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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, 2022

OR

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

For the transition period from to

Commission File Number 001-35366

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.)

1111 Kane Concourse Suite 301
Bay Harbor Island, FL 33154
(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 7, 2022
Common Stock, $0.001 par value	108,615,240
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

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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, which may result in the identification of safety or efficacy concerns. 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 expect such losses to continue in the future.
- We have funded our operations in part through the assumption of debt, and the applicable lending agreements may restrict our operations. Further, the occurrence of any default event under an 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 additional capital by issuing equity or equity-linked securities, our existing stockholders will be diluted.

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

- Our operating income derives primarily from the sale of our partner company Journey's dermatology products, particularly Qbrexza, Accutane, Targadox, Ximino, Exelderm, Amzeeq, and Zilxi. 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. Four of Journey's marketed products, Qbrexza, Amzeeq, Zilxi and Ximino, as well as DFD-29, a modified release oral minocycline for the treatment of rosacea licensed from Dr. Reddy's Laboratories, 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 current and 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 product supply. 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, and subsequently, Amzeeq, two products 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.

General and Other Risks

- On October 31, 2022, we received a letter from the Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") indicating that the bid price of the Company's common stock, par value $0.001 per share (the "Common Stock"), had closed below $1.00 per share for 30 consecutive business days and, as a result, the Company is not in compliance with Nasdaq Listing Rule 5550(a)(2), which sets forth the minimum bid price requirement for continued listing on The Nasdaq Capital Market. Our Common Stock may be subject to delisting from The Nasdaq Capital Market if we are unable to regain compliance which may decrease the market liquidity and market price of our Common Stock.

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, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 208,351	$ 305,744
Accounts receivable, net	28,533	23,112
Inventory	15,230	9,862
Other receivables - related party	153	678
Prepaid expenses and other current assets	5,727	7,066
Total current assets	257,994	346,462
Property, plant and equipment, net	13,773	15,066
Operating lease right-of-use asset, net	19,756	19,005
Restricted cash	2,220	2,220
Intangible asset, net	28,424	12,552
Other assets	1,394	1,198
Total assets	**$ 323,561**	**$ 396,503**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 93,817	$ 90,660
Deferred revenue	1,093	2,611
Income taxes payable	—	345
Operating lease liabilities, short-term	2,271	2,104
Partner company line of credit	—	812
Partner company installment payments - licenses, short-term, net	9,122	4,510
Total current liabilities	106,303	101,042
Notes payable, long-term, net	91,165	42,937
Operating lease liabilities, long-term	21,474	20,987
Partner company installment payments - licenses, long-term, net	1,374	3,627
Other long-term liabilities	1,893	2,033
Total liabilities	**222,209**	**170,626**
Commitments and contingencies (Note 13)		
Stockholders' equity		
Cumulative redeemable perpetual preferred stock, $0.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 108,259,353 shares issued and outstanding as of September 30, 2022; 170,000,000 shares authorized, 101,435,505 shares issued and outstanding as of December 31, 2021, respectively	108	101
Additional paid-in-capital	668,650	656,033
Accumulated deficit	(607,090)	(547,463)
Total stockholders' equity attributed to the Company	61,671	108,674
Non-controlling interests	39,681	117,203
Total stockholders' equity	101,352	225,877
Total liabilities and stockholders' equity	**$ 323,561**	**$ 396,503**

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,	
	2022	2021	2022	2021
Revenue				
Product revenue, net	$ 16,043	$ 19,610	$ 55,074	$ 45,617
Collaboration revenue	364	1,446	1,518	4,646
Revenue - related party	48	29	118	252
Other revenue	73	—	2,629	—
Net revenue	16,528	21,085	59,339	50,515
Operating expenses				
Cost of goods sold - product revenue	7,221	11,167	23,057	22,559
Research and development	29,855	27,367	99,707	70,226
Research and development - licenses acquired	47	713	48	15,585
Selling, general and administrative	30,139	22,221	85,457	59,145
Wire transfer fraud loss	—	9,540	—	9,540
Total operating expenses	67,262	71,008	208,269	177,055
Loss from operations	(50,734)	(49,923)	(148,930)	(126,540)
Other income (expense)				
Interest income	419	132	711	505
Interest expense and financing fee	(3,393)	(4,444)	(8,897)	(9,393)
Foreign exchange loss	(21)	—	(21)	—
Change in fair value of investments	—	8,376	—	39,294
Change in fair value of derivative liability	—	(2)	—	(184)
Grant income	669	—	669	—
Total other income (expense)	(2,326)	4,062	(7,538)	30,222
Net loss	**(53,060)**	**(45,861)**	**(156,468)**	**(96,318)**
Net loss attributable to non-controlling interests	30,549	25,080	96,841	63,180
Net loss attributable to common stockholders	**$ (22,511)**	**$ (20,781)**	**$ (59,627)**	**$ (33,138)**
Net loss per common share - basic and diluted	$ (0.59)	$ (0.56)	$ (1.77)	$ (1.19)
Net loss per common share attributable to non - controlling interests - basic and diluted	$ (0.34)	$ (0.31)	$ (1.10)	$ (0.78)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.25)	$ (0.26)	$ (0.68)	$ (0.41)
Weighted average common shares outstanding - basic and diluted	89,424,947	81,348,243	88,291,970	81,056,165

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, 2022

	Series A Perpetual Preferred Stock		Common Stock		Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of June 30, 2022	**3,427,138**	**$ 3**	**107,717,647**	**$ 108**	**$ 661,691**	**$ (584,579)**	**$ 70,479**	**$ 147,702**
Stock-based compensation expense	—	—	—	—	6,837	—	—	6,837
Issuance of common stock related to equity plans	—	—	307,328	—	—	—	—	—
Issuance of common stock for at-the-market offering, net	—	—	234,378	—	223	—	—	223
Preferred A dividends declared and paid	—	—	—	—	(2,008)	—	—	(2,008)
Partner company's at-the-market offering, net	—	—	—	—	1,717	—	—	1,717
Issuance of common stock under partner company's ESPP	—	—	—	—	90	—	—	90
Partner company's dividends declared and paid	—	—	—	—	(188)	—	—	(188)
Issuance of partner company's common shares for research and development expenses	—	—	—	—	8	—	—	8
Partner company's exercise of options for cash	—	—	—	—	31	—	—	31
Non-controlling interest in partner companies	—	—	—	—	249	—	(249)	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	(30,549)	(30,549)
Net loss attributable to common stockholders	—	—	—	—	—	(22,511)	—	(22,511)
Balance as of September 30, 2022	**3,427,138**	**$ 3**	**108,259,353**	**$ 108**	**$ 668,650**	**$ (607,090)**	**$ 39,681**	**$ 101,352**

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)
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
Partner company's warrants issued in conjunction with debt	—	—	—	—	—		—	—	—
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 Nine Months Ended September 30, 2022

	Series A Preferred Stock		Common Stock		Paid-In	Accumulated	Non-Controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	Equity
Balance as of December 31, 2021	**3,427,138**	**$ 3**	**101,435,505**	**$ 101**	**$ 656,033**	**$ (547,463)**	**$ 117,203**	**$ 225,877**
Stock-based compensation expense	—	—	—	—	17,481	—	—	17,481
Issuance of common stock related to equity plans	—	—	2,953,703	3	(3)	—	—	—
Issuance of common stock under ESPP	—	—	135,464	—	99	—	—	99
Issuance of common stock for at-the-market offering, net	—	—	3,734,681	4	5,746	—	—	5,750
Preferred A dividends declared and paid	—	—	—	—	(6,024)	—	—	(6,024)
Partner companies' at-the-market offering, net	—	—	—	—	16,193	—	—	16,193
Partner company's exercise of options for cash	—	—	—	—	142	—	—	142
Issuance of common stock under partner company's ESPP	—	—	—	—	206	—	—	206
Partner company's dividends declared and paid	—	—	—	—	(563)	—	—	(563)
Partner company's net settlement of shares withheld for taxes	—	—	—	—	(1,698)	—	—	(1,698)
Reversal of partner company's common shares for research and development expenses	—	—	—	—	(27)	—	—	(27)
Partner company's warrants issued in conjunction with debt	—	—	—	—	384	—	—	384
Non-controlling interest in partner companies	—	—	—	—	(19,319)	—	19,319	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	(96,841)	(96,841)
Net loss attributable to common stockholders	—	—	—	—	—	(59,627)	—	(59,627)
Balance as of September 30, 2022	**3,427,138**	**$ 3**	**108,259,353**	**$ 108**	**$ 668,650**	**$ (607,090)**	**$ 39,681**	**$ 101,352**

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	Additional 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 company's offering, net	—	—	—	—	—	—	—	—	—
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 Statements of Cash Flows
($ in thousands)

	Nine Months Ended September 30,	
	2022	2021
Cash Flows from Operating Activities:		
Net loss	$ (156,468)	$ (96,318)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation expense	2,286	1,868
Loss on disposal of property and equipment	255	—
Bad debt (reserve) expense	10	(67)
Amortization of debt discount	1,500	1,623
Accretion of partner company convertible preferred shares	—	1,034
Non-cash interest	619	616
Prepayment penalty of Oaktree Note	—	450
Amortization of product revenue license fee	3,050	1,983
Amortization of operating lease right-of-use assets	1,425	1,259
Stock-based compensation expense	17,481	12,449
Issuance (reversal) of partner company's common shares for research and development expenses	(27)	136
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
Change in fair value of investment in Caelum	—	(39,294)
Change in fair value of partner company derivative liability	—	184
Research and development-licenses acquired, expense	40	15,449
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:		
Accounts receivable	(5,431)	(7,743)
Inventory	673	(10,210)
Other receivables - related party	525	(203)
Prepaid expenses and other current assets	1,339	2,854
Other assets	(77)	(695)
Accounts payable and accrued expenses	4,410	33,953
Accounts payable and accrued expenses - related party	—	74
Deferred revenue	(1,518)	3,354
Income taxes payable	13	—
Lease liabilities	(1,522)	(1,358)
Other long-term liabilities	(140)	130
Net cash used in operating activities	(131,557)	(77,844)
Cash Flows from Investing Activities:		
Purchase of research and development licenses	(40)	(9,830)
Purchase of property and equipment	(2,624)	(2,609)
Proceeds from the sale of partner company's fixed assets	127	—
Purchase of intangible asset	—	(400)
Acquisition of VYNE products	(20,000)	—
Net cash used in investing activities	(22,537)	(12,839)

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,	
	2022	2021
Cash Flows from Financing Activities:		
Payment of Series A perpetual preferred stock dividends	$ (6,024)	$ (6,023)
Proceeds from issuance of common stock for at-the-market offering, net	5,750	2,748
Proceeds from issuance of common stock under ESPP	99	137
Proceeds from partner companies' ESPP	206	309
Partner company's dividends declared and paid	(563)	(562)
Payment of costs related to partner company's sale of stock	(371)	—
Proceeds from partner companies' at-the-market offering, net	16,193	101,874
Proceeds from partner company convertible preferred shares, net	—	16,971
Proceeds from exercise of partner companies' equity grants	142	7
Partner company's net settlement of shares withheld for taxes	(1,698)	—
Payment of partner company's deferred financing cost	(119)	—
Payment of debt issuance costs associated with Oaktree Note	—	(95)
Repayment of partner company installment payments - licenses	(3,000)	(5,300)
Payment of debt issuance costs associated with partner company convertible preferred shares	(214)	(13)
Proceeds from partner company long-term debt, net	47,112	—
Repayment of partner company's line of credit	(812)	—
Net cash provided by financing activities	56,701	110,053
Net (decrease) increase in cash and cash equivalents and restricted cash	(97,393)	19,370
Cash and cash equivalents and restricted cash at beginning of period	307,964	234,996
Cash and cash equivalents and restricted cash at end of period	$ 210,571	$ 254,366
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 6,595	$ 5,025
Cash paid for tax	$ 1,462	$ 661
Supplemental disclosure of non-cash financing and investing activities:		
Settlement of restricted stock units into common stock	$ 3	$ 3
Unpaid fixed assets	$ 21	$ 1,376
Partner company's unpaid intangible assets	$ 4,740	$ —
Unpaid partner company's debt offering cost	$ 1,050	$ 214
Unpaid partner company's deferred offering cost	$ —	$ 264
Partner company derivative warrant liability associated with partner company convertible preferred shares	$ —	$ 362
Partner company's warrants issued in conjunction with debt	$ 384	$ —
Unpaid research and development licenses acquired	$ —	$ 1,800
Lease liabilities arising from obtaining right-of-use assets	$ 2,176	$ 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 joint ventures, and at entities the Company founded and in which it maintains significant minority ownership positions (also referred to as partner companies). 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, Mayo Foundation for Medical Education and Research, 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 the partners achieve their goals. Partner companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out-licensings, sales transactions, and public and private financings. To date, four partner companies are publicly-traded, and two have consummated strategic partnerships with industry leaders AstraZeneca plc as successor-in-interest to Alexion Pharmaceuticals, Inc., ("AstraZeneca") and Sentynl Therapeutics, Inc. ("Sentynl").

Our subsidiary and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates include Avenue Therapeutics (Nasdaq: ATXI, "Avenue"), Aevitas Therapeutics, Inc. ("Aevitas"), Baergic Bio, Inc. ("Baergic"), Caelum Biosciences, Inc. ("Caelum"), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. (Nasdaq: CKPT, "Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Journey Medical Corporation (Nasdaq: DERM, "Journey" or "JMC"), Mustang Bio, Inc. (Nasdaq: MBIO, "Mustang"), Oncogenuity, Inc. ("Oncogenuity") and Urica Therapeutics, Inc. ("Urica").

As used throughout this filing, the words "we", "us" and "our" may refer to Fortress individually or together with our affiliates and partners, and the word "partner" refers to either entities that are publicly traded and in which we own or control a majority of the ownership position or third party entities with whom we have a significant business relationship, each as dictated by context. We refer to private companies in which we own or control a majority of the ownership position as our subsidiaries; however, instances of either term should be read as applying to either or both as dictated by context.

