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, 2023

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 Islands, 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 10, 2023
Common Stock, $0.001 par value	8,942,751
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, to one or more of its subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context.

Risks Inherent in Drug Development

- Many of our 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 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, Amzeeq, Zilxi, Targadox, Ximino (until September 2023), and Exelderm. Any issues relating to the manufacture, sale, utilization, or reimbursement of Journey's products (including products liability claims) could significantly impact our operating results.
- A significant portion 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 (until September 2023), 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 Journey's 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 subsidiaries and partner companies have also entered into, and intend in the future to enter into, arrangements under which we and/or they have agreed to contingent dispositions of such 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 had developed and commercialized such products ourselves.

- Our growth and success depend on our acquiring or in-licensing products or product candidates and integrating such products into our businesses.
- We may act as guarantor and/or indemnitor of certain obligations of our subsidiaries and partner companies, which could require us to pay substantial amounts based on damages incurred by such entities.

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, and Zilxi, three 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 product sales 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

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

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, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 72,307	$ 178,266
Accounts receivable, net	7,989	28,208
Inventory	11,024	14,159
Other receivables - related party	165	138
Prepaid expenses and other current assets	6,341	9,661
Total current assets	97,826	230,432
Property, plant and equipment, net	6,854	13,020
Operating lease right-of-use asset, net	17,507	19,991
Restricted cash	2,438	2,688
Intangible asset, net	21,102	27,197
Other assets	4,822	973
Total assets	**$ 150,549**	**$ 294,301**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	$ 81,406	$ 97,446
Income taxes payable	84	—
Common stock warrant liabilities	5,430	13,869
Operating lease liabilities, short-term	2,413	2,447
Partner company convertible preferred shares, short-term, net	3,797	2,052
Partner company line of credit	—	2,948
Partner company installment payments - licenses, short-term, net	3,000	7,235
Other short-term liabilities	1,221	1,718
Total current liabilities	97,351	127,715
Notes payable, long-term, net	45,791	91,730
Operating lease liabilities, long-term	18,944	21,572
Partner company installment payments - licenses, long-term, net	—	1,412
Other long-term liabilities	1,706	1,847
Total liabilities	**163,792**	**244,276**
Commitments and contingencies (Note 14)		
Stockholders' equity (deficit)		
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, 2023 and December 31, 2022, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 8,937,587 and 7,366,283 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	9	7
Additional paid-in-capital	702,253	675,944
Accumulated deficit	(685,591)	(634,233)
Total stockholders' equity attributed to the Company	16,674	41,721
Non-controlling interests	(29,917)	8,304
Total stockholders' equity (deficit)	(13,243)	50,025
Total liabilities and stockholders' equity (deficit)	**$ 150,549**	**$ 294,301**

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, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Revenue				
Product revenue, net	$ 15,279	$ 16,043	$ 44,405	$ 55,074
Collaboration revenue	182	364	546	1,518
Revenue - related party	31	48	97	118
Other revenue	19,260	73	19,519	2,629
Net revenue	34,752	16,528	64,567	59,339
Operating expenses				
Cost of goods sold - product revenue	6,429	7,221	20,645	23,057
Research and development	20,288	29,855	87,702	99,707
Research and development - licenses acquired	60	47	4,293	48
Selling, general and administrative	21,733	30,139	71,512	85,457
Asset impairment	—	—	3,143	—
Total operating expenses	48,510	67,262	187,295	208,269
Loss from operations	(13,758)	(50,734)	(122,728)	(148,930)
Other income (expense)				
Interest income	547	419	2,296	711
Interest expense and financing fee	(2,534)	(3,393)	(13,255)	(8,897)
Change in fair value of warrant liabilities	4,542	—	10,708	—
Other income (expense)	620	648	(2,049)	648
Total other income (expense)	3,175	(2,326)	(2,300)	(7,538)
Loss before income tax expense	(10,583)	(53,060)	(125,028)	(156,468)
Income tax expense	141	—	142	—
Net loss	**(10,724)**	**(53,060)**	**(125,170)**	**(156,468)**
Net loss attributable to non-controlling interests	5,679	30,549	73,812	96,841
Net loss attributable to Fortress	**(5,045)**	**(22,511)**	**(51,358)**	**(59,627)**
Preferred A dividends declared and paid	(2,008)	(2,008)	(6,024)	(6,024)
Net loss attributable to common stockholders	**$ (7,053)**	**$ (24,519)**	**$ (57,382)**	**$ (65,651)**
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.94)	$ (4.11)	$ (7.94)	$ (11.15)
Weighted average common shares outstanding - basic and diluted	7,498,653	5,961,663	7,231,004	5,886,131

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 (Deficit)
($ in thousands except for share amounts)

For the Three Months Ended September 30, 2023

	Series A Perpetual Preferred Stock		Common Stock		Common Shares Issuable	Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balance as of June 30, 2023	**3,427,138**	**$ 3**	**8,777,157**	**$ 9**	**$ 23**	**$ 699,020**	**$ (680,546)**	**$ (34,452)**	**$ (15,943)**
Stock-based compensation expense	—	—	—	—	—	4,377	—	—	4,377
Issuance of common stock related to equity plans	—	—	28,112	—	—	—	—	—	—
Issuance of common stock for at-the-market offering, net	—	—	117,578	—	—	837	—	—	837
Common shares issued for dividend on partner company's convertible preferred shares	—	—	14,740	—	(23)	91	—	—	68
Preferred A dividends declared and paid	—	—	—	—	—	(2,008)	—	—	(2,008)
Partner companies' offerings, net	—	—	—	—	—	9,261	—	—	9,261
Partner company's at-the-market offering, net	—	—	—	—	—	160	—	—	160
Issuance of common stock under partner company's ESPP	—	—	—	—	—	90	—	—	90
Partner company's dividends declared and paid	—	—	—	—	—	(185)	—	—	(185)
Partner company's exercise of options for cash	—	—	—	—	—	21	—	—	21
Dissolution of subsidiary non-controlling interests	—	—	—	—	—	—	—	802	802
Non-controlling interest in partner companies	—	—	—	—	—	(9,412)	—	9,412	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	(5,679)	(5,679)
Net loss attributable to common stockholders	—	—	—	—	—	—	(5,045)	—	(5,045)
Balance as of September 30, 2023	**3,427,138**	**$ 3**	**8,937,587**	**$ 9**	**$ —**	**$ 702,253**	**$ (685,591)**	**$ (29,917)**	**$ (13,243)**

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		Common Shares Issuable	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**	**7,181,175**	**$ 7**	**$ —**	**$ 661,792**	**$ (584,579)**	**$ 70,479**	**$ 147,702**
Stock-based compensation expense	—	—	—	—	—	6,837	—	—	6,837
Issuance of common stock related to equity plans	—	—	20,488	—	—	—	—	—	—
Issuance of common stock for at-the-market offering, net	—	—	15,625	—	—	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)
Reversal 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**	**7,217,288**	**$ 7**	**$ —**	**$ 668,751**	**$ (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 (Deficit)
($ in thousands except for share amounts)

For the Nine Months Ended September 30, 2023

	Series A Preferred Stock		Common Stock		Paid-In	Accumulated	Total Non-Controlling	Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	Equity (Deficit)
Balance as of December 31, 2022	**3,427,138**	**$ 3**	**7,366,283**	**$ 7**	**$ 675,944**	**$ (634,233)**	**$ 8,304**	**$ 50,025**
Stock-based compensation expense	—	—	—	—	13,325	—	—	13,325
Issuance of common stock related to equity plans	—	—	211,969	—	—	—	—	—
Issuance of common stock for public offering, net	—	—	1,109,525	1	13,154	—	—	13,155
Issuance of common stock for at-the-market offering, net	—	—	224,003	1	2,004	—	—	2,005
Common shares issued for dividend on partner company's convertible preferred shares	—	—	25,807	—	199	—	—	199
Preferred A dividends declared and paid	—	—	—	—	(6,024)	—	—	(6,024)
Partner companies' offerings, net	—	—	—	—	31,238	—	—	31,238
Partner companies' at-the-market offering, net	—	—	—	—	160	—	—	160
Partner company's exercise of options for cash	—	—	—	—	24	—	—	24
Issuance of common stock under partner company's ESPP	—	—	—	—	178	—	—	178
Partner company's dividends declared and paid	—	—	—	—	(556)	—	—	(556)
Issuance of partner company's common shares for research and development expenses	—	—	—	—	1,233	—	—	1,233
Warrants	—	—	—	—	272	—	—	272
Deconsolidation/dissolution of subsidiary non-controlling interests	—	—	—	—	—	—	6,693	6,693
Non-controlling interest in partner companies	—	—	—	—	(28,898)	—	28,898	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	(73,812)	(73,812)
Net loss attributable to common stockholders	—	—	—	—	—	(51,358)	—	(51,358)
Balance as of September 30, 2023	**3,427,138**	**$ 3**	**8,937,587**	**$ 9**	**$ 702,253**	**$ (685,591)**	**$ (29,917)**	**$ (13,243)**

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	Additional Accumulated	Non-Controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	Equity
Balance as of December 31, 2021	**3,427,138**	**$ 3**	**6,762,367**	**$ 7**	**$ 656,127**	**$ (547,463)**	**$ 117,203**	**$ 225,877**
Stock-based compensation expense	—	—	—	—	17,481	—	—	17,481
Issuance of common stock related to equity plans	—	—	196,913	—	—	—	—	—
Issuance of common stock under ESPP	—	—	9,030	—	99	—	—	99
Issuance of common stock for at-the-market offering, net	—	—	248,978	—	5,750	—	—	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**	**7,217,288**	**$ 7**	**$ 668,751**	**$ (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 Statements of Cash Flows
($ in thousands)

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Cash Flows from Operating Activities:		
Net loss	$ (125,170)	$ (156,468)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation expense	1,853	2,286
(Gain) loss on sale of property and equipment	(1,351)	255
Bad debt expense	492	10
Amortization of debt discount	2,524	1,500
Accretion of partner company convertible preferred shares	687	—
Non-cash interest	353	619
Loss on extinguishment of debt	2,796	—
Amortization of acquired intangible assets	2,952	3,050
Reduction in the carrying amount of operating lease right-of-use assets	1,561	1,425
Stock-based compensation expense	13,325	17,481
Issuance (reversal) of partner company's common shares for research and development expenses	1,233	(27)
Common shares issued/issuable for dividend on partner company's convertible preferred shares	199	—
Change in fair value of partner companies' warrant liabilities	(10,708)	—
Research and development - licenses acquired, expense	3,060	40
Loss from deconsolidation/dissolution of subsidiaries	4,127	—
Asset impairment loss	3,143	—
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:		
Accounts receivable	19,727	(5,431)
Inventory	3,135	673
Other receivables - related party	(27)	525
Prepaid expenses and other current assets	3,217	1,339
Other assets	(1,107)	(77)
Accounts payable and accrued expenses	(17,018)	4,410
Deferred revenue	—	(1,518)
Income taxes payable	84	13
Lease liabilities	(1,739)	(1,522)
Other long-term liabilities	(638)	(140)
Net cash used in operating activities	(93,290)	(131,557)
Cash Flows from Investing Activities:		
Purchase of research and development licenses	(3,000)	(40)
Purchase of property and equipment	(35)	(2,624)
Proceeds from sale of property and equipment	6,000	127
Other	(5)	—
Acquired intangible assets	(5,000)	(20,000)
Net cash used in investing activities	(2,040)	(22,537)

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,	
	2023	2022
Cash Flows from Financing Activities:		
Payment of Series A perpetual preferred stock dividends	$ (6,024)	$ (6,024)
Proceeds from issuance of common stock for public offering, net	13,248	—
Proceeds from issuance of common stock for at-the-market offering, net	2,056	5,750
Proceeds from issuance of common stock under ESPP	—	99
Proceeds from partner companies' ESPP	178	206
Partner company’s dividends declared and paid	(556)	(563)
Proceeds from partner companies' sale of stock and warrants, net	33,805	(371)
Proceeds from partner companies' at-the-market offering, net	160	16,193
Proceeds from exercise of partner companies’ equity grants	24	142
Partner company’s net settlement of shares withheld for taxes	—	(1,698)
Payment of partner company's deferred financing cost	—	(119)
Repayment of partner company installment payments - licenses	(1,000)	(3,000)
Proceeds from partner company convertible preferred shares	854	—
Payment of debt issuance costs associated with partner company convertible preferred shares	(210)	(214)
(Repayment of) Proceeds from partner company long-term debt, net	(91)	47,112
Repayment of partner company long-term debt	(50,375)	—
Proceeds from partner company's line of credit	28,000	—
Repayment of partner company's line of credit	(30,948)	(812)
Net cash (used in) provided by financing activities	(10,879)	56,701
Net decrease in cash and cash equivalents and restricted cash	(106,209)	(97,393)
Cash and cash equivalents and restricted cash at beginning of period	180,954	307,964
Cash and cash equivalents and restricted cash at end of period	$ 74,745	$ 210,571
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 6,590	$ 6,595
Cash paid (refunded) for income taxes	$ (17)	$ 1,462
Supplemental disclosure of non-cash financing and investing activities:		
Settlement of restricted stock units into common stock	$ —	$ 3
Unpaid fixed assets	$ —	$ 21
Partner company's unpaid intangible assets	$ —	$ 4,740
Unpaid partner company’s debt offering cost	$ —	$ 1,050
Unpaid partner company’s offering cost	$ 575	$ —
Partner company derivative warrant liability associated with partner company convertible preferred shares	$ 33	$ —
Warrants	$ —	$ 384
Unpaid at-the-market offering cost	$ 50	$ —
Prepaid public offering cost	$ 94	$ —
Unpaid research and development licenses acquired	$ 60	$ —

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 it does through Fortress itself and through partner companies and subsidiaries. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who work in concert with its extensive network of key opinion leaders to identify and evaluate promising products and product candidates for potential acquisition. The Company 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 Center, St. Jude Children's Research Hospital ("St. Jude"), 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 ("Mayo Clinic"), 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 finance expertise to help the partners achieve their goals. Partner companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out-licensings, sales transactions, and public and private financings. To date, four partner companies are publicly-traded, and three subsidiaries have consummated strategic partnerships with industry leaders, including AstraZeneca plc as successor-in-interest to Alexion Pharmaceuticals, Inc. ("AstraZeneca") and Sentynl Therapeutics, Inc. ("Sentynl").

Our subsidiaries and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates are: Avenue Therapeutics, Inc. (Nasdaq: ATXI, "Avenue"), Baergic Bio, Inc. ("Baergic", a subsidiary of Avenue), 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, to one or more of its subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context. Generally, "subsidiary" refers to a private Fortress subsidiary, "partner company" refers to a public Fortress subsidiary, and "partner" refers to entities with whom one of the foregoing parties has a significant business relationship, such as an exclusive license or an ongoing product-related payment obligation. The context in which any such term is used throughout this document, however, may dictate a different construal from the foregoing.

Reverse Stock Split

On October 9, 2023 Fortress filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation, as amended, to effect a 1-for-15 reverse stock split of its issued and outstanding Common Stock (the "Reverse Stock Split"). The Reverse Stock Split was approved on August 10, 2023 by the Company's Board of Directors and by the Company's stockholders at a special meeting held on October 9, 2023, with the authorization to determine the final ratio (within a specified range) having been granted to the Company's Board of Directors. As a result of the Reverse Stock Split, every 15 shares of the Company's pre-reverse split Common Stock was combined and reclassified as one share of Common Stock. The proportionate voting rights and other rights of common stockholders were not affected by the Reverse Stock Split, other than as the result of payment for fractional shares. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise have held a fractional share of Common Stock received a cash payment in lieu thereof.

The Reverse Stock Split became effective, and commenced trading on Nasdaq on a post-split basis, on October 10, 2023. The Company's post-reverse split Common Stock has a new CUSIP number, 34960Q307, but the par value and other terms of the Common Stock were not affected by the Reverse Stock Split.

All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock and warrants outstanding at October 10, 2023, which resulted in a proportional decrease in the number of shares of the Company's Common Stock reserved for issuance upon exercise or vesting of such stock options, restricted stock and warrants, and, in the case of stock options and warrants, a proportional increase in the exercise price of all such stock options and warrants.

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

No fractional shares were issued in connection with the Reverse Stock Split, and stockholders who would otherwise be entitled to a fraction of one share received a proportional cash payment.

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 subsidiaries/partner companies, and the proceeds from the exercise of warrants and stock options. The Company has incurred losses from operations and negative cash flows from operating activities since inception and expects to continue to incur substantial losses for the next several years as it continues to fully develop and prepare regulatory filings and obtain regulatory approvals for its existing and new product candidates. The Company's current cash and cash equivalents, including $8.9 million, net, raised from the sale of common stock and warrants on November 14, 2023, 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 subsidiaries/partner companies, grants or other arrangements to develop and prepare regulatory filings and obtain regulatory approvals for the existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for the potential products, sales and marketing capabilities. If such funding is not available or not available on terms acceptable to the Company, the Company's current development plans and plans for expansion of its general and administrative infrastructure may be curtailed. Fortress also has the ability, subject to limitations imposed by Rule 144 of the Securities Act of 1933 (the "Securities Act") 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.

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 Annual Report on Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 31, 2023 (the "2022 Form 10-K"), from which the Company derived the balance sheet data at December 31, 2022, as well as Checkpoint's Form 10-K, filed with the SEC on March 31, 2023, Mustang's Form 10-K, filed with the SEC on March 30, 2023, Avenue's Form 10-K, filed with the SEC on March 31, 2023, and Journey's Form 10-K, filed with the SEC on March 31, 2023.

The Company's unaudited condensed consolidated financial statements include the results of the Company's subsidiaries for which it has voting control but does not own 100% of the outstanding equity of the subsidiaries. For consolidated entities where the Company owns less than 100% of the subsidiary, but retains voting control, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations and presents non-controlling interests as a component of stockholders' equity on its consolidated balance sheets. All intercompany income and/or expense items are eliminated entirely in consolidation prior to the allocation of net gain/loss attributable to non-controlling interest, which is based on ownership interests as calculated quarterly for each subsidiary.

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

Use of Estimates

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. The Company's significant estimates include, but are not limited to, provisions for product returns, coupons, rebates, chargebacks, discounts, allowances and distribution fees paid by Journey to certain wholesalers, inventory realization, recoverability of intangible assets, useful lives assigned to long-lived assets and amortizable intangible 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, 2023 and December 31, 2022, the Company had $2.4 million and $2.7 million, respectively, of restricted cash representing pledges to secure debt obligations and letters of credit in connection with certain office leases, and an undertaking posted by Cyprium to secure potential damages in an injunctive proceeding.

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, 2023 and 2022:

	September 30, 2023	September 30, 2022
Cash and cash equivalents	$ 72,307	$ 208,351
Restricted cash	2,438	2,220
Total cash and cash equivalents and restricted cash	$ 74,745	$ 210,571

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2022 Form 10-K, other than the following:

Non-Controlling Interests

The Company records net loss attributable to non-controlling interests in its consolidated statements of operations and presents non-controlling interests as a component of stockholders' equity on its consolidated balance sheets. All intercompany income and/or expense items are eliminated entirely in consolidation prior to the allocation of net gain/loss attributable to non-controlling interest, which is based on a quarterly calculation of ownership interests for each relevant subsidiary.

Subsidiary preferred shares and Class A common shares, if issued, are included in the ownership calculation on a 1:1 basis consistent with how the relevant contractual agreements provide for the allocation and distribution of earnings. These shares, if any, are convertible at Fortress' election on a 1:1 basis into common stock (with adjustments for stock splits, if any) and upon conversion would have the same voting rights as the common stock. Only preferred stock and Class A common stock held by Fortress have majority voting rights, which rights would terminate upon conversion into common stock. The Company allocates the subsidiaries' net loss/income to the non-controlling interest on a quarterly basis, and the calculation of non-controlling interest ownership percentage is determined as the average of the prior quarter and the current quarter's non-controlling ownership interest.

