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

FORM 10-Q

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

For the quarterly period ended September 30, 2026

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, 2026
Common Stock, $0.001 par value	33,742,297
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 OF 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 Part 2, 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 our 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 substantial additional capital, which we may be unable to raise as needed and which may impede our R&D programs, commercialization efforts, or planned acquisitions.
- Our board of directors has paused payments of dividends on our preferred stock, and there can be no assurance that monthly dividend payments will be resumed in a timely manner, or at all.
- If we raise additional capital by issuing equity, equity-linked securities or securities convertible into or exercisable for equity 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 Emrosi, Qbrexza, Accutane, Amzeeq, Zilxi, Targadox, Exelderm, Luxamend, and Eurax. 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, Emrosi, Qbrexza, Amzeeq and Zilxi, currently have patent protection. Five of Journey's marketed products, Accutane, Targadox, Exelderm, Eurax, and Luxamend, do not have patent protection or otherwise are not eligible for patent protection. With respect to Journey products that are covered by valid claims of issued patents, such patents may be subject to invalidation, which would harm our operating income.
- Continued sales and coverage, including formulary inclusion without the need for a prior authorization or step edit therapy, of our products for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government 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.
- The Company's business may be materially adversely affected by the imposition of duties and tariffs and other trade barriers and retaliatory countermeasures implemented by the U.S. and other governments.

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, and are likely to continue acting as, guarantor and/or indemnitor of certain obligations of our subsidiaries and partner companies, which could require us to pay substantial amounts in certain circumstances.

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 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 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 Approved

- If our product candidates, if approved, 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

- We have previously failed to satisfy certain continued listing rules of The Nasdaq Stock Market LLC ("Nasdaq"), and if we again are unable to meet the continued listing requirements and/or regain compliance with such rules, our Common Stock and Preferred Stock may be subject to delisting from The Nasdaq Capital Market. The delisting of our securities from the Nasdaq may decrease the market liquidity and market price of our Common Stock and Preferred Stock.

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

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

	September 30, 2026	December 31, 2025
ASSETS		
Current assets		
Cash and cash equivalents	$ 152,186	$ 79,381
Accounts receivable, net	47,387	29,783
Inventory	7,772	9,624
Other receivables - related party	54	158
Prepaid expenses and other current assets	2,964	4,895
Total current assets	210,363	123,841
Property and equipment, net	2,320	2,519
Operating lease right-of-use asset, net	11,028	12,302
Restricted cash	1,220	1,220
Equity investments, at fair value	29,452	17,660
Intangible assets, net	24,541	27,605
Other assets	1,291	401
Total assets	**$ 280,215**	**$ 185,548**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 56,628	$ 47,125
Income taxes payable	5,119	356
Common stock warrant liabilities	—	1
Operating lease liabilities, short-term	2,513	2,127
Partner company notes payable, short-term	7,500	—
Other current liabilities	—	135
Total current liabilities	71,760	49,744
Notes payable, long-term, net	18,077	52,417
Operating lease liabilities, long-term	10,861	12,672
Partner company redeemable perpetual preferred liability	—	7,085
Other long-term liabilities	2,496	1,447
Total liabilities	**103,194**	**123,365**
Commitments and contingencies (Note 14)		
Stockholders' equity		
Cumulative redeemable perpetual preferred stock, $0.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 33,490,362 and 31,364,094 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	33	31
Additional paid-in-capital	789,953	783,891
Accumulated deficit	(629,992)	(734,052)
Total stockholders' equity attributed to the Company	159,997	49,873
Non-controlling interests	17,024	12,310
Total stockholders' equity	177,021	62,183
Total liabilities and stockholders' equity	**$ 280,215**	**$ 185,548**

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue				
Product revenue, net	$ 18,925	$ 17,025	$ 52,685	$ 45,173
Other revenue	234	606	1,229	2,010
Net revenue	19,159	17,631	53,914	47,183
Operating expenses				
Cost of goods - (excluding amortization of acquired intangible assets)	5,884	5,755	18,245	15,484
Amortization of acquired intangible assets	969	1,064	3,064	3,193
Research and development	1,678	208	3,023	12,268
Selling, general and administrative	17,821	17,415	54,519	81,670
Total operating expenses	26,352	24,442	78,851	112,615
Loss from operations	(7,193)	(6,811)	(24,937)	(65,432)
Other income (expense)				
Interest income	1,295	736	3,446	1,848
Interest expense and financing fee	(2,498)	(2,742)	(7,342)	(8,065)
Gain on sale of priority review voucher, net of expenses	—	—	158,873	—
Change in fair value of partner company derivative liability	—	—	(7,085)	—
Gain (loss) on common stock warrant liabilities	—	(2)	1	(399)
Gain from deconsolidation of subsidiary	104	—	186	27,127
Other income (expense)	(18)	17,672	11,764	17,599
Total other income (expense)	(1,117)	15,664	159,843	38,110
Income (loss) before income tax expense	(8,310)	8,853	134,906	(27,322)
Income tax (benefit) expense	(56)	26	5,395	196
Net income (loss)	**(8,254)**	**8,827**	**129,511**	**(27,518)**
Attributable to non-controlling interests	2,409	(2,977)	(25,451)	38,270
Net income (loss) attributable to Fortress	**$ (5,845)**	**$ 5,850**	**$ 104,060**	**$ 10,752**
Preferred A dividends cumulated, and Fortress' share of subsidiary deemed dividends	(2,008)	(2,174)	(6,024)	(6,436)
Net income (loss) attributable to common stockholders	**$ (7,853)**	**$ 3,675**	**$ 98,036**	**$ 4,316**
Net income (loss) per common share attributable to common stockholders - basic	$ (0.23)	$ 0.13	$ 2.94	$ 0.16
Net income (loss) per common share attributable to common stockholders - diluted	$ (0.23)	$ 0.11	$ 2.51	$ 0.14
Weighted average common shares outstanding - basic	33,746,832	27,244,474	33,394,537	27,075,216
Weighted average common shares outstanding - diluted	33,746,832	33,100,961	38,997,513	30,695,996