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 from the proceeds resulting 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, sales of partner companies, grants or other arrangements to fully develop and prepare regulatory filings and obtain regulatory approvals for the existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for the potential products, sales and marketing capabilities. If such funding is not available or not available on terms acceptable to the Company, the Company's current development plan and plans for expansion of its general and administrative infrastructure 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 ongoing COVID-19 pandemic.

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

The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the unaudited condensed consolidated financial statements have read or have access to the audited financial statements for the preceding fiscal year for each of Avenue, Checkpoint, Mustang and Journey. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the Company's Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 28, 2022 (the "2021 Form 10-K"), from which the Company derived the balance sheet data at December 31, 2021, as well as Checkpoint's Form 10-K, filed with the SEC on March 28, 2022, Mustang's Form 10-K, filed with the SEC on March 23, 2022, Avenue's Form 10-K, filed with the SEC on March 25, 2022, and Journey's Form 10-K, filed with the SEC on March 28, 2022.

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

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

Use of Estimates

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

Restricted Cash

The Company records cash held in trust or pledged to secure certain debt obligations as restricted cash. As of September 30, 2022 and December 31, 2021, the Company had $2.2 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, 2022, and 2021:

	September 30,	
	2022	2021
Cash and cash equivalents	$ 208,351	$ 252,721
Restricted cash	2,220	1,645
Total cash and cash equivalents and restricted cash	$ 210,571	$ 254,366

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the Company's Form 10-K filed with the SEC on March 28, 2022.

Recently Issued Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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. Early adoption will be permitted. The Company is currently evaluating the impact of this standard on its consolidated 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 smaller reporting companies in 2023. The Company is currently assessing the impact of the adoption of this ASU on its consolidated financial statements.

3. Collaboration Agreement

Cyprium

Agreement with Sentynl

On February 24, 2021, Cyprium entered into an 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"). As further compensation, Cyprium is eligible to receive up to an additional $12.0 million, to be paid (i) $3.0 million upon NDA acceptance by the FDA 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, 2022, none of these future milestones was deemed probable.

Upon the transfer of CUTX-101 to Sentynl, Cyprium would be eligible to earn up to an additional five potential sales milestones totaling up to $255.0 million, in addition to royalties on CUTX-101 net sales ranging from mid-single digits up to the mid-twenties. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.

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

In connection with the $8.0 million upfront payment from 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-month period ending September 30, 2022 and 2021, the company recognized revenue of $0.4 million and $1.4 million, respectively. For the nine months ended September 30, 2022 and 2021, the company recognized revenue of $1.5 million and $4.6 million, respectively.

4. Inventory

($ in thousands)	September 30, 2022	December 31, 2021
Raw materials	$ 7,124	$ 5,572
Work-in-process	26	—
Finished goods	8,152	4,290
Inventory reserve	(72)	—
Total inventories	$ 15,230	$ 9,862

5. Property, Plant and Equipment

Fortress' property, plant and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	September 30, 2022	December 31, 2021
Computer equipment	3	$ 744	$ 739
Furniture and fixtures	5	1,387	1,387
Machinery & equipment	5	8,414	6,550
Leasehold improvements	2-15	13,175	13,175
Buildings	40	581	581
Construction in progress [1]	N/A	1,095	2,028
Total property and equipment		25,396	24,460
Less: Accumulated depreciation		(11,623)	(9,394)
Property, plant and equipment, net		$ 13,773	$ 15,066

Note 1: Relates to the Mustang cell processing facility.

Fortress' depreciation expense for the three months ended September 30, 2022 and 2021 was approximately $0.8 million and $0.7 million, respectively, and for the nine months ended September 30, 2022 and 2021 was approximately $2.3 million and $1.9 million, respectively. Fortress' depreciation expense is recorded in both research and development expense and general and administrative expense in the condensed consolidated statement of operations.

6. Intangibles, net

VYNE Therapeutics Product Acquisition ("VYNE Product Acquisition")

In January 2022, Journey entered into a definitive agreement (the "VYNE APA") to acquire two FDA-Approved Topical Minocycline Products, Amzeeq (minocycline) topical foam 4%, and Zilxi (minocycline) topical foam 1.5%, and a Molecule Stabilizing Technology™ proprietary platform from VYNE Therapeutics, Inc. ("VYNE") for an upfront payment of $20.0 million and an additional $5.0 million payment on the one (1)-year anniversary of the closing (The "VYNE Product Acquisition"). Journey also acquired the associated inventory.

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

The VYNE APA also provides for contingent net sales milestone payments. In the first calendar year in which annual sales reach each of $100 million, $200 million, $300 million, $400 million and $500 million, a one-time payment of $10 million, $20 million, $30 million, $40 million and $50 million, respectively, will be paid in that year only, per product, totaling up to $450 million. In addition, Journey will pay VYNE 10% of any upfront payment received by Journey from a licensee or sublicensee of the products in any territory outside of the United States, subject to exceptions for certain jurisdictions as detailed in the VYNE APA.

The following table summarizes the aggregate consideration transferred for the assets acquired by Journey in connection with the VYNE Product Acquisition:

($ in thousands)	**Aggregate Consideration Transferred**
Consideration transferred to VYNE at closing	$ 20,000
Fair value of deferred cash payment due January 2023	4,740
Transaction costs	223
Total consideration transferred at closing	$ 24,963

The fair value of the deferred cash payment is being accreted to the $5.0 million January 2023 cash payment over a one-year period through interest expense. The fair value of the deferred cash payment of $4.9 million at September 30, 2022 is included in partner company installment payments – short term on the condensed consolidated balance sheets.

The following table summarizes the assets acquired in the VYNE Product Acquisition:

($ in thousands)	**Assets Recognized**
Inventory	$ 6,041
Identifiable intangibles:	
Amzeeq	15,162
Zilxi	3,760
Fair value of net identifiable assets acquired	$ 24,963

The table below provides a summary of the Journey intangible assets as of September 30, 2022 and December 31, 2021, respectively:

($ in thousands)	**Estimated Useful Lives (Years)**	**September 30, 2022**	**December 31, 2021**
Intangible assets – product licenses	3 to 9	$ 37,925	$ 19,003
Accumulated amortization		(9,501)	(6,451)
Net intangible assets		$ 28,424	$ 12,552

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

For the three months ended September 30, 2022 and 2021, Journey's amortization expense related to its product licenses was $1.0 million and $0.7 million, respectively. For the nine months ended September 30, 2022 and 2021, Journey's amortization expense related to its product licenses was $3.1 million and $2.0 million, respectively. Journey records amortization expense related to its product licenses as a component of cost of goods sold on the condensed consolidated statement of operations.

The future amortization of these intangible assets is as follows:

($ in thousands)	Total Amortization
Three Months Ended December 31, 2022	$ 1,017
December 31, 2023	4,067
December 31, 2024	4,068
December 31, 2025	4,067
December 31, 2026	2,855
Thereafter	8,408
Sub-total	$ 24,482
Asset not yet placed in service:	3,942
Total	$ 28,424

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, 2022 and 2021, the purchase prices of licenses acquired were classified as research and development-licenses acquired in the unaudited condensed consolidated statement of operations.

Journey

On June 29, 2021, Journey entered a license, collaboration, and assignment agreement (the "DFD-29 Agreement") to obtain the global rights for the development and commercialization of a late-stage development modified release oral minocycline for the treatment of rosacea ("DFD-29") with DRL. Pursuant to the terms and conditions of the DFD-29 Agreement, Journey paid $10.0 million upfront. Additional contingent regulatory and commercial milestone payments totaling up to $158.0 million are also payable. Royalties ranging from approximately ten percent to twenty percent are payable on net sales of the DFD-29 product. Journey also agreed to pay DRL additional consideration of approximately $5 million in cash or shares upon an IPO of Journey's common stock, which occurred in November 2021 and resulted in the issuance of 545,131 unregistered shares of Journey common stock to DRL. The restrictions on the unregistered shares of Journey's common stock are governed by the terms set forth in the DFD-29 Agreement and applicable securities laws.

Additionally, the DFD-29 Agreement requires Journey to fund and oversee Phase 3 clinical trials approximating $24.0 million, based upon the current development plan and budget. In March 2022, JMC dosed the first patient in the Phase 3 clinical program of DFD-29. Journey's expenses related to the DFD-29 Phase 3 clinical trials were approximately $2.1 million and $0.7 million, respectively, for the three months ended September 30, 2022 and 2021, and $5.8 million and $0.7 million, respectively, for the nine months ended September 30, 2022 and 2021.

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

8. Debt and Interest

Debt

Total debt consists of the following:

($ in thousands)	September 30, 2022	December 31, 2021	Interest rate	Maturity
Oaktree Note	$ 50,000	$ 60,450	11.00 %	August - 2025
EWB term loan	20,000	—	8.38 %	January - 2026
Runway Note	31,050	—	11.69 %	April - 2027
Less: Discount on notes payable	(9,885)	(7,063)		
Repayment of Oaktree Note	—	(10,450)		
Total notes payable	$ 91,165	$ 42,937		

Oaktree Note

In August 2020, 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 Agreement contains customary representations and warranties and customary affirmative and negative covenants as well as certain financial covenants, including, among other things, (i) maintenance of minimum liquidity and (ii) a minimum revenue test that requires Journey's annual revenue to be equal to or to exceed annual revenue projections set forth in the agreement. Failure by the Company or Journey, as applicable, to comply with the Oaktree Agreement covenants will result in an event of default, subject to certain cure rights of the Company. The Company was in compliance with all applicable covenants under the Oaktree Agreement as of September 30, 2022.

The Company is required to make quarterly interest-only payments until the fifth anniversary of the closing date, August 27, 2025, 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 Company is required to make mandatory prepayments of the Oaktree Note under various circumstances as defined in the Oaktree Agreement. No mandatory prepayments were required in the nine months ended September 30, 2022.

Journey Working Capital Line of Credit Amendment and Term Loan

On January 12, 2022, Journey entered into a third amendment (the "Amendment") of its loan and security agreement with East West Bank, which increased the borrowing capacity of Journey's revolving line of credit to $10.0 million, from $7.5 million, and added a term loan ("EWB term loan") not to exceed $20.0 million. Both the revolving line of credit and the EWB term loan mature on January 12, 2026. In January 2022 and August 2022, Journey borrowed $15.0 million and $5.0 million, respectively, against the term loan. The EWB term loan bears interest at a floating rate equal to 1.73% above the prime rate and is payable monthly. The EWB term loan effective interest rate at September 30, 2022 was 8.38%. The EWB term loans contain an interest only payment period through January 12, 2024, with an extension through July 12, 2024 if certain covenants are met, after which the outstanding balance of each term loan is payable in equal monthly installments of principal, plus all accrued interest, through the EWB term loan maturity date. Journey may prepay all or any part of the EWB term loan without penalty or premium, but may not re-borrow any amount, once repaid. Any outstanding borrowing against the revolving line of credit bears interest at a floating rate equal to 0.70% above the prime rate. The Amendment includes customary financial covenants such as collateral ratios and minimum liquidity provisions as well as audit provisions, which pertain solely to Journey. Journey was in compliance with all applicable financial covenants under the Amendment as of September 30, 2022.

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

Journey accounted for the Amendment as a debt modification whereby the remaining unamortized debt issuance costs related to the original revolving facility together with any lender fees and direct third-party costs incurred to issue the Amendment are considered associated with the new arrangement. The fees allocated to the revolving line are capitalized as deferred debt costs (asset) and amortized over the new four-year term of the amended revolving facility. The fees allocated to the EWB term loan are recorded as a debt discount and amortized to interest expense over the four-year term of the EWB term loan under the effective interest method.

There was no outstanding balance on the revolving line of credit at September 30, 2022, and $0.8 million outstanding at December 31, 2021.

Mustang Runway Growth Finance Corp. ("Runway") Debt Facility

On March 4, 2022 (the "Closing Date"), Mustang entered into a $75.0 million long-term debt facility with Runway Growth Finance Corp. (the "Mustang Term Loan" or the "Runway Note"). Under the Mustang Term Loan, $30.0 million of the $75.0 million loan was funded on the Closing Date, with the remaining $45.0 million available if and when Mustang achieves certain predetermined milestones.

The Mustang Term Loan matures on April 15, 2027 (the "Maturity Date"). Starting March 15, 2022, Mustang will make monthly payments of interest only until April 1, 2024 (the "Amortization Date"). The Amortization Date may be extended to April 1, 2025 if Mustang achieves certain predetermined milestones based on equity raises and the initiation of certain clinical trials. After that, Mustang will make monthly payments of interest and principal. If the Amortization Date is extended to April 1, 2025, the monthly payments will be recalculated in equal amounts according to the remaining number of payment dates through the Maturity Date. All unpaid outstanding principal and accrued and unpaid interest will be due and payable in full on the Maturity Date.

The Runway Note accrues interest at a variable annual rate equal to 8.75% plus the greater of (i) 0.50% and (ii) the three-month LIBOR Rate for U.S. dollar deposits or the rate otherwise reasonably determined by the Lender to be the rate at which U.S. dollar deposits with a term of three months would be offered by banks in London or other offshore interbank markets (the "Applicable Rate"); provided that the Applicable Rate will not be less than 9.25%. At September 30, 2022 the Applicable Rate was 11.69%.

Mustang has the option to prepay all of the outstanding Runway Note but not less than all. Prepayment would include outstanding principal, accrued interest, prepayment fee and final payment which is equal to the original principal amount of the Runway Note times 3.5% or $1.1 million and is accreted over the life of the loan.

In addition, the Runway Note is secured by a lien on substantially all of Mustang's assets other than certain intellectual property assets and certain other excluded collateral, and it contains a minimum liquidity covenant and other covenants including among other items, limits on indebtedness and repurchase of stock from employees, officers and directors. Mustang was in compliance with all applicable covenants as of September 30, 2022.

The Runway Note contains customary events of default, in certain circumstances subject to customary cure periods. Following an event of default and any cure period, if applicable, Runway will have the right upon notice to accelerate all amounts outstanding under the Runway Note, in addition to other remedies available to the lenders as secured creditors of the Mustang.