The Company continually assesses whether changes to existing relationships or future transactions may result in the consolidation or deconsolidation of subsidiaries and/or partner companies.

Recently Issued Accounting Pronouncements

As of September 30, 2023, there were no new accounting pronouncements or updates to recently issued accounting pronouncements disclosed in the 2022 Form 10-K that would materially affect the Company's present or future results of operations, overall financial condition, liquidity, or disclosures upon adoption.

3. Asset Purchase Agreements

Aevitas

Agreement with 4D Molecular Therapeutics ("4DMT")

On April 21, 2023, Aevitas entered into an Asset Purchase Agreement (the "4DMT APA") with 4DMT under which 4DMT acquired Aevitas' proprietary rights to its short-form human complement factor H ("sCFH") asset for the treatment of complement-mediated diseases. Under the terms of the 4DMT APA, 4DMT will make cash payments totaling up to $140 million if certain late-stage development, regulatory and sales milestones are met with respect to sCFH. A range of single-digit royalties on net sales are also payable. The aforementioned payments are payable solely to Aevitas, and 4DMT will be responsible for license payment obligations to the licensor of sCFH, University of Pennsylvania. 4DMT is not a related party to the Company and has assumed all ongoing development costs. The fair value of the interest in Aevitas retained by the Company is based on the risk-adjusted present value of the aforementioned potential cash payments (see Note 6, Fair Value Measurements).

In connection with the 4DMT APA, the preferred shares of Aevitas held by the Company converted to Aevitas common shares, at which point the Company no longer maintained voting control of Aevitas. As a result, the Company deconsolidated its holdings in Aevitas. In connection with this transaction, the Company recorded a loss on deconsolidation of Aevitas on its condensed consolidated financial statements during the nine months ended September 30, 2023.

The Company recognized the following related to the deconsolidation of Aevitas:

($ in thousands)		**Nine Months Ended September 30, 2023**
Fair value of interests retained	$	2,585
Non-controlling interest share		(5,891)
Other		(63)
Loss from deconsolidation of subsidiary	$	(3,369)

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

Mustang

Agreements with uBriGene (Boston) Biosciences, Inc. ("uBriGene")

On May 18, 2023, Mustang entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with uBriGene, as amended by a first amendment thereto, dated June 29, 2023, and further amended by a second amendment thereto, dated as of July 28, 2023 (collectively the "Amended Asset Purchase Agreement"), pursuant to which Mustang agreed, subject to the terms and conditions therein, to sell its leasehold interest in its cell processing facility located in Worcester, MA (the "Facility") and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility to uBriGene. On July 28, 2023, (the "Closing Date"), pursuant to the terms and conditions of the Amended Asset Purchase Agreement, Mustang completed the sale of Mustang's assets primarily relating to the manufacturing and production of cell and gene therapies to uBriGene for base consideration of $6.0 million. Mustang recorded a gain of $1.4 million in connection with the sale of the assets for the three and nine months ended September 30, 2023, and recorded approximately $0.3 million of the base consideration as deferred income, to be recognized upon the transfer of the lease. Certain assets, including Mustang's lease of the Facility and related contracts did not transfer to uBriGene on the Closing date. uBriGene will be obligated to pay to Mustang a contingent amount of $5.0 million less certain severance obligations and payments payable in connection with the transfer of certain contracts related to the transferred assets, if Mustang, within two years of the closing date: (i) completes one or more issuances of equity securities in an aggregate gross amount equal to or greater than $10.0 million after the closing and (ii) obtains consent of the landlord to the proposed lease transfer within two years after the closing date. The lease transfer would include leasehold improvements with a book value at September 30, 2023 of $3.5 million.

The Asset Purchase Agreement contemplates that Mustang will seek to procure the consent and approval of the landlord of the Facility, WCS-377 Plantation Street, Inc. (the "Landlord"), and the Landlord informed Mustang that it will not consider the lease transfer request until receipt of the final determination letter from with the U.S. Committee on Foreign Investment in the United States ("CFIUS"), although there can be no guarantee that, even if CFIUS does approve the below-described Facility Transaction, the Landlord will approve the lease transfer. In connection with the sale of its leasehold interest in the Facility and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility (the "Facility Transaction") to uBriGene and an indirect, wholly owned subsidiary of UBriGene (Jiangsu) Biosciences Co., Ltd., a Chinese contract development and manufacturing organization, Mustang and uBriGene previously submitted a voluntary notice with CFIUS. Following an initial 45-day review period and subsequent 45-day investigation period, on November 13, 2023, CFIUS requested Mustang and uBriGene to withdraw and re-file their joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction, and whether and to what extent mitigation of risk would be feasible. Upon CFIUS's request, Mustang and uBriGene submitted a request to withdraw and re-file their joint voluntary notice to CFIUS, and on November 13, 2023, CFIUS granted this request, accepting the joint voluntary notice and commenced a new 45-day review period commencing on November 14, 2023, which may be followed by a further 45-day investigation period. Unless and until the lease is transferred to uBriGene, Mustang will retain its Facility lease and Facility personnel, and will continue to occupy the leasehold premises and manufacture there its lead product candidates, including MB-106, pursuant to the arrangements described under a manufacturing services agreement and a sub-contracting CDMO (contract development and manufacturing organization) agreement.

As contemplated by the Amended Asset Purchase Agreement, on the Closing Date, Mustang and uBriGene entered into a Manufacturing Services Agreement (the "Manufacturing Services Agreement"). Under the Manufacturing Services Agreement, Mustang contracted uBriGene to manufacture Mustang's lead product candidates, including MB-106, and Mustang committed to spend at least $8 million over a period of two years after the closing of the transaction to purchase manufacturing and related services (the "Manufacturing Services") from uBriGene (the "Minimum Commitment"). Mustang paid uBriGene 25% of the Minimum Commitment at the time of signing of the Manufacturing Services Agreement and will pay the remainder of the Minimum Commitment over the following two years. Subject to Mustang's payment of its Minimum Commitment, uBriGene will provide to Mustang a manufacturing rebate, payable in cash at the end of the second year of the Manufacturing Services Agreement term, for any amounts paid for Manufacturing Services in excess of the Minimum Commitment (but in no event will such rebate exceed $3 million). In connection with the Manufacturing Services Agreement, Mustang will provide uBriGene with the customary licenses to use intellectual property rights specific to Mustang's cell and gene therapies to the extent reasonably necessary for uBriGene's performance under the Manufacturing Services Agreement. Mustang intends to expense manufacturing costs under the Manufacturing Services Agreement and the sub-contracting Manufacturing Services Agreement, pursuant to which uBriGene contracted with Mustang to perform the Manufacturing Services to be performed by uBriGene under the Manufacturing Services Agreement and account for reimbursed costs associated with the agreements as an offset to such expense. For the three months ended September 30, 2023, Mustang has expensed $1.7 million of manufacturing costs under the Manufacturing Services Agreement.

In addition, as contemplated by the Asset Purchase Agreement, on the Closing Date, Mustang and uBriGene entered into a sub-contracting Manufacturing Services Agreement (the "Sub-Contracting CDMO Agreement"). Under the terms of the Sub-Contracting CDMO Agreement, Mustang will manufacture its lead product candidates, including MB-106, and may from time to time manufacture other products as requested by uBriGene. In addition, under the Sub-Contracting CDMO Agreement, Mustang and uBriGene agreed to establish a joint steering committee comprising two representatives from each of Mustang and uBriGene to review, discuss and decide on operational matters relating to the services to be performed by Mustang under such agreement, including matters relating to expenses. For the three months ended September 30, 2023, Mustang received $2.5 million in reimbursed costs associated with the Sub-Contracting CDMO Agreement.

Cyprium

Agreement with Sentynl

On February 24, 2021, Cyprium entered into a development and asset purchase agreement (the "Sentynl APA") with Sentynl, a U.S.-based specialty pharmaceutical company owned by the Zydus Group. Under the Sentynl APA, Sentynl provided certain development funding for Cyprium's CUTX-101 program, with Cyprium remaining in control of development of such program; upon approval of the New Drug Application ("NDA") for CUTX-101 by the U.S. Food and Drug Administration ("FDA"), Cyprium is obligated to assign the NDA and certain other assets pertaining to the CUTX-101 program to Sentynl, after which point Sentynl will commercialize the drug and owe Cyprium royalties and regulatory and sales milestones.

The Sentynl APA contains an alternative "Approval Deadline Transfer" mechanism pursuant to which, in the event that CUTX-101 NDA approval has not been obtained by September 30, 2023, then Sentynl may elect, during the subsequent 45-day period, to assume control over development of CUTX-101 by effecting a Closing under the Sentynl APA. Cyprium has received notice of Sentynl's election to effect the Approval Deadline Transfer, with Closing of such transfer anticipated to occur in November 2023. The Approval Deadline Transfer obligates Sentynl to pay Cyprium $4.5 million in connection with the Closing. Following such Closing, Sentynl will be obligated to use commercially reasonable efforts to develop and commercialize CUTX-101, including the funding of the same. Additionally, following such Closing, Cyprium remains eligible to receive up to $133.5 million in aggregate development and sales milestones under the Agreement and royalties on net sales of CUTX-101 as follows: (i) 3% of annual net sales up to $75 million; (ii) 8.75% of annual net sales between $75 million and $100 million; and (iii) 12.5% of annual net sales in excess of $100 million.

Cyprium expects the Approval Deadline Transfer will result in a reduction in its development-related spending on the CUTX-101 program. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101 (see Note 19, Subsequent Events).

With respect to the $8.0 million upfront payment from Sentynl, the Company recognized revenue over the period in which the development activities occurred using an input method based upon the costs incurred to date in relation to the total estimated costs to complete the development activities. For the three months ended September 30, 2023 and 2022, the Company recognized revenue from this arrangement of $0.2 million and $0.4 million, respectively. For the nine months ended September 30, 2023 and 2022, the Company recognized revenue of $0.5 million and $1.5 million, respectively.

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

Avenue

Agreements with InvaGen Pharmaceuticals Inc. (“InvaGen”)

On November 12, 2018, Avenue entered into a Stock Purchase and Merger Agreement (the “Avenue SPMA”) with InvaGen, and Madison Pharmaceuticals Inc. (the “Merger Sub”), which contemplated: (i) the purchase by InvaGen of a 33.3% stake in Avenue; and (ii) the contingent sale of Avenue to InvaGen. The first stage stock purchase closed in February 2019: InvaGen acquired approximately 0.4 million shares of Avenue’s common stock at $90.00 per share for total gross consideration of $35.0 million, representing a 33.3% stake in Avenue’s capital stock on a fully diluted basis. Under a contingent second stage closing, InvaGen could have acquired the remaining shares of Avenue’s capital stock (in some cases compulsorily and in some cases at InvaGen’s option), pursuant to a reverse triangular merger with Avenue remaining as the surviving entity. On November 1, 2021, Avenue delivered InvaGen notice of termination of the Avenue SPMA, meaning that the second stage acquisition of Avenue by InvaGen pursuant to the Avenue SPMA was no longer possible. In July 2022 Avenue entered into a Share Repurchase Agreement (the “Share Repurchase Agreement”) with InvaGen. In connection with the closing of the Share Repurchase Agreement, which occurred on October 31, 2022, all of the rights retained by InvaGen pursuant to the Stockholders Agreement entered into by and among Avenue, InvaGen and Fortress on November 12, 2018, were terminated.

In connection with the closing by Avenue of an underwritten public offering on October 11, 2022, Avenue consummated the transactions contemplated by the Share Repurchase Agreement with InvaGen, pursuant to which Avenue repurchased 100% of the shares in Avenue held by InvaGen (the “InvaGen Shares”) for a purchase price of $3 million. In addition, under the Share Repurchase Agreement Avenue agreed to pay InvaGen an additional amount as a contingent fee, payable in the form of seven and a half percent (7.5%) of the proceeds of future financings, up to $4 million. In connection with the closing of the January 2023 Avenue Registered Direct and Private Placement (see Note 13, Stockholders’ Equity), which occurred on January 31, 2023, Avenue made a payment of $0.2 million to InvaGen on February 3, 2023. In connection with the closing of an offering in November (see Note 19, Subsequent Events), Avenue owes a fee of approximately $0.3 million to InvaGen.

4. Inventory

($ in thousands)	**September 30, 2023**	**December 31, 2022**
Raw materials	$ 4,664	$ 6,454
Work-in-process	458	395
Finished goods	6,683	7,739
Inventory reserve	(781)	(429)
Total inventories	$ 11,024	$ 14,159

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

5. Property, Plant and Equipment

At September 30, 2023 and December 31, 2022, property, plant and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	September 30, 2023	December 31, 2022
Computer equipment	3	$ 595	$ 739
Furniture and fixtures	5	1,017	1,387
Machinery & equipment	5	—	8,632
Leasehold improvements	15	13,175	13,175
Buildings	40	581	581
Construction in progress	N/A	—	952
Total property and equipment		15,368	25,466
Less: Accumulated depreciation		(8,514)	(12,446)
Property, plant and equipment, net		$ 6,854	$ 13,020

Fortress' depreciation expense for the three months ended September 30, 2023 and 2022 was approximately $0.4 million and $0.8 million, respectively, and for the nine months ended September 30, 2023 and 2022 was approximately $1.9 million and $2.3 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. Fair Value Measurements

Fair Value of Aevitas

The Company valued its retained investment in Aevitas, as part of the deconsolidation of its holdings (see Note 3, Asset Purchase Agreements) in accordance with ASC Topic 820, *Fair Value Measurements and Disclosures*, and estimated the fair value to be $2.6 million based on a per share value of $0.328. The following inputs were utilized to derive the value: risk free rate of return of 3.7%, volatility of 80% and a discount for lack of marketability of 39.7%.

Common Stock Warrant Liabilities

($ in thousands)	Warrants liabilities
Balance at December 31, 2022	$ 13,869
Avenue common stock warrants	2,235
Urica placement agent warrants	33
Change in fair value of common stock warrants - Avenue	(1,544)
Change in fair value of common stock warrants - Checkpoint	(9,179)
Change in fair value of placement agent warrants - Urica	16
Balance at September 30, 2023	$ 5,430

Checkpoint

On December 16, 2022, Checkpoint closed on an offering for the sale of shares of its common stock and pre-funded warrants as part of a registered direct offering (the "Checkpoint December 2022 Registered Direct Offering"). The common stock and the pre-funded warrants were sold together with common stock warrants and placement agent warrants (the "Checkpoint December 2022 Common Stock and Placement Agent Warrants"). Net proceeds from the Checkpoint December 2022 Registered Direct Offering were $6.7 million after deducting commissions and other transaction costs.

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

The Company deemed the Checkpoint December 2022 Common Stock and Placement Agent Warrants to be classified as liabilities on the balance sheet as they contain terms for redemption of the underlying security that are outside its control. The Checkpoint December 2022 Common Stock and Placement Agent Warrants were recorded at the time of closing at a fair value determined by using the Black-Scholes model. As the total fair value of the common stock warrant liability exceeded the total proceeds, no proceeds were allocated to Checkpoint common stock and pre-funded warrants as part of the transaction. Checkpoint revalued the Checkpoint December 2022 Common Stock and Placement Agent Warrants at December 31, 2022, resulting in a fair value of $11.2 million.

The Company revalued the Checkpoint December 2022 Common Stock and Placement Agent Warrants at September 30, 2023 using the Black-Scholes model. This resulted in a decrease in common stock warrant liability of $9.2 million, with an offsetting gain recorded to change in fair value of warrant liabilities in the unaudited condensed consolidated Statements of Operations.

($ in thousands)		Checkpoint Warrant Liability
Common Stock Warrant liabilities at December 31, 2022	$	11,170
Change in fair value of common stock warrant liabilities		(9,179)
Common Stock Warrant liabilities at September 30, 2023	$	1,991

A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the warrant liability that are categorized within Level 3 of the fair value hierarchy was as follows:

Checkpoint Warrants		September 30, 2023		December 31, 2022
Exercise price	$	4.08 - 5.41	$	4.08 - 5.41
Volatility		91.4 - 102.8 %		82.4 - 89.4 %
Expected life		0.7 - 4.2		1.5 - 5.0
Risk-free rate		4.6 - 5.5 %		4.0 - 4.7 %

Avenue

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 (the “October 2022 Warrants”), which were sold pursuant to a partial exercise of the underwriter’s over-allotment option. Avenue received net proceeds of approximately $10.3 million at closing after deducting underwriting discounts and commissions and other expenses of the offering.

On January 27, 2023, Avenue entered into an agreement with a single institutional investor for the sale of 448,000 shares of common stock at a price of $1.55 per share and pre-funded warrants to purchase 1,492,299 shares of common stock at $1.549 per pre-funded warrant. Each pre-funded warrant had an exercise price of $0.001 per share. In a concurrent private placement, Avenue also agreed to issue to the same investor a total of 1,940,299 warrants to purchase up to one share of common stock (the “January 2023 Warrants”) each at an exercise price of $1.55 per share and a purchase price of $0.125. Avenue received approximately $2.8 million in net proceeds from both transactions and recorded $2.2 million in expense associated with the issuance of the common warrants (see Note 13, Stockholders’ Equity).

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The October 2022 Warrants originally contained a one-time down-round price protection feature. In connection with the January 2023 Registered Direct and Private Placement, the down-round price protection feature was triggered and the exercise price for the October 2022 Warrants was permanently adjusted to $1.55, which was the offering price for the January 2023 Registered Direct and Private Placement. The Black-Scholes model was used to value the October 2022 Warrants and January 2023 Warrants as of September 30, 2023.

The Company deemed the warrants to be classified as liabilities on the balance sheet as they contain terms for redemption of the underlying security that are outside its control. The October 2022 Warrants were recorded at the time of closing at a fair value of $8.3 million.

($ in thousands)		Avenue Warrant Liability
Common Stock Warrant liabilities at December 31, 2022	$	2,609
Issuance of Avenue common warrants		2,235
Change in fair value of common stock warrant liabilities		(1,544)
Common Stock Warrant liabilities at September 30, 2023	$	3,300

A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the warrant liability that are categorized within Level 3 of the fair value hierarchy was as follows:

	September 30, 2023	January 31 2023	December 31 2022
Stock price	$ 0.71	$ 1.38	$ 1.16
Risk-free interest rate	4.60 - 5.03 %	3.90 %	4.02 %
Expected dividend yield	—	—	—
Expected term in years	2.4 - 4.0	3.00	4.78
Expected volatility	141 - 165 %	160 %	93 %

Urica

The fair value of Urica's contingently issuable placement agent warrants in connection with Urica's first close of its preferred offering in December 2022, was measured using a Monte Carlo simulation valuation methodology. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Urica's warrant liability that are categorized within Level 3 of the fair value hierarchy was as follows:

	September 30, 2023	December 31 2022
Risk-free interest rate	5.50 %	3.94 %
Expected dividend yield	—	—
Expected term in years	0.8	1.5
Expected volatility	85.7 %	70.7 %

At September 30, 2023 and December 31, 2022 the value of the Urica's contingent payment warrant was approximately $0.1 million.

7. Intangibles, net

The Company's finite-lived intangible assets consist of intangible assets acquired by Journey. During the nine months ended September 30, 2023, Journey experienced lower net product revenues and gross profit levels for its Ximino products. Based on these results, Journey revised the financial outlook and plans for its Ximino products. Journey assessed the revised forecast for Ximino and determined that this constituted a triggering event and the results of the analysis indicated the carrying amount was not expected to be recovered. Journey recorded an intangible asset impairment charge of $3.1 million during the nine months ended September 30, 2023. This non-cash charge was recorded to loss on impairment of intangible assets on the unaudited condensed consolidated statements of operations.