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, 2026

	Series A Perpetual Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of June 30, 2026	**3,427,138**	**$ 3**	**33,311,012**	**$ 33**	**$ 788,251**	**$ (624,147)**	**$ 41,946**	**$ 206,086**
Stock-based compensation expense	—	—	—	—	2,149	—	—	2,149
Issuance of common stock related to equity plans	—	—	179,350	—	—	—	—	—
Issuance of common stock under partner company's ESPP	—	—	—	—	75	—	—	75
Partner company's dividends declared and paid	—	—	—	—	(23,199)	—	—	(23,199)
Issuance of subsidiary's common shares for research and development expenses	—	—	—	—	107	—	—	107
Partner company's exercise of options for cash	—	—	—	—	45	—	—	45
Issuance of subsidiary warrants for contingent liability	—	—	—	—	12	—	—	12
Non-controlling interest in partner companies	—	—	—	—	22,513	—	(22,513)	—
Attributable to non-controlling interests	—	—	—	—	—	—	(2,409)	(2,409)
Net loss attributable to Fortress	—	—	—	—	—	(5,845)	—	(5,845)
Balance as of September 30, 2026	**3,427,138**	**$ 3**	**33,490,362**	**$ 33**	**$ 789,953**	**$ (629,992)**	**$ 17,024**	**$ 177,021**

For the Three Months Ended September 30, 2025

	Series A Perpetual Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of June 30, 2025	**3,427,138**	**$ 3**	**29,752,775**	**$ 30**	**$ 779,856**	**$ (735,965)**	**$ (6,541)**	**$ 37,383**
Stock-based compensation expense	—	—	—	—	3,197	—	—	3,197
Issuance of common stock related to equity plans	—	—	106,378	—	—	—	—	—
Partner company's warrant exercises	—	—	—	—	7,144	—	—	7,144
Partner company's at-the-market offering, net	—	—	—	—	6,891	—	—	6,891
Issuance of common stock under partner company's ESPP	—	—	—	—	118	—	—	118
Partner company's dividends declared and paid	—	—	—	—	(166)	—	—	(166)
Partner company's exercise of options for cash	—	—	—	—	103	—	—	103
Exercise of warrants	—	—	1,258,382	1	1,687	—	—	1,688
Shares withheld related to net settlement of warrants	—	—	(112,365)	—	—	—	—	—
Non-controlling interest in partner companies	—	—	—	—	(12,887)	—	12,887	—
Attributable to non-controlling interests	—	—	—	—	—	—	2,977	2,977
Net income attributable to Fortress	—	—	—	—	—	5,850	—	5,850
Balance as of September 30, 2025	**3,427,138**	**$ 3**	**31,005,170**	**$ 31**	**$ 785,943**	**$ (730,115)**	**$ 9,323**	**$ 65,185**

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, 2026

	Series A Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2025	**3,427,138**	**$ 3**	**31,364,094**	**$ 31**	**$ 783,891**	**$ (734,052)**	**$ 12,310**	**$ 62,183**
Stock-based compensation expense	—	—	—	—	6,782	—	—	6,782
Issuance of common stock related to equity plans	—	—	1,397,885	1	(1)	—	—	—
Issuance of common stock under ESPP	—	—	34,087	—	74	—	—	74
Exchange of partner company preferred shares	—	—	—	—	(165)	—	—	(165)
Issuance of common stock under partner company's ESPP	—	—	—	—	223	—	—	223
Partner company's dividends declared and paid	—	—	—	—	(23,199)	—	—	(23,199)
Issuance of partner company's common shares for research and development expenses	—	—	—	—	107	—	—	107
Exercise of warrants	—	—	694,296	1	1,217	—	—	1,218
Issuance of subsidiary warrants for contingent liability	—	—	—	—	12	—	—	12
Partner company's exercise of options for cash	—	—	—	—	275	—	—	275
Non-controlling interest in partner companies	—	—	—	—	20,737	—	(20,737)	—
Attributable to non-controlling interests	—	—	—	—	—	—	25,451	25,451
Net income attributable to Fortress	—	—	—	—	—	104,060	—	104,060
Balance as of September 30, 2026	**3,427,138**	**$ 3**	**33,490,362**	**$ 33**	**$ 789,953**	**$ (629,992)**	**$ 17,024**	**$ 177,021**

For the Nine Months Ended September 30, 2025

	Series A Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2024	**3,427,138**	**$ 3**	**27,908,839**	**$ 28**	**$ 763,573**	**$ (740,867)**	**$ (24,381)**	**$ (1,644)**
Stock-based compensation expense	—	—	—	—	26,280	—	—	26,280
Issuance of common stock related to equity plans	—	—	1,278,005	1	(1)	—	—	—
Issuance of common stock under ESPP	—	—	35,546	—	43	—	—	43
Redemption of partner company preferred shares	—	—	—	—	(265)	—	—	(265)
Issuance of common stock for at-the-market offering, net	—	—	539,563	1	1,008	—	—	1,009
Partner companies' offerings, net and warrant exercises	—	—	—	—	61,238	—	—	61,238
Partner companies' at-the-market offering, net	—	—	—	—	13,631	—	—	13,631
Issuance of common stock under partner company's ESPP	—	—	—	—	217	—	—	217
Partner company's dividends declared and paid	—	—	—	—	(498)	—	—	(498)
Exercise of warrants	—	—	1,355,582	1	2,279	—	—	2,280
Shares withheld related to net settlement of warrants	—	—	(112,365)	—	—	—	—	—
Partner company's exercise of options for cash	—	—	—	—	343	—	—	343
Deconsolidation of subsidiary non-controlling interests	—	—	—	—	—	—	(9,931)	(9,931)
Non-controlling interest in partner companies	—	—	—	—	(81,905)	—	81,905	—
Attributable to non-controlling interests	—	—	—	—	—	—	(38,270)	(38,270)
Net income attributable to Fortress	—	—	—	—	—	10,752	—	10,752
Balance as of September 30, 2025	**3,427,138**	**$ 3**	**31,005,170**	**$ 31**	**$ 785,943**	**$ (730,115)**	**$ 9,323**	**$ 65,185**