Pursuant to the terms of the Runway Note, upon closing Mustang paid Runway upfront fees out of proceeds of $0.4 million consisting of a 1% commitment fee and a deposit of $0.1 million. In addition, Mustang paid other cash fees directly to third parties comprising of an advisory fee and legal fees totaling $2.3 million. Mustang also issued to Runway a warrant to purchase up to 748,036 of Mustang common shares with an exercise price of $0.8021 per share, pursuant to the terms of the Runway Note. In addition, the provisions of the warrant provide for additional warrants to be issued upon funding of the loan tranches.

The fair value of the warrant was determined utilizing a Black Scholes Model with the following assumptions: risk free rate of return 1.74%, volatility of 57.3%, 10-year life yielding a value of approximately $0.4 million at March 4, 2022. The fair value of the warrant was recorded in debt discount and will be amortized over the life of the note.

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

For the three and nine months ended September 30, 2022, Mustang amortized approximately $0.1 million and $0.3 million, respectively, of debt discount associated with the Runway Note, which was included in interest expense in the condensed consolidated statement of operations.

Partner Company Installment Payments – Licenses

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

	September 30, 2022		
($ in thousands)	Short-term	Long-term	Total
Partner company installment payments - licenses	$ 9,563	$ 1,437	$ 11,000
Less: imputed interest	(441)	(63)	(504)
Total partner company installment payments - licenses	$ 9,122	$ 1,374	$ 10,496

	December 31, 2021		
($ in thousands)	Short-term	Long-term	Total
Partner company installment payments - licenses	$ 5,000	$ 4,000	$ 9,000
Less: imputed interest	(490)	(373)	(863)
Total partner company installment payments - licenses	$ 4,510	$ 3,627	$ 8,137

Interest Expense

The following tables show 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,					
	2022			2021		
($ in thousands)	*Interest*	*Fees*	Total	*Interest*	*Fees*	Total
LOC Fees	$ 11	$ —	$ 11	$ 14	$ —	$ 14
Oaktree Note	1,406	395	1,801	2,136	342	2,478
Partner company convertible preferred shares	—	—	—	1,034	378	1,412
Partner company dividend payable	—	—	—	365	—	365
Partner company installment payments - licenses	201	—	201	175	—	175
Partner company notes payable	1,221	159	1,380	—	—	—
Total Interest Expense and Financing Fee	$ 2,839	$ 554	$ 3,393	$ 3,724	$ 720	$ 4,444

	Nine Months Ended September 30,					
	2022			2021		
($ in thousands)	*Interest*	*Fees*	Total	*Interest*	*Fees*	Total
LOC Fees	$ 37	$ —	$ 37	$ 37	$ —	$ 37
Oaktree Note	4,171	1,126	5,297	5,455	975	6,430
Partner company convertible preferred shares	—	—	—	1,034	648	1,682
Partner company dividend payable	—	—	—	628	—	628
Partner company installment payments - licenses	619	—	619	616	—	616
Partner company notes payable	2,570	374	2,944	—	—	—
Total Interest Expense and Financing Fee	$ 7,397	$ 1,500	$ 8,897	$ 7,770	$ 1,623	$ 9,393

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

9. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

($ in thousands)	September 30, 2022	December 31, 2021
Accounts payable	$ 55,765	$ 47,429
Accrued expenses:		
Professional fees	2,468	1,835
Salaries, bonus and related benefits	8,876	8,809
Research and development	5,905	7,932
Research and development - license maintenance fees	686	4,640
Research and development - milestones	4,600	850
Accrued royalties payable	2,585	3,833
Accrued coupon and rebates	7,970	10,603
Return reserve	2,962	3,240
Accrued interest	271	—
Other	1,729	1,489
Total accounts payable and accrued expenses	$ 93,817	$ 90,660

10. Non-Controlling Interests

Non-controlling interests in consolidated entities are as follows:

	For the Nine Months Ended September 30, 2022	As of September 30, 2022	
($ in thousands)	Net loss attributable to non-controlling interests	Non-controlling interests in consolidated entities	Non-controlling ownership
Urica	$ (870)	$ (1,182)	34.5 %
Aevitas	(475)	(5,637)	45.2 %
Avenue [2]	(2,984)	(31)	81.8 %
Baergic	(261)	(2,434)	39.0 %
Cellvation	(161)	(1,759)	21.7 %
Checkpoint [1]	(33,568)	(1,078)	80.7 %
Coronado SO	—	(290)	13.0 %
Cyprium	(732)	(3,272)	29.0 %
Helocyte	(283)	(5,787)	17.9 %
JMC	(7,355)	11,189	42.7 %
Mustang [2]	(49,944)	52,225	81.2 %
Oncogenuity	(187)	(1,495)	27.4 %
Tamid	(21)	(768)	22.8 %
Total	$ (96,841)	$ 39,681	

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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($ in thousands)	For the Year Ended December 31, 2021 Net loss attributable to non-controlling interests	As of December 31, 2021 Non-controlling interests in consolidated entities	Non-controlling ownership
Urica	(1,353)	$ (1,795)	34.5 %
Aevitas	(901)	(5,060)	45.9 %
Avenue [2]	(2,909)	2,830	82.0 %
Baergic	(39)	(2,086)	39.0 %
Cellvation	(131)	(1,544)	21.7 %
Checkpoint [1]	(39,226)	24,238	81.5 %
Coronado SO	—	(290)	13.0 %
Cyprium	(807)	(2,204)	29.8 %
Helocyte	(89)	(5,529)	18.3 %
JMC	(5,652)	17,498	41.6 %
Mustang [2]	(48,518)	93,009	82.7 %
Oncogenuity	(497)	(1,124)	24.9 %
Tamid	(1)	(740)	22.8 %
Total	$ (100,123)	$ 117,203	

Note 1: Checkpoint and JMC are consolidated with Fortress' operations because Fortress maintains voting control through its ownership of 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 Class A Preferred Shares which provide super-majority voting rights.

11. 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, 2022:

	Nine Months Ended September 30, 2022	2021
Warrants to purchase Common Stock	4,030,487	4,535,804
Options to purchase Common Stock	811,924	836,732
Unvested Restricted Stock	18,446,254	16,372,752
Unvested Restricted Stock Units	51,111	209,595
Total	23,339,777	21,954,883

12. Stockholders' Equity

Common Stock

At the Company's 2022 Annual Meeting of Stockholders held on June 21, 2022, its stockholders approved an amendment to its certificate of incorporation to increase the number of authorized shares of Common Stock available to issue by 30 million to 200 million. The amendment was filed with the Secretary of State of the State of Delaware on July 11, 2022.

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Equity Incentive Plan

The Company has in effect the 2013 Stock Incentive Plan, as amended (the "Incentive Plan"). The Incentive Plan was adopted in 2013 by our stockholders and the compensation committee of the Company's board of directors; eligible awardees of stock-based awards under the Incentive Plan include directors, officers, employees and consultants. In June 2022, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 3.0 million shares, for a total of 16.0 million shares.

As of September 30, 2022, 4,510,462 shares are available for issuance under the Incentive Plan.

Stock-based Compensation

The following table summarizes the stock-based compensation expense from stock option, employee stock purchase programs and restricted Common Stock awards and warrants for the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2022	2021	2022	2021
Employee and non-employee awards	$ 2,548	$ 2,185	$ 7,506	$ 6,236
Executive awards of Fortress Companies' stock	1,531	377	2,217	1,070
Partner Companies:				
Avenue	26	69	638	299
Checkpoint	781	779	2,285	2,319
Mustang	496	884	1,810	2,427
Journey	1,438	7	2,985	41
Other	17	25	40	57
Total stock-based compensation expense	$ 6,837	$ 4,326	$ 17,481	$ 12,449

For the three months ended September 30, 2022 and 2021, approximately $1.0 million and $1.1 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 $5.8 million and $3.2 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, 2022 and 2021, approximately $3.6 million and $3.1 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 $13.9 million and $9.4 million, respectively, was included in general and administrative expenses in connection with grants made to employees, members of the board of directors and consultants.

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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, 2021	1,018,490	$ 5.04	$ 368,344	1.68
Granted	2,500	2.50	—	9.26
Expired	(370,000)	6.27	—	—
Options vested and expected to vest at September 30, 2022	650,990	$ 4.34	$ —	1.81
Options vested and exercisable at September 30, 2022	650,990	$ 4.34	$ —	1.81

As of September 30, 2022, 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, 2021	18,060,000	$ 2.64
Restricted stock granted	2,375,972	2.50
Restricted stock vested	(199,824)	2.72
Restricted stock units granted	668,536	2.03
Restricted stock units forfeited	(187,500)	3.77
Restricted stock units vested	(552,282)	3.45
Unvested balance at September 30, 2022	20,164,902	$ 2.57

As of September 30, 2022 and 2021, the Company had unrecognized stock-based compensation expense related to restricted stock and restricted stock unit awards of approximately $22.9 million and $21.1 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 2.0 years and 3.1 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, 2021	4,505,621	$ 3.20	$ 68,800	3.93
Expired	(2,596,171)	3.26	—	
Outstanding as of September 30, 2022	1,909,450	$ 3.11	$ —	7.71
Exercisable as of September 30, 2022	1,774,450	$ 3.19	$ —	7.86

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In connection with the Oaktree Note (see Note 8), 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 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 filed a registration statement on Form S-3 to register the resale of the shares of Common Stock issuable upon exercise of the Oaktree Warrants that was declared effective by the SEC on November 20, 2020.

Long-Term Incentive Program ("LTIP")

On July 15, 2015, the Company's stockholders approved the LTIP for the Company's Chairman, President and Chief Executive Officer, Dr. Rosenwald, and Executive Vice Chairman, Strategic Development, Mr. Weiss (amended and restated with stockholder approval on June 7, 2017). The LTIP consists of a program to grant equity interests in the Company and in the Company's subsidiaries, and a performance-based bonus program that is designed to result in performance-based compensation that is deductible without limit under Section 162(m) of the Internal Revenue Code of 1986, as amended.

On January 1, 2022 and 2021, the Compensation Committee granted 1,102,986 and 1,030,339 shares each to Dr. Rosenwald and Mr. Weiss, respectively. These equity grants were made in accordance with the LTIP, and represent 1% of total outstanding shares of the Company as of the dates of such grants. The shares will vest in full if the employee is either in the service of the Company as an employee, Board member or consultant (or any combination of the foregoing) on the tenth anniversary of the LTIP, or the eligible employee has had an involuntary Separation from Service (as defined in the LTIP). The only other vesting condition – one based on achievement of an increase in the Company's market capitalization – has already been achieved, with respect to each annual award under the LTIP. The shares awarded under the LTIP will also vest in full (and the Company's repurchase option on each tranche of shares granted thereunder will accordingly lapse) upon the occurrence of a Corporate Transaction (as defined in the LTIP), if the eligible employee is in service to the Company on the date of such Corporate Transaction. The fair value of each grant on the grant date was approximately $2.8 million for the 2022 grant and $3.3 million for the 2021 grant. For the three months ended September 30, 2022 and 2021, the Company recorded stock compensation expense related to LTIP grants of approximately $1.3 million and $1.0 million, respectively, and for the nine months ended September 30, 2022 and 2021, recorded expense of approximately $4.0 million and $2.9 million, respectively, on the condensed consolidated statement of operations.

Capital Raises

2021 Shelf

On July 23, 2021, the Company filed a shelf registration statement 333-255185 on Form S-3, which was declared effective on July 30, 2021 (the "2021 Shelf"). No securities have been taken down under the 2021 Shelf as of September 30, 2022.

Common Stock At-the-Market Offering and 2020 Shelf

On May 18, 2020, the Company filed a shelf registration statement on Form S-3, which was declared effective on May 26, 2020 (the "2020 Shelf"). In connection with the 2020 Shelf, the Company entered into an At Market Issuance Sales Agreement ("2020 Common ATM"), governing potential sales of the Company's Common Stock.

For the nine-month period ended September 30, 2022, the Company issued approximately 3.7 million shares of Common Stock at an average price of $1.59 per share for gross proceeds of $5.9 million. For the nine-month period ended September 30, 2021, the Company issued approximately 0.8 million shares at an average price of $3.60 for gross proceeds of $2.8 million pursuant to the 2020 Common ATM. Approximately $11.5 million of securities remain available for sale under the 2020 Shelf at September 30, 2022.

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Mustang At-the-Market Offering (the "Mustang ATM")

During the nine months ended September 30, 2022, Mustang issued approximately 7.9 million shares of common stock at an average price of $0.84 per share for gross proceeds of $6.6 million through the Mustang ATM. In connection with these sales, Mustang paid aggregate fees of approximately $0.1 million. 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 through the Mustang ATM. In connection with these sales, Mustang paid aggregate fees of approximately $1.3 million.

Pursuant to the terms of the Founder's Agreement between the Company and Mustang (see Note 14), Mustang issued to Fortress 2.5% of the aggregate number of shares of Mustang common stock issued in connection with the shares issued through the Mustang ATM. Accordingly, Mustang issued 241,260 shares of common stock to Fortress at a weighted average price of $1.16 per share for the nine months ended September 30, 2022 and recorded 6,987 shares issuable to Fortress in connection with the shares issued through the Mustang ATM. Mustang issued 517,304 shares of common stock at a weighted average price of $3.84 per share to Fortress for the nine months ended September 30, 2021 in connection with the shares issued through 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. Through the Mustang 2020 S-3, Mustang may sell up to a total of $100.0 million of its securities. As of September 30, 2022, approximately $8.0 million of the Mustang 2020 S-3 remains available for sales of securities.

On April 23, 2021, Mustang filed a shelf registration statement No. 333-255476 on Form S-3 (the "Mustang 2021 S-3"), which was declared effective on May 24, 2021. Through the Mustang 2021 S-3, Mustang may sell up to a total of $200 million of its securities. As of September 30, 2022, $200 million of the Mustang 2021 S-3 remains available for sales of securities.

Checkpoint At-the-Market Offering (the "Checkpoint ATM")

During the nine months ended September 30, 2022, Checkpoint issued 5,157,914 shares of common stock through the Checkpoint ATM for aggregate total gross proceeds of approximately $9.9 million at an average selling price of $1.93 per share. During the nine months ended September 30, 2021, Checkpoint issued approximately 10.9 million shares of common stock through the Checkpoint ATM for aggregate total gross proceeds of approximately $37.2 million at an average selling price of $3.42 per share.