VYNE Therapeutics Product Acquisition ("VYNE Product Acquisition")

In January 2022, Journey entered into an agreement with VYNE Therapeutics, Inc. ("VYNE") 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 for an upfront payment of $20.0 million and an additional $5.0 million payment on the one-year anniversary of the closing (the "VYNE Product Acquisition Agreement"). This expanded Journey's product portfolio to eight marketed branded dermatology products. Journey also acquired certain associated inventory.

The VYNE Product Acquisition Agreement 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 Product Acquisition Agreement.

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

($ 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 was accreted to the $5.0 million January 2023 cash payment over a one-year period through interest expense. Journey made the $5 million deferred cash payment in January 2023.

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

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

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The intangible assets acquired as part of the VYNE Product Acquisition Agreement were valued using an income approach, while the inventory was valued using a final sales value less cost to dispose approach.

The table below provides a summary of the Journey intangible assets as of September 30, 2023 and December 31, 2022, respectively:

($ in thousands)	Estimated Useful Lives (Years)	September 30, 2023	December 31, 2022
Intangible assets – product licenses	3 to 9	$ 37,925	$ 37,925
Accumulated amortization		(13,680)	(10,728)
Impairment loss		(3,143)	—
Net intangible assets		$ 21,102	$ 27,197

For the three months ended September 30, 2023 and 2022, Journey's amortization expense related to its product licenses was $0.8 million and $1.0 million, respectively. For the nine months ended September 30, 2023 and 2022, Journey's amortization expense related to its product licenses was $3.0 million and $3.1 million, respectively. Journey records amortization expense related to its product licenses as a component of cost of goods sold on the unaudited condensed consolidated statement of operations.

The future amortization of these intangible assets is as follows:

($ in thousands)	Total Amortization
Three months ended December 31, 2023	$ 813
December 31, 2024	3,258
December 31, 2025	3,258
December 31, 2026	2,470
December 31, 2027	1,775
Thereafter	5,586
Sub-total	$ 17,160
Asset not yet placed in service	3,942
Total	$ 21,102

8. License Agreements

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 subsidiaries and 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, 2023 and 2022, the purchase price of the license acquired was classified as research and development-licenses acquired in the unaudited condensed consolidated statement of operations.

Journey

In June 2021, Journey entered a license, collaboration, and assignment agreement (the "DFD-29 Agreement") to obtain global rights for the development and commercialization of a late-stage development modified release oral minocycline for the treatment of rosacea ("DFD-29") with Dr. Reddy's Laboratories, Ltd ("DRL"); provided, that DRL retained certain rights to the program in select markets including Brazil, Russia, India and China. Based on the development and commercialization of DFD-29, additional contingent regulatory and commercial milestone payments totaling $158.0 million may also become payable by Journey. Journey is required to pay royalties ranging from approximately ten percent to fifteen percent on net sales of the DFD-29 product, subject to certain reductions. Additionally, Journey was required to fund and oversee the Phase 3 clinical trials beginning upon the license of DFD-29 in 2021. The Phase 3 clinical trials substantially concluded in July 2023 upon Journey's receipt of positive topline results from the trials. For the three months ended September 30, 2023 and 2022, Journey expensed $2.0 million and $2.7 million, respectively, to research and development expense, and for the nine months ended September 30, 2023 and 2022 expensed $5.5 million, and $6.2 million, respectively, to research and development expense related to the development of DFD-29.

On August 31, 2023, Journey entered into a license agreement (the "New License Agreement") with Maruho Co., Ltd., a Japanese company specializing in dermatology ("Maruho"), whereby Journey agreed to grant an exclusive license to Maruho to develop and commercialize Qbrexza® for the treatment of primary axillary hyperhidrosis, in South Korea, Taiwan, Hong Kong, Macau, Thailand, Indonesia, Malaysia, Philippines, Singapore, Vietnam, Brunei, Cambodia, Myanmar and Laos (the "Territory"). Under the terms of the New License Agreement, in exchange for the exclusive rights to Qbrexza in the Territory and the amendment to the royalty payments associated with the Japanese license, Maruho paid $19.0 million to Journey as a non-refundable upfront payment. Prior to the date of the New License Agreement, Journey and Maruho were party to an existing exclusive amended and restated license agreement (the "First A&R License Agreement"), under which Maruho acquired exclusive license rights to Qbrexza® in Japan. In connection with Journey's entry into the New License Agreement, Journey and Maruho also entered into the Second Amended and Restated Exclusive License Agreement (the "Second A&R License Agreement"), which supersedes the First A&R License Agreement. The Second A&R License Agreement contains modifications that remove Maruho's obligation to pay Journey royalties on its net sales of Rapifort® (the Japanese equivalent of Qbrexza®) in Japan for sales occurring after October 1, 2023 and removes Maruho's obligation to pay $10 million to Journey in the event that Maruho achieves net sales of at least ¥4 billion (yen) of Rapifort® during a single fiscal year. All other remaining potential milestone payment obligations, which aggregate to $45 million, remain in full force and effect.

Avenue

On February 28, 2023, Avenue entered into a license agreement with AnnJi Pharmaceutical Co. Ltd. ("AnnJi"), whereby Avenue obtained an exclusive license (the "AnnJi License Agreement") from AnnJi to intellectual property rights pertaining to the molecule known as JM17, which activates Nrf1 and Nrf2, enhances androgen receptor degradation and underlies AJ201, a clinical product candidate currently in a Phase 1b/2a clinical trial in the U.S. for the treatment of spinal and bulbar muscular atrophy ("SBMA"), also known as Kennedy's Disease. Under the AnnJi License Agreement, in exchange for exclusive rights to the intellectual property underlying the AJ201 product candidates, Avenue agreed to pay $3.0 million, of which $2.0 million was paid on April 27, 2023 and $1 million was paid on September 8, 2023.

The license provided under the AnnJi License Agreement is exclusive as to all oral forms of AJ201 for use in all indications (other than androgenetic alopecia and Alzheimer's disease) in the United States, Canada, the European Union, the United Kingdom and Israel. The AnnJi License Agreement also contains customary representations and warranties and provisions related to confidentiality, diligence, indemnification and intellectual property protection. Avenue will initially be obligated to obtain both clinical and commercial supply of AJ201 exclusively through AnnJi. AnnJi retains the manufacturing rights for AJ201 and Avenue has the option to acquire those rights from AnnJi as described in the AnnJi License Agreement.

Pursuant to the terms of the AnnJi License Agreement, Avenue was also obligated to issue two tranches of shares of its common stock and make additional payments including: reimbursement of payments up to $10.8 million in connection with the product's Phase 1b/2a clinical trial (which AnnJi is currently administering with Joint Steering Committee Oversight before assigning the IND to Avenue upon such trial's conclusion, and which is reflective of market pricing for the services to be received), up to $14.5 million in connection with certain development milestones pertaining to the first indication in the U.S., up to $27.5 million in connection with certain drug development milestones pertaining to additional indications and development outside the U.S., up to $165 million upon the achievement of certain net sales milestones ranging from $75 million to $750 million in annual net sales, and royalty payments based on a percentage of net sales ranging from mid-single digits to the low-double digits, which are subject to potential diminution in certain circumstances.

In connection with the signing of the AnnJi License Agreement, Avenue issued 831,618 shares of its common stock to AnnJi ("First Tranche Shares") and recognized expense of $0.9 million; and issued 276,652 shares of common stock ("Second Tranche Shares"), recorded at a fair value of $0.3 million, on September 26, 2023 upon enrollment of the eighth patient in the ongoing Phase 1b/2a SBMA clinical trial. The fair value was calculated based on the closing price of Avenue's stock as of February 28, 2023, the date Avenue entered into the AnnJi License Agreement. Avenue and AnnJi entered into a Subscription Agreement, dated as of February 28, 2023, that provided for the issuance of First Tranche Shares which were issued March 30, 2023. In the event that the common stock of Avenue ceases to be traded on a national securities exchange, AnnJi has the right to sell the common stock of Avenue back to Avenue at a price of $2.10, subject to the terms of the AnnJi License Agreement.

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Checkpoint

In October 2015, Fortress entered into a collaboration agreement with Adimab, LLC ("Adimab") to discover and optimize antibodies using their proprietary core technology platform. Under this agreement, Adimab optimized cosibelimab, Checkpoint's anti-PD-L1 antibody which it originally licensed from Dana-Farber. In January 2019, Fortress transferred the rights to the optimized antibody to Checkpoint, and Checkpoint entered into a collaboration agreement directly with Adimab on the same day. Under the terms of the agreement, Adimab is eligible to receive payments from Checkpoint of up to an aggregate of approximately $2.5 million upon various filings for regulatory approvals to commercialize the product. In addition, Adimab is eligible to receive royalty payments based on a tiered low single digit percentage of net sales.

In February 2023, Checkpoint expensed a non-refundable milestone payment of $2.2 million to research and development expenses upon the United States Food and Drug Administration's filing acceptance of the Company's Biologics License Application ("BLA") for cosibelimab in metastatic or locally advanced cutaneous squamous cell carcinoma.

9. Debt and Interest

Debt

Total debt consists of the following:

($ in thousands)	September 30, 2023	December 31, 2022	Interest rate	Maturity
Oaktree Note	$ 50,000	$ 50,000	11.00 %	August - 2025
EWB Term Loan	—	20,000	10.20 %	January - 2026
Runway Note	—	31,050	13.77 %	April - 2027
Less: Discount on notes payable	(4,209)	(9,320)		
Total notes payable	$ 45,791	$ 91,730		

Oaktree Note

In August 2020, Fortress, as borrower, entered into a $60.0 million senior secured credit agreement with Oaktree Fund Administration, LLC and the lenders from time-to-time thereto (collectively, "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 Oaktree 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, 2023.

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, 2023.

Journey Working Capital Line of Credit Amendment and Term Loan with East West Bank

In July 2023, Journey voluntarily repaid the entire $10.0 million outstanding term loan principal balance under its credit facility with East West Bank (the "EWB Facility"). The repayment satisfied all of Journey's outstanding debt obligations under the EWB Facility. Journey has no further obligations to East West Bank.

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

On April 11, 2023, the long-term debt facility with Runway Growth Finance Corp. (the "Mustang Term Loan" or the "Runway Note"), was terminated upon receipt by Runway of a payoff amount of $30.7 million from Mustang comprising of principal, interest and the applicable final payment amount. A loss on extinguishment of $2.8 million was recorded to interest expense in the unaudited condensed consolidated statement of operations for the nine months ended September 30, 2023.

Urica 8% Cumulative Convertible Class B Preferred Offering

In December 2022 and February 2023 Urica closed private offerings of its 8% Cumulative Convertible Class B Preferred Stock (the "Urica Preferred Stock"), at a price of $25.00 per share ("Subscription Price") pursuant to which it sold a total of 135,494 shares of Urica Preferred Stock for gross proceeds of $3.4 million, before deducting underwriting discounts and commissions and offering expenses of approximately $0.5 million (the "Urica Offering"). A non-cash contingent warrant value of $0.1 million was also recorded in debt discount (see Note 6, Fair Value Measurements).

Dividends on the Urica Preferred Stock are payable monthly by Fortress in shares of Fortress Common Stock based upon a 7.5% discount to the average trading price over the 10-day period preceding the dividend payment date. Dividends will be recorded as interest expense and were immaterial in 2022. For the three and nine month periods ended September 30, 2023, the Company recorded expense of $0.1 million and $0.2 million associated with the Urica dividends owed on the outstanding Urica Preferred Stock.

The shares mandatorily convert into Urica common stock upon either: (i) a qualified financing pursuant to which Urica raises at least $20 million in aggregate gross proceeds; or (ii) a sale of Urica (in each case, at a 20% discount to the lowest price per share at which Urica common stock is issued/sold in such transaction). Additionally, in the event that neither such a qualified financing nor a sale of Urica has occurred prior to June 27, 2024, then each holder of Urica Preferred Stock is eligible to receive, at Fortress' election, one of: (x) a cash payment equal to the product of the Subscription Price and the number of shares of Urica Preferred Stock held by such holder; (y) a number of shares of Fortress Common Stock equal to the Fortress share exchange amount; or (z) a combination of the foregoing (in each case plus cash in lieu of any fractional shares, plus cash in lieu of accumulated and unpaid dividends otherwise payable in Fortress shares up to the conversion/exchange date).

The Urica Preferred Stock have no voting rights and have liquidation rights on parity with all equity securities issued by Urica, and junior to all equity securities issued by Urica with terms outlining senior rank and current and future indebtedness.

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

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Interest Expense

The following table shows the details of interest expense for all debt arrangements during the periods presented. Interest expense includes contractual interest, and 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,					
	2023			2022		
($ in thousands)	*Interest*	*Fees*	Total	*Interest*	*Fees*	Total
Oaktree Note	1,425	459	1,884	1,406	395	1,801
Partner company convertible preferred shares	234	140	374	—	—	—
Partner company installment payments - licenses	177	—	177	201	—	201
Partner company notes payable	33	58	91	1,221	159	1,380
Other	8	—	8	11	—	11
Total Interest Expense and Financing Fee	$ 1,877	$ 657	$ 2,534	$ 2,839	$ 554	$ 3,393

	Nine Months Ended September 30,					
	2023			2022		
($ in thousands)	*Interest*	*Fees*	Total	*Interest*	*Fees*	Total
Oaktree Note	4,206	1,595	5,801	4,171	1,126	5,297
Partner company convertible preferred shares	886	439	1,325	—	—	—
Partner company installment payments - licenses	353	—	353	619	—	619
Partner company notes payable[1]	4,834	490	5,324	2,570	374	2,944
Other	120	332	452	37	—	37
Total Interest Expense and Financing Fee	$ 10,400	$ 2,856	$ 13,255	$ 7,397	$ 1,500	$ 8,897

Note 1: Includes loss on extinguishment of $2.8 million recorded by Mustang related to payoff of the Runway Note on April 11, 2023.

10. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

($ in thousands)	September 30, 2023	December 31, 2022
Accounts payable	$ 44,731	$ 57,244
Accrued expenses:		
Professional fees	2,295	1,693
Salaries, bonus and related benefits	8,585	9,772
Research and development	7,446	7,390
Research and development - license maintenance fees	4,456	632
Research and development - milestones	—	4,600
Accrued royalties payable	1,794	2,627
Accrued coupon and rebates	6,099	7,604
Return reserve	4,523	3,689
Accrued interest	16	342
Other	1,461	1,853
Total accounts payable and accrued expenses	$ 81,406	$ 97,446

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11. Non-Controlling Interests

Non-controlling interests in consolidated entities are as follows:

($ in thousands)	For the Nine Months Ended September 30, 2023 Net loss attributable to non-controlling interests	As of September 30, 2023 Non-controlling interests in consolidated entities	Non-controlling ownership
Avenue[1]	(9,298)	(3,346)	88.3 %
Cellvation	(25)	(1,949)	21.3 %
Checkpoint[2]	(26,625)	(16,966)	89.1 %
Coronado SO	—	(290)	13.0 %
Cyprium	(1,335)	(5,491)	28.3 %
Helocyte	45	(5,994)	17.5 %
JMC[2]	(515)	8,035	46.2 %
Mustang[1]	(34,026)	3,184	79.4 %
Oncogenuity	(11)	(1,721)	27.0 %
Urica	$ (2,022)	$ (5,379)	33.0 %
Total	$ (73,812)	$ (29,917)	

($ in thousands)	For the Year Ended December 31, 2022 Net loss attributable to non-controlling interests	As of December 31, 2022 Non-controlling interests in consolidated entities	Non-controlling ownership
Aevitas[3]	(425)	(5,753)	45.2 %
Avenue[1]	(2,355)	3,054	89.9 %
Baergic[4]	(113)	—	— %
Cellvation	(102)	(1,791)	21.3 %
Checkpoint[2]	(48,406)	(16,008)	82.2 %
Coronado SO	—	(291)	13.0 %
Cyprium	(1,173)	(3,817)	29.0 %
Helocyte	(122)	(5,900)	17.9 %
JMC[2]	(12,458)	7,429	43.7 %
Mustang[1]	(60,821)	37,640	81.3 %
Oncogenuity	(111)	(1,575)	27.4 %
Tamid[5]	(1)	(776)	22.8 %
Urica	$ (1,251)	$ (3,908)	40.2 %
Total	$ (127,338)	$ 8,304	

Note 1: 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.

Note 2: 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 3: Effective April 21, 2023, Aevitas ceased to be a controlled Fortress entity and as such is no longer consolidated (see Note 3, Asset Purchase Agreements).

Note 4: Fortress' ownership in Baergic was transferred to Avenue as of November 7, 2022 (see Note 15, Related Party Transactions).

Note 5: Tamid was dissolved in the quarter ended September 30, 2023.

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12. Net Loss per Common Share

Basic and diluted net loss per share attributed to common stockholders is calculated by dividing the net loss attributed to Fortress (less the Series A Preferred dividends) by the weighted-average number of shares of Common Stock outstanding during the period, not including unvested restricted stock, and without consideration for Common Stock equivalents. Diluted net loss per share is the same as the basic loss per share due to net losses in all periods.

The Company updated its presentation of net loss attributable to common stockholders and its net loss per share as an immaterial correction to reflect the preferred stock dividend which is $2.0 million per quarter. The dividend was appropriately reflected in the statement of changes in stockholders' equity (deficit) and statement of cash flows and are not impacted by this change in presentation. For the quarter ended September 30, 2022, the net loss attributable to Fortress increased from ($22.5) million to ($24.5) million and the net loss per share increased from ($3.75) to ($4.11) per share. For the nine months ended September 30, 2022, the net loss attributable to Fortress increased from ($59.6) million to ($65.7) million and the net loss per share increased from ($10.20) to ($11.15) per share.

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, 2023:

	Nine Months Ended September 30,	
	2023	2022
Warrants to purchase Common Stock	127,296	268,699
Options to purchase Common Stock	34,890	54,128
Unvested Restricted Stock	1,369,105	1,229,750
Unvested Restricted Stock Units	152	3,407
Total	1,531,443	1,555,985

13. Stockholders' Equity

Reverse Stock Split

On October 9, 2023 Fortress filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation, as amended, to effect the 1-for-15 Reverse Stock Split. The Reverse Stock Split was approved on August 10, 2023 by the Company's Board of Directors and by the Company's stockholders at a special meeting held on October 9, 2023, with the authorization to determine the final ratio (within a specified range) having been granted to the Company's Board of Directors. As a result of the Reverse Stock Split, every 15 shares of the Company's pre-reverse split Common Stock was combined and reclassified as one share of Common Stock. The proportionate voting rights and other rights of common stockholders were not affected by the Reverse Stock Split, other than as the result of payment for fractional shares. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise have held a fractional share of Common Stock received a cash payment in lieu thereof.

All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock and warrants outstanding at October 10, 2023, which resulted in a proportional decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock and warrants, and, in the case of stock options and warrants, a proportional increase in the exercise price of all such stock options and warrants.

No fractional shares were issued in connection with the Reverse Stock Split, and stockholders who would otherwise be entitled to a fraction of one share received a proportional cash payment.