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, 2026	2025
Cash Flows from Operating Activities:		
Net income (loss)	$ 129,511	$ (27,518)
Reconciliation of net income (loss) to net cash provided by (used in) operating activities:		
Depreciation expense	285	311
Bad debt expense (recovery)	78	(170)
Amortization of debt discount	1,752	1,065
Gain on termination of partner company lease	—	(394)
Loss on extinguishment of debt	1,009	—
Amortization of acquired intangible assets	3,064	3,193
Settlement of partner company payables	(109)	(1,373)
Reduction in the carrying amount of operating lease right-of-use assets	1,274	1,467
Stock-based compensation expense	6,782	26,280
Change in fair value of investment	(11,791)	(15,075)
Change in fair value of partner company derivative liability	7,085	—
Change in fair value of partner companies' warrant liabilities	(1)	399
Issuance of subsidiary common shares for research and development expense	107	—
Gain from deconsolidation of subsidiary	(186)	(27,127)
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:		
Accounts receivable	(17,682)	(7,582)
Inventory	1,852	2,613
Other receivables - related party	104	29
Prepaid expenses and other current assets	2,258	4,099
Other assets	(890)	309
Accounts payable and accrued expenses	9,611	(10,649)
Income taxes payable	4,763	73
Lease liabilities	(1,425)	(1,674)
Other current and long-term liabilities	926	(1,509)
Net cash provided by (used in) operating activities	138,377	(53,233)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(86)	—
Proceeds from sale of property and equipment	—	1,165
Net cash increase upon deconsolidation of subsidiary	—	8,956
Net cash (used in) provided by investing activities	(86)	10,121
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock for at-the-market offering, net	—	1,008
Proceeds from issuance of common stock under ESPP	74	43
Exercise of warrants for cash	1,218	2,279
Proceeds from partner company's ESPP	223	217
Partner company’s dividends declared and paid	(23,199)	(498)
Exchange of partner company preferred shares	(165)	(265)
Redemption of partner company preferred shares	(14,170)	—
Proceeds from partner companies' equity offerings and warrant exercises, net	—	61,581
Proceeds from partner companies' at-the-market offering, net	(141)	13,631
Proceeds from exercise of partner company's options, net	275	—
Repayment of Oaktree Note and debt issuance costs	(29,601)	(5,636)
Repayment of partner company installment payments - licenses	—	(625)
Net cash provided by (used in) financing activities	(65,486)	71,735
Net increase in cash and cash equivalents and restricted cash	72,805	28,623
Cash and cash equivalents and restricted cash at beginning of period	80,601	58,815
Cash and cash equivalents and restricted cash at end of period	$ 153,406	$ 87,438
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 4,937	$ 5,678
Cash paid for income taxes	$ 164	$ 49

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 focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holdings and dividend and royalty income. Fortress works 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 arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center, Dana-Farber Cancer Institute, Nationwide Children's Hospital, Columbia University, the University of Pennsylvania, AstraZeneca plc, Dr. Reddy's Laboratories, Ltd., and Sun Pharmaceutical Industries Limited ("Sun Pharma").

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and financial expertise to help its subsidiaries and partner companies achieve their goals. Partner and subsidiary 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, three partner companies are publicly-traded, and four subsidiaries have consummated strategic partnerships with industry leaders, including AstraZeneca plc as successor-in-interest to Alexion Pharmaceuticals, Inc. ("AstraZeneca"), Sentynl Therapeutics, Inc. ("Sentynl"), Axsome Therapeutics, Inc. ("Axsome"), and Sun Pharma.

Our subsidiary and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates are: Journey Medical Corporation (Nasdaq: DERM, "Journey"), Mustang Bio, Inc. (Nasdaq: MBIO, "Mustang"), Avenue Therapeutics, Inc. (OTCID: ATXI, "Avenue"), Cellvation, Inc. ("Cellvation"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), LemmaTx, Inc. ("LemmaTx"), Oncogenuity, Inc. ("Oncogenuity"), Urica Therapeutics, Inc. ("Urica") and FBIO Acquisition Corp. LXII ("AcqCorpLXII"). Checkpoint Therapeutics, Inc. ("Checkpoint"), previously a partner company, was acquired by Sun Pharma in May 2025. Baergic Bio, Inc. ("Baergic"), previously a subsidiary of Avenue, was acquired by Axsome in November 2025.

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 an entity 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.

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

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. The Company has incurred losses from operations and negative cash flows from operating activities since inception and expects to continue to incur losses from operations for the next several years as it continues to develop and commercialize its existing and new product candidates. Current cash and cash equivalents as of September 30, 2026 of $114.1 million for Fortress and private subsidiaries primarily funded by Fortress ("Parent Entity") are considered sufficient to fund the Parent Entity's operations for at least 12 months following the date of filing of this Quarterly Report on Form 10-Q. However, the Company may need to raise additional funding through strategic relationships, public or private equity or debt financings, sale of 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 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 8 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, 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, 2026 (the "2025 Form 10-K"), from which the Company derived the balance sheet data at December 31, 2025, as well as Mustang's Form 10-K, filed with the SEC on March 19, 2026, Avenue's Form 10-K, filed with the SEC on March 30, 2026, and Journey's Form 10-K, filed with the SEC on March 26, 2026.

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 coupons, chargebacks, wholesaler fees, specialty pharmacy discounts, managed care rebates, product returns, inventory realization, valuation of intangible assets, useful lives assigned to long-lived assets and amortizable intangible assets, fair value of equity investments, stock options and warrants, stock-based compensation, common stock issued to acquire licenses, accrued expenses and contingencies. Due to the uncertainty inherent in such estimates, actual results may differ from these estimates.

Segment Reporting

The Company views its operations and manages its business in segments that align with the Company's public subsidiaries with Fortress being comprised of the parent entity and the private subsidiaries, including intersegment revenue consisting of various fees paid by the subsidiaries to Fortress that are eliminated in consolidation. Each public subsidiary is a biopharmaceutical company focused on acquiring, developing, and commercializing assets in different therapeutic and disease areas. The Company's chief operating decision maker ("CODM") is its chief executive officer.

The CODM reviews profit and loss information for each segment to assess the performance of the Company and each of its public subsidiaries. The accounting policies of the segments are the same as those described in this Note 2. See Note 16 for segment information.

Investment in Equity Securities

The Company invests in certain entities over which it holds significant influence but not control. Generally, such investments would be accounted for using the equity method of accounting. However, for those investments for which the Company has elected the fair value option, the Company measures such investments at fair value on the condensed consolidated balance sheet with subsequent changes in fair value recognized in other (income) expense, net on the Company's condensed consolidated statement of operations. The Company elected the fair value option for certain investments that would otherwise have been accounted for using the equity method because the Company believes that fair value measurement provides more relevant information for users of its financial statements and is consistent with the Company's investment strategy.