Pursuant to the Founders Agreement between the Company and Checkpoint (see Note 14), Checkpoint issued to Fortress 2.5% of the aggregate number of shares of Checkpoint common stock issued through the Checkpoint ATM. Accordingly, Checkpoint issued 128,931 shares of common stock to Fortress for the nine months ended September 30, 2022 at a weighted average price of $1.85 per share and issued 271,515 shares of common stock at a weighted average price of $3.41 for the nine months ended September 30, 2021.

The Checkpoint S-3 is a shelf registration statement filed by Checkpoint in November 2020 that was declared effective in December 2020, through which Checkpoint may sell up to $100 million of its securities. At September 30, 2022, approximately $44.7 million of the Checkpoint shelf remains available for sale through the Checkpoint S-3.

Journey Convertible Preferred Shares

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. As of September 30, 2021, Journey completed five closings and issued an aggregate of 758,680 Journey 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.

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13. Commitments and Contingencies

During the three and nine months ended September 30, 2022, Mustang entered into a new lease for office space commencing on July 1, 2022. The lease has a term of 7 years and 7 months, with rent obligations beginning on November 1, 2022. Base rent is $49,000 per month and increases to $56,000 per month during the term of the lease. The first 24 months of rent payments are abated, and the lease includes a $0.3 million tenant improvement allowance. There were no other material changes in our contractual obligations and commitments, including our lease obligations, as described in our 2021 Form 10-K.

During the three and nine months ended September 30, 2022 and 2021, the Company recorded the following as lease expense to current period operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2022	2021	2022	2021
Operating lease cost	$ 940	$ 819	$ 2,589	$ 2,429
Shared lease costs	(542)	(446)	(1,592)	(1,367)
Variable lease cost	198	190	459	547
Total lease expense	$ 596	$ 563	$ 1,456	$ 1,609

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

	Nine Months Ended September 30,	
($ in thousands)	2022	2021
Operating cash flows from operating leases	$ (2,615)	$ (2,498)
Right-of-use assets exchanged for new operating lease liabilities	$ 2,176	$ —
Weighted-average remaining lease term – operating leases (years)	4.9	5.6
Weighted-average discount rate – operating leases	6.5 %	6.3 %

($ in thousands)	Future Lease Liability
Three Months Ended December 31, 2022	$ 883
Year Ended December 31, 2023	3,270
Year Ended December 31, 2024	3,307
Year Ended December 31, 2025	3,864
Year Ended December 31, 2026	3,879
Other	16,058
Total operating lease liabilities	31,261
Less: present value discount	(7,516)
Net operating lease liabilities, short-term and long-term	$ 23,745

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

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14. 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 owns approximately 10.7% of the Company's issued and outstanding Common Stock as of September 30, 2022. 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, 2022.

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 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. In connection with the shared services agreement, for the three months ended September 30, 2022 and 2021 the Company invoiced TGTX $0.1 million and $0.1 million, respectively. For the nine months ended September 30, 2022 and 2021, the Company invoiced TGTX $0.7 million and $0.3 million, respectively. At September 30, 2022, there were no amounts due from TGTX related to this arrangement.

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 arrangement, Journey began reimbursing 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 in November 2021. For the three and nine months ended September 30, 2022, the Company's employees have provided services to Journey totaling approximately $7,000 and $0.1 million, respectively.

Desk Share Agreement with TGTX

The Desk Share Agreement with TGTX, as amended, requires TGTX to pay their share of the average annual rent for office space in New York, NY and Waltham, MA based on actual percentage of the office space occupied on a month-by-month basis. For the three months ended September 30, 2022 and 2021, the Company had paid $0.8 million and $0.7 million in rent, respectively, and in connection with the Company's Desk Share Agreement with TGTX, has invoiced TGTX approximately $0.5 million and $0.4 million, respectively, for their prorated share of the rent base. For the nine months ended September 30, 2022 and 2021, the Company had paid $2.2 million and $2.1 million in rent, respectively, and invoiced TGTX approximately $1.4 million and $1.2 million, respectively, for their prorated share of the rent base. At September 30, 2022, there were no amounts due from TGTX related to this arrangement.

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Contribution Agreement with Avenue

On May 11, 2022, the Company entered into a stock contribution agreement (the "Contribution Agreement") with Avenue, pursuant to which the Company agreed to transfer ownership of 100% of its shares (common and preferred) in Baergic to Avenue. Under the Contribution Agreement, the Company also agreed to assign to Avenue certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement, by and between Fortress and Baergic, dated as of March 9, 2017, and Management Services Agreement, by and between Fortress and Baergic, dated as of March 9, 2017. Consummation of the transactions contemplated by the Contribution Agreement is subject to the satisfaction of certain conditions precedent, including, inter alia: (i) the closing of an equity financing by Avenue resulting in gross proceeds of at least $7.5 million, (ii) the agreement by minority Avenue shareholder InvaGen Pharmaceuticals, Inc. ("InvaGen") to (A) have 100% of its shares in Avenue repurchased by Avenue and (B) terminate certain of the agreements into which it entered with Avenue and/or the Company in connection with InvaGen's 2019 equity investment in Avenue, which would eliminate certain negative consent rights of InvaGen over Avenue and restore certain rights and privileges of Fortress in Avenue (all upon terms to be agreed upon with InvaGen); and (iii) the sustained listing of Avenue's common stock on the Nasdaq Capital Market. On October 11, 2022, Avenue announced the closing of an underwritten public offering in which it received net proceeds of approximately $10.4 million. The offering, together with the October 2022 repurchase of Avenue common shares held by InvaGen, resulted in the consummation of the Contribution Agreement in November 2022 (see Note 18).

Founders Agreement

The Company has entered into Founders Agreements and, in some cases, exchange agreements with certain of its subsidiaries as described in the 2021 Form 10-K. The following table summarizes, by partner company, the effective date of the Founders Agreements and Payment-in-Kind ("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:

Partner Company	Effective Date [1]	PIK Dividend as a % of fully diluted outstanding capitalization	Class of Stock Issued
Aevitas	July 28, 2017	2.5 %	Common Stock
Avenue	February 17, 2015	0.0 %[2]	Common Stock
Baergic	December 17, 2019 [5]	2.5 %[3]	Common Stock
Cellvation	October 31, 2016	2.5 %	Common Stock
Checkpoint	March 17, 2015	0.0 %[4]	Common Stock
Cyprium	March 13, 2017	2.5 %	Common Stock
Helocyte	March 20, 2015	2.5 %	Common Stock
Mustang	March 13, 2015	2.5 %	Common Stock
Oncogenuity	April 22, 2020 [5]	2.5 %	Common Stock
Urica	November 7, 2017 [5]	2.5 %	Common Stock

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

Note 2: PIK dividends in Avenue were not paid or accrued while InvaGen retained certain rights under that certain Stockholders Agreement, dated as of November 12, 2018, by and among the Company, Avenue, InvaGen and the other stockholder parties thereto (the "Avenue Stockholders Agreement"). In connection with the closing of Avenue's public offering, InveGen's shares were repurchased under a Share Repurchase Agreement in October 2022 and upon the closing of the Share Repurchase Agreement, also in October 2022, all of the rights retained by InvaGen pursuant to the avenue Stockholders Agreement were terminated and all of Fortress' rights were restored (see Note 18).

Note 3: Due to the November 2022 consummation of the Contribution Agreement between the Company and Avenue, Avenue is now eligible to receive the PIK dividend and equity fee payable by Baergic in accordance with the terms of the Founders Agreement and Baergic's certificate of incorporation.

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Note 4: Instead of a PIK dividend, Checkpoint pays the Company an annual equity fee in shares of Checkpoint's common stock equal to 2.5% of Checkpoint's fully diluted outstanding capitalization.

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

Management Services Agreements

The Company has entered in Management Services Agreements (the "MSAs") with certain of its partner companies as described in the 2021 Form 10-K. 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:

Partner company	Effective Date	Annual MSA Fee (Income)/Expense
Aevitas	July 28, 2017	$ 500
Avenue[1]	February 17, 2015	—
Baergic[2]	March 9, 2017	500
Cellvation	October 31, 2016	500
Checkpoint	March 17, 2015	500
Cyprium	March 13, 2017	500
Helocyte	March 20, 2015	500
Mustang	March 13, 2015	1,000
Oncogenuity	February 10, 2017	500
Urica	November 7, 2017	500
Fortress		(5,000)
Consolidated (Income)/Expense		$ —

Note 1: MSA fees from Avenue were not paid or accrued so long as InvaGen held certain rights under the Avenue Stockholders Agreement. InvaGen's shares in Avenue were repurchased in October 2022, and all existing agreements between InvaGen and Avenue (including the Avenue Stockholders Agreement) were terminated as of the closing of the Share Repurchase Agreement in October 2022 (see Note 18). Fortress has been eligible to receive MSA fees from Avenue since such closing occurred.

Note 2: Due to the November 2022 consummation of the Contribution Agreement between the Company and Avenue, Avenue (and not the Company) is now eligible to receive MSA fees from Baergic in accordance with the terms of the Founders Agreement and Baergic's certificate of incorporation.

15. Segment Information

The Company operates in two reportable segments, Dermatology Product Sales and Pharmaceutical and Biotechnology Product Development. The accounting policies of the Company are consistently applied to all segments. The following tables summarize, for the periods indicated, operating results from continued operations by reportable segment:

($ in thousands) Three Months Ended September 30, 2022	Dermatology Products Sales[1]	Pharmaceutical and Biotechnology Product Development	Consolidated
Net revenue	$ 16,116	$ 412	$ 16,528
Cost of goods - product revenue	(7,221)	—	(7,221)
Research and development	(2,812)	(27,090)	(29,902)
Selling, general and administrative	(15,574)	(14,565)	(30,139)
Other expense	(577)	(1,749)	(2,326)
Segment loss	$ (10,068)	(42,992)	$ (53,060)

Note 1: Dermatology Product Sales segment reflects stand-alone income tax expense that has been eliminated in consolidation.

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($ 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
Cost of goods - product revenue	(11,167)	—	(11,167)
Research and development	(794)	(27,286)	(28,080)
Selling, general and administrative	(10,755)	(11,466)	(22,221)
Wire transfer fraud loss	(9,540)	—	(9,540)
Other expense	(1,375)	5,437	4,062
Segment income (loss)	$ (14,021)	$ (31,840)	$ (45,861)

Nine Months Ended September 30, 2022	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net revenue	$ 57,703	$ 1,636	$ 59,339
Cost of goods - product revenue	(23,057)	—	(23,057)
Research and development	(6,687)	(93,068)	(99,755)
Selling, general and administrative	(45,517)	(39,940)	(85,457)
Other income	(1,413)	(6,125)	(7,538)
Segment loss	$ (18,971)	$ (137,497)	$ (156,468)

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

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

($ in thousands) September 30, 2022	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Total Assets
Intangible assets, net	$ 28,424	$ —	$ 28,424
Tangible assets	79,721	215,416	295,137
Total segment assets	$ 108,145	$ 215,416	$ 323,561

($ in thousands) December 31, 2021	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Total Assets
Intangible assets, net	$ 12,552	$ —	$ 12,552
Tangible assets	84,732	299,219	383,951
Total segment assets	$ 97,284	$ 299,219	$ 396,503

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

16. Revenues from Contracts and Significant Customers

Disaggregation of Total Revenue

Journey has the following actively marketed products, Qbrexza®, Accutane®, Targadox®, Ximino®, Exelderm®, Luxamend®, Amzeeq® and Zilxi®. All of Journey's product revenues are 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 (see Note 14). Other revenue consists of a net $2.5 million milestone payment made to Journey triggered by Qbrexza® (Rapifort® Wipes 2.5%) receiving manufacturing and marketing approval in Japan in February 2022.

The net $2.5 million milestone payment reflects a milestone payment of $10 million to Journey from their exclusive licensing partner in Japan, Maruho Co., Ltd. ("Maruho"), offset by a $7.5 million payment to Dermira, pursuant to the terms of the Qbrexza APA between Journey and Dermira. The table below summarizes the Company's revenue for the three and nine months ending September 30, 2022 and 2021:

	Three months ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue				
Qbrexza®	$ 6,265	$ 6,636	$ 19,752	$ 11,204
Accutane®	4,121	3,531	14,228	5,672
Amzeeq®	1,161	—	5,892	—
Targadox®	1,168	5,184	6,558	18,110
Ximino®	1,773	2,864	3,775	6,277
Zilxi®	554	—	1,851	—
Exelderm®	1,001	1,366	3,018	4,319
Other branded revenue	—	29	—	35
Collaboration revenue	364	1,446	1,518	4,646
Revenue – related party	48	29	118	252
Other revenue	73	—	2,629	—
Net revenue	$ 16,528	$ 21,085	$ 59,339	$ 50,515

The above table includes the authorized generic product within the line items for Targadox®, Ximino® and Exelderm®.

Significant Customers

For the three-month period ending September 30, 2022, none of the Company's dermatology products customers accounted for more than 10% of its total gross product revenue. For the three-month period ending September 30, 2021, one of the Company's dermatology products customers accounted for 10.1% of its total gross product revenue.

For the nine-month periods ending September 30, 2022 and 2021, none of the Company's dermatology products customers accounted for more than 10% of its total gross product revenue.

At September 30, 2022 and December 31, 2021, two of the Company's dermatology products customers accounted for more than 10% of its total accounts receivable balance, at 17% and 11%, and 16% and 13%, respectively.

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

17. Income taxes

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

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

Income tax expense for the three and nine months ended September 30, 2022 and 2021 is based on the estimated annual effective tax rate. The Company expects a net DTA with a full valuation allowance and 0% estimated annual effective tax rate for 2022. No income tax expense was recognized for the three or nine months ended September 30, 2022 or 2021.