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Stock-based Compensation

As of September 30, 2023, the Company had four equity compensation plans: the Fortress Biotech, Inc. 2007 Stock Incentive Plan (the "2007 Plan"), the Fortress Biotech, Inc. 2013 Stock Incentive Plan, as amended (the "2013 Plan"), the Fortress Biotech, Inc. 2012 Employee Stock Purchase Plan (the "ESPP") and the Fortress Biotech, Inc. Long Term Incentive Plan ("LTIP"). In June 2023, the Company's Board of Directors and stockholders approved an amendment to the 2013 Plan to increase the number of authorized shares issuable by approximately 0.5 million shares, for a total of approximately 1.9 million shares across the 2007 and 2013 Plans and approved an amendment to the ESPP to increase the number of shares issuable by approximately 0.1 million shares. As of September 30, 2023, approximately 0.5 million shares are available for issuance under the 2007 and 2013 Plans.

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, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2023	2022	2023	2022
Employee and non-employee awards	$ 2,077	$ 2,548	$ 6,785	$ 7,506
Executive awards of Fortress Companies' stock	385	1,531	1,202	2,217
Partner Companies:				
Avenue	561	26	599	638
Checkpoint	689	781	2,225	2,285
Mustang	100	496	380	1,810
Journey	558	1,438	2,077	2,985
Other	7	17	57	40
Total stock-based compensation expense	$ 4,377	$ 6,837	$ 13,325	$ 17,481

For the three months ended September 30, 2023 and 2022, approximately $0.9 million and $1.0 million, respectively, of stock-based compensation expense was included in research and development expenses in connection with equity grants made to employees and consultants and approximately $3.5 million and $5.8 million, respectively, was included in general and administrative expenses in connection with grants made to employees, members of the board of directors and consultants. For the nine months ended September 30, 2023 and 2022, approximately $2.3 million and $3.6 million, respectively, of stock-based compensation expense was included in research and development expenses in connection with equity grants made to employees and consultants and approximately $11.0 million and $13.9 million, respectively, was included in general and administrative expenses in connection with grants made to employees, members of the board of directors and consultants.

Stock Options

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

	Number of shares	Weighted average exercise price	Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Options vested and expected to vest at December 31, 2022	176,732	$ 22.08	$ 230,000	5.64
Forfeited	(166)	37.50	—	—
Expired	(16,333)	133.22	—	—
Options vested and expected to vest at September 30, 2023	160,233	$ 10.74	$ —	5.43
Options vested and exercisable at September 30, 2023	40,232	$ 61.70	$ —	0.99

As of September 30, 2023, Fortress had $0.4 million in unrecognized stock-based compensation expense related to options which is expected to be recognized over the remaining weighted-average vesting period of 2.7 years.

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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, 2022	1,370,001	$ 35.44
Restricted stock granted	171,905	9.91
Restricted stock vested	(49,911)	36.10
Restricted stock units granted	12,666	11.19
Restricted stock units forfeited	(19,183)	42.05
Restricted stock units vested	(40,020)	45.30
Unvested balance at September 30, 2023	1,445,458	$ 31.81

As of September 30, 2023 and 2022, the Company had unrecognized stock-based compensation expense related to restricted stock and restricted stock unit awards of approximately $13.5 million and $22.9 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 1.7 years and 2.0 years, respectively.

Warrants

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

	Number of shares	Weighted average exercise price	Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Outstanding as of December 31, 2022	127,296	$ 46.58	$ —	7.45
Outstanding as of September 30, 2023	127,296	$ 10.06	$ —	6.71
Exercisable as of September 30, 2023	118,296	$ 8.48	$ —	6.86

In connection with the Oaktree Note (see Note 9, Debt and Interest), the Company had issued warrants to Oaktree and certain of its affiliates to purchase up to approximately 0.1 million shares of Common Stock at a purchase price of $48.00 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 registration statement No. 333-249983 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.

On June 13, 2023, the Company entered into a Letter Agreement (the “Letter Agreement”) by and among the Company, Oaktree and certain of its affiliates, pursuant to which the Company agreed to lower the exercise price of the existing warrants to $8.136 per share (adjusted for the Reverse Stock Split) and issue amended and restated warrants reflecting the new exercise price (the “Amended and Restated Warrants”), as consideration for the warrant holders’ agreement to permit the Company and/or certain of its subsidiaries to take certain actions. The Amended and Restated Warrants are exercisable on or after June 13, 2023 and expire August 27, 2030.

The Oaktree Warrants were previously determined to have met the criteria for equity classification. The Oaktree Warrants were reported as a component of additional paid in capital within Stockholders’ equity, and the value ascribed to the warrants was recorded as debt discount of the Oaktree Note and is amortized utilizing the effective interest method over the term of the Oaktree Note. The modification of the warrants resulted in a change in value of $0.3 million which was recorded as interest expense in the condensed consolidated statement of operations for the nine-months ended September 30, 2023.

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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, 2023 and 2022, the Compensation Committee granted 81,286 and 73,532 shares each to Dr. Rosenwald and Mr. Weiss, respectively. These equity grants were made in accordance with the LTIP, and each award represents 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 $0.8 million for the 2023 grant and $1.0 million for the 2022 grant. For the three months ended September 30, 2023 and 2022, the Company recorded stock compensation expense related to LTIP grants of approximately $1.5 million and $1.3 million, respectively, and for the nine months ended September 30, 2023 and 2022, recorded stock compensation expense related to LTIP grants of approximately $4.4 million and $4.0 million, respectively, on the unaudited condensed consolidated statement of operations.

Capital Raises

2021 Shelf

On July 23, 2021, the Company filed a shelf registration statement (File No. 333-258145) on Form S-3, which was declared effective on July 30, 2021 (the "2021 Shelf"). Approximately $110.1 million of securities remain available for sale under the 2021 Shelf as of September 30, 2023.

2020 Shelf

On May 18, 2020, the Company filed a shelf registration statement (File No. 333-238327) on Form S-3, which was declared effective on May 26, 2020 (the "2020 Shelf") and expired on May 26, 2023.

At the Market Offering

In connection with the 2020 Shelf, the Company entered into an At Market Issuance Sales Agreement ("Fortress ATM"), governing potential sales of the Company's Common Stock. On May 26, 2023, the Fortress ATM was amended to reflect potential future sales under the 2021 Shelf.

For the nine months ended September 30, 2023, the Company issued approximately 0.2 million shares at an average price of $9.61 for gross proceeds of $2.2 million pursuant to the Fortress ATM. For the nine months ended September 30, 2022, the Company issued approximately 0.3 million shares at an average price of $23.85 for gross proceeds of $5.9 million pursuant to the Fortress ATM.

Registered Direct Offering and Concurrent Private Placement

On February 10, 2023, the Company completed a registered direct offering of Common Stock pursuant to which it issued and sold approximately 1.1 million shares of its common stock at a purchase price of $12.53 per share and secured approximately $13.2 million in net proceeds after deducting estimated offering expenses.

The Company also simultaneously closed on a concurrent private placement with investors in the registered direct offering, for the pro rata rights to acquire, in the aggregate, securities exercisable into approximately 3.5% of the outstanding shares of common stock in each of the Company's next 20 new operating subsidiaries (the "Contingent Subsidiary Securities"). The Contingent Subsidiary Securities will only be issued to the extent such a new operating subsidiary first consummates a specified corporate development transaction within the next five years, and will be exercisable immediately upon issuance, with an exercise period of 10 years, at an exercise price equal to the fair market value of one share of common stock of the subsidiary on the date of the corporate development transaction. The Company's stockholders approved the issuance of the rights and Contingent Subsidiary Securities at a special meeting of stockholders on April 10, 2023, as required by Nasdaq Listing Rule 5635.

Mustang 2020 and 2021 Shelf Registration Statements and At-the-Market Offering (the "Mustang ATM")

On October 23, 2020, Mustang filed a shelf registration statement (File 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, 2023, approximately $7.8 million of the Mustang 2020 S-3 remains available for sales of securities.

On April 23, 2021, Mustang filed a shelf registration statement (File 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, 2023, there have been no sales of securities under the Mustang 2021 S-3.

On July 2018, Mustang entered into an At-the-Market Issuance Sales Agreement (the "Mustang ATM") with B. Riley Securities, Inc. (formerly B. Riley FBR, Inc.), Cantor Fitzgerald & Co., National Securities Corporation (now B. Riley FBR, Inc.), and Oppenheimer & Co. Inc., relating to the sale of shares of common stock pursuant to the Mustang 2020 S-3. Under the Mustang ATM, Mustang pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. On December 31, 2020, the Mustang ATM was amended to add H.C. Wainwright & Co., LLC as an Agent. On April 14, 2023, the Mustang ATM was amended to add the limitations imposed by General Instruction I.B.6 to Form S-3 and remove Oppenheimer & Co., Inc. as an Agent.

During the nine months ended September 30, 2023, Mustang issued approximately 52,000 shares of common stock at an average price of $3.15 per share for gross proceeds of $0.2 million through the Mustang ATM. During the nine months ended September 30, 2022, Mustang issued approximately 0.5 million shares of common stock at an average price of $12.61 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. Pursuant to the Company's Founders Agreement with Mustang, Mustang recorded 1,297 shares issuable to Fortress for the nine months ended September 30, 2023, and issued 13,131 shares of common stock to Fortress at a weighted average price of $13.56 per share for the nine months ended September 30, 2022, in connection with the shares issued under the Mustang ATM.

Checkpoint 2020 and 2023 Shelf Registration Statements

The Checkpoint 2020 S-3 shelf registration statement (File No. 333-251005) 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, 2023, approximately $8.7 million of the securities remains available for sale through the Checkpoint 2020 S-3.

In March 2023, Checkpoint filed shelf registration statement (File No. 333-270843) on Form S-3 (the "Checkpoint 2023 S-3"), which was declared effective May 5, 2023. Under the Checkpoint 2023 S-3, Checkpoint may sell up to a total of $150 million of its securities. As of September 30, 2023, approximately $91.7 million of the securities remains available for sale through the Checkpoint 2023 S-3.

Checkpoint Registered Direct Offerings

In July 2023, Checkpoint closed on a registered direct offering (the “Checkpoint July 2023 Registered Direct Offering”) for the issuance and sale of an aggregate of 2,427,186 shares of its common stock at a purchase price of $3.09 per share. In addition, the offering includes 809,062 shares of common stock in the form of pre-funded warrants at a price of $3.0899. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 3,236,248 shares of common stock and Series B warrants to purchase up to 3,236,248 shares of common stock. The Series A warrants are exercisable immediately upon issuance and will expire five years following the issuance date and have an exercise price of $2.84 per share and the Series B warrants are exercisable immediately upon issuance and will expire eighteen months following the issuance date and have an exercise price of $2.84 per share (collectively, the “Checkpoint July 2023 Common Stock Warrants”). The total gross proceeds from the offering were approximately $10.0 million with net proceeds of approximately $9.1 million after deducting approximately $0.9 million in commissions and other transaction costs. The Checkpoint July 2023 Common Stock Warrants met the criteria for equity classification. As of September 30, 2023, all of the pre-funded warrants from the Checkpoint July 2023 Registered Direct Offering were fully exercised.

In May 2023, Checkpoint closed on a registered direct offering (the “Checkpoint May 2023 Registered Direct Offering”) for the issuance and sale of an aggregate of 1,650,000 shares of its common stock at a purchase price of $3.071 per share in a registered direct offering. In addition, the offering includes 1,606,269 shares of common stock in the form of pre-funded warrants at a price of $3.0709. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 3,256,269 shares of common stock and Series B warrants to purchase up to 3,256,269 shares of common stock. The Series A and B warrants (the “Checkpoint May 2023 Common Stock Warrants”) are exercisable immediately upon issuance with an exercise price of $2.821 per share and the Series A warrants will expire five years following the issuance date and the Series B warrants will expire eighteen months following the issuance. The total gross proceeds from the offering were approximately $10.0 million with net proceeds of approximately $9.1 million after deducting approximately $0.9 million in commissions and other transaction costs. The shares of common stock, pre-funded warrants and Checkpoint May 2023 Common Stock Warrants were registered for sale under the Checkpoint 2023 Form S-3. The Checkpoint May 2023 Common Stock Warrants met the criteria for equity classification. As of September 30, 2023, all of the pre-funded warrants from the Checkpoint May 2023 Registered Direct Offering were fully exercised.

In April 2023, Checkpoint closed on a registered direct offering for the issuance and sale of an aggregate of 1,700,000 shares of Checkpoint common stock at a purchase price of $3.60 per share of Checkpoint common stock and accompanying warrants in a registered direct offering priced at-the-market under Nasdaq rules. In a concurrent private placement, Checkpoint issued and sold Series A warrants to purchase up to 1,700,000 shares of Checkpoint common stock and Series B warrants to purchase up to 1,700,000 shares of Checkpoint common stock. The Series A and B warrants (collectively the “Checkpoint April 2023 Common Stock Warrants”) are exercisable immediately upon issuance with an exercise price of $3.35 per share. The Series A warrants will expire five years following the issuance date and the Series B warrants will expire eighteen months following the issuance date. The total gross proceeds from the offering were approximately $6.1 million with net proceeds of approximately $5.5 million after deducting approximately $0.6 million in commissions and other transaction costs. The 1,700,000 shares of common stock were registered for sale under the November 2020 Form S-3. The Company filed a separate registration statement on Form S-3 to register the Checkpoint April 2023 Common Stock Warrants, which was declared effective May 5, 2023. The Checkpoint April 2023 Common Stock Warrants met the criteria for equity classification.

In February 2023, Checkpoint closed on a registered direct offering (the “Checkpoint February 2023 Direct Offering”) with a single institutional investor for the issuance and sale of 1,180,000 shares of its common stock and 248,572 pre-funded warrants which were subsequently fully exercised in February 2023. Each pre-funded warrant is exercisable for one share of common stock. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 1,428,572 shares of common stock and Series B warrants to purchase up to 1,428,572 shares of common stock (the Series A warrants and Series B warrants collectively the “Checkpoint February 2023 Common Stock Warrants”), at a purchase price of $5.25 per share of common stock and associated common stock warrants, and $5.2499 per pre-funded warrant and associated common stock warrants. Net proceeds from the Checkpoint February 2023 Direct Offering were $6.7 million after deducting commissions and other transaction costs. The February 2023 Checkpoint Common Stock Warrants met the criteria for equity classification. In March 2023, Checkpoint filed a registration statement on Form S-3 to register the warrants, which was declared effective on May 5, 2023.

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Pursuant to the Company’s Founders Agreement with Checkpoint, Checkpoint issued to Fortress 2.5% of the aggregate number of shares of common stock issued in the registered direct offerings noted above. Accordingly, Checkpoint issued 240,526 shares of common stock to Fortress at a weighted average price of $3.36 per share for the nine months ended September 30, 2023.

Avenue

Avenue January 2023 Registered Direct and Private Placement

In January 2023, Avenue entered into a Securities Purchase Agreement (the “Avenue Registered Purchase Agreement”) with a single institutional accredited investor, pursuant to which Avenue agreed to issue and sell (i) 448,000 shares (the “Avenue Shares”) of Avenue’s common stock at a price per share of $1.55, and (ii) pre-funded warrants (the “Avenue Pre-funded Warrants”) to purchase 1,492,299 shares of common stock, at a price per Avenue Pre-funded Warrant equal to the price per share, less $0.001 (the “Avenue Registered Offering”). The Avenue Pre-funded Warrants have an exercise price of $0.001 per share, became exercisable upon issuance and remain exercisable until exercised in full. Avenue received approximately $3.0 million in gross proceeds from the Avenue Registered Offering, before deducting placement agency fees and estimated offering expenses.

Also in January 2023 Avenue entered into a Securities Purchase Agreement (the “Avenue PIPE Purchase Agreement”) with the same institutional accredited investor for a private placement offering (“Avenue Private Placement”) of the January 2023 Warrants to purchase 1,940,299 shares of Avenue common stock. Pursuant to the Avenue PIPE Purchase Agreement, Avenue agreed to issue and sell the January 2023 Warrants at an offering price of $0.125 per January 2023 Warrant to purchase one share of Avenue common stock. The January 2023 Warrants have an exercise price of $1.55 per share (subject to adjustment as set forth in the January 2023 Warrants), are exercisable immediately after issuance and will expire three years from the date on which the January 2023 Warrants become exercisable. The January 2023 Warrants contain standard anti-dilution adjustments to the exercise price including for share splits, share dividend, rights offerings and pro rata distributions. The Avenue Private Placement closed on January 31, 2023, concurrently with the Avenue Registered Offering. The gross proceeds to Avenue from the Avenue Private Placement, before deducting placement agent fees and other estimated offering expenses payable by Avenue, were approximately $0.2 million.

Avenue September 2023 Private Placement

In connection with the Avenue September 2023 Private Placement (see Note 15, Related Party Transactions), Avenue entered into a registration rights letter agreement (the “Avenue Registration Rights Letter Agreement”) with the Avenue Private Placement Investors. Pursuant to the Avenue Registration Rights Letter Agreement, Avenue will be required to file, on or prior to September 8, 2024 (the “Avenue Private Placement Filing Date”), a resale registration statement (the “Avenue Private Placement Resale Registration Statement”) with the SEC to register the resale of the Avenue September 2023 Private Placement Shares.

Journey 2022 Shelf Registration Statement and At-the-Market Offering

On December 30, 2022, Journey filed a shelf registration statement (File No. 333-269079) on Form S-3 (the “Journey 2022 S-3”), which was declared effective on January 26, 2023. Through the Journey 2022 S-3, Journey may sell up to a total of $150 million of its securities. As of September 30, 2023, there have been no sales of securities under the Journey 2022 S-3. In connection with the Journey 2022 S-3, Journey entered into an At Market Issuance Sales Agreement governing potential sales of up to 4,900,000 shares of Journey's Common Stock.

14. Commitments and Contingencies

During three and nine months ended September 30, 2023 and 2022, the Company recorded the following as lease expense to current period operations:

($ in thousands)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Operating lease cost	$ 687	$ 940	$ 2,656	$ 2,589
Shared lease costs	(526)	(542)	(1,560)	(1,592)
Variable lease cost	220	198	620	459
Total lease expense	$ 381	$ 596	$ 1,716	$ 1,456

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

($ in thousands)	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Operating cash flows from operating leases	$ (2,652)	$ (2,615)
Right-of-use assets exchanged for new operating lease liabilities	$ (923)	$ 2,176
Weighted-average remaining lease term – operating leases (years)	4.2	4.9
Weighted-average discount rate – operating leases	6.28 %	6.5 %

($ in thousands)	Future Lease Liability
Three months ended December 31, 2023	$ 900
Year Ended December 31, 2024	3,796
Year Ended December 31, 2025	3,799
Year Ended December 31, 2026	3,535
Year Ended December 31, 2027	3,191
Other	11,669
Total operating lease liabilities	26,890
Less: present value discount	(5,533)
Net operating lease liabilities, short-term and long-term	$ 21,357

Indemnification

In accordance with its certificate of incorporation, bylaws and indemnification agreements, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date, and the Company has director and officer insurance to address such claims. The Company and its subsidiaries and partner companies also provide indemnification of contractual counterparties (sometimes without monetary caps) to clinical sites, service providers and licensors.

University of Tennessee Research Foundation v. Caelum Biosciences, Inc.