Restricted Cash

The Company records cash held in trust or pledged to secure certain debt obligations as restricted cash. As of September 30, 2026 and December 31, 2025, the Company had $1.2 million of restricted cash representing pledges to secure letters of credit in connection with certain office leases.

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 as of the dates presented:

	September 30,	
($ in thousands)	**2026**	**2025**
Cash and cash equivalents	$ 152,186	$ 86,218
Restricted cash	1,220	1,220
Total cash and cash equivalents and restricted cash	$ 153,406	$ 87,438

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

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2025 Form 10-K, other than the following:

Contingent Consideration

The Company accounts for rights to contingent consideration received in connection with the disposal of a business as contingencies that are not recognized before realization. Sales-based contingent consideration is recognized when the underlying qualifying sales have occurred, the Company has an enforceable right to payment, and the amount is realized or realizable and determinable. Amounts recognized are presented as other income because they represent additional consideration from the disposal.

Recently Issued Accounting Pronouncements

As of September 30, 2026, there were no new accounting pronouncements or updates to recently issued accounting pronouncements disclosed in the 2025 Form 10-K that affect the Company's present or future results of operations, overall financial condition, liquidity, or disclosures upon adoption.

3. Asset Purchase and Merger Agreements

Cyprium Agreement with Sentynl

Cyprium is party to a development and asset purchase agreement with Sentynl, pursuant to which Sentynl assumed control of the development and commercialization of CUTX-101 (now marketed as ZYCUBO) in December 2023. In connection with such assumption by Sentynl, Cyprium received a $4.5 million payment and was no longer responsible for development activities. Cyprium is eligible to receive up to $128 million in aggregate sales-based milestone payments, as well as tiered royalties on net sales ranging from 3% to 12.5%.

Royalty revenue is recognized as the underlying sales occur in accordance with the sales- or usage-based royalty exception under ASC 606. For the three and nine months ended September 30, 2026, Cyprium recognized $0.2 million and $0.5 million, respectively, in royalty revenue related to net sales of ZYCUBO.

In January 2026, the U.S. Food and Drug Administration ("FDA") approved ZYCUBO for the treatment of Menkes disease in pediatric patients. In connection with the approval, a Rare Pediatric Disease priority review voucher ("PRV") was issued and transferred to Cyprium.

In February 2026, Cyprium entered into an asset purchase agreement to sell the PRV (the "PRV APA") for gross proceeds of $205 million. The transaction closed on March 30, 2026. In connection with the closing of the PRV sale, Cyprium was obligated to remit 20% of the gross proceeds, or $41 million, to the Eunice Kennedy Shriver National Institute of Child Health and Human Development ("NIH") and 2.5% of gross proceeds, or $5.1 million, to a third-party pursuant to an agreement. In addition, Cyprium is obligated to pay the third-party 4.0% of all royalty and milestone payments received in excess of an aggregate of $25.0 million, inclusive of certain specified prior payments.

In connection with the closing of the PRV sale, Cyprium's preferred stock was automatically redeemed in accordance with its terms (see Note 15).

In July 2026, the board of directors of Cyprium declared a cash dividend of approximately $118.6 million to its shareholders. Based on the Company's ownership interest in Cyprium, approximately $95.4 million of the dividend was paid to Fortress with the remaining amount paid to noncontrolling shareholders of Cyprium.

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

Checkpoint Transaction

In March 2025, the Company's then-subsidiary Checkpoint entered into a merger agreement with Sun Pharma. The merger transaction under such agreement closed on May 30, 2025, resulting in the deconsolidation of Checkpoint. The Company received total cash proceeds of $28.0 million and recognized a gain on deconsolidation of $27.1 million after derecognizing Checkpoint's net liabilities and noncontrolling interests. The Company determined that the transaction did not represent a strategic shift and therefore was not accounted for as a discontinued operation.

Pursuant to the merger, former Checkpoint shareholders received $4.10 in cash and one non-tradable contingent value right ("CVR") per share. The CVRs entitle holders to contingent cash payments of up to $0.70 upon the achievement of specified regulatory milestones related to the approval of Checkpoint's UNLOXCYT (cosibelimab-ipdl) product in certain European markets within defined time periods.

The Company accounted for the CVR as variable consideration that is constrained until the underlying milestones are achieved. As of September 30, 2026, no milestones have been met and no amounts have been recognized.

In connection with the transaction, Fortress is entitled to receive royalties equal to 2.5% of worldwide net sales of certain products under a royalty agreement with Sun Pharma, and during the three and nine months ended September 30, 2026, the Company recognized approximately $0.1 million and $0.2 million, respectively, of contingent consideration income based on net sales occurring during those periods. Such amounts are presented within the gain from deconsolidation of subsidiary in the condensed consolidated statement of operations.

The Company also entered into a transition services agreement with Checkpoint, which ended in September 2025.

Urica Agreement with Crystalys Therapeutics, Inc. ("Crystalys")

In July 2024, Urica entered into an asset purchase agreement and related agreements with Crystalys, pursuant to which Urica sold the rights to its dotinurad program and related intellectual property. In consideration, Urica received equity representing approximately 35% of Crystalys' outstanding shares, subject to anti-dilution protections, with a minimum ownership of 15% until certain financing thresholds are met. The investment is accounted for under the equity method, for which the Company elected the fair value option. Anti-dilution shares valued at $3.2 million were received in the nine months ended September 30, 2026 and the anti-dilution right was extinguished. Urica also recognized an unrealized gain of $8.6 million due to an increase in the fair value of Urica's investment based on pricing established in Crystalys' arm's-length equity financing completed in July 2026 (see Note 6). At September 30, 2026, Urica held approximately 9% of Crystalys' fully diluted equity.

The Company has the right to appoint a director to Crystalys' board of directors. Urica is also entitled to a 3% secured royalty on future net sales of dotinurad; such royalties are considered variable consideration and are constrained, and no revenue has been recognized.