18. Subsequent Events

On October 11, 2022, Avenue announced the closing of an underwritten public offering of 3,636,365 common and pre-funded units. Each common unit consists of one share of common stock and one warrant to purchase one share of common stock, and each pre-funded unit consists of one pre-funded warrant to purchase one share of common stock and one warrant to purchase one share of common stock. Each share of common stock (or pre-funded warrant) was sold together with one warrant at a combined purchase price of $3.30 per common unit (or $3.2999 per pre-funded unit after reducing $0.0001 attributable to the exercise price of the pre-funded warrants). Avenue also simultaneously closed on the sale of an additional 545,454 warrants to purchase common stock, which were sold pursuant to a partial exercise of the underwriter's over-allotment option. Avenue received net proceeds of approximately $10.4 million at closing after deducting underwriting discounts and commissions and other expenses of the offering. This transaction, along with Avenue's repurchase of the shares held by InvaGen and the closing of the Share Repurchase Agreement between Avenue and InvaGen in October 2022, resulted in the November 2022 consummation of the Contribution Agreement between the Company and Avenue (see Note 14).

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 condensed consolidated financial statements and the related notes included elsewhere in this Form 10-Q. Our 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, or implied by the forward-looking statements. In evaluating our business, you should carefully consider the information set forth under Item 1A "Risk Factors" in this Quarterly Report on Form 10-Q. 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 its 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, comprised of scientists, doctors and finance professionals, who identify and evaluate promising products and product candidates for potential acquisition by new or existing partner companies. Our subsidiary and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates include Avenue Therapeutics (Nasdaq: ATXI, "Avenue"), Aevitas Therapeutics, Inc. ("Aevitas"), Baergic Bio, Inc. ("Baergic"), Caelum Biosciences, Inc. ("Caelum"), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. (Nasdaq: CKPT, "Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Journey Medical Corporation (Nasdaq: DERM, "Journey" or "JMC"), Mustang Bio, Inc. (Nasdaq: MBIO, "Mustang"), Oncogenuity, Inc. ("Oncogenuity") and Urica Therapeutics, Inc. ("Urica").

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, Mayo Foundation for Medical Education and Research, 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 financial expertise to help the 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, four partner companies are publicly-traded, and two have executed strategic partnerships with industry leaders AstraZeneca and Sentynl.

Recent Events

Marketed Dermatology Products

- Our eight branded and three authorized generic prescription drugs for dermatological conditions are actively marketed in the U.S. by our partner company, Journey.
- During the three months ended September 30, 2022 and 2021, JMC generated net product revenue of $16.0 million and $19.6 million, respectively.
- During the nine months ended September 30, 2022 and 2021, JMC generated net product revenue of $55.1 million and $45.6 million, respectively.

Late Stage Product Candidates

Cosibelimab (Anti-PD-L1 Antibody for Solid Tumors (formerly CK-301))

- In July 2022, Checkpoint successfully completed two pre-BLA meetings with U.S Food and Drug Administration ("FDA") (chemistry, manufacturing and controls ("CMC") and clinical/non-clinical). Based upon favorable interactions with the agency, the planned BLA submission in January 2023 will include both the metastatic and locally advanced cutaneous squamous cell carcinoma indications. Checkpoint also reached agreement with the FDA on all key aspects discussed with regard to the content of the upcoming BLA submission.
- Cosibelimab was sourced by Fortress and is currently in development at our partner company, Checkpoint.

CUTX-101 (Copper Histidinate for Menkes disease)

- In December 2021, we initiated the rolling submission of an NDA to the FDA for CUTX-101, which is expected to be completed in 2023.
- Cyprium is currently in a dispute with its contract manufacturing organization (the "CMO"), regarding the CMO's attempt to terminate a Master Services Agreement (together with related work orders, the "MSA") between Cyprium and the CMO. Cyprium believes the CMO's grounds for purporting to terminate the MSA are without merit and is currently availing itself of all appropriate legal remedies in efforts to ensure that the CMO abides by its obligations under the MSA and/or to pursue monetary damages claims against the CMO. To that end, Cyprium obtained a temporary restraining order in August 2022 and a preliminary injunction in September 2022 from a court in New York State; the injunction invalidated the CMO's attempted termination of the MSA and prohibited the CMO from further attempts to terminate the MSA during the pendency of dispute resolution procedures.
- CUTX-101 is currently in development at our partner company, Cyprium.

DFD-29 (modified release oral minocycline for the treatment of rosacea)

- As of November 2022, Journey enrolled 75% in the Phase 3 clinical program of DFD-29 for the treatment of papulopustular rosacea. Topline data are anticipated in the first half of 2023 with an NDA filing expected in the second half of 2023.
- DFD-29 is currently in development at our partner company, Journey Medical Corp.

IV Tramadol

- In September 2022, Avenue received the official meeting minutes from the FDA regarding a meeting conducted on August 9, 2022, for IV Tramadol. At the meeting, Avenue presented a study design for a single safety clinical trial that Avenue believes could address the concerns regarding risks related to opioid stacking. The FDA stated that the proposed study design appears reasonable and agreed on various study design aspects with the expectation that additional feedback would be provided to Avenue upon review of a more detailed study protocol. Avenue intends to incorporate the FDA's suggestions from the meeting minutes and submit a detailed study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol.
- IV Tramadol was sourced by Fortress and is currently in development at our partner company, Avenue.

Triplex (Cytomegalovirus ("CMV") vaccine)

- In August 2022, we announced Triplex received a grant from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health that could provide over $20 million in non-dilutive funding. This award will fund a multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of cytomegalovirus in patients undergoing liver transplantation.
- Triplex is currently the subject of five ongoing trials, funded by non-dilutive sources, in various settings including: CMV control in stem cell and solid organ transplantation, the treatment of HIV; and in combination with a CAR T cell therapy for the treatment of NHL.
- Triplex was sourced by Fortress and is currently in development at our partner company, Helocyte.

MB-107 and MB-207 (Lentiviral Gene Therapies for X-linked Severe Combined Immunodeficiency (XSCID))

- In 2023, we expect to enroll the first patient in a pivotal multicenter Phase 2 clinical trial under Mustang's IND to evaluate MB-107, a lentiviral gene therapy for the treatment of infants under the age of two with XSCID.
- Also in 2023, we expect to enroll the first patient in Mustang Bio's pivotal multicenter Phase 2 clinical trial of MB-207, a lentiviral gene therapy for the treatment of patients with XSCID who have been previously treated with a hematopoietic stem cell transplantation and for whom re-treatment is indicated.
- MB-107 and MB-207 were sourced by Fortress and are currently in development at our partner company, Mustang.

Early Stage Product Candidates

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

- On October 6, 2022, Mustang announced the first patient treated in its multicenter Phase ½ Clinical Trial of MB-106, a first-in-class CD20-targeted, autologous CAR T cell therapy to treat B-cell non-Hodgkin lymphoma and chronic lymphocytic leukemia. This multicenter trial under Mustang's Investigational New Drug Application ("IND") builds upon the initial, ongoing Phase ½ clinical trial taking place at Fred Hutch in a single-center study under Fred Hutch's IND. Mustang expects to enroll 3 to 6 patients in this multicenter trial by the end of 2022.
- Interim data from 28 patients treated in the initial, ongoing Phase ½ investigator-sponsored clinical trial at Fred Hutch continue to support MB-106 as a viable CAR T cell therapy for B-NHLs and CLL. An overall response rate of 96% and complete response ("CR") rate of 75% were observed in a wide range of hematologic malignancies including follicular lymphoma ("FL"), CLL, diffuse large B-cell lymphoma, and Waldenstrom macroglobulinemia. Twelve patients have experienced CR for more than 12 months (10 ongoing); four patients with CR for more than two years and the longest patient with CR is at 33 months. Six patients with partial response ("PR") improved to CR and all remain in ongoing CR. All three patients previously treated with CD19 CAR T cell therapy responded to treatment with MB-106. A favorable safety profile for MB-106 as an outpatient therapy remains with no CRS or ICANS ≥ Grade 3. CAR-T persistence results in deepening responses following initial 28-day assessments.
- MB-106 was sourced by Fortress and is currently in development at our partner company, Mustang.

Dotinurad (Urate Transporter (URAT1) Inhibitor)

- In June 2022, we initiated a Phase 1 clinical trial to evaluate Dotinurad in healthy volunteers in the United States. Dotinurad is in development for the treatment of gout and possibly other hyperuricemic conditions. We anticipate topline data from the Phase 1 trial in the first half of 2023.
- Dotinurad (URECE® tablet) was approved in Japan in 2020 as a once-daily oral therapy for gout and hyperuricemia. Dotinurad was efficacious and well-tolerated in more than 500 Japanese patients treated for up to 58 weeks in Phase 3 clinical trials. The clinical program supporting approval included over 1,000 patients.
- Dotinurad was sourced by Fortress and is currently in development at our partner company, Urica Therapeutics.

MB-109 (MB-101 (IL13Rα2-targeted CAR T Cell Therapy) + MB-108 oncolytic virus)

- In April 2022, Mustang announced interim data from two ongoing investigator-sponsored Phase 1 clinical trials evaluating two clinical candidates, MB‑101 (IL13Rα2‑targeted CAR T cell therapy licensed from City of Hope) and MB-108 (herpes simplex virus type 1 oncolytic virus licensed from Nationwide Children's Hospital) for the treatment of recurrent glioblastoma. Mustang is in the process of completing IND-enabling manufacturing and preclinical activities requested by the FDA in a Pre-IND meeting and expects to file an IND for a Mustang-sponsored Phase 1 trial in 2023.
- MB-101 and MB-108 were sourced by Fortress and are currently in development at our partner company, Mustang.

MB-110 Ex Vivo Lentiviral Gene Therapy for RAG1 Severe Combined Immunodeficiency ("RAG1-SCID")

- In July 2022, we announced that the first patient successfully received LV-RAG1 *ex vivo* lentiviral gene therapy to treat recombinase-activating gene-1 ("RAG1") severe combined immunodeficiency (RAG1-SCID"), in an ongoing Phase ½ multicenter clinical trial taking place in Europe.
- LV-RAG1 is exclusively licensed by Mustang for the development of MB-110, a first-in-class *ex vivo* lentiviral gene therapy for the treatment of RAG1-SCID.
- MB-110 was sourced by Fortress and is currently in development at our partner company, Mustang.

General Corporate

- In September 2022, Avenue effected a 1-for-15 reverse stock split to bring the company in compliance with the minimum bid price listing requirement of the Nasdaq Capital Market.
- In October 2022, Avenue closed a $12 million underwritten public offering. Avenue received net proceeds of approximately $10.4 million at closing after deducting underwriting discounts and commissions and other expenses of the offering. $3 million of the net proceeds were utilized to repurchase the shares owned by a certain minority investor. With the completion of the offering and the reverse-split, Avenue received correspondence from Nasdaq indicating that the company had evidenced compliance for continued listing on The Nasdaq Capital Market.

- On October 31, 2022, Fortress received a letter from the Listing Qualifications Staff of Nasdaq indicating that the bid price of the Company's common stock had closed below $1.00 per share for 30 consecutive business days and, as a result, Fortress is not in compliance with Nasdaq minimum bid price requirement. Nasdaq's notice has no immediate effect on the listing of the common stock on Nasdaq. The Company intends to closely monitor the closing bid price of the Common Stock and consider all available options to remedy the bid price deficiency, but no decision regarding any action has yet been made.
- In November 2022, Avenue announced the completion of the acquisition of Baergic from Fortress, pursuant to the Stock Contribution Agreement dated May 11, 2022.
- Also in November 2022, holders of a majority of the voting power of the capital stock of Checkpoint approved a 1-for-10 reverse stock split of Checkpoint's common stock. Checkpoint expects its common shares will begin trading on a split-adjusted basis on The Nasdaq Capital Market in December 2022. The Board of Directors determined the 1-for-10 ratio to be appropriate in order to improve the marketability and liquidity of Checkpoint's common stock and to remain in compliance with all of Nasdaq's continued listing requirements.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. Applying these principles requires our judgment in determining the appropriateness of acceptable accounting principles and methods of application in diverse and complex economic activities. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of revenues, expenses, assets and liabilities, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and other assumptions that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

For a discussion of our critical accounting estimates, see the MD&A in the Company's Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 28, 2022 ("2021 Form 10-K"). There were no material changes in our critical accounting estimates or accounting policies from December 31, 2021.

Accounting Pronouncements

During the nine-month period ended September 30, 2022, there were no new accounting pronouncements or updates to recently issued accounting pronouncements disclosed in the 2021 Form 10-K that are expected to materially affect the Company's present or future 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 the 2021 Form 10-K, have reduced disclosure obligations regarding executive compensation and certain other matters, and smaller reporting companies are permitted to delay adoption of certain recent accounting pronouncements discussed in Note 2 to our consolidated financial statements in this report on Form 10-Q.

Results of Operations

General

For the three months ended September 30, 2022 and 2021, we generated $16.5 million and $21.1 million, respectively, of net revenue, of which $16.0 million and $19.6 million, respectively, relates primarily to the sale of Journey branded and generic products and approximately $48,000 and $29,000, respectively, relates to Checkpoint's collaborative agreements with TGTX. Collaboration revenue of $0.4 million and $1.4 million, respectively, recognized in the quarters ended September 30, 2022 and 2021 is a result of Cyprium's agreement with Sentynl. Other revenue of $0.1 million in the quarter ended September 30, 2022 includes Journey's receipt of royalties from its exclusive out-licensing partner for Qbrexza.

For the nine months ended September 30, 2022 and 2021, we generated $59.3 million and $50.5 million, respectively, of net revenue, of which $55.1 million and $45.6 million, respectively, relates primarily to the sale of Journey branded and generic products and approximately $0.1 million and $0.3 million, respectively, relates to Checkpoint's collaborative agreements with TGTX. Collaboration revenue of $1.5 million and $4.6 million, respectively, recognized in the nine months ended September 30, 2022 and 2021 is a result of Cyprium's agreement with Sentynl. Other revenue of $2.6 million in the nine months ended September 30, 2022 includes Journey's receipt of royalties as well as a $2.5 million milestone payment from its' exclusive out-licensing partner for Qbrexza.