Caelum Biosciences, Inc. ("Caelum"), a former subsidiary of Fortress that was sold to AstraZeneca's Alexion ("Alexion") in October 2021, is the defendant in a lawsuit brought by The University of Tennessee Research Foundation ("UTRF") captioned as *University of Tennessee Research Foundation v. Caelum Biosciences, Inc.*, No. 19-cv-00508, which is pending in the United States District Court for the Eastern District of Tennessee (the "UTRF Litigation"). UTRF brought claims against Caelum, for, *inter alia*, tortious interference and trade secret misappropriation. UTRF primarily alleges that Caelum unauthorizedly used non-patent trade secrets owned by UTRF in the development of Caelum's 11-1F4 monoclonal antibody, known as CAEL-101. Under the agreement pursuant to which Alexion acquired Caelum (as amended, the "DOSPA"), Fortress has indemnification obligations of Caelum under certain circumstances, including for certain of Caelum's legal expenses and potential damages arising out of the UTRF Litigation (with such indemnification capped in the aggregate as to Fortress at the amount of Caelum acquisition proceeds received by Fortress and which, at Caelum's election, may be satisfiable in the form of offsets against future amounts that Caelum may owe Fortress under the DOSPA). Caelum is defending the UTRF Litigation, with Fortress participating in such defense and maintaining a consent right over any potential settlements. Caelum's legal fees and costs in defending the UTRF Litigation are being reimbursed by Fortress by distribution from a $15 million escrow account established concurrently with the acquisition of Caelum; Fortress considers the amount remaining in escrow to be in excess of the amount of its anticipated out-of-pocket indemnifiable costs and damages in the UTRF Litigation and therefore has not accrued any liability pertaining to this indemnity. Caelum and Fortress both believe the UTRF Litigation is without merit and intend to continue defending it vigorously (including exhausting all appeals if applicable). Caelum's motion for summary judgment is currently pending, and a trial is scheduled for March 2024 with respect to any of UTRF's claims that may survive summary judgment.

15. 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 11.5% of the Company's issued and outstanding Common Stock as of September 30, 2023. The Company's Executive Vice Chairman, Strategic Development owns approximately 11.0% of the Company's issued and outstanding Common Stock as of September 30, 2023.

Avenue September 2023 Private Placement

In September 2023, Avenue entered into an unwritten agreement with Fortress and the Company's Chairman, President and Chief Executive Officer, a director on the board of directors of Avenue (the "Private Placement Investors"), pursuant to which Avenue agreed to issue and sell 767,085 shares (the "Avenue September 2023 Private Placement Shares") of Avenue common stock, par value $0.0001 per share, for an aggregate purchase price of approximately $550,000 in a private placement transaction (the "Avenue September 2023 Private Placement") exempt from the registration requirements of the Securities Act, and the rules and regulations of the SEC thereunder. The Avenue common shares were purchased by the Private Placement Investors at a price per Avenue September 2023 Private Placement Share of $0.717, which was the "consolidated closing bid price" of the Avenue common stock on the Nasdaq Capital Market as of September 7, 2023, in compliance with Nasdaq Listing Rule 5365(c). The gross proceeds to Avenue from the Avenue September 2023 Private Placement were approximately $550,000. Avenue did not incur any underwriting or placement agent fees associated with the Avenue September 2023 Private Placement. Avenue intends to use the net proceeds from the Avenue September 2023 Private Placement for working capital and other general corporate purposes.

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, 2023 and 2022 the Company invoiced TGTX $0.1 million and $0.1 million, respectively; for the nine months ended September 30, 2023 and 2022, the Company invoiced TGTX $0.3 million and $0.7 million, respectively. At September 30, 2023, $0.1 million is due from TGTX related to this arrangement.

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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. In addition, Journey reimburses the Company for various payroll-related costs and selling, general and administrative costs incurred by Fortress for the benefit of Journey. For the three months ended September 30, 2023 and 2022, the Company's employees have provided services to Journey totaling approximately $11,000 and $7,000, respectively; for the nine months ended September 30, 2023 and 2022, the Company's employees have provided services to Journey totaling approximately $47,000 and $0.1 million, respectively. At September 30, 2023, approximately $11,000 is due from Journey related to this arrangement.

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, the latter until December 31, 2022 only, based on actual percentage of the office space occupied on a month-by-month basis. For the three months ended September 30, 2023 and 2022, the Company had paid $0.6 million and $0.9 million in rent, respectively, and in connection with the Company's Desk Share Agreement with TGTX, has invoiced TGTX approximately $0.5 million and $0.5 million, respectively, for their prorated share of the rent base. For the nine months ended September 30, 2023 and 2022, the Company had paid $1.5 million and $1.4 million in rent, respectively, and in connection with the Company's Desk Share Agreement with TGTX, has invoiced TGTX approximately $1.4 million and $1.4 million, respectively, for their prorated share of the rent base. At September 30, 2023, there was no balance due from TGTX related to this arrangement.

Checkpoint Collaborative Agreements with TGTX

Checkpoint has entered into various agreements with TGTX to develop and commercialize certain assets in connection with its licenses, including a collaboration agreement for some of the Dana Farber licensed antibodies, and a sublicense agreement for the Jubilant family of patents. Checkpoint believes that by partnering with TGTX to develop these compounds in therapeutic areas outside of its business focus, it may substantially offset its preclinical costs and milestone costs related to the development and marketing of these compounds in solid tumor indications. Effective September 30, 2023, Checkpoint and TGTX agreed to mutually terminate both the collaboration agreement and the sublicense agreement.

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 3, Asset Purchase Agreements).

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

Cyprium 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock Dividend Obligation

Pursuant to a private placement in August 2020, Cyprium sold shares of its 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock ("Cyprium PPS"); as of September 30, 2023, there are 316,600 shares of Cyprium PPS outstanding.

Pursuant to the terms of the Cyprium PPS, shareholders on the record date are entitled to receive a monthly cash dividend of $0.19531 per share which yields an annual dividend of $2.34375 per share. The Cyprium PPS will automatically be redeemed upon the first (and only the first) bona fide, arm's-length sale of a Priority Review Voucher (a "PRV Sale") issued by the FDA in connection with the approval of CUTX-101, Cyprium's copper histidinate product candidate. Upon the PRV Sale, each share of Cyprium PPS will be automatically redeemed in exchange for a payment equal to twice (2x) the $25.00 liquidation preference, *plus* accumulated and unpaid dividends to, but excluding, the redemption date.

An optional exchange to Fortress Series A Preferred Stock is available after 24 months from the issuance date so long as a sale of the PRV has not occurred. Additionally, if a PRV Sale has not occurred by September 30, 2024 the Cyprium PPS is either automatically exchanged for Fortress Series A Preferred Stock or cash at the discretion of Fortress. The Cyprium PPS is fully and unconditionally guaranteed by Fortress.

Founders Agreement

The Company has entered into Founders Agreements and, in some cases, exchange agreements with certain of its subsidiaries as described in the 2022 Form 10-K. The following table summarizes, by partner company/subsidiary, 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/Subsidiary	**Effective Date [1]**	**PIK Dividend as a % of fully diluted outstanding capitalization**	**Class of Stock Issued**
Avenue	February 17, 2015	2.5 %[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	- %[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, InvaGen'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 3, Asset Purchase Agreements, to the Unaudited Condensed Consolidated Financial Statements).

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

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.
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/subsidiary first acquires, whether by license or otherwise, ownership rights in a product.

Management Services Agreements

The Company has entered into Management Services Agreements (the "MSAs") with certain of its partner companies/subsidiaries as described in the 2022 Form 10-K. The following table summarizes the effective date of each MSA and the annual consulting fee payable by the partner company/subsidiary to the Company in quarterly installments:

Partner Company/Subsidiary	Effective Date	Annual MSA Fee (Income)/Expense
Avenue[1]	February 17, 2015	500
Baergic[2]	March 9, 2017	—
Cellvation	October 31, 2016	500
Checkpoint	March 17, 2015	500
Cyprium	March 13, 2017	500
Helocyte	March 20, 2015	500
Mustang	March 13, 2015	500
Oncogenuity	February 10, 2017	500
Urica	November 7, 2017	500
Fortress		(4,000)
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. 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.

Fees and Stock Grants Received by Fortress

Fees recorded in connection with Fortress' agreements with its subsidiaries and partner companies are eliminated in consolidation. These include management services fees, issuance of common shares of partner companies in connection with third party raises and annual stock dividend or issuances on the anniversary date of respective Founders Agreements.

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

16. 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, 2023	Dermatology Products Sales[1]	Pharmaceutical and Biotechnology Product Development	Consolidated
Net revenue	$ 34,539	$ 213	$ 34,752
Cost of goods - product revenue	(6,429)	—	(6,429)
Research and development	(2,229)	(18,119)	(20,348)
Selling, general and administrative	(8,636)	(13,097)	(21,733)
Other expense	(361)	3,536	3,175
Income tax expense	(95)	(46)	(141)
Segment income (loss)	$ 16,789	(27,513)	$ (10,724)

Nine Months Ended September 30, 2023	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net revenue	$ 63,924	$ 643	$ 64,567
Cost of goods - product revenue	(20,645)	—	(20,645)
Research and development	(6,036)	(85,959)	(91,995)
Selling, general and administrative	(34,069)	(37,443)	(71,512)
Asset impairment	(3,143)	—	(3,143)
Other income	(1,646)	(654)	(2,300)
Income tax expense	(95)	(47)	(142)
Segment loss	$ (1,710)	$ (123,460)	$ (125,170)

($ in thousands) Three Months Ended September 30, 2022	Dermatology Products Sales	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)

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 expense	(1,413)	(6,125)	(7,538)
Segment loss	$ (18,971)	$ (137,497)	$ (156,468)

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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The following tables summarize, for the periods indicated, total assets by reportable segment:

($ in thousands) September 30, 2023	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Total Assets
Intangible assets, net	$ 21,102	$ —	$ 21,102
Tangible assets	44,816	84,631	129,447
Total segment assets	$ 65,918	$ 84,631	$ 150,549

($ in thousands) December 31, 2022	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Total Assets
Intangible assets, net	$ 27,197	$ —	$ 27,197
Tangible assets	77,963	189,141	267,104
Total segment assets	$ 105,160	$ 189,141	$ 294,301

17. Revenues from Contracts and Significant Customers

Disaggregation of Total Revenue

Journey has the following actively marketed products, Qbrexza, Accutane, Targadox, Ximino (until September 2023), Exelderm, 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, Asset Purchase Agreements). The Company's related party revenue is from Checkpoint's collaborations with TGTX (see Note 15, Related Party Transactions). Other revenue consists of Journey's royalty revenue related to Qbrexza, and for the three and nine-month period ended September 30, 2023, includes a $19 million non-refundable upfront payment from Maruho related to a license granted by Journey to Maruho for the development and commercialization of Qbrexza in additional territories in Asia. Other revenue for the nine-month period ended September 30, 2022 includes a net $2.5 million milestone payment.

The table below summarizes the Company's revenue for the three and nine months ending September 30, 2023 and 2022:

	Three months ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue				
Qbrexza	$ 5,865	$ 6,265	$ 18,038	$ 19,752
Accutane	4,882	4,121	15,109	14,228
Amzeeq	2,336	1,161	4,904	5,892
Zilxi	681	554	1,567	1,851
Targadox	929	1,168	2,386	6,558
Exelderm	764	1,001	1,813	3,018
Ximino	(199)	1,773	567	3,775
Luxamend	21	—	21	—
Collaboration revenue	182	364	546	1,518
Revenue – related party	31	48	97	118
Other revenue	19,260	73	19,519	2,629
Net revenue	$ 34,752	$ 16,528	$ 64,567	$ 59,339

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

Significant Customers

For the three and nine-month periods ending September 30, 2023, none of Journey's dermatology products customers accounted for more than 10% of its total gross product revenue.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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At September 30, 2023, two of Journey's dermatology products customers accounted for more than 10% of its total accounts receivable balance at 25% and 15%. At December 31, 2022, two of the Company's dermatology products customers accounted for more than 10% of its total accounts receivable balance at 16.7% and 10.4%.

18. 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, 2023 and 2022 is based on the estimated annual effective tax rate, and includes interest related to unrecognized tax benefits. The Company expects a net deferred tax asset with a full valuation allowance and 0% estimated annual effective tax rate for 2023. Income tax expense recognized for the three and nine months ended September 30, 2023 was $0.1 million. No income tax expense was recognized in 2022.

19. Subsequent Events

Mustang

In October 2023, Mustang closed on the October 2023 Registered Direct Offering for the issuance and sale of an aggregate of (i) 920,000 shares of its common stock and (ii) pre-funded warrants to purchase up to 1,688,236 shares of its common stock at a purchase price of $1.70 per share and $1.699 per pre-funded warrant in a registered direct offering priced at-the-market under the rules of The Nasdaq Stock Market LLC. In a concurrent private placement, Mustang issued and sold 2,588,236 unregistered warrants to purchase shares of common stock. The unregistered warrants have an exercise price of $1.58, were exercisable immediately upon issuance and will expire five and one-half years following the issuance date. The total gross proceeds from the offering were approximately $4.4 million with net proceeds of approximately $3.9 million after deducting approximately $0.5 million in commissions and other transaction costs.

Avenue

In November 2023, Avenue closed on a public offering of the issuance and sale of an aggregate of 16,633,400 units at a purchase price of $0.3006 per unit. Each unit consists of (i) one share of common stock (or pre-funded warrant in lieu of), and (ii) one Series A warrant to purchase one share of common stock, exercisable immediately upon issuance at a price of $0.3006 per share and expiring five years following the issuance date, and (iii) one Series B warrant to purchase one share of common stock, exercisable immediately upon issuance at a price of $0.3006 per share and expiring eighteen months following the issuance date. The total gross proceeds from the offering were approximately $5.0 million with net proceeds of approximately $3.9 million after deducting approximately $1.1 million in commissions and other transaction costs. In connection with the closing of the November 2023 public offering, Avenue owes a fee of $0.3 million to InvaGen.

Checkpoint

In October 2023, Checkpoint entered into an inducement offer letter agreement with a holder of certain of its existing warrants to exercise for cash an aggregate of 6,325,354 shares of Checkpoint's common stock at a reduced exercise price of $1.76 per share. The warrants were issued to the holder on December 16, 2022 with an exercise price of $4.075 per share and on February 22, 2023 with an exercise price of $5.00 per share as part of registered direct offerings. The shares of Checkpoint common stock issuable upon exercise of the warrants were registered pursuant to effective registration statements on Form S-3 (File No. 333-251005) and Form S-3 (File No. 333-

270474), respectively. As part of the inducement, Checkpoint agreed to issue new unregistered Series A Warrants to purchase up to 6,325,354 shares of Checkpoint Common Stock and new unregistered Series B Warrants to purchase up to 6,325,354 shares of Checkpoint Common Stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $1.51 per share. The Series A warrants will expire five years following the issuance date and the Series B warrants will expire twenty-four months following the issuance date. The total gross proceeds from the offering were approximately $11.1 million with net proceeds of approximately $10.0 million after deducting approximately $1.1 million in commissions and other transaction costs.

Fortress

In November 2023, Fortress closed on a public offering of the issuance and sale of an aggregate of 5,885,000 units at a purchase price of $1.70 per unit. Each unit consists of (i) one share of common stock, and (ii) one warrant to purchase one share of common stock, exercisable immediately upon issuance at a price of $1.70 per share and expiring five years following the issuance date. The total gross proceeds from the offering were approximately $10.0 million with net proceeds of approximately $8.9 million after deducting placement agent fees and other transaction costs. Certain directors and officers of the Company participated in the offering and purchased an aggregate amount of approximately $2.9 million of units at the same purchase price.

On October 9, 2023 Fortress filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation, as amended, to effect the 1-for-15 Reverse Stock Split. The Reverse Stock Split was approved on August 10, 2023 by the Company's Board of Directors and by the Company's stockholders at a special meeting held on October 9, 2023, with the authorization to determine the final ratio (within a specified range) having been granted to the Company's Board of Directors. As a result of the Reverse Stock Split, every 15 shares of the Company's pre-reverse split Common Stock was combined and reclassified as one share of Common Stock. The proportionate voting rights and other rights of common stockholders were not affected by the Reverse Stock Split, other than as the result of payment for fractional shares. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise have held a fractional share of Common Stock received a cash payment in lieu thereof.

As a result of the foregoing transactions and as of the date of this filing, the Company believes it has stockholders' equity of at least $2.5 million and therefore satisfies the minimum Nasdaq listing requirement set forth in Nasdaq Listing Rule 5550(b)(1).

Cyprium

On February 24, 2021, Cyprium entered into a development and asset purchase agreement (the "Sentynl APA") with Sentynl Therapeutics, Inc. ("Sentynl"), a U.S.-based specialty pharmaceutical company owned by the Zydus Group. Under the Sentynl APA, Sentynl provided certain development funding for Cyprium's CUTX-101 program, with Cyprium remaining in control of development of such program; upon approval of the New Drug Application ("NDA") for CUTX-101 by the U.S. Food and Drug Administration ("FDA"), Cyprium is obligated to assign the NDA and certain other assets pertaining to the CUTX-101 program to Sentynl, after which point Sentynl will commercialize the drug and owe Cyprium royalties and regulatory and sales milestones.

The Sentynl APA contains an alternative "Approval Deadline Transfer" mechanism pursuant to which, in the event that CUTX-101 NDA approval has not been obtained by September 30, 2023, then Sentynl may elect, during the subsequent 45-day period, to assume control over development of CUTX-101 by effecting a Closing under the Sentynl APA. Following such Closing, Sentynl will be obligated to use commercially reasonable efforts to develop and commercialize CUTX-101, including the funding of the same. Additionally, following such Closing, Cyprium remains eligible to receive up to $133.5 million in aggregate development and sales milestones under the Agreement and royalties on net sales of CUTX-101 as follows: (i) 3% of annual net sales up to $75 million; (ii) 8.75% of annual net sales between $75 million and $100 million; and (iii) 12.5% of annual net sales in excess of $100 million.

Cyprium has received notice of Sentynl's election to effect the Approval Deadline Transfer, with Closing of such transfer anticipated to occur in November 2023. The Approval Deadline Transfer obligates Sentynl to pay Cyprium $4.5 million in connection with the Closing. Cyprium expects the Approval Deadline Transfer will result in a reduction in its development-related spending on the CUTX-101 program. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.

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. 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, to one or more subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context. . Actual results could differ materially, from those projected in, or implied by the forward-looking statements due to a variety of factors, including, in particular, risks relating to:

- our growth strategy;
- financing and strategic agreements and relationships;
- our need for substantial additional funds and uncertainties relating to financings;
- our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis;
- our ability to attract, integrate and retain key personnel;
- the early stage of products under development;
- the results of research and development activities;
- uncertainties relating to preclinical and clinical testing;
- the ability to secure and maintain third-party manufacturing, marketing and distribution of our and our partner companies' products and product candidates;
- government regulation;
- patent and intellectual property matters; and
- competition.

Overview

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 we do through Fortress itself and through partner companies and subsidiaries. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who work in concert with our extensive network of key opinion leaders to identify and evaluate promising products and product candidates for potential acquisition. We have executed 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 Center, St. Jude Children's Research Hospital ("St. Jude"), 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 ("Mayo Clinic"), 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 three subsidiaries have consummated strategic partnerships with industry leaders, including AstraZeneca plc as successor-in-interest to Alexion Pharmaceuticals, Inc. ("AstraZeneca") and Sentynl Therapeutics, Inc. ("Sentynl").

Our subsidiaries and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates are: Avenue Therapeutics, Inc. (Nasdaq: ATXI, "Avenue"), Baergic Bio, Inc. ("Baergic," a subsidiary of Avenue), 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").

