic aspects of Operation Warp Speed, a major reorganization intended to better align FDA's activities with the national effort to develop COVID-19 countermeasures. Dr. Woodcock later named Acting Commissioner of FDA on January 20, 2021. These changes to leadership, enhanced focus on COVID-19 countermeasures, and the reorganization and rededication or critical resources, both at FDA and within similar governmental authorities across the world, are likely to impact the ability of new products and services from being developed or commercialized in a timely manner.

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

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

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

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

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

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

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

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

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Index

Exhibit Number	Exhibit Title
31.1	Certification of Chairman, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chairman, President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.(*)
101.SCH	Inline XBRL Taxonomy Extension Schema Document.(*)
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.(*)
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.(*)
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.(*)
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.(*)
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
\+ Certain confidential portions of this exhibit have been omitted pursuant to Item 601(b) of Regulation S-K.

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 15, 2021

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 15, 2021

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 15, 2021

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 15, 2021

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, 2021 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 15, 2021

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, 2021, 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 15, 2021

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