For the three months ended September 30, 2022 and 2021, we had $7.2 million or 45.0% of product revenue, and $11.2 million or 56.9% of product revenue, net, respectively, of costs of goods sold in connection with the sale of Journey's marketed products. The decrease is related to lower overall sales volume and related royalty expense. In addition to the impact of sales volume, royalty expense was also impacted by a contractual double digit percentage decrease in the royalty rate of Qbrexza that occurred in May 2022.

For the nine months ended September 30, 2022 and 2021, we had $23.1 million or 41.9% of product revenue, and $22.6 million or 49.5% of product revenue, net, respectively, of costs of goods sold in connection with the sale of Journey's marketed products. The increase is a result of higher sales volume, incremental royalties from Qbrexza and Accutane, which were launched in the first half of 2021, and an incremental increase in amortization of acquired intangible assets due to the acquisition of Amzeeq and Zilxi from VYNE in January 2022.

As of September 30, 2022, we had an accumulated deficit of $607.1 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.

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, 2022, research and development expenses were approximately $29.9 million and $99.7 million, respectively. For the three and nine months ended September 30, 2021, research and development expenses were approximately $27.4 million and $70.2 million, respectively Additionally, during the three and nine months ended September 30, 2021, we expensed approximately $0.7 million and $15.6 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, 2022 and 2021, was $1.0 million and $1.1 million, respectively. Noncash, stock-based compensation expense included in research and development for the nine months ended September 30, 2022 and 2021, was $3.6 million and $3.1 million, respectively.

The table below provides a summary of research and development costs associated with the development of our licenses by entity, for the three and nine months ended September 30, 2022 and 2021, by entity:

($ in thousands)	Three Months Ended September 30, 2022	2021	% of total 2022	2021	Nine Months Ended September 30, 2022	2021	% of total 2022	2021
Research & Development								
Fortress	$ 515	$ 651	2 %	2 %	$ 1,889	$ 1,979	2 %	3 %
Partner Companies:								
Avenue	194	278	1 %	1 %	2,153	864	2 %	1 %
Checkpoint	8,866	9,384	30 %	34 %	35,589	20,795	36 %	30 %
JMC	2,812	718	9 %	3 %	6,687	747	6 %	1 %
Mustang	15,309	14,028	51 %	51 %	46,537	36,430	47 %	52 %
Other[1]	2,159	2,308	7 %	9 %	6,852	9,411	7 %	13 %
Total Research & Development Expense	**$ 29,855**	**$ 27,367**	**100 %**	**100 %**	**$ 99,707**	**$ 70,226**	**100 %**	**100 %**

Note 1: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

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, 2022 and 2021, selling, general and administrative expenses were approximately $30.1 million and $22.2 million, respectively. Noncash, stock-based compensation expense included in selling, general and administrative expenses for the three months September 30, 2022 and 2021, was $5.8 million and $3.2 million, respectively. For the nine months ended September 30, 2022 and 2021, selling, general and administrative expenses were approximately $85.5 million and $59.1 million, respectively. Noncash, stock-based compensation expense included in selling, general and administrative expenses for the nine months September 30, 2022 and 2021, was $13.9 million and $9.4 million, respectively.

The table below provides a summary of selling, general and administrative costs for the three and nine months ended September 30, 2022 and 2021, by entity:

($ in thousands)	Three Months Ended September 30, 2022	2021	% of Total 2022	2021	Nine Months Ended September 30, 2022	2021	% of Total 2022	2021
Selling, General & Administrative								
Fortress	$ 7,781	$ 5,989	26 %	27 %	$ 21,334	$ 18,425	26 %	31 %
Partner Companies:								
Avenue	469	594	1 %	3 %	1,978	1,960	2 %	3 %
Checkpoint	1,695	1,760	6 %	8 %	5,604	5,110	6 %	9 %
JMC[1]	15,574	11,003	52 %	49 %	45,517	24,848	53 %	42 %
Mustang	3,232	2,219	11 %	10 %	8,485	6,508	10 %	11 %
Other[2]	1,388	656	4 %	3 %	2,539	2,294	3 %	4 %
Total Selling, General & Administrative Expense	**$ 30,139**	**$ 22,221**	**100 %**	**100 %**	**$ 85,457**	**$ 59,145**	**100 %**	**100 %**

Note 1: Includes cost of outsourced sales force for the three months ended September 30, 2022 and 2021 of $6.3 million and $5.1 million, respectively, and for the nine months ended September 30, 2022 and 2021 of $17.8 million and $11.1 million, respectively.

Note 2: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

Comparison of three months ended September 30, 2022 and 2021

($ in thousands)	Three Months Ended September 30, 2022	2021	Change $	Change %
Revenue				
Product revenue, net	$ 16,043	$ 19,610	$ (3,567)	(18)%
Collaboration revenue	364	1,446	(1,082)	(75)%
Revenue – related party	48	29	19	66 %
Other revenue	73	—	73	100 %
Net revenue	16,528	21,085	(4,557)	(22)%
Operating expenses				
Cost of goods sold – product revenue	7,221	11,167	(3,946)	(35)%
Research and development	29,855	27,367	2,488	9 %
Research and development – licenses acquired	47	713	(666)	(93)%
Selling, general and administrative	30,139	22,221	7,918	36 %
Wire transfer fraud loss	—	9,540	(9,540)	(100)%
Total operating expenses	67,262	71,008	(3,746)	(5)%
Loss from operations	(50,734)	(49,923)	(811)	2 %
Other income (expense)				
Interest income	419	132	287	217 %
Interest expense and financing fee	(3,393)	(4,444)	1,051	(24)%
Foreign exchange loss	(21)	—	(21)	100 %
Change in fair value of investments	—	8,376	(8,376)	(100)%
Change in fair value of derivative liability	—	(2)	2	(100)%
Grant income	669	—	669	100 %
Total other income (expense)	(2,326)	4,062	(6,388)	(157)%
Net Loss	**(53,060)**	**(45,861)**	**(7,199)**	**16 %**
Less: net loss attributable to non-controlling interest	30,549	25,080	5,469	22 %
Net loss attributable to common stockholders	**$ (22,511)**	**$ (20,781)**	**$ (1,730)**	**8 %**

Net revenue decreased $4.6 million, or 22%, from the three months ended September 30, 2021 to the three months ended September 30, 2022 primarily due to the $3.6 million decrease in product revenue, net associated Targadox and its authorized generic, as a result of continued generic competition. In addition, net product revenues of Ximino and its authorized generic, as well as Exelderm and its authorized generic, have been negatively impacted by contract manufacturer product shortages, which have since been resolved. Collaboration revenue as a result of Cyprium's agreement with Sentynl decreased $1.1 million in the quarter ended September 30, 2022. Revenue-related party consists of patent fees related to Checkpoint's collaborations with TGTX. Other revenue of $0.1 million for the quarter ended September 30, 2022 consists of Journey's royalty revenue associated with Qbrexza.

Cost of goods sold decreased by $3.9 million, or 35%, from the three months ended September 30, 2021 to the three months ended September 30, 2022. The decrease is primarily due to a $2.1 million decrease in the product royalties we are required to pay as a result of lower sales in the three-month period ended September 30, 2022 compared to the year-earlier period, and, to a lesser extent, a contractual double digit percentage decrease in the royalty rate of Qbrexza that occurred in May 2022. In addition, the three-month period ended September 30, 2021 included an inventory step-up of $3.0 million for inventory units sold related to the acquired finished goods of Qbrexza® in 2021. Offsetting, in part, the above decreases are increases in cost of goods sold related to higher amortization of licenses of approximately $0.4 million, and higher freight, testing and product validation costs of approximately $0.7 million as a result of our newly acquired and launched products, Amzeeq and Zilxi (acquired in January 2022) and a $0.1 million increase in FDA manufacturing fees from the prior-year quarter.

Research and development expenses increased $2.5 million or 9% from the three months ended September 30, 2021 to the three months ended September 30, 2022. The following table shows the change in research and development spending by Fortress and its partner companies:

($ in thousands)	Three Months Ended September 30, 2022	2021	Change $	Change %
Research & Development				
Stock-based compensation				
Fortress	$ 375	$ 275	$ 100	36 %
Partner Companies:				
Avenue	8	25	(17)	(67)%
Checkpoint	276	161	115	72 %
JMC	34	—	34	100 %
Mustang	302	655	(353)	(54)%
Other[1]	5	2	3	129 %
Sub-total stock-based compensation expense	1,000	1,118	(118)	(11)%
Other Research & Development				
Fortress	140	376	(236)	(63)%
Partner Companies:				
Avenue	186	253	(67)	(27)%
Checkpoint	8,590	9,223	(633)	(7)%
JMC	2,778	718	2,060	287 %
Mustang	15,007	13,373	1,634	12 %
Other[1]	2,154	2,306	(152)	(7)%
Total Research & Development Expense	**$ 29,855**	**$ 27,367**	**$ 2,488**	**9 %**

Note 1: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

The decrease in stock-based compensation for the quarter ended September 30, 2022 is primarily due to the effect of new equity grants to key employees at Checkpoint offset by Mustang's decrease in stock based compensation of $0.4 million.

JMC's research and development expense increase of $2.1 million is related to clinical trial expenses to develop DFD-29, for which dosing began in March 2022, and these costs are expected to increase as more patients are enrolled. Mustang's increase in research and development spending of $1.6 million is primarily attributable to increased expenses of $0.6 million for personnel related expenses in connection with the advancement of its clinical programs, $0.3 million for third party clinical trial and sponsored research costs, $0.4 million for laboratory supplies and $0.8 million for various other costs, partially offset by a $0.5 million decrease in consulting and outside services costs. The decreased spending at Checkpoint of $0.6 million is attributable primarily to decreased costs related to Checkpoint's manufacturing costs for cosibelimab of $1.0 million, as well as decreased clinical costs of $1.2 million related to Checkpoint's product candidates, offset by $0.9 million increase in personnel costs due to increased headcount, and $0.6 million increase in regulatory costs. The decrease in "Other" of $0.2 million is attributable to the decreased spend in the three months ended September 30, 2022 as compared to the three months ended September 30, 2021 for Cyprium, as the prior quarter spend related to costs for the preparation of Cyprium's rolling NDA submission, and Oncogenuity, as the license was returned to Columbia, offset by an increase in spending at Urica due to costs associated with the Phase 1 clinical trial to evaluate Dotinurad, which was initiated in June 2022.

General and administrative expenses increased $7.9 million, or 36%, from the three months ended September 30, 2021 to the three months ended September 30, 2022. The following table shows the change in general and administrative spending by Fortress and its partner companies:

($ in thousands)	Three Months Ended September 30, 2022	2021	Change $	Change %
Selling, General & Administrative				
Stock-based compensation				
Fortress	$ 3,704	$ 2,287	$ 1,417	62 %
Partner Companies:				
Avenue	18	44	(26)	(60)%
Checkpoint	505	618	(113)	(18)%
JMC	1,404	7	1,397	19958 %
Mustang	194	229	(35)	(15)%
Other[2]	12	23	(11)	(47)%
Sub-total stock-based compensation expense	5,837	3,208	2,629	82 %
Other Selling, General & Administrative				
Fortress	4,077	3,702	375	10 %
Partner Companies:				
Avenue	451	550	(99)	(18)%
Checkpoint	1,190	1,142	48	4 %
JMC[1]	14,170	10,996	3,174	29 %
Mustang	3,038	1,990	1,048	53 %
Other[2]	1,376	633	743	117 %
Total Selling, General & Administrative Expense	**$ 30,139**	**$ 22,221**	**$ 7,918**	**36 %**

Note 1: Includes cost of outsourced sales force for the three months ended September 30, 2022 and 2021 of $6.2 million and $5.1 million, respectively.
Note 2: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

For the quarter ended September 30, 2022, the increase in general and administrative expenses of $7.9 million, or 36%, is primarily attributable to Journey's expanded salesforce and increased sales and marketing costs associated with product portfolio, as well as Mustang's increase in professional fees and outside services, and personnel related expenses. The increase in "Other" is due to increased professional fees at Cyprium and Baergic.

Total other income (expense) decreased $6.4 million, or 157%, from income of $4.1 million for the three months ended September 30, 2021 to expense of $2.3 million for the three months ended September 30, 2022, primarily due to the change in fair value of the Company's investment in Caelum of $8.4 million recorded in the three months ended September 30, 2021. There is no comparable change in fair value of investment in Caelum in the current quarter as Caelum was acquired in the fourth quarter of 2021 by AstraZeneca. Grant income of $0.7 million recorded in the three months ended September 30, 2022 relates to Mustang's income related to its NIH grant.

Net loss attributable to Common Stockholders increased $1.7 million, or 8%, from a net loss of $20.8 million for the three months ended September 30, 2021 to a net loss of $22.5 million for the three months ended September 30, 2022.

Comparison of nine months ended September 30, 2022 and 2021

($ in thousands)	Nine Months Ended September 30, 2022	2021	Change $	Change %
Revenue				
Product revenue, net	$ 55,074	$ 45,617	$ 9,457	21 %
Collaboration revenue	1,518	4,646	(3,128)	(67)%
Revenue – related party	118	252	(134)	(53)%
Other revenue	2,629	—	2,629	100 %
Net revenue	59,339	50,515	8,824	17.5 %
Operating expenses				
Cost of goods sold – product revenue	23,057	22,559	498	2 %
Research and development	99,707	70,226	29,481	42 %
Research and development – licenses acquired	48	15,585	(15,537)	(100)%
Selling, general and administrative	85,457	59,145	26,312	44 %
Wire transfer fraud loss	—	9,540	(9,540)	(100)%
Total operating expenses	208,269	177,055	31,214	18 %
Loss from operations	(148,930)	(126,540)	(22,390)	18 %
Other income (expense)				
Interest income	711	505	206	41 %
Interest expense and financing fee	(8,897)	(9,393)	496	(5)%
Foreign exchange loss	(21)	—	(21)	100 %
Change in fair value of investments	—	39,294	(39,294)	(100)%
Change in fair value of derivative liability	—	(184)	184	(100)%
Grant income	669	—	669	100 %
Total other income (expense)	(7,538)	30,222	(37,760)	(125)%
Net loss	**(156,468)**	**(96,318)**	**(60,150)**	**62 %**
Less: net loss attributable to non-controlling interest	96,841	63,180	33,661	53 %
Net loss attributable to common stockholders	**$ (59,627)**	**$ (33,138)**	**$ (26,489)**	**80 %**

Net revenues increased $8.8 million, or 18%, from the nine months ended September 30, 2021 to the nine months ended September 30, 2022 primarily due to incremental revenues from Qbrexza, acquired and launched during the second quarter of 2021, the revenue growth of Accutane, launched at the end of the first quarter of 2021, and incremental net revenues as a result of our newly acquired and launched products, Amzeeq and Zilxi (acquired in January 2022). Offsetting, in part, the increases above is a decrease in the net product revenue of Targadox and its authorized generic as a result of continued generic competition. In addition, net product revenues of Ximino and its authorized generic, and Exelderm and its authorized generic, have been negatively impacted by contract manufacturer product shortages. These shortages were resolved in the third quarter of 2022. Collaboration revenue as a result of Cyprium's agreement with Sentynl decreased $3.1 million for the nine months ended September 30, 2022 due to the prolonged timeline for the NDA submission. Other revenue of $2.6 million for the nine months ended September 30, 2022 is a result of a milestone payment of $10 million to Journey from their exclusive licensing partner in Japan, Maruho, offset by a $7.5 million payment to Dermira, pursuant to the terms of the Qbrexza APA between Journey and Dermira. Revenue-related party consists of patent fees related to Checkpoint's collaborations with TGTX.