Recent Events

Revenue

- During the three months ended September 30, 2023 and 2022, total net revenue was $34.8 million and $16.5 million, respectively, which include net product revenue from Journey's commercial portfolio of eight branded and three generic prescription dermatology of $15.3 million and $16.0 million, respectively.
- During the nine months ended September 30, 2023 and 2022, total net revenue was $64.6 million and $59.3 million, respectively, which include net product revenue from Journey's commercial portfolio of eight branded and three generic prescription dermatology products of $44.4 million and $55.1 million, respectively.
- On August 31, 2023, Journey Medical entered into an exclusive license agreement with Maruho Co., Ltd. ("Maruho"), a Japanese company specializing in dermatology and also Journey's exclusive licensing partner that developed and is commercializing Qbrexza (Rapifort®) in Japan. Under the terms of the Agreement, Journey Medical received a $19 million nonrefundable upfront payment and granted Maruho an exclusive license to develop and commercialize Qbrexza® (Rapifort® / DRM04 / glycopyrronium tosylate hydrate) for the treatment of hyperhidrosis, in South Korea, Taiwan, Hong Kong, Macau, Thailand, Indonesia, Malaysia, Philippines, Singapore, Vietnam, Brunei, Cambodia, Myanmar and Laos (the "Territory"). Maruho is responsible for all development and commercialization costs for the program throughout the Territory.

Late Stage Product Candidates

Cosibelimab (anti-PD-L1 antibody)

- In July 2023, Checkpoint announced new, longer-term data for cosibelimab from its pivotal studies in locally advanced and metastatic cutaneous squamous cell carcinoma ("cSCC"). These results demonstrate a deepening of response over time, resulting in substantially higher complete response rates than previously reported (55% objective response rate; 23% complete response rate in locally advanced cSCC and 50% objective response rate; 13% complete response rate in metastatic cSCC). Furthermore, responses continue to remain durable over time.
- In June 2023, Checkpoint announced that new pharmacokinetic modeling data on cosibelimab supporting the extension to an every-three-week dosing regimen were presented today at the Population Approach Group Europe ("PAGE") 2023 annual meeting. Results support comparability of cosibelimab 800 mg every-two-week and 1200 mg every-three-week dosing regimens.
- Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024 for cosibelimab's Biologics License Application ("BLA").
- Cosibelimab was sourced by Fortress and is currently in development at Checkpoint.

CUTX-101 (copper histidinate for Menkes disease)

- Our subsidiary, Cyprium has completed two pivotal studies in patients with Menkes disease treated with CUTX-101, copper histidinate (CuHis). In a pre-specified analysis of the studies, a 79% reduction in the risk of death was observed in patients treated within four weeks of birth, compared with a historical control cohort of untreated patients, and median overall survival (OS) was 177.1 months for CUTX-101 compared to 16.1 months for historical control, with a hazard ratio (HR) of (95% CI) = 0.208 (0.094, 0.463) p<0.0001. A 75% reduction in the risk of death was also observed in patients treated after four weeks of birth compared with untreated historical control subjects and median OS was 62.4 and 17.6 months, respectively; HR (95% CI) = 0.253 (0.119, 0.537); p<0.0001.

- In 2021, Cyprium signed a Development and Asset Purchase Agreement with Sentynl Therapeutics, Inc. (“Sentynl”), a wholly owned subsidiary of Zydus Lifesciences Ltd., for CUTX-101 to treat Menkes disease. In October 2023, Cyprium received notice of Sentynl’s election to assume control over the development of CUTX-101, with closing of such transfer anticipated to occur in November 2023. The Approval Deadline Transfer obligates Sentynl to pay Cyprium $4.5 million in connection with the Closing. Sentynl will be obligated under the agreement to use commercially reasonable efforts to develop and commercialize CUTX-101, including the funding of the same. Additionally, Cyprium remains eligible to receive up to $133.5 million in aggregate development and sales milestones under the Agreement and royalties on net sales of CUTX-101 as follows: (i) 3% of annual net sales up to $75 million; (ii) 8.75% of annual net sales between $75 million and $100 million; and (iii) 12.5% of annual net sales in excess of $100 million. Cyprium expects the transfer of the NDA will result in a reduction in its development-related spending on the CUTX-101 program. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.
- The CUTX-101 rolling NDA submission is ongoing and expected to be completed by Sentynl pursuant to the transfer of the development of CUTX-101.
- Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval of CUTX-101.
- CUTX-101 was sourced by Fortress and is currently in development at Cyprium.

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

- In July 2023, Journey announced positive topline data from the two DFD-29 Phase 3 clinical trials for the treatment of rosacea and achieved co-primary and all secondary endpoints with subjects completing the 16-week treatment with no significant safety issues. DFD-29 demonstrated statistical superiority compared to Oracea® and placebo for Investigator’s Global Assessment (IGA) treatment success and the reduction in total inflammatory lesion count in both studies.
- In June 2023, Journey announced positive topline data from the Phase 1 clinical trial assessing the impact of DFD-29 on the microbial flora of healthy adults and also evaluated the safety and tolerability of DFD-29. The study achieved all primary objectives and no significant safety issues were noted during the study. The results indicate that DFD-29 can be safely used for up to 16 weeks with no significant risk of microbiota suppression or development of resistance.
- Journey expects to submit an NDA for DFD-29 to the FDA in the second half of 2023.
- DFD-29 is being developed for the treatment of rosacea in collaboration with Dr. Reddy’s Laboratories Ltd.

CAEL-101 (Light Chain Fibril-reactive Monoclonal Antibody for AL Amyloidosis)

- On October 5, 2021, AstraZeneca acquired Caelum Biosciences, Inc. (“Caelum”), a former subsidiary of Fortress 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.
- There are two ongoing Phase 3 studies of CAEL-101 for AL amyloidosis. (ClinicalTrials.gov identifiers: NCT04512235 and NCT04504825).
- Based on its public statements, AstraZeneca has estimated that it expects the FDA to accept its BLA submission for review in the second half of 2024.
- CAEL-101 (anselamimab) was sourced by Fortress and was developed by Caelum (founded by Fortress) until its acquisition by AstraZeneca in October 2021.

IV Tramadol

- In July 2023, Avenue reached an agreement with the FDA on key elements of the Phase 3 safety study, including the primary endpoint and statistical analysis approach, for intravenous (“IV”) tramadol, which is in development for the treatment of acute post-operative pain in a medically supervised setting. The agreed upon non-inferiority study is designed to assess the theoretical risk of opioid-induced respiratory depression related to opioid stacking on IV tramadol compared to IV morphine.
- IV tramadol was sourced by Fortress and is currently in development at Avenue.

Triplex (cytomegalovirus ("CMV") vaccine)

- In October 2023, we announced an exclusive option agreement with City of Hope ("COH") for patent rights to use Triplex, a cytomegalovirus vaccine, in combination with cytomegalovirus ("CMV")-specific, Anti-Human Immunodeficiency Virus ("HIV") Chimeric Antigen Receptor ("CAR") (collectively, CMV/HIV-CAR) T Cells for the treatment of adults living with HIV. Additionally, the California Institute for Regenerative Medicine ("CIRM") recently awarded a $11.3 million grant to COH to fund a Phase 1 clinical trial involving the CMV/HIV-CAR T cells. In preclinical studies, administration of the dual-action CAR T cells followed by administration of a CMV vaccine successfully eradicated HIV, including from latent reservoirs.
- In June 2023, we announced that the National Cancer Institute awarded a $3.2 million grant to City of Hope for clinical studies of Triplex, a CMV vaccine being developed by Helocyte and City of Hope. This award will fund two planned multicenter, placebo-controlled, randomized Phase 2 studies to evaluate the potential safety and immunological response of Triplex and its ability to enhance CMV-specific T cell immunity in stem cell donors to reduce the risk of CMV events in recipients of allogeneic hematopoietic cell transplant.
- The Phase 2 clinical trial of Triplex for adults co-infected with HIV and CMV is now fully enrolled with topline data anticipated in 2024. The study aims to show that vaccination with Triplex can potentially reduce the in intensity of highly active antiretroviral therapy ("HAART") which is used in up to 1.7 million treated HIV patients.
- Triplex is also the subject of a grant from the National Institute of Allergy and Infectious Diseases that could provide over $20 million in non-dilutive funding for a 420-patient multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation. The trial is expected to begin enrollment this year and we believe this data set could ultimately be used to support approval of Triplex in this setting.
- Triplex is also currently the subject of three additional ongoing clinical trials including: pediatric patients undergoing stem cell transplant; adults co-infected with CMV and HIV; and in combination with a CAR T cell therapy for adults with non-Hodgkin lymphoma.
- Triplex was sourced by Fortress and is currently in development at Helocyte.

Early Stage Product Candidates

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

- In August 2023, Mustang announced initial data from its ongoing multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 CAR T cell therapy. Initial data show clinical responses from four of four indolent lymphoma patients, including two complete responses in FL patients, one of which was previously treated with CD19 CAR-T cell therapy.
- In June 2023, updated results were presented from the Waldenstrom macroglobulinemia ("WM") cohort from the single center clinical study at Fred Hutch and showed 83% (5/6) of WM patients treated with MB-106 responded to treatment, including two complete responses ("CR"), 1 very good partial response ("VGPR"), 1 partial response ("PR"), and 1 minor response, with the remaining patient experiencing stable disease. No grade 3 or 4 cytokine release syndrome ("CRS") or grade 2, 3, or 4 immune effector cell-associated neurotoxicity syndrome ("ICANS") has been observed.
- Also in June 2023, final data were presented on the follicular lymphoma ("FL") cohort from the single center clinical study at Fred Hutch and showed a 95% overall response rate ("ORR") and 80% CR rate across all patients, and 100% ORR and 91% CR at the two highest dose levels, including one patient previously treated with CD19-targeted CAR T cell therapy. No grade 3 or higher CRS was observed, and no ICANS of any grade was observed.
- The FDA granted Orphan Drug Designation to MB-106 for the treatment of WM, and results from the indolent lymphoma arm of the ongoing Mustang-sponsored multicenter trial are expected to support an accelerated Phase 2 registration strategy for WM, with the first pivotal Phase 2 WM patient to be treated potentially in mid-2024.
- MB-106 was sourced by Fortress and is currently in development at Mustang.

Dotinurad (urate transporter (URAT1) inhibitor for gout)

- In the third quarter of 2023, we initiated a Phase 1b clinical trial in patients with gout and hypericemia in the U.S. to confirm the comparability of U.S. patients' response to dotinurad with data generated in Japan, and to assess drug-drug interactions, if any, with allopurinol.
- Data announced in June 2023 from the Phase 1 clinical trial in healthy volunteers showed comparable pharmacokinetic, pharmacodynamic and safety profile between U.S. and Japanese healthy subjects.
- 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 Urica.

MB-109 (IL13Rα2-targeted CAR T Cells + HSV-1 oncolytic virus)

- In October 2023, Mustang announced that the FDA has accepted its IND application to initiate a Phase 1 open label, multicenter clinical trial to assess the safety, tolerability and efficacy of MB-109, a novel combination of MB-101 (IL13Rα2-targeted CAR-T cell therapy) and MB-108 (herpes simplex virus 1 oncolytic virus), for the treatment of IL13Rα2+ recurrent glioblastoma (“rGBM”) and high-grade astrocytoma.
- As previously reported, preclinical data presented at the American Association for Cancer Research Annual Meeting 2022 supported this combination therapy to optimize results to treat rGBM. The combination leverages MB-108 to make cold tumors “hot,” thereby potentially improving the efficacy of MB-101 CAR-T cell therapy. Data presented separately on MB-101 and MB-108 showed infusions were well tolerated in highly refractory GBM patients. Two patients treated solely with MB-101 who had high levels of intratumoral CD3+ T cells pre-therapy (i.e., “hot” tumors) achieved complete responses lasting 7.5 and 31+ months, respectively.
- 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

- 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 1/2 clinical trial taking place in Europe.
- Leiden University Medical Center is continuing to treat patients and expects to expand the trial to other centers in 2023.
- 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.

AJ201 (Nrf1 and Nrf2 activator, androgen receptor degradation enhancer)

- In July 2023, we announced that our partner company Avenue dosed the first patient in a Phase 1b/2a study, which is evaluating AJ201 in the U.S. for the treatment of spinal and bulbar muscular atrophy, also known as Kennedy's Disease.
- In September 2023, we announced the eighth patient was dosed in the trial. Topline data for the Phase 1b/2a clinical trial of AJ201 in SBMA are expected in the first half of 2024.
- AJ201 was sourced by Fortress and is currently in development at Avenue.

BAER-101(GABA$_A$ α2/3 positive allosteric modulator)

- In August 2023, Avenue reported preclinical results for BAER-101, a potentially best in class GABA$_A$ α2,3 positive allosteric modulator, demonstrating it significantly suppressed seizures in a translational animal model of absence epilepsy. In an *in vivo* evaluation using the SynapCell's Genetic Absence Epilepsy Rat from Strasbourg (“GAERS”) model of absence epilepsy, BAER-101 fully suppressed seizure activity with a minimal effective dose of 0.3 mg/kg, PO. The effect was fast in onset and stable throughout the duration of testing. The detailed preclinical results are expected to be submitted at an upcoming scientific meeting. The combination of safety and tolerability in hundreds of patients and the preclinical efficacy data support BAER-101’s continued development.
- BAER-101 was sourced by Fortress and is currently in development at Baergic Bio, a subsidiary of Avenue.

General Corporate

- In November 2023, Fortress closed on a public offering of the issuance and sale of an aggregate of 5,885,000 units at a purchase price of $1.70 per unit. Each unit consists of (i) one share of common stock, and (ii) one warrant to purchase one share of common stock, exercisable immediately upon issuance at a price of $1.70 per share and expiring five years following the issuance date. The total gross proceeds from the offering were approximately $10.0 million with net proceeds of approximately $8.9 million after deducting placement agent fees and other transaction costs. Certain directors and officers of the Company participated in the offering and purchased an aggregate amount of approximately $2.9 million of units at the same purchase price.
- In November 2023, Avenue closed on a public offering of the issuance and sale of an aggregate of 16,633,400 units at a purchase price of $0.3006 per unit. Each unit consists of (i) one share of common stock (or pre-funded warrant in lieu of), and (ii) one Series A warrant to purchase one share of commons stock, exercisable immediately upon issuance at a price of $0.3006 per share and expiring five years following the issuance date, and (iii) one Series B warrant to purchase one share of common stock, exercisable immediately upon issuance at a price of $0.3006 per share and expiring eighteen months following the issuance date. Total gross proceeds from the offering were approximately $5.0 million.

- In October 2023, Mustang closed on the October 2023 Registered Direct Offering for the issuance and sale of (i) 920,000 shares of common stock and (ii) pre-funded warrants to purchase up to 1,668,236 shares of its common stock. In a concurrent private placement, Mustang also issued and sold unregistered warrants to purchase up to 2,588,236 shares of common stock in. The unregistered warrants have an exercise price of $1.58, were exercisable immediately upon issuance and will expire five and one-half years following the issuance date. Total gross proceeds from the offering were approximately $4.4 million.
- In October 2023, Checkpoint entered into an inducement offer letter agreement with a holder of certain of its existing warrants to exercise for cash an aggregate of 6,325,354 shares of Checkpoint's common stock at a reduced exercise price of $1.76 per share. The warrants were issued to the holder on December 16, 2022 with an exercise price of $4.075 per share and on February 22, 2023 with an exercise price of $5.00 per share as part of registered direct offerings. As part of the inducement, Checkpoint agreed to issue new unregistered Series A Warrants to purchase up to 6,325,354 shares of Checkpoint Common Stock and new unregistered Series B Warrants to purchase up to 6,325,354 shares of Checkpoint Common Stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $1.51 per share. The Series A warrants will expire five years following the issuance date and the Series B warrants will expire twenty-four months following the issuance date. Total gross proceeds from the offering were approximately $11.1 million.
- In October 2023, Fortress effected a 1-for-15 reverse stock split of its issued and outstanding common stock which brought the Company into compliance with Nasdaq's $1.00 per share minimum bid price requirement for continued listing.
- In July 2023, Mustang announced that it amended its previously announced asset purchase agreement with uBriGene (Boston) Biosciences Inc. ("uBriGene"), the U.S. subsidiary of uBriGene Group, a leading cell and gene therapy contract development and manufacturing organization ("CDMO"), and closed the transaction. Per the terms of the amended asset purchase agreement, at closing, uBriGene acquired all of Mustang's assets primarily relating to the manufacturing and production of cell and gene therapies at Mustang's cell and gene therapy manufacturing facility in Worcester, Massachusetts, for upfront consideration of $6 million in cash. An additional $5 million contingent payment will be payable to Mustang upon (i) Mustang's raising $10 million in gross proceeds from equity raises following the closing of the transaction and (ii) completion of the assignment of Mustang's lease to uBriGene, which remains subject to landlord's approval, within two years of the closing.. Until the lease is transferred to uBriGene, Mustang will retain its facility lease and facility personnel, and will continue to occupy the leasehold premises and manufacture there its lead product candidate, MB-106.
- In July 2023, Checkpoint closed on a registered direct offering for the issuance and sale of an aggregate of 2,427,186 shares of its common stock at a purchase price of $3.09 per share of common stock priced at-the-market under Nasdaq rules, and a concurrent private placement of two series of warrants to purchase Checkpoint common stock, for total gross proceeds of approximately $10.0 million.

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 section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 31, 2023 (the "2022 Form 10-K"). There were no material changes in our critical accounting estimates or accounting policies from December 31, 2022.

Accounting Pronouncements

As of September 30, 2023, there were no new accounting pronouncements or updates to recently issued accounting pronouncements disclosed in the 2022 Form 10-K that are expected to materially affect the Company's present or future financial statements upon adoption.

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 chose to present only the two most recent fiscal years of audited financial statements in the 2022 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.

Results of Operations

General

For the three months ended September 30, 2023 and 2022, we generated $34.8 million and $16.5 million, respectively, of net revenue, of which $15.3 million and $16.0 million, respectively, relates primarily to the sale of Journey branded and generic. Collaboration revenue of $0.2 million and $0.4 million, respectively, recognized in the quarters ended September 30, 2023 and 2022 is a result of Cyprium's agreement with Sentynl. Other revenue of approximately $19.3 million and $0.1 million include Journey's receipt of royalties from its exclusive out-licensing partner for Qbrexza in Japan, Maruho as well as a $19 million non-refundable upfront payment from Maruho related to a license granted by Journey to Maruho for the development and commercialization of Qbrexza in additional territories in Asia. Journey will no longer be eligible to receive royalties from Maruho after October 1, 2023.

For the nine months ended September 30, 2023 and 2022, we generated $64.6 million and $59.3 million, respectively, of net revenue, of which $44.4 million and $55.1 million, respectively, relates primarily to the sale of Journey branded and generic products. Collaboration revenue of $0.5 million and $1.5 million, respectively, recognized in the nine months ended September 30, 2023 and 2022 is a result of Cyprium's agreement with Sentynl. Other revenue of approximately $19.5 million and $2.6 million for the nine months ended September 30, 2023 and 2022, respectively include Journey's receipt of royalties from Maruho as well as a one-time receipt of $19 million from Maruho related to the Qbrexza license granted by Journey to Maruho as noted above.

As of September 30, 2023, we had an accumulated deficit of $685.6 million. While we may generate revenue in the future 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.

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, 2023 and 2022, by entity:

($ in thousands)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	% of total 2023	% of total 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	% of total 2023	% of total 2022
Research & Development								
Fortress	$ 515	$ 515	2 %	2 %	$ 1,652	$ 1,889	2 %	2 %
Subsidiaries/Partner Companies:								
Avenue	831	194	4 %	1 %	4,781	2,153	5 %	2 %
Checkpoint	5,495	8,866	27 %	30 %	35,266	35,589	40 %	36 %
JMC	2,229	2,812	11 %	9 %	6,036	6,687	6 %	6 %
Mustang	9,424	15,309	46 %	51 %	34,150	46,537	39 %	47 %
Other[1]	1,794	2,159	11 %	7 %	5,818	6,852	8 %	7 %
Total Research & Development Expense	**$ 20,288**	**$ 29,855**	**101 %**	**100 %**	**$ 87,702**	**$ 99,707**	**100 %**	**100 %**

Note 1: Includes the following subsidiaries: Aevitas (until April 2023), Baergic (until November 2022), 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.