The agreements included a repurchase option allowing Urica to reacquire the assets for up to $6.4 million plus accrued interest. Prior to the expiration of this repurchase option, amounts received were recorded as a liability and accreted to the repurchase price, with accretion recognized as interest expense. For the three and nine months ended September 30, 2025, accretion of $0.7 million and $1.3 million was included in interest expense and financing fees in the condensed consolidated statement of operations. In September 2025, upon the closing of Crystalys' Series A financing, the repurchase option expired and the Company reversed the related $2.6 million liability, recognizing the amount as other income for the year ended December 31, 2025.

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

Avenue

Under a share repurchase agreement between Avenue and InvaGen Pharmaceuticals, Inc. ("InvaGen") under which Avenue repurchased all of InvaGen's shares in Avenue, 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 net proceeds of future financings, up to $4.0 million, which Avenue accounts for as a derivative. Due to the uncertainty related to future financings, the estimated fair value of the derivative is not material. Avenue recognizes changes in fair value within general and administrative expenses in the unaudited consolidated statement of operations. In connection with equity financings, in the three and nine months ended September 30, 2025, Avenue made payments totaling nil and $0.2 million, respectively, to InvaGen. No such payments were owed or made for the comparable periods in 2026. Approximately $1.4 million in aggregate has been paid by Avenue to InvaGen under the share repurchase agreement through September 30, 2026.

4. Inventory

($ in thousands)	September 30, 2026	December 31, 2025
Finished goods	$ 5,966	$ 7,389
Work-in-process	540	174
Raw materials	2,307	3,057
Inventory at cost	8,813	10,620
Inventory reserve	(1,041)	(996)
Total inventory	$ 7,772	$ 9,624

5. Property and Equipment

($ in thousands)	Useful Life (Years)	September 30, 2026	December 31, 2025
Computer equipment	3	$ 595	$ 595
Furniture and fixtures	5	437	1,017
Leasehold improvements	3 - 15	5,512	5,470
Buildings	40	581	581
Total property and equipment		7,125	7,663
Impairment - Leasehold Improvements		(2,176)	(2,176)
Less: Accumulated depreciation		(2,629)	(2,968)
Property and equipment, net		$ 2,320	$ 2,519

Fortress' depreciation expense for the three months ended September 30, 2026 and 2025 was approximately $0.1 million and $0.1 million, respectively. Fortress' depreciation expense for the nine months ended September 30, 2026 and 2025 was approximately $0.3 million and $0.3 million, respectively.

Fortress' depreciation expense is recorded in both research and development expense and selling, general and administrative expense in the condensed consolidated statement of operations.

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

6. Fair Value Measurements

Urica's Equity Investment in Crystalys

Urica values its equity investment in Crystalys using an option pricing model backsolve method and level 3 inputs. During the three and nine months ended September 30, 2026, the Company recognized nil and $11.8 million, respectively, of other income in the unaudited condensed consolidated statement of operations related to additional shares received pursuant to the anti-dilution provisions and changes in the estimated fair value of the investment due to Crystalys' Series B financing. The following inputs were utilized to derive the value: risk free rate of return: 4.24%; volatility: 80%; and a discount for lack of marketability: 30.3%. There are significant judgments and estimates inherent in the determination of the fair value, such as those regarding the selection of comparable companies used in estimating volatility, and the probability of possible future events. Such estimates involve inherent uncertainties and the application of significant judgment. Changes in judgments could have a material impact on our results of operations.

At September 30, 2026, the total fair value of Urica's investment in Crystalys was approximately $26.9 million, which also represents the cumulative unrealized gain since acquisition of the investment.

Fair Value of Aevitas

The Company valued its retained investment in Aevitas, which is accounted for as an equity method investment for which the Company elected the fair value option, and estimated the fair value using level 3 inputs to be $2.6 million. The Company has not recognized any gains, losses, or impairments on the investment in 2026, 2025, or on a cumulative basis.

Common Stock Warrant Liabilities

($ in thousands)	Warrant liabilities
Balance at December 31, 2024	$ 214
Change in fair value of common stock warrants - Avenue	(15)
Change in fair value of common stock warrants - Checkpoint	108
Deconsolidation of Checkpoint	(306)
Balance at December 31, 2025	1
Change in fair value of common stock warrants - Avenue	(1)
Balance at September 30, 2026	$ —

Avenue

Avenue has previously issued freestanding warrants to purchase shares of its common stock in connection with financing activities. Avenue's outstanding warrants to purchase common stock were originally issued in October 2022 (the "October 2022 Warrants"). The October 2022 Warrants are classified as liabilities on the balance sheet as they contain terms for redemption of the underlying security that are outside the Company's control. The Black-Scholes Model is used to value the warrants classified as liabilities and the approach required Avenue to estimate inputs including expected volatility and expected term and is most significantly impacted by the volatility of the Avenue's common stock price. These inputs are inherently subjective and require significant analysis and judgment to develop.

The fair value of the October 2022 Warrants was measured at the time of issuance and is re-measured at each financial reporting date with any changes in fair value being recognized in change in fair value of warrant liabilities, a component of other income (expense), in the consolidated statements of operations and comprehensive income (loss). Avenue will continue to re-measure the fair value of the October 2022 Warrant liabilities until exercise or expiration of the warrants on October 10, 2027.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the Avenue warrant liability that are categorized within Level 3 of the fair value hierarchy was as follows:

	September 30, 2026	December 31, 2025
Stock price	$ 0.27	$ 0.68
Risk-free interest rate	4.02 %	3.75 %
Expected dividend yield	—	—
Expected term in years	1.0	1.8
Expected volatility	242 %	151 %

Partner Company Derivative Liability

The partner company derivative liability associated with Cyprium's 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock ("Cyprium PPS") increased in fair value by $7.1 million during the three months ended March 31, 2026. The increase in fair value was due to the settlement of the derivative in connection with the redemption of the Cyprium PPS (Level 1) and the liability was extinguished in connection with the redemption of the Cyprium PPS (see Note 15) during the three months ended March 31, 2026.

As of September 30, 2026, no transfers occurred between Level 1, Level 2, and Level 3 instruments.