Cost of goods sold increased by $0.5 million, or 2%, from the nine months ended September 30, 2021 to the nine months ended September 30, 2022 due to higher product cost of goods sold of $2.1 million driven by increased net product sales from period-to-period, increased amortization of $1.1 million related to acquired intangible assets from the acquisition of Amzeeq and Zilxi in January 2022, costs of approximately $1.1 million related to freight, product validation and stability testing for Amzeeq and Zilxi. The above increases to cost goods sold from period-to-period are offset, in part, by a decrease as the nine-month period ended September 30, 2021 included an inventory step-up of $4.2 million for inventory units sold related to the acquired finished goods of Qbrexza in 2021.

Research and development expenses increased $29.5 million or 42% from the nine months ended September 30, 2021 to the nine months ended September 30, 2022. The following table shows the change in research and development spending by Fortress and its partner companies.

($ in thousands)	Nine Months Ended September 30, 2022	2021	Change $	Change %
Research & Development				
Stock-based compensation				
Fortress	$ 1,218	$ 869	$ 349	40 %
Partner Companies:				
Avenue	297	108	189	175 %
Checkpoint	752	480	272	57 %
JMC	34	—	34	100
Mustang	1,262	1,633	(371)	(23)%
Other[1]	8	7	1	7 %
Sub-total stock-based compensation expense	3,571	3,097	474	358 %
Other Research & Development				
Fortress	671	1,110	(439)	(40)%
Partner Companies:				
Avenue	1,856	756	1,100	145 %
Checkpoint	34,837	20,315	14,522	71 %
JMC	6,653	747	5,906	791 %
Mustang	45,275	34,797	10,478	30 %
Other[1]	6,844	9,404	(2,560)	(27)%
Total Research & Development Expense	**$ 99,707**	**$ 70,226**	**$ 29,481**	**42 %**

Note 1: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

The increase in stock-based compensation for the nine months ended September 30, 2022 is primarily due to the effect of new equity grants to key employees and non-employees at Fortress, Avenue and Checkpoint.

The increased spending at Checkpoint of $14.5 million is attributable primarily to increased costs related to Checkpoint's manufacturing costs for cosibelimab of $9.5 million as validation work continues, as well as increased clinical costs of $0.7 million related to Checkpoint's product candidates, $2.4 million increase in personnel costs due to increased headcount, and $0.8 million increase in other costs. Mustang's increase in research and development spending of $10.5 million is primarily attributable to higher expenses of $4.0 million for personnel related expenses in connection with the advancement of Mustang's programs, $2.4 million for third party clinical trial costs, $1.8 million for laboratory supplies, $1.3 million for plasmid manufacturing costs, $0.5 million for depreciation expense, and $0.5 million for other expenses. Avenue's increase of $1.1 million is primarily due to $1.0 million increase in expenses related to advisory committee preparation costs as well as $0.1 million increase in personnel-related costs. JMC's research and development expense increase of $5.9 million is related to clinical trial expenses to develop DFD-29 for which dosing began in March 2022. The decrease in "Other" of $2.6 million is attributable to the decreased spend in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021 for Cyprium, as the prior year-to-date spend related to costs for the preparation of Cyprium's rolling NDA submission.

General and administrative expenses increased $26.3 million, or 44%, from the nine months ended September 30, 2021 to the nine months ended September 30, 2022. The following table shows the change in general and administrative spending by Fortress and its partner companies:

($ in thousands)	Nine Months Ended September 30, 2022	2021	Change $	Change %
Selling, General & Administrative				
Stock-based compensation				
Fortress	$ 8,505	$ 6,437	$ 2,068	32 %
Partner Companies:				
Avenue	341	191	150	78 %
Checkpoint	1,533	1,839	(306)	(17)%
JMC	2,951	40	2,911	7280 %
Mustang	549	794	(245)	(31)%
Other[2]	31	51	(20)	(29)%
Sub-total stock-based compensation expense	13,910	9,352	4,558	49 %
Other Selling, General & Administrative				
Fortress	12,829	11,988	841	7 %
Partner Companies:				
Avenue	1,637	1,769	(132)	(7)%
Checkpoint	4,071	3,271	800	24 %
JMC[1]	42,566	24,808	17,758	72 %
Mustang	7,936	5,714	2,222	39 %
Other[2]	2,508	2,243	265	12 %
Total Selling, General & Administrative Expense	**$ 85,458**	**$ 59,145**	**$ 26,312**	**44 %**

Note 1: Includes cost of outsourced sales force for the nine months ended September 30, 2022 and 2021 of $17.8 million and $11.1 million, respectively.
Note 2: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

For the nine months ended September 30, 2022, the increase in general and administrative expenses of $26.3 million, or 44%, is primarily attributable to Journey's increased sales and marketing costs associated with the expanded product portfolio, and expansion of its outsourced salesforce, Mustang's increase in professional fees and outside services, and personnel related expenses. The increase at Checkpoint is due to increased professional fees.

Total other income (expense) decreased $37.8 million, or 125%, from income of $30.2 million for the nine months ended September 30, 2021 to expense of $7.5 million for the nine months ended September 30, 2022, primarily due to the change in fair value of the Company's investment in Caelum of $39.3 million recorded in the nine months ended September 30, 2021. There is no comparable change in fair value of investment in Caelum in the nine months ended September 30, 2022 as Caelum was acquired in the fourth quarter of 2021 by AstraZeneca. The fair value increase was offset slightly by the increase in grant income of $0.7 million, comprised of Mustang's income from its NIH grant.

Net loss attributable to Common Stockholders increased $26.5 million, or 80%, from a net loss of $33.1 million for the nine months ended September 30, 2021 to a net loss of $59.6 million for the nine months ended September 30, 2022.

Liquidity and Capital Resources

We will require additional financing to fully develop and prepare regulatory filings and obtain regulatory approvals for our existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for our potential products, and sales and marketing capabilities. We have funded our operations to date primarily through the sale of equity and debt securities. We believe that our current cash and cash equivalents is sufficient to fund operations for at least the next twelve months. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We may seek funds through equity or debt financings, joint venture or similar development collaborations, the sale of partner companies (such as the stock purchase of Caelum by AstraZeneca that resulted from an option exercise), royalty financings, or through other sources of financing; the rising interest rate environment may cause the Company to pay more interest on its various debt instruments, which could lead to higher operating expenses. 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 ongoing COVID-19 pandemic. However, the Company is continuing to assess the effect on its operations by monitoring ongoing development in connection with the continuing COVID-19 pandemic and the actions implemented to combat the virus throughout the world.

Cash Flows for the Nine Months Ended September 30, 2022 and 2021

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

	For the Nine Months Ended September 30, 2022					
($ in thousands)	Fortress[1]	Avenue	Checkpoint	JMC	Mustang	Total
Statement of cash flows data:						
Total cash (used in)/provided by:						
Operating activities	$ (26,402)	$ (3,427)	$ (42,254)	$ (9,698)	$ (49,776)	$ (131,557)
Investing activities	(5)	—	—	(20,000)	(2,532)	(22,537)
Financing activities	(739)	(119)	7,997	15,508	34,054	56,701
Net increase in cash and cash equivalents and restricted cash	$ (27,146)	$ (3,546)	$ (34,257)	$ (14,190)	$ (18,254)	$ (97,393)

	For the Nine Months Ended September 30, 2021					
($ in thousands)	Fortress[1]	Avenue	Checkpoint	JMC	Mustang	Total
Statement of cash flows data:						
Total cash (used in)/provided by:						
Operating activities	$ (20,530)	$ (2,547)	$ (16,828)	$ 1,025	$ (38,964)	$ (77,844)
Investing activities	(150)	—	—	(8,800)	(3,889)	(12,839)
Financing activities	(13,352)	—	36,259	21,218	65,928	110,053
Net increase in cash and cash equivalents and restricted cash	$ (34,032)	$ (2,547)	$ 19,431	$ 13,443	$ 23,075	$ 19,370

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

	Nine Months Ended September 30,		
($ in thousands)	2022	2021	Change
Statement of cash flows data:			
Total cash (used in)/provided by:			
Operating activities	$ (131,557)	$ (77,844)	$ (53,713)
Investing activities	(22,537)	(12,839)	(9,698)
Financing activities	56,701	110,053	(53,352)
Net increase in cash and cash equivalents and restricted cash	$ (97,393)	$ 19,370	$ (116,763)

Operating Activities

Net cash used in operating activities increased $53.7 million from the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2022. The increase is due to the increase of $60.2 million in net loss, $15.4 million increase in research and development – licenses acquired, expense, and the $21.9 million increase in cash resulting from changes in operating assets and liabilities, offset by the $39.3 million decrease in the fair value of the investment in Caelum for the nine months ended September 30, 2022, as well as the $5.0 million increase in stock-based compensation expense.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2021 of $12.8 million, as compared to net cash used in investing activities of $22.5 million for the nine months ended September 30, 2022 is a $9.7 million change in cash flows from investing activities. The change is primarily due to the $20.0 million acquisition of the VYNE products by JMC during the nine months ended September 30, 2022, offset by the $9.8 million decrease in cash used in the purchase of research and development licenses and $0.4 million decrease in cash used in the purchase of intangible assets.

Financing Activities

Net cash provided by financing activities was $110.1 million for the nine months ended September 30, 2021, compared to $56.7 million of net cash provided by financing activities for the nine months ended September 30, 2022, is a decrease of $53.4 million. During the nine months ended September 30, 2022, net proceeds from at-the-market offerings for partner companies decreased $85.7 million, and net proceeds from partner company convertible preferred shares offering decreased $17.0 million, offset by $47.1 million in proceeds from partner company long-term debt.

We fund our operations through cash on hand, the sale of equity and debt securities, from the sale of partner companies, and from the proceeds resulting from the exercise of warrants and stock options. At September 30, 2022, we had cash and cash equivalents of $208.4 million, of which $61.4 million relates to Fortress and the private partner companies, primarily funded by Fortress, $20.5 million relates to Checkpoint, $91.4 million relates to Mustang, $34.9 million relates to Journey, and $0.2 million relates to Avenue. Restricted cash related to our leases at September 30, 2022 was $2.2 million, of which $1.2 million relates to Fortress and $1.0 million relates to Mustang.

Sources of Liquidity

Stock Offerings and At-The-Market Share Issuances

Subsequent to the end of the third quarter of 2022, in October 2022, Avenue announced the closing of an underwritten public offering of 3,636,365 common and pre-funded units. Each common unit consists of one share of common stock and one warrant to purchase one share of common stock, and each pre-funded unit consists of one pre-funded warrant to purchase one share of common stock and one warrant to purchase one share of common stock. Each share of common stock (or pre-funded warrant) was sold together with one warrant at a combined purchase price of $3.30 per common unit (or $3.2999 per pre-funded unit after reducing $0.0001 attributable to the exercise price of the pre-funded warrants). Avenue also simultaneously closed on the sale of an additional 545,454 warrants to purchase common stock, which were sold pursuant to a partial exercise of the underwriter's over-allotment option. Avenue received net proceeds of approximately $10.4 million at closing after deducting underwriting discounts and commissions and other expenses of the offering.

In November 2021, through an underwritten public offering, Avenue sold 2,238,805 shares of its common stock at a price of $1.34 per share resulting in net proceeds of $2.6 million. In addition, in December 2021, through an underwritten public offering, Avenue sold 1,910,100 shares of its common stock at a price of $1.07 per share resulting in net proceeds of $1.8 million. Avenue effected a reverse stock split in September 2022 where, as a result of the reverse stock split, every 15 shares of Avenue common stock were combined and converted into one share of new common stock, without any change in the par value per share. The 2021 Avenue public offerings are presented on a pre-split basis.

In July 2021, JMC privately offered and issued 758,680 shares of its 8% Cumulative Convertible Class A Preferred Stock ("Class A Preferred Stock") at a price of $25.00 per share, for gross proceeds of $19.0 million. In November 2021, Journey completed an initial public offering ("IPO") of its common stock, in which Journey sold 3,520,000 common shares at $10.00 per share, resulting in net proceeds of approximately $30.6 million after deducting underwriting discounts and other offering costs. In connection with the closing of the IPO, Journey issued 2,231,346 shares of common stock resulting from the conversion of all of the Class A Preferred Stock.

In November 2020, Checkpoint filed shelf registration statement No. 333-251005 on Form S-3 (the "Checkpoint 2020 S-3") that was declared effective in December 2020. During the nine months ended September 30, 2022, Checkpoint issued 5,157,914 shares of common stock through the Checkpoint ATM for aggregate total gross proceeds of approximately $9.9 million at an average selling price of $1.93 per share. At September 30, 2022, approximately $44.7 million of the Checkpoint shelf remains available for sale through the Checkpoint S-3.