The table below provides a summary of selling, general and administrative costs for the three and nine months ended September 30, 2023 and 2022, by entity:

($ in thousands)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	% of Total 2023	% of Total 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	% of Total 2023	% of Total 2022
Selling, General & Administrative								
Fortress	$ 6,066	$ 7,781	28 %	26 %	$ 17,849	$ 21,334	25 %	26 %
Subsidiaries/Partner Companies:								
Avenue	1,079	469	5 %	1 %	2,733	1,978	4 %	2 %
Checkpoint	1,861	1,695	9 %	6 %	5,625	5,604	8 %	6 %
JMC	8,636	15,574	40 %	52 %	34,069	45,517	47 %	53 %
Mustang	2,056	3,232	9 %	11 %	7,291	8,485	10 %	10 %
Other[1]	2,035	1,388	9 %	4 %	3,945	2,539	6 %	3 %
Total Selling, General & Administrative Expense	**$ 21,733**	**$ 30,139**	**100 %**	**100 %**	**$ 71,512**	**$ 85,457**	**100 %**	**100 %**

Note 1: Includes the following subsidiaries: Aevitas (until April 2023), Baergic (until November 2022), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

Comparison of three months ended September 30, 2023 and 2022

($ in thousands)	Three Months Ended September 30, 2023	2022	Change $	%
Revenue				
Product revenue, net	$ 15,279	$ 16,043	$ (764)	(5)%
Collaboration revenue	182	364	(182)	(50)%
Revenue – related party	31	48	(17)	(35)%
Other revenue	19,260	73	19,187	26,284 %
Net revenue	34,752	16,528	18,224	110 %
Operating expenses				
Cost of goods sold – product revenue	6,429	7,221	(792)	(11)%
Research and development	20,288	29,855	(9,567)	(32)%
Research and development – licenses acquired	60	47	13	28 %
Selling, general and administrative	21,733	30,139	(8,406)	(28)%
Total operating expenses	48,510	67,262	(18,752)	(28)%
Loss from operations	(13,758)	(50,734)	36,976	(73)%
Other income (expense)				
Interest income	547	419	128	31 %
Interest expense and financing fee	(2,534)	(3,393)	859	(25)%
Change in fair value of warrant liabilities	4,542	—	4,542	100 %
Other income	620	648	(28)	(4)%
Total other income (expense)	3,175	(2,326)	5,501	(237)%
Loss before income tax expense	(10,583)	(156,468)	145,885	(93)%
Income tax expense	141	—	141	100 %
Net Loss	**(10,724)**	**(53,060)**	**42,336**	**(80)%**
Less: net loss attributable to non-controlling interest	5,679	30,549	(24,870)	(81)%
Net loss attributable to Fortress	**$ (5,045)**	**$ (22,511)**	**$ 17,466**	**(78)%**

Net revenue increased $18.2 million, or 110%, from the three months ended September 30, 2022 to the three months ended September 30, 2023 due to the receipt of the $19 million payment from Maruho related to the Qbrexza license granted to Maruho for the development and commercialization of Qbrexza in additional territories in Asia.

Total net product revenues decreased by $0.8 million, or 5%, to $15.3 million for the three-month period ended September 30, 2023, from $16.0 million for the three-month period ended September 30, 2022. The decrease is primarily due to lower net revenue from Ximino resulting from lower unit volumes due to the winding down of the product during the third quarter, along with higher coupon redemption volumes. We discontinued selling Ximino on September 29, 2023.

For the three months ended September 30, 2023 and 2022, Journey had $6.4 million or 42% of product revenue, and $7.2 million or 45% of product revenue, net, respectively, of costs of goods sold in connection with the sale of Journey's marketed products. The $0.8 million or 11% decrease is predominantly due to the contractual decrease in Journey's Qbrexza royalty from period to period, which accounted for $0.6 million of the decrease, as well as lower sales volume of this product in the current quarter.

Research and development expenses decreased $9.6 million or 32% from the three months ended September 30, 2022 to the three months ended September 30, 2023. The following table shows the change in research and development spending by Fortress and its subsidiaries and partner companies:

($ in thousands)	Three Months Ended September 30, 2023	2022	Change $	%
Research & Development				
Stock-based compensation				
Fortress	$ 401	$ 375	$ 26	7 %
Subsidiaries/Partner Companies:				
Avenue	144	8	136	1,701 %
Checkpoint	303	276	27	10 %
JMC	24	34	(10)	(28)%
Mustang	(18)	302	(320)	(106)%
Other[1]	1	5	(4)	(80)%
Sub-total stock-based compensation expense	855	1,000	(145)	(14)%
Other Research & Development				
Fortress	114	140	(26)	(19)%
Subsidiaries/Partner Companies:				
Avenue	687	186	501	269 %
Checkpoint	5,192	8,590	(3,398)	(40)%
JMC	2,205	2,778	(573)	(21)%
Mustang	9,442	15,007	(5,565)	(37)%
Other[1]	1,793	2,154	(361)	(17)%
Total Research & Development Expense	**$ 20,288**	**$ 29,855**	**$ (9,567)**	**(32)%**

Note 1: Includes the following subsidiaries: Aevitas (until April 2023), Baergic (until November 2022), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

The decrease in stock-based compensation for the quarter ended September 30, 2023 is primarily due to Mustang's decrease in stock based compensation of $0.3 million related to forfeitures.

The decrease of approximately $5.6 million at Mustang is primarily attributed to decreased expenses of $3.2 million for personnel related costs, which includes approximately $1.5 million of costs reimbursed through the subcontracting agreement with uBriGene, $1.2 million for lab supplies, $3.1 million for program related costs, primarily reflecting the termination of certain Mustang programs, $0.6 million for facility and depreciation expenses, which includes approximately $0.2 million of costs reimbursed through the subcontracting agreement with uBriGene, partially offset by higher expenses of $1.5 million for services provided by uBriGene and $1.0 million for other expenses. The decreased research and development spending at Checkpoint of $3.4 million is attributable primarily to decreased expenses related to Checkpoint's commercial manufacturing costs and inventory build for cosibelimab of $1.6 million, due to the timing of manufacturing batches supporting a potential 2024 product launch, decreased clinical costs of $1.1 million related to Checkpoint's product candidates, particularly the CK-301-101 study, and decreased regulatory costs of $0.7 million due to the BLA filing in early 2023. JMC's research and development expense decrease of $0.6 million is related to lower clinical trial expenses to develop DFD-29 as the Phase 3 trial is now completed. The increase at Avenue of $0.5 million is attributable to the increased spend related to the Phase 1b/2a clinical trial evaluating AJ201 for the treatment of spinal and bulbar muscular atrophy, also known as Kennedy's Disease. The first patient was dosed in July 2023.

General and administrative expenses decreased $8.4 million, or 28%, from the three months ended September 30, 2022 to the three months ended September 30, 2023. The following table shows the change in selling, general and administrative spending by entity:

($ in thousands)	Three Months Ended September 30, 2023	2022	Change $	%
Selling, General & Administrative				
Stock-based compensation				
Fortress	$ 2,061	$ 3,704	$ (1,643)	(44)%
Subsidiaries/Partner Companies:				
Avenue	417	18	399	2218 %
Checkpoint	386	505	(119)	(24)%
JMC	534	1,404	(870)	(62)%
Mustang	118	194	(76)	(39)%
Other[1]	6	12	(6)	(47)%
Sub-total stock-based compensation expense	3,522	5,837	(2,315)	(40)%
Other Selling, General & Administrative				
Fortress	4,005	4,077	(72)	(2)%
Subsidiaries/Partner Companies:				
Avenue	662	451	211	47 %
Checkpoint	1,475	1,190	285	24 %
JMC	8,102	14,170	(6,068)	(43)%
Mustang	1,938	3,038	(1,100)	(36)%
Other[1]	2,029	1,376	653	47 %
Total Selling, General & Administrative Expense	**$ 21,733**	**$ 30,139**	**$ (8,406)**	**(28)%**

Note 1: Includes the following subsidiaries: Aevitas (until April 2023), Baergic (until November 2022), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

For the quarter ended September 30, 2023, the decrease in selling, general and administrative expenses of $8.4 million, or 28%, is primarily attributable to Journey's continued cost reduction initiative designed to improve operational efficiencies, optimize expenses and reduce overall costs to better align costs with their revenue-generating capabilities. In connection with the cost reduction initiative, Journey executed a headcount reduction to its salesforce and implemented marketing and other cost cuts. Mustang's decrease in general and administrative expenses is attributed to led by a $0.3 million decrease in legal expense, which includes transaction-related expenses from the sale of property and equipment related to uBriGene, $0.4 million decrease in consulting and outside services, and $0.2 million decrease in personnel costs. The decrease in stock compensation expense at Fortress of $1.6 million is due to the decrease in the Company's share price.

The increase in other income (expense) of $5.5 million, with other income from the quarter ended September 30, 2023 of $3.2 million as compared to the other expense of $2.3 million for the quarter ended September 30, 2022 is due to the $4.5 million decrease in fair value of warrant liabilities, comprised of warrants issued by Checkpoint and Avenue, and $0.9 million decrease in interest expense and financing fees, due to Mustang's payoff of its debt with Runway and Journey's payoff of its debt with EWB.

Net loss attributable to Fortress decreased $17.5 million, or 78%, from a net loss of $22.5 million for the three months ended September 30, 2022 to a net loss of $5.0 million for the three months ended September 30, 2023.

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Comparison of nine months ended September 30, 2023 and 2022

($ in thousands)	Nine Months Ended September 30, 2023	2022	Change $	%
Revenue				
Product revenue, net	$ 44,405	$ 55,074	$ (10,669)	(19)%
Collaboration revenue	546	1,518	(972)	(64)%
Revenue – related party	97	118	(21)	(18)%
Other revenue	19,519	2,629	16,890	642 %
Net revenue	64,567	59,339	5,228	8.8 %
Operating expenses				
Cost of goods sold – product revenue	20,645	23,057	(2,412)	(10)%
Research and development	87,702	99,707	(12,005)	(12)%
Research and development – licenses acquired	4,293	48	4,245	8844 %
Selling, general and administrative	71,512	85,457	(13,945)	(16)%
Asset impairment	3,143	—	3,143	100 %
Total operating expenses	187,295	208,269	(20,974)	(10)%
Loss from operations	(122,728)	(148,930)	26,202	(18)%
Other income (expense)				
Interest income	2,296	711	1,585	223 %
Interest expense and financing fee	(13,255)	(8,897)	(4,358)	49 %
Change in fair value of warrant liabilities	10,708	—	10,708	100 %
Other income (expense)	(2,049)	648	(2,697)	(416)%
Total other expense	(2,300)	(7,538)	5,238	(69)%
Loss before income tax expense	(125,028)	(156,468)	31,440	(20)%
Income tax expense	142	—	142	100 %
Net loss	**(125,170)**	**(156,468)**	**31,298**	**(20)%**
Less: net loss attributable to non-controlling interest	73,812	96,841	(23,029)	(24)%
Net loss attributable to Fortress	**$ (51,358)**	**$ (59,627)**	**$ 8,269**	**(14)%**

Net revenues increased $5.2 million, or 8.8%, from the nine months ended September 30, 2022 to the nine months ended September 30, 2023 primarily due to the receipt of the $19 million payment (other revenue) from Maruho related to the Qbrexza license granted to Maruho for the development and commercialization of Qbrexza in territories in Asia. This increase was offset by lower product revenue, net of $10.7 million or 19%, due to lower unit sales volumes from Targadox, Ximino and Exelderm; Targadox is affected by continued generic competition. Ximino sales have been discontinued as of September 29, 2023. Collaboration revenue as a result of Cyprium's agreement with Sentynl decreased $1.0 million for the nine months ended September 30, 2023 due to the extended timeline for the CUTX-101 NDA submission.

Cost of goods sold decreased by $2.4 million, or 10%, from the nine months ended September 30, 2022 to the nine months ended September 30, 2023 due to lower product royalties driven by lower sales volumes and a decrease in the Journey product royalties related to Qbrexza from a contractual decrease in the royalty rate occurring in May 2022.

Research and development expenses decreased $12.0 million or 12% from the nine months ended September 30, 2022 to the nine months ended September 30, 2023. The following table shows the change in research and development spending by Fortress and its partner companies:

	Nine Months Ended September 30,		Change	
($ in thousands)	2023	2022	$	%
Research & Development				
Stock-based compensation				
Fortress	$ 1,200	$ 1,218	$ (18)	(2)%
Partner Companies:				
Avenue	150	297	(147)	(49)%
Checkpoint	880	752	128	17 %
JMC	88	34	54	160
Mustang	—	1,262	(1,262)	(100)%
Other[1]	1	8	(7)	(94)%
Sub-total stock-based compensation expense	2,319	3,571	(1,252)	(66)%
Other Research & Development				
Fortress	452	671	(219)	(33)%
Partner Companies:				
Avenue	4,631	1,856	2,775	150 %
Checkpoint	34,386	34,837	(451)	(1)%
JMC	5,948	6,653	(705)	(11)%
Mustang	34,149	45,275	(11,126)	(25)%
Other[1]	5,818	6,844	(1,026)	(15)%
Total Research & Development Expense	**$ 87,702**	**$ 99,707**	**$ (12,004)**	**(12)%**

Note 1: Includes the following partner companies: Aevitas (until April 2023), Baergic (until November 2022), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

The decrease in stock-based compensation for the nine months ended September 30, 2023, is primarily due to forfeitures at Mustang and the effect of lower stock prices.

The increase of $2.8 million of research and development expense at Avenue is primarily associated with an increase of $4.0 million in AJ201 clinical study expenses offset by a decrease of $0.9 million in IV tramadol advisory committee preparation and costs, $0.2 million decrease in bonus costs. Mustang's decrease in research and development spending of $11.1 million is primarily attributable to decreased expenses of $4.5 million for lab supplies and $4.6 million for third party clinical trial costs, reflecting the termination of certain Mustang programs. The decrease in research and development expense at JMC of $0.7 million is due to lower clinical trial expenses to develop DFD-29 as the Phase 3 trials are now complete.

General and administrative expenses decreased $13.9 million, or 16%, from the nine months ended September 30, 2022 to the nine months ended September 30, 2023. The following table shows the change in general and administrative spending by Fortress and its partner companies.

($ in thousands)	Nine Months Ended September 30, 2023	2022	Change $	%
Selling, General & Administrative				
Stock-based compensation				
Fortress	$ 6,787	$ 8,505	$ (1,718)	(20)%
Partner Companies:				
Avenue	449	341	108	32 %
Checkpoint	1,345	1,533	(188)	(12)%
JMC	1,989	2,951	(962)	(32)%
Mustang	380	549	(169)	(31)%
Other[1]	56	31	25	92 %
Sub-total stock-based compensation expense	11,006	13,910	(2,904)	(21)%
Other Selling, General & Administrative				
Fortress	11,061	12,829	(1,768)	(14)%
Partner Companies:				
Avenue	2,284	1,637	647	40 %
Checkpoint	4,280	4,071	209	5 %
JMC	32,080	42,566	(10,486)	(25)%
Mustang	6,911	7,936	(1,025)	(13)%
Other[1]	3,890	2,508	1,382	55 %
Total Selling, General & Administrative Expense	**$ 71,512**	**$ 85,457**	**$ (13,945)**	**(16)%**

Note 1: Includes the following partner companies: Aevitas (until April 2023), Baergic (until November 2022), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

For the nine months ended September 30, 2023, the decrease in general and administrative expenses of $13.9 million, or 16%, is primarily attributable to attributable to Journey's implementation of a cost reduction initiative designed to improve operational efficiencies, optimize expenses and reduce overall costs to better align costs with their revenue-generating capabilities. In connection with the cost reduction initiative, Journey executed a headcount reduction to its salesforce and implemented marketing and other cost cuts.

Regarding the asset impairment charge in the nine-month period ended September 30, 2023, Journey recorded a loss of $3.1 million related to the impairment of the Ximino intangible asset. Ximino sales have been discontinued as of September 29, 2023.

Total other expense decreased $5.2 million, or 69%, from expense of $7.5 million for the nine months ended September 30, 2022 to expense of $2.3 million for the nine months ended September 30, 2023, primarily due to the increase in interest expense and financing fees of $4.4 million, inclusive of Mustang's loss from extinguishment of their Runway debt of $2.8 million, offset by the change in fair value of warrant liabilities of $10.7 million and the increase in interest income of $1.6 million.

Net loss attributable to Fortress decreased $8.3 million, or 14%, from a net loss of $59.6 million for the nine months ended September 30, 2022 to a net loss of $51.4 million for the nine months ended September 30, 2023.

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, including $8.9 million, net, raised from the sale of common stock and warrants on November 14, 2023, are sufficient to fund operations for at least the next 12 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 sales of subsidiaries/partner companies, 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.

Cash Flows for the Nine Months Ended September 30, 2023 and 2022

Components of cash flows from publicly-traded partner companies comprise:

	For the Nine Months Ended September 30, 2023					
($ in thousands)	Fortress[1]	Avenue	Checkpoint	JMC	Mustang	Total
Statement of cash flows data:						
Total cash (used in)/provided by:						
Operating activities	$ (24,943)	$ (7,127)	$ (40,757)	$ 21,760	$ (42,223)	$ (93,290)
Investing activities	44	(3,000)	—	(5,000)	5,916	(2,040)
Financing activities	9,131	3,580	30,461	(24,014)	(30,037)	(10,879)
Net increase in cash and cash equivalents and restricted cash	$ (15,768)	$ (6,547)	$ (10,296)	$ (7,254)	$ (66,344)	$ (106,209)

	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)	$ (49,777)	$ (131,557)
Investing activities	(5)	—	—	(20,000)	(2,532)	(22,537)
Financing activities	(739)	(119)	7,997	15,508	34,055	56,701
Net increase in cash and cash equivalents and restricted cash	$ (27,146)	$ (3,546)	$ (34,257)	$ (14,190)	$ (18,254)	$ (97,393)

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

	Nine Months Ended September 30,		
($ in thousands)	2023	2022	Change
Statement of cash flows data:			
Total cash (used in)/provided by:			
Operating activities	$ (93,290)	$ (131,557)	$ 38,267
Investing activities	(2,040)	(22,537)	20,497
Financing activities	(10,879)	56,701	(67,580)
Net increase in cash and cash equivalents and restricted cash	$ (106,209)	$ (97,393)	$ (8,816)

Operating Activities

Net cash used in operating activities decreased $38.3 million from the nine months ended September 30, 2022, as compared to the nine months ended September 30, 2023. The decrease is due to the decrease of $31.3 million in net loss, $7.4 million decrease in cash resulting from changes in operating assets and liabilities, $4.1 million loss from the deconsolidation of subsidiaries, and $3.1 million asset impairment loss related to JMC's write-off of Ximino, offset by the $10.7 million gain on the change in the fair value of subsidiaries/partner companies' warrant liabilities.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2022 of $22.5 million, as compared to $2.0 million of cash used in investing activities for the nine months ended September 30, 2023 is a $20.5 million change in cash flows from investing activities. The change is primarily due to JMC's $20.0 million acquisition of the products acquired from VYNE Therapeutics, Inc. during 2022 and $2.6 million used in the purchase of property and equipment for the nine months ended September 30, 2022 as compared to $5.0 million used in investing activities for the nine months ended September 30, 2023 for the deferred cash payment made to VYNE related to the acquisition of Amzeeq and Zilxi and $3.0 million used for the purchase of research and development licenses for the payment Avenue made to AnnJi related to the license for AJ201, offset by the $6 million in proceeds from the sale of property and equipment from Mustang's transaction with uBriGene.