7. Intangible Assets, net

The Company's finite-lived intangible assets consist of intangible assets acquired by Journey. The table below provides a summary of the Journey intangible assets for the periods presented:

($ in thousands)	Estimated Useful Lives (Years)	September 30, 2026	December 31, 2025
Intangible assets – product licenses	3 to 15	$ 52,925	$ 52,925
Accumulated amortization		(25,241)	(22,177)
Accumulated Impairment loss		(3,143)	(3,143)
Net intangible assets		$ 24,541	$ 27,605

For the three months ended September 30, 2026 and 2025, Journey's amortization expense related to its product licenses was $1.0 million and $1.1 million, respectively, and for the nine months ended September 30, 2026 and 2025, Journey's amortization expense related to its product licenses was $3.1 million and $3.2 million, respectively.

In December 2025, Journey received FDA approval for Eurax, an anti-itch product acquired in 2020. Prior to FDA approval, the anti-itch product had been presented as an intangible asset not yet placed in service totaling $3.9 million. Journey began amortizing Eurax in January 2026.

The future amortization of intangible assets is as follows:

For the years ended: *($ in thousands)*	Total Amortization
Remainder of 2026	$ 969
2027	3,338
2028	3,159
2029	3,159
2030	3,159
Thereafter	10,757
Total	$ 24,541

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

8. License Agreements

AcqCorpLXII

License for FB-607

In September 2026, AcqCorpLXII entered into a license agreement with Cedars-Sinai Medical Center ("CSMC") and other named parties, pursuant to which AcqCorpLXII obtained an exclusive worldwide license (the "CSMC License") to rifaximin combined with N-acetylcysteine, referred to as FB-607 or RNIB21, for the prevention, treatment, diagnosis, detection and monitoring of diseases and conditions in humans and animals, including irritable bowel syndrome with diarrhea. Upfront consideration consisted of $0.2 million in cash, 2,750,000 shares of the common stock of AcqCorpLXII valued at approximately $0.1 million, and 237,733 shares of Fortress common stock valued at $0.5 million. Subsequent to the transaction, Fortress remains the majority owner and controlling shareholder of AcqCorpLXII. The transaction was accounted for as an asset acquisition, and acquisition costs of $1.0 million, including transaction costs, were expensed as research and development during the three and nine months ended September 30, 2026.

The CSMC License provides for development and regulatory milestones of up to $25.0 million, commercial milestones of up to $35.0 million, royalties of low-to-mid single digits, and tiered sublicensing revenue payments, in each case to be paid by AcqCorpLXII to CSMC. AcqCorpLXII is also obligated to reimburse historical patent costs following equity financings exceeding $10.0 million in aggregate gross proceeds; such costs totaled approximately $0.5 million as of the license date. Separate commitments, subject to specified conditions, include future clinical study funding of up to $1.0 million.

As of September 30, 2026, no milestones had been achieved, no royalties or sublicense payments were payable, and the patent-cost reimbursement financing condition had not been satisfied.

Avenue

License for clenbuterol ("ATX-04")

In February 2026, Avenue entered into a license agreement with Duke University ("Duke"), pursuant to which Avenue obtained an exclusive worldwide license (the "ATX-04 License") from Duke to certain patents and know-how pertaining to ATX-04, a selective β2-adrenergic agonist for Pompe disease, for the treatment of lysosomal storage diseases.

Under the ATX-04 License, Avenue made an upfront payment to Duke and has an obligation to make development, regulatory, and commercial milestone payments upon the achievement of certain milestones. In addition, Avenue is obligated to pay a tiered low single-digit royalty on future net sales of ATX-04.

Beginning with calendar year 2028 and until first regulatory approval, Avenue is obligated to make minimum annual royalty payments. In the event the ATX-04 License is terminated, minimum royalty obligations will cease, and Avenue will only be responsible for amounts due up to the termination date.

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 the Company require substantial completion of research and development, regulatory and marketing approval efforts in order to reach technological feasibility and have no alternate use. For the nine months ended September 30, 2026, there was a nominal amount of expense recognized by Avenue for the ATX-04 License.

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AnnJi Pharmaceutical Co. Ltd. ("AnnJi") License Termination

In April 2025, Avenue and AnnJi entered into a License Termination and Program Transfer Agreement, pursuant to which the prior license agreement for AJ201 was terminated, the parties dismissed all pending dispute resolution proceedings and provided mutual releases of claims, and Avenue transferred all rights to the program back to AnnJi. Avenue also agreed to a 48-month non-compete in specified territories.

In connection with the termination, Avenue repurchased shares previously issued to AnnJi for nominal consideration and paid $0.2 million for legal expense reimbursement, which was accounted for as consideration payable to a customer and reduced revenue recognized.

AnnJi paid Avenue $1.6 million (net of withholding taxes) for the transfer of the underlying rights under the License Termination and Program Transfer Agreement. Avenue recognized $1.4 million as other revenue in the nine months ended September 30, 2025, representing the consideration for the transfer of rights less the consideration for legal expenses.

Avenue is also eligible to receive (i) up to $5.0 million in development and regulatory milestones, (ii) up to $17.0 million in commercial milestones, (iii) royalties of 1.75% on net sales of AJ201, subject to reduction in certain circumstances, and (iv) a share of sublicensing income, subject to specified caps and minimums. These amounts represent variable consideration and are constrained until the achievement of the specified milestones.

Journey

Journey holds global rights to Emrosi (Minocycline Hydrochloride Modified Release Capsules, 40 mg) pursuant to a license agreement with Dr. Reddy's Laboratories, Ltd., under which Journey has made upfront and milestone payments, including $15.0 million upon FDA approval in November 2024, at which time the licensed assets were assigned to Journey. Journey may be required to make additional regulatory and commercial milestone payments of up to $150.0 million and pays royalties ranging from 10% to 14% on net sales, subject to reduction in certain circumstances.

In 2022, Journey acquired Amzeeq and Zilxi from Vyne Therapeutics, Inc., including contingent sales-based milestone payments of up to $450.0 million. As part of the transaction, Journey assumed a license agreement with Cutia Therapeutics (HK) Limited ("Cutia"), under which Cutia has rights to commercialize the products in Greater China and Journey supplies finished product and earns low single-digit royalties on net sales.

In August 2025, Journey commenced commercial supply of product to Cutia and recognized approximately $42,000 and $0.8 million, and $0.6 million and $0.6 million, respectively, of other revenue for the three and nine months ended September 30, 2026 and 2025 related to product sales.