In October 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. During the nine months ended September 30, 2022, Mustang issued approximately 7.9 million shares of common stock at an average price of $0.84 per share for gross proceeds of $6.6 million through the Mustang ATM. In connection with these sales, Mustang paid aggregate fees of approximately $0.1 million. As of September 30, 2022, approximately $8.0 million of the Mustang 2020 S-3 remains available for sales of securities.

In May 2020, the Company filed a shelf registration statement on Form S-3, which was declared effective on May 26, 2020 (the "2020 Shelf"). In connection with the 2020 Shelf, the Company entered into an At Market Issuance Sales Agreement ("2020 Common ATM"), governing potential sales of the Company's Common Stock. For the nine-month period ended September 30, 2022, the Company issued approximately 3.7 million shares of Common Stock at an average price of $1.59 per share for gross proceeds of $5.9 million through the 2020 Common ATM. Approximately $11.5 million of securities remain available for sale through the 2020 Shelf at September 30, 2022.

Debt

In March 2022, Mustang announced completion of a $75 million long-term debt facility with Runway. Of the $75 million, $30 million was funded upon closing, and the additional $45 million available through the facility may be funded upon Mustang's achieving certain predetermined milestones. Proceeds from the facility will be used to support the ongoing clinical development of key investigational product candidates within Mustang's pipeline and for general working capital purposes.

In April 2021, JMC entered into an agreement with East West Bank ("EWB") in which EWB provided a $7.5 million working capital line of credit. In January 2022, Journey entered into the Amendment of its loan and security agreement with East West Bank, which increased the borrowing capacity of Journey's revolving line of credit to $10.0 million and added a term loan not to exceed $20.0 million. Journey borrowed $15.0 million against the first tranche of the term loan in January 2022, to facilitate the VYNE Product Acquisition, and another $5.0 million in August 2022.

In August 2020, 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"). AstraZeneca's notification of its intent to acquire Caelum, received on September 28, 2021, was 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. The Company repaid the $10.5 million on October 12, 2021. At September 30, 2022, the remaining principal outstanding on the Oaktree Note was $50.0 million.

Strategic Partnerships

In October 2021, AstraZeneca acquired Caelum for an upfront payment of approximately $150 million paid to Caelum shareholders, of which approximately $56.9 million was paid to Fortress, net of Fortress' $6.4 million portion of the $15 million, 24-month escrow holdback amount and other miscellaneous transaction expenses. The agreement also provides for additional potential payments to Caelum shareholders totaling up to $350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive 42.4% of all potential milestone payments, which together with the upfront payment, would total up to approximately $212 million.

In February 2021, Cyprium entered into an 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"). As further compensation, Cyprium is eligible to receive up to an additional $12.0 million, to be paid (i) $3.0 million upon NDA acceptance by the FDA and (ii) $9.0 million upon FDA approval of the NDA and transfer of CUTX-101 to Sentynl.

Contractual Obligations

We enter into contracts in the normal course of business with licensors, contract research organizations (CROs), contract manufacturing organizations (CMOs) and other third parties for the procurement of various products and services, including without limitation biopharmaceutical development, biologic assay development, commercialization, clinical and preclinical development, clinical trials management, pharmacovigilance and manufacturing and supply. These contracts typically do not contain minimum purchase commitments (although they may) and are generally terminable by us upon written notice. Payments due upon termination or cancelation/delay consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation; in certain cases, our contractual arrangements with CROs and CMOs include cancelation and/or delay fees and penalties.

During the nine months ended September 30, 2022, Mustang entered into a new lease for office space commencing on July 1, 2022. The lease has a term of 7 years and 7 months, with rent obligations beginning on November 1, 2022. Base rent is $49,000 per month and increases to $56,000 per month during the term of the lease. The first 24 months of rent payments are abated, and the lease includes a $0.3 million tenant improvement allowance. There were no other material changes in our contractual obligations and commitments, including our lease obligations, as described in our 2021 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, the Company is not required to provide the information required by this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness, as of September 30, 2022, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

There are no reportable events or material developments with respect to previously disclosed proceedings for the quarter ended September 30, 2022. To our knowledge, except as previously disclosed, there are no 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, 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock, $0.001 par value ("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 Quarterly Report on Form 10-Q 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 Avenue, Checkpoint, Journey and Mustang 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 Avenue, Checkpoint, Journey or Mustang 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. As used throughout this filing, the words "we", "us" and "our" may refer to Fortress individually or together with our affiliates and partners, as dictated by context.

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 BLA or 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/or 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, 2021, the total amount of debt outstanding, net of the debt discount, was $42.9 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 the Oaktree Agreement with Oaktree. The Oaktree 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 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 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 operations of approximately $188.5 million and $94.3 million for the years ended December 31, 2021 and 2020, respectively. At December 31, 2021, we had an accumulated deficit of approximately $547.5 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 Series A 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, 2021 and 2020, we incurred R&D expenses of approximately $113.2 million and $61.3 million, respectively. We expect to continue to spend significant amounts on our growth strategy. We believe that our current cash and cash equivalents will enable us to continue to fund operations in the normal course of business for at least the next 12 months 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.

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, Amzeeq, Zilxi, 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. Four of our marketed products, Qbrexza, Amzeeq, Zilxi 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 currently competes with one AB rated generic product. 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 on 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 products 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. Several federal agencies including FDA, CMS and HHS, in addition to state and local governments, regulate drug product development and marketing. 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.

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.

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.

In the United States there is significant interest in containing healthcare costs and increasing the scrutiny of pharmaceutical pricing practices. Congress has continually 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), regularly evaluate and hold hearings on legislation intended to address various elements of the prescription drug supply chain and prescription drug pricing. Proposals include a significant overhaul of the Medicare Part D benefit design, addressing patent "loopholes", and efforts to cap the increase in drug prices, create drug price, and efforts to allow the Secretary of HHS to negotiate drug prices with prescription drug manufacturers. 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 former Trump Administration took several regulatory steps and proposed numerous prescription drug cost control measures. Similarly, the Biden Administration has identified promoting competition and lowering drug prices as a priority.

State legislatures are similarly active in proposing and passing legislation and regulations aimed at controlling pharmaceutical and biological prices and drug cost transparency.

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, including prescription drugs. 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 and prescription drugs 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.

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 and consummated several partnerships and/or contingent sales of our assets and subsidiaries, including an equity investment and contingent acquisition agreement between Caelum and AstraZeneca (which transaction has consummated) and a development funding and contingent asset purchase between Cyprium and Sentynl. Each of these arrangements has been time-consuming and has diverted management's attention. As a result of these consummated/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.

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, and may again enter 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, regulatory agencies or other third parties.

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. If we become obligated to pay all or a portion of such indemnification amounts, our business and the market value of our common stock and/or debt securities may be materially adversely impacted. For instance, under that certain Indemnification Agreement, dated as of November 12, 2018 by and among us, Avenue and InvaGen (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 Stock Purchase and Merger Agreement of even date therewith, as such representations and warranties were given as of the dates of signing and first closing. The Indemnification Agreement was terminated effective October 2022, but we may enter into similar arrangements in the future.

Additionally, we have agreed in the past, and may agree in the future, to act as guarantor in connection with equity or debt raises by our partner companies, pursuant to which we may become obligated either to pay what could be a significant amount of cash or issue what could be a significant number of shares of Fortress Common Stock or perpetual preferred stock if certain events occur or do not occur, which could lead to a depletion of resources or dilution to our Common Stock, or both.

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.

Russian military action in Europe may impact foreign countries in which certain of our partner companies may have enrolled, or had planned to enroll patients in clinical trials, and any such clinical trials may be delayed or suspended.

In February 2022, Russia commenced a military invasion of Ukraine. Russia's invasion and the ensuing response by Ukraine may disrupt our partner companies' ability to conduct clinical trials in Russia, Ukraine, Belarus, and Georgia, and potentially other neighboring countries. Although the impact of Russia's military action is highly unpredictable, certain clinical trial sites may be affected, including those of our partner company Checkpoint in Russia, Ukraine, Belarus, and Georgia. Those clinical trial sites may suspend or terminate trials, and patients could be forced to evacuate or choose to relocate, making them unavailable for initial or further participation in clinical trials. Alternative sites to fully and timely compensate for clinical trial activities in these areas may not be available and our partner companies may need to find other countries to conduct these clinical trials. Clinical trial interruptions may delay our partner companies' plans for clinical development and approvals for their product candidates, which could increase their costs and jeopardize their ability to commence product sales and generate revenues, which could adversely affect the value of our investment in our partner companies.

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, pass any regulatory agency inspection or otherwise perform under our agreements with them 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, 2021, we had an accumulated deficit of approximately $547.5 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.

The contractual provisions we may be forced to agree upon in services, manufacturing, supply and other agreements may be inordinately one-sided, vis-à-vis current or historical standard market terms (especially as pertains contractual liability and indemnification paradigms), and as a result we may be subject to liabilities that are not attributable to our own actions or the actions of our personnel.

There is a finite number of service providers who can perform the services or produce the materials or product candidates that we need, and we therefore often have a limited number of options in choosing such service providers. The standard market terms in many of the agreements into which we customarily enter with such service providers are subject to evolution over time, often-times in favor of our counterparties. Also, some such agreements are "adhesion contracts" under which our contractual counterparties refuse to entertain any modifications to their template documentation. One area where service providers often have and exert leverage over us is the negotiation of liability language – specifically the application of liability damages "caps" to certain of such service providers' indemnification obligations. In any circumstance where we've been compelled to agree to such language, it is conceivable that we will be liable to third parties for liabilities in excess of such caps that are attributable to the actions, forbearances and/or culpability of such service providers (and not to those of us and our personnel).

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 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

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 and Other 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, availability 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, third-party software, 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 and other malicious code, 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 have been 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, clinical trial enrollment, 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 107.0 million outstanding shares of our Common Stock, inclusive of outstanding equity awards, as of December 31, 2021, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), or an effective registration statement. In addition, pursuant to our current shelf registration statement on Form S-3, from time to time we may issue and sell shares of our Common Stock or Preferred Stock having an aggregate offering price of up to $17.4 million as of December 31, 2021. 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 all of 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. Continued focus on COVID-19 countermeasures, and the reorganization and rededication or critical resources, both at FDA and within similar governmental authorities across the world, may 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.

If we fail to comply with the continuing listing standards of Nasdaq, our common stock could be delisted from the exchange.

On October 31, 2022, the Company received a letter from the Staff of Nasdaq indicating that the bid price of the Company's Common Stock had closed below $1.00 per share for 30 consecutive business days and, as a result, the Company is not in compliance with Nasdaq Listing Rule 5550(a)(2), which sets forth the minimum bid price requirement for continued listing on The Nasdaq Capital Market. Nasdaq's notice has no immediate effect on the listing of the Company's Common Stock on Nasdaq. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company is afforded a 180-calendar day grace period, through May 1, 2023, to regain compliance with the bid price requirement. Compliance can be achieved by evidencing a closing bid price of at least $1.00 per share for a minimum of ten (10) consecutive business days, although the Staff may, in its discretion, require compliance for a longer period of time (generally no more than 20 consecutive business days) during the 180-calendar day grace period.

If the Company does not regain compliance with the bid price requirement by May 1, 2023, the Company may be eligible for an additional 180-calendar day compliance period so long as it satisfies the criteria for initial listing on Nasdaq and the continued listing requirement for market value of publicly held shares and the Company provides written notice to Nasdaq of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. In the event the Company is not eligible for the second grace period, the Nasdaq staff will provide written notice that the Common Stock is subject to delisting; however, the Company may request a hearing before the Nasdaq Hearings Panel (the "Panel"), which request, if timely made, would stay any further suspension or delisting action by the Staff pending the conclusion of the hearing process and expiration of any extension that may be granted by the Panel. There can be no assurance that the Company would be successful in its efforts to maintain the Nasdaq listing.

The Company intends to closely monitor the closing bid price of the Common Stock and consider all available options to remedy the bid price deficiency, but no decision regarding any action has yet been made. If we were unable to meet the continued listing requirements of the Nasdaq, our Common Stock could be delisted from the Nasdaq. Any such delisting of our Common Stock could have an adverse effect on the market price of, and the efficiency of the trading market for, our Common Stock, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and less coverage of us by securities analysts, if any. Also, if in the future we were to determine that we need to seek additional equity capital, being delisted from Nasdaq could have an adverse effect on our ability to raise capital in the public or private equity markets.

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
3.1	Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. (formerly Coronado Biosciences, Inc.) dated April 21, 2010 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 10 (file No. 001-54463) filed with the SEC on July 15, 2011).
3.2	First Certificate of Amendment of Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated May 20, 2011 (incorporated by reference to Exhibit 3.2 of the Registrant's Form 10 (file No. 001-54463) filed with SEC on July 15, 2011).
3.3	Second Certificate of Amendment of Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated October 1, 2013 (incorporated by reference to Exhibit 3.8 of the Registrant's Annual Report on Form 10-K (file No. 001-35366) filed with SEC on March 14, 2014).
3.4	Third Certificate of Amendment of Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated April 22, 2015 (incorporated by reference to Exhibit 3.9 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with SEC on April 27, 2015).
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated June 18, 2020 (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with SEC on June 19, 2020).
3.6	Certificate of Amendment to the Certificate of Designations and Rights and Preferences of the Fortress Biotech, Inc. 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock under the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated June 18, 2020 (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on June 19, 2020).
3.7	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated June 23, 2021 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 10-K (file No. 001-35366) filed with SEC on June 23, 2021).
3.8	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated July 8, 2022 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K (file No. 001-35366) filed with SEC on July 11, 2022).
3.9	Second Amended and Restated Bylaws of Fortress Biotech, Inc. (formerly Coronado Biosciences, Inc.) (incorporated by reference to Exhibit 3.7 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with SEC on October 31, 2013).
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.

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 14, 2022

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 14, 2022

By: /s/ David Jin
David Jin, 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 14, 2022

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, David Jin, 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 14, 2022

By: /s/ David Jin
David Jin
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, 2022 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 14, 2022

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, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Jin, 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 14, 2022

By: /s/ David Jin
David Jin
Chief Financial Officer
(Principal Financial Officer)