Financing Activities

Net cash used by financing activities was $10.9 million for the nine months ended September 30, 2023, compared to $56.7 million of net cash provided by financing activities for the nine months ended September 30, 2022, a decrease of $67.6 million. During the nine months ended September 30, 2023, cash used by partner companies to pay off long term debt and a line of credit totaled $81.3 million, offset by net proceeds from subsidiaries'/partner companies' sale of stock and warrants of $33.8 million and $13.2 million in proceeds from the Company's registered direct offering.

We fund our operations through cash on hand, the sale of equity and debt securities, from the sales of subsidiaries/partner companies, and from the proceeds resulting from the exercise of warrants and stock options. At September 30, 2023, we had cash and cash equivalents of $72.3 million, of which $36.0 million relates to Fortress and the private subsidiaries, primarily funded by Fortress, $1.8 million relates to Checkpoint, $9.6 million relates to Mustang, $24.7 million relates to Journey, and $0.2 million relates to Avenue. Restricted cash at September 30, 2023 was $2.4 million, of which $1.2 million relates to Fortress, $0.8 million relates to Mustang, and $0.4 million relates to Cyprium.

Sources of Liquidity

Stock Offerings and At-The-Market Share Issuances

On July 23, 2021, the Company filed a shelf registration statement (File No. 333-258145) on Form S-3, which was declared effective on July 30, 2021 (the "2021 Shelf"). Approximately $110.1 million of securities remain available for sale under the 2021 Shelf as of September 30, 2023.

For the nine months ended September 30, 2023, the Company issued approximately 0.2 million shares at an average price of $9.61 for gross proceeds of $2.2 million pursuant to the Fortress ATM. For the nine months ended September 30, 2022, the Company issued approximately 0.3 million shares at an average price of $23.85 for gross proceeds of $5.9 million pursuant to the Fortress ATM.

On February 10, 2023, the Company completed a registered direct offering of Common Stock pursuant to which it issued and sold approximately 1.1 million shares of its Common Stock at a purchase price of $12.53 per share and secured approximately $13.2 million in net proceeds after deducting estimated offering expenses.

On October 23, 2020, Mustang filed a shelf registration statement (File 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, 2023, approximately $7.8 million of the Mustang 2020 S-3 remains available for sales of securities.

On April 23, 2021, Mustang filed a shelf registration statement (File 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, 2023, there have been no sales of securities under the Mustang 2021 S-3.

During the nine months ended September 30, 2023, Mustang issued approximately 52,000 shares of common stock at an average price of $3.15 per share for gross proceeds of $0.2 million through the Mustang ATM. During the nine months ended September 30, 2022, Mustang issued approximately 0.5 million shares of common stock at an average price of $12.61 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.

In October 2023, Mustang closed on the October 2023 Registered Direct Offering for the issuance and sale of an aggregate of 2,588,236 shares of its common stock at a purchase price of $1.70 per share in a registered direct offering priced at-the-market under Nasdaq rule. In addition, the offering includes 2,588,236 shares of common stock in the form of pre-funded warrants at a price of $1.58. The common stock and the pre-funded warrants were sold together. The warrants are exercisable immediately upon issuance and will expire five and one-half years following the issuance date. Total gross proceeds from the offering were approximately $4.4 million.

The Checkpoint 2020 S-3 is a shelf registration statement (File No. 333-251005) 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, 2023, approximately $8.7 million of the Checkpoint shelf remains available for sale through this Checkpoint Form S-3.

In March 2023, Checkpoint filed shelf registration statement (File No. 333-270843) on Form S-3 (the "Checkpoint 2023 S-3"), which was declared effective May 5, 2023. Under the Checkpoint 2023 S-3, Checkpoint may sell up to a total of $150 million of its securities. As of September 30, 2023, approximately $91.7 million of the securities remains available for sale through the Checkpoint 2023 S-3.

In October 2023, Checkpoint entered into an inducement offer letter agreement with a holder of certain of its existing warrants to exercise for cash an aggregate of 6,325,354 shares of Checkpoint's common stock at a reduced exercise price of $1.76 per share. The warrants were issued to the holder on December 16, 2022 with an exercise price of $4.075 per share and on February 22, 2023 with an exercise price of $5.00 per share as part of registered direct offerings. The shares of Checkpoint common stock issuable upon exercise of the warrants were registered pursuant to effective registration statements on Form S-3 (File No. 333-251005) and Form S-3 (File No. 333-270474), respectively. As part of the inducement, Checkpoint agreed to issue new unregistered Series A Warrants to purchase up to 6,325,354 shares of Checkpoint Common Stock and new unregistered Series B Warrants to purchase up to 6,325,354 shares of Checkpoint Common Stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $1.51 per share. The Series A warrants will expire five years following the issuance date and the Series B warrants will expire twenty-four months following the issuance date. The total gross proceeds from the offering were approximately $11.1 million with net proceeds of approximately $10.0 million after deducting approximately $1.1 million in commissions and other transaction costs.

In July 2023, Checkpoint closed on the July 2023 Registered Direct Offering for the issuance and sale of an aggregate of 2,427,186 shares of its common stock at a purchase price of $3.09 per share in a registered direct offering. In addition, the offering includes 809,062 shares of common stock in the form of pre-funded warrants at a price of $3.0899. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 3,236,248 shares of common stock and Series B warrants to purchase up to 3,236,248 shares of common stock. The Series A warrants are exercisable immediately upon issuance and will expire five years following the issuance date and have an exercise price of $2.84 per share and the Series B warrants are exercisable immediately upon issuance and will expire eighteen months following the issuance date and have an exercise price of $2.84 per share. Total gross proceeds from the offering were approximately $10.0 million. As of September 30, 2023, all of the pre-funded warrants from the July 2023 Registered Direct Offering were fully exercised.

In May 2023, Checkpoint closed on a registered direct offering (the "Checkpoint May 2023 Registered Direct Offering") for the issuance and sale of an aggregate of 1,650,000 shares of its common stock at a purchase price of $3.071 per share in a registered direct offering. In addition, the offering includes 1,606,269 shares of common stock in the form of pre-funded warrants at a price of $3.0709, Series A warrants to purchase up to 3,256,269 shares of common stock, and Series B warrants to purchase up to 3,256,269 shares of common stock. Total gross proceeds from the offering were approximately $10.0 million. As of September 30, 2023, all of the pre-funded warrants from the Checkpoint May 2023 Registered Direct Offering were fully exercised.

In April 2023, Checkpoint closed on a registered direct offering for the issuance and sale of an aggregate of 1,700,000 shares of Checkpoint common stock at a purchase price of $3.60 per share of Checkpoint common stock and accompanying warrants in a registered direct offering priced at-the-market under Nasdaq rules. In a concurrent private placement, Checkpoint issued and sold Series A warrants to purchase up to 1,700,000 shares of Checkpoint common stock and Series B warrants to purchase up to 1,700,000 shares of Checkpoint common stock. Total gross proceeds from the offering were approximately $6.1 million.

In February 2023, Checkpoint closed on a registered direct offering (the "Checkpoint February 2023 Direct Offering") with a single institutional investor for the issuance and sale of 1,180,000 shares of its common stock and 248,572 pre-funded warrants which were subsequently fully exercised in February 2023. Each pre-funded warrant is exercisable for one share of common stock. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 1,428,572 shares of common stock and Series B warrants to purchase up to 1,428,572 shares of common stock, at a purchase price of $5.25 per share of common stock and associated common stock warrants, and $5.2499 per pre-funded warrant and associated common stock warrants. Net proceeds from the Checkpoint February 2023 Direct Offering were $6.7 million after deducting commissions and other transaction costs.

On December 30, 2022, Journey filed a shelf registration statement (File No. 333-269079) on Form S-3 (the "Journey 2022 S-3"), which was declared effective on January 23, 2023. Through the Journey 2022 S-3, Journey may sell up to a total of $150 million of its securities. As of September 30, 2023, there have been no sales of securities under the Journey 2022 S-3. In connection with the Journey 2022 S-3, Journey entered into an At Market Issuance Sales Agreement governing potential sales of up to 4,900,000 shares of Journey's Common Stock.

In November 2023, Avenue closed on a public offering of the issuance and sale of an aggregate of 16,633,400 units at a purchase price of $0.3006 per unit. Each unit consists of (i) one share of common stock (or pre-funded warrant in lieu of), and (ii) one Series A warrant to purchase one share of commons stock, exercisable immediately upon issuance at a price of $0.3006 per share and expiring five years following the issuance date, and (iii) one Series B warrant to purchase one share of common stock, exercisable immediately upon issuance at a price of $0.3006 per share and expiring eighteen months following the issuance date. Total gross proceeds from the offering were approximately $5.0 million.

In January 2023, Avenue entered into an agreement with a single institutional investor for the registered direct offering and sale of 448,000 shares of common stock at $1.55 per share and pre-funded warrants to purchase 1,492,299 shares of common stock at a price of $1.549 per share. In a concurrent private placement, Avenue also agreed to issue to the same investor a total of 1,940,299 warrants to purchase up to one share of common stock each at an exercise price of $1.55 per share at a purchase price of $0.125 per warrant. Avenue received $3.0 million in total gross proceeds after deducting estimated offering expenses.

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, 2023, there were no material changes in our contractual obligations and commitments, including our lease obligations, as described in our 2022 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, 2023, 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, 2023. 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, our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock, $0.001 par value (the "Series A Preferred Stock" or "FBIOP") or any other type of equity or debt securities we may issue from time to time (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 partner companies 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 subsidiaries and partner companies such that, if any of the negative outcomes associated with any such risk is experienced by one of our subsidiaries or partner companies, the value of Fortress' holdings in such entity may decline. As used throughout this filing, the words "we", "us" and "our" may refer to Fortress individually, to one or more subsidiaries and/or partner companies, or to all such entities as a group, 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 may 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 termination of a given development program or 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 restricts our and certain of our partner companies' abilities to take certain actions.

At December 31, 2022, the total amount of debt outstanding, net of the debt discount, was $91.7 million. If we default on our obligations, the holders of our debt may declare the outstanding amounts immediately payable together with accrued interest, and/or take possession of any pledged collateral. If an event of default occurs, we may be unable to cure it within the applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment and we may be unable to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. In addition, current or future debt obligations may limit our ability to finance future operations, satisfy capital needs, or to engage in, expand or pursue our business activities. Such restrictions may also prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding debt, which may not be desirable or possible.

On August 27, 2020, we entered into the Oaktree Agreement with Oaktree. The Oaktree Agreement contains certain affirmative and negative covenants restricting our and certain of our subsidiaries' and 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 subsidiaries' and partner companies' ability to enter into certain transactions or arrangements that management otherwise believes would be in our best interests, such as dispositions that would result in cash inflows to Fortress and/or our subsidiaries and 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 $203.6 million and $188.5 million for the years ended December 31, 2022 and 2021, respectively. At December 31, 2022, we had an accumulated deficit of approximately $634.2 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 subsidiaries 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 and partner companies, 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 and partner companies.

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, 2022 and 2021, we incurred R&D expenses of approximately $134.2 million and $113.2 million, respectively. We expect to continue to spend significant amounts on our growth strategy. We believe that our current cash and cash equivalents will enable us to continue to fund operations in the normal course of business for at least the next 12 months from the filing of this Quarterly Report on Form 10-Q. 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 if 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 other equity securities that are convertible or exercisable 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 Journey's dermatology products, especially Qbrexza, Amzeeq, Zilxi, 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, a significant portion 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 Journey's 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.

A significant portion 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 impact on our operating income. Three of Journey's marketed products, Qbrexza, Amzeeq and Zilxi, as well as DFD-29, 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.

Accutane currently competes in the Isotretinoin market with five other therapeutically equivalent A/3B rated products. Targadox currently competes with one therapeutically equivalent A/B 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.

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 subsidiaries, 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 (the acquisition component of which has consummated) and a development funding and contingent asset purchase between Cyprium and Sentynl (the acquisition component of which has not yet consummated). 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 subsidiaries, partner companies or their assets, we may surrender our ability to realize long-term value from such asset or company, in the form of foregone product sales, 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 company is granted FDA approval for commercialization following the execution of documentation governing the sale by us of such asset or company, the transferee of such asset or company 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 companies, 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 partner companies. We have also entered into, and may again enter into, certain arrangements with our subsidiaries, partner companies and/or 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 partner companies, 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 subsidiaries, partner 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 affected.

For instance, Caelum is the defendant in a lawsuit brought by The University of Tennessee Research Foundation ("UTRF") captioned as *University of Tennessee Research Foundation v. Caelum Biosciences, Inc.*, No. 19-cv-00508, which is pending in the United States District Court for the Eastern District of Tennessee (the "UTRF Litigation"). UTRF brought claims against Caelum, for, inter alia, tortious interference and trade secret misappropriation. UTRF primarily alleges that Caelum unauthorizedly used non-patent trade secrets owned by UTRF in the development of Caelum's 11-1F4 monoclonal antibody, known as CAEL-101. Under the agreement pursuant to which Alexion acquired Caelum (as amended, the "DOSPA"), Fortress has indemnification obligations of Caelum under certain circumstances, including for certain of Caelum's legal expenses and potential damages arising out of the UTRF Litigation (with such indemnification capped in the aggregate as to Fortress at the amount of Caelum acquisition proceeds received by Fortress and which, at Caelum's election, may be satisfiable in the form of offsets against future amounts that Caelum may owe Fortress under the DOSPA). Caelum is defending the UTRF Litigation, with Fortress participating in such defense and maintaining a consent right over any potential settlements. Caelum's legal fees and costs in defending the UTRF Litigation are being reimbursed by Fortress by distribution from a $15 million escrow account established concurrently with the acquisition of Caelum; Fortress considers the amount remaining in escrow to be in excess of the amount of its anticipated out-of-pocket indemnifiable costs and damages in the UTRF Litigation and therefore has not accrued any liability pertaining to this indemnity. Caelum and Fortress both believe the UTRF Litigation is without merit and intend to continue defending it vigorously (including exhausting all appeals if applicable). Caelum's motion for summary judgment is currently pending, and a trial is scheduled for March 2024 with respect to any of UTRF's claims that may survive summary judgment.

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, including with respect to Company's obligation to issue Fortress Common Stock as dividends on the Urica Therapeutics, Inc. 8% Cumulative Convertible Class B Preferred Stock and the Company's obligation to issue shares of the Series A Preferred Stock in the event of certain exchanges of the Cyprium Therapeutics, Inc. 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (see Note 9, Debt and Interest, and Note 15, Related Party Transactions, to the Unaudited Condensed Consolidated Financial Statements herein). Under these and other future similar obligations, 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.

Under the provisions of the Cyprium Perpetual Preferred Stock, in the event that Cyprium has not sold a Priority Review Voucher issued by the U.S. Food and Drug Administration in connection with its approval of a New Drug Application ("NDA") for CUTX-101, Cyprium's copper histidinate product candidate (the "PRV Sale"), by September 18, 2024, then Fortress is obligated to exchange all shares of Cyprium Perpetual Preferred Stock that remain outstanding as of such date for: (i) cash, (ii) shares of FBIOP, or (iii) a combination of the foregoing (in each case with an aggregate value equal to the subscription price for such Cyprium Perpetual Preferred Stock and with the composition of such payments and/or issuances to be determined at Fortress' discretion), *plus* cash in lieu of fractional shares and accumulated and unpaid dividends to, but excluding, the exchange date. As of the date of this filing, approximately $7.6 million ~~of subscriptions~~ of Cyprium Perpetual Preferred Stock remain outstanding~~, reflecting the combined value of cash payments or Fortress Series A Preferred Stock (or some combination of the foregoing) that will need to be paid or issued by Fortress on or prior to September 18, 2024, if the PRV Sale has not occurred by such date~~. Also, as previously disclosed on October 26, 2023, Fortress and Cyprium anticipate that Sentynl will, in November 2023, assume control over development of the CUTX-101 program; there is no guarantee that Sentynl will obtain NDA approval prior to September 18, 2024.

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 partner companies, subsidiaries, 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 partner companies, subsidiaries, 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, or the appearance of conflicts of interest may nonetheless arise. The existence and consequences of such potential or perceived 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 we may need to find other countries to conduct these clinical trials. Clinical trial interruptions may delay our plans for clinical development and approvals for our product candidates, which could increase costs and jeopardize our ability to commence product sales and generate revenues.

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 to the manufacturing and supply functions they provide, third-party manufacturers also play a key role in our efforts to obtain marketing approval for our product candidates, by interacting with, providing important information to, and hosting inspections by, applicable regulatory authorities. If a given contract development and manufacturing organization upon whom we rely in such a capacity is unwilling or unable to perform these activities on our behalf, the successful development and/or approval of the applicable product candidate could be delayed significantly.

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.

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, 2022, we had an accumulated deficit of approximately $634.2 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 development-stage 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 subsidiaries and 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 and/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 our strategy to mitigate development risk, we generally intend on developing product candidates with previously-validated mechanisms of action and seek 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 or acquired products, we could make inaccurate assumptions and conclusions about our current or future product candidates, and our research and development efforts could be compromised.

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 in broadly scoped indemnification by us of service providers and/or 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 their indemnities (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 our 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 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 majority of 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 we 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 play a primary role in the recommendation and prescription of our 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 were investigated 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. The federal government has been able to seize a significant amount of cryptocurrency assets associated with the breach. Once the cryptocurrency has been converted back into U.S. dollars, Journey expects to receive a notification letter to initiate the return of the cash. This process could take as long as six months or more to complete. 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 or other issuances of a substantial number of shares of our Common Stock, or the perception that such sales or issuances may occur, may adversely impact the price of our Common Stock.

Almost all of our outstanding shares of our Common Stock, inclusive of outstanding equity awards, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act, or an effective registration statement. In addition, pursuant to our current shelf registration statements on Form S-3, from time to time we may issue and sell shares of our Common Stock or Series A Preferred Stock having an aggregate offering price of up to $136.1 million as of December 31, 2022. Any sale of a substantial number of shares of our Common Stock or our Series A 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 subsidiaries and partner companies 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 subsidiaries and partner companies 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 holders of our Common Stock 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 31, 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 of Nasdaq 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. On May 2, 2023 the Staff granted the Company a second 180-calendar day grace period pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(ii), through October 30, 2023.

On October 9, 2023, Fortress filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation, as amended, to effect the 1-for-15 Reverse Stock Split. The Reverse Stock Split was approved on August 10, 2023, by the Company's Board of Directors and by the Company's stockholders at a special meeting held on October 9, 2023. The Reverse Stock Split was intended to bring the Company into compliance with Nasdaq's $1.00 per share minimum bid price requirement for continued listing. Since then, Nasdaq has determined that for 10 consecutive business days, the closing bid price of the Company's Common Stock has been at $1.00 per share or greater, and on October 24, 2023, was formally notified by Nasdaq that the Company evidenced compliance with the $1.00 bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rules 5550(a)(2), and that accordingly, the listing matter was closed.

If we again are 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 determine that we need to seek additional equity capital, being delisted from the Nasdaq Capital Market 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. 000-54463) 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. 000-54463) 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	Certificate of Amendment of the Amended and Restated Certificate of Incorporation, as Amended, of Fortress Biotech, Inc. dated October 9, 2023 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K (file No. 001-35366) filed with SEC on October 10, 2023.
3.10	Third Amended and Restated Bylaws of Fortress Biotech, Inc. (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with SEC on August 14, 2023).
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.
\# Management contract or compensatory plan.

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, 2023	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, 2023	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 the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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 control over financial reporting.

Dated: November 14, 2023

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

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 control over financial reporting.

Dated: November 14, 2023

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, 2023, 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.

Dated: November 14, 2023

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, 2023, 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.

Dated: November 14, 2023

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