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

9. Debt and Interest

Debt

Total debt consists of the following:

	September 30, 2026	December 31, 2025		
($ in thousands)	Journey SWK Term Loan	Fortress 2024 Oaktree Note	Journey SWK Term Loan	Total Notes Payable
Notes payable, short-term	$ 7,500	$ —	$ —	$ —
Notes payable, long-term	17,500	29,494	25,000	54,494
Total notes payable	25,000	29,494	25,000	54,494
Plus: yield protection premium/exit fee	1,250	295	1,250	1,545
Less: Debt discount	(673)	(2,649)	(973)	(3,622)
Total notes payable, net	$ 25,577	$ 27,140	$ 25,277	$ 52,417

As of September 30, 2026, the carrying value of the notes payable approximates their fair value as the interest rates are variable and approximate the market rates for loans with similar terms and risk characteristics.

2024 Oaktree Note

On September 30, 2026, the $50.0 million senior secured credit agreement (the "2024 Oaktree Agreement"), as amended (the "New Oaktree Agreement"), was terminated upon the receipt by Oaktree Fund Administration, LLC ("Oaktree") of a payoff amount of $15.6 million from the Company comprising principal, interest and yield protection premium. A loss on extinguishment of $1.0 million was recorded to interest expense and financing fees on the unaudited condensed consolidated statement of operations for the three and nine months ended September 30, 2026.

The Company had originally entered into the New Oaktree Agreement in July 2024. The Company had borrowed $35.0 million at closing and could have drawn up to an additional $15.0 million, subject to lender approval. The loans bore interest at a rate equal to the three-month SOFR plus 7.625% (subject to a 2.50% floor and 5.75% cap), had an interest-only period through maturity, and were set to mature on June 30, 2028. At September 30, 2026, prior to pay-off, the interest rate applicable to the 2024 Oaktree Note was 11.35722%. The Company was required to make quarterly interest-only payments until the maturity date, except 12.5% of the then-outstanding principal balance of the loans was due on September 30, 2027, 12.5% of the principal balance of the loans was due on December 31, 2027, 37.5% of the principal balance of the loans was due on March 31, 2028, and the remaining principal amount was due on the maturity date.

The New Oaktree Agreement contained customary affirmative and negative covenants and financial covenants, including minimum liquidity, minimum net sales, capital raise requirements, and minimum ownership thresholds, each subject to specified thresholds and conditions. The Company's obligations were secured by substantially all of its assets.

In February 2026, the Company had entered into the Second Amendment to the New Oaktree Agreement, which modified certain financial covenants. Upon the occurrence of a Cyprium monetization event related to the sale of the PRV and if the outstanding principal balance was less than or equal to $15.0 million, the minimum liquidity requirement was reduced to $2.0 million and the minimum net sales, capital raise, and minimum ownership of Journey covenants were eliminated. The minimum liquidity requirement was no longer applicable if the outstanding principal balance was less than or equal to $10.0 million.

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The Second Amendment also required the Company to apply proceeds from a Cyprium monetization event to repay amounts advanced to Cyprium and to make a mandatory prepayment of $10.0 million, plus accrued interest and applicable fees, under the New Oaktree Agreement.

In March 2026, the Company made aggregate prepayments on the loan, including the required monetization-related prepayment, reducing the outstanding principal balance to $15.0 million. As a result, the minimum liquidity requirement was reduced to $2.0 million, and the minimum net sales, capital raise, and minimum stake in Journey covenants were no longer applicable.

The Company was in compliance with all applicable financial covenants under the New Oaktree Agreement prior to its payoff on September 30, 2026.

SWK Term Loan

In December 2023, Journey entered into a Credit Agreement (the "Credit Agreement") with SWK Funding LLC ("SWK"). The Credit Agreement provides for a term loan facility (the "Credit Facility") in the original principal amount of up to $20.0 million. On the closing date of the facility, Journey drew $15.0 million. In June 2024, Journey drew the remaining $5.0 million under the Credit Facility. In July 2024, Journey entered into an amendment (the "First Amendment") to the Credit Agreement with SWK. The First Amendment increased the original principal amount of the Credit Facility from $20.0 million to $25.0 million. The $5.0 million of additional principal added in the First Amendment was contractually required to be drawn upon FDA approval of Emrosi, subject to Journey receiving approval on or before June 30, 2025. Journey received FDA approval for Emrosi in November 2024 and drew on the remaining $5.0 million.

Term loans under the Credit Facility ("SWK Term Loans") accrue interest, which is payable quarterly in arrears, and bear interest at a rate per annum equal to the three-month term SOFR (subject to a SOFR floor of 5%) plus 7.75%. The interest rate resets quarterly. The effective interest rate on the SWK Term Loans as of September 30, 2026 was 14.09%.

In September 2025, Journey entered into the Third Amendment to the Credit Agreement (the "Third Amendment"). The Third Amendment, among other things, extends the maturity date of Journey's existing Credit Facility from December 27, 2027 to June 27, 2028. The Third Amendment also modifies the Revenue-Based Payment provision, as defined in the Credit Agreement, by lowering the applicable revenue threshold, measured based on the twelve months ended December 31, 2025, from $70.0 million to $60.0 million. Journey satisfied the $60.0 million Revenue-Based Payment provision as of December 31, 2025. Accordingly, the interest-only period under the Credit Facility was extended by one year, with scheduled principal repayments commencing in February 2027 rather than February 2026. Thereafter, Journey will make quarterly principal payments equal to $2.5 million per quarter, or 10.0%, of the outstanding principal amount of the funded SWK Term Loans, with any remaining principal balance due on the maturity date.

Journey may at any time prepay the outstanding principal balance of the SWK Term Loans in whole or in part. Upon repayment in full of the SWK Term Loans, Journey will pay an exit fee equal to 5% of the original principal amount of the SWK Term Loans. Additionally, Journey paid an origination fee of $0.2 million on the closing date of the Credit Facility and incurred issuance costs of $0.2 million, both of which have been recorded as a debt discount. Journey is accreting the carrying value of the SWK Term Loans to the original principal balance plus the exit fee over the term of the loan using the effective interest method. The amortization of the discount is accounted for as interest expense.

The Credit Facility also includes both revenue and liquidity covenants, restrictions as to payment of dividends, and is secured by substantially all assets of Journey. As of September 30, 2026, Journey was in compliance with the financial covenants under the Credit Facility.

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Interest Expense

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. The following table shows the components of interest expense for all debt arrangements during the periods presented:

	Three Months Ended September 30,					
	2026			2025		
($ in thousands)	*Interest*	*Fees*	Total	*Interest*	*Fees*	Total
2024 Oaktree note[1]	$ 436	$ 1,126	$ 1,562	$ 904	$ 204	$ 1,108
Partner company notes payable	814	105	919	814	123	937
Partner company contingent call option accretion[2]	—	—	—	677	—	677
Other	17	—	17	20	—	20
Total interest expense and financing fee	$ 1,267	$ 1,231	$ 2,498	$ 2,415	$ 327	$ 2,742

Note 1: Includes loss on extinguishment of $1.0 million related to the payoff of the 2024 Oaktree note on September 30, 2026.
Note 2: Relates to Urica's optional repurchase obligation to Crystalys (see Note 3), which expired in 2025.

	Nine Months Ended September 30,					
	2026			2025		
($ in thousands)	*Interest*	*Fees*	Total	*Interest*	*Fees*	Total
2024 Oaktree note[1]	$ 1,698	$ 2,756	$ 4,454	$ 3,280	$ 717	$ 3,997
Partner company notes payable	2,417	300	2,717	2,417	348	2,765
Partner company contingent call option accretion[2]	—	—	—	1,283	—	1,283
Other	171	—	171	20	—	20
Total interest expense and financing fee	$ 4,286	$ 3,056	$ 7,342	$ 7,000	$ 1,065	$ 8,065

Note 1: Includes loss on extinguishment of $1.0 million related to the payoff of the 2024 Oaktree note on September 30, 2026.
Note 2: Relates to Urica's optional repurchase obligation to Crystalys (see Note 3), which expired in 2025.

10. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

($ in thousands)	September 30, 2026	December 31, 2025
Accounts payable	$ 12,909	$ 14,238
Accrued expenses:		
Professional fees	1,907	1,055
Salaries, bonus and related benefits	5,956	7,880
Research and development	1,134	277
Accrued partner company royalties payable	2,210	1,805
Accrued partner company coupons and rebates	24,510	16,547
Partner company return reserve	3,329	2,177
Other[1]	4,673	3,146
Total accounts payable and accrued expenses	$ 56,628	$ 47,125

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Note 1: Includes approximately $1.4 million of accrued consideration for Mustang, including approximately $0.1 million of accrued interest, related to Mustang's obligation to repurchase assets from uBriGene (Boston) Biosciences, Inc. ("uBriGene") in 2024. The asset repurchase consisted of purchase consideration of an upfront payment of $0.1 million, and a deferred amount of approximately $1.3 million due twelve months after closing; however, Mustang can elect to delay its payment obligation for the deferred amount for additional six-month periods, upon written notice to uBriGene, if Mustang's net assets are below $20 million. Beginning in June 2025, the deferred amount began accruing interest at a rate of 5% per annum. In September 2026, Mustang's net assets were below $20 million, and it elected to delay the payment.

11. Non-Controlling Interests

The Company's ownership interests in its consolidated subsidiaries at September 30, 2026 were similar to December 31, 2025, with the exception of increases at the public subsidiaries that pay an annual Payment-in-Kind ("PIK") dividend to Fortress (see Note 15): Avenue increased 3.1%, and Mustang increased 4.0%. Cyprium increased 6.5% due to the conversion of a portion of the intercompany note payable balance into equity during the nine months ended September 30, 2026 (see Note 15). The Company's ownership interest in AcqCorpLXII decreased to 70.6% due to the equity issuance related to the CSMC License in the three months ended September 30, 2026 (see Note 8).

12. Net Income (Loss) per Common Share

Basic net income or loss per share attributed to common stockholders is calculated by dividing the net income or loss attributed to Fortress, less the Series A Preferred dividends and subsidiary deemed dividends, by the weighted-average number of shares of Common Stock outstanding during the period, not including unvested restricted stock and other potentially dilutive securities. Diluted net income (loss) per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as warrants, stock options, restricted stock units, and restricted stock using the treasury stock method, if dilutive. The impact of these items is anti-dilutive during periods of net loss.

For the three months ended September 30, 2026 and 2025, the effect on the net income (loss) per share calculation from Series A Preferred dividends (cumulated but undeclared) (see Note 13) was $2.0 million and $2.0 million, respectively, and partner company preferred and deemed dividends were nil and $0.2 million, respectively. For the nine months ended September 30, 2026 and 2025, the effect on the net income (loss) per share calculation from Series A Preferred dividends (cumulated but undeclared) (see Note 13) was $6.0 million and $6.0 million, respectively, and partner company preferred and deemed dividends were nil and $0.4 million, respectively.

The following potentially dilutive securities were excluded from the computation of net income (loss) per common share for the periods presented because their effect would have been anti-dilutive:

	September 30,	
	2026	2025
Warrants to purchase Common Stock	5,822,037	13,050,619
Options to purchase Common Stock	—	18,896
Unvested Restricted Stock and deferred Restricted Stock	239,459	2,368,386
Unvested Restricted Stock units and deferred Restricted Stock units	1,253,417	2,748,772
Total	7,314,913	18,186,673

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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The computation of basic and diluted net income (loss) per common share is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands, except share and per share amounts)	2026	2025	2026	2025
Net income (loss) attributable to common stockholders	$ (7,853)	$ 3,675	$ 98,036	$ 4,316
Weighted average common shares outstanding - basic	33,746,832	27,244,474	33,394,537	27,075,216
Dilutive effect of potential common shares	—	5,856,487	5,602,976	3,620,780
Weighted average common shares outstanding - diluted	33,746,832	33,100,961	38,997,513	30,695,996
Net income (loss) per common share attributable to common stockholders - basic	$ (0.23)	$ 0.13	$ 2.94	$ 0.16
Net income (loss) per common share attributable to common stockholders - diluted	$ (0.23)	$ 0.11	$ 2.51	$ 0.14

13. Stockholders' Equity

9.375% Series A Cumulative Redeemable Perpetual Preferred Stock Dividends

In July 2024, Fortress announced that the Company's Board of Directors had paused the monthly dividend of $0.1953125 per share of the Company's 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (the "Series A Preferred Stock"). In accordance with the terms of the Series A Preferred Stock, dividends on the Series A Preferred Stock will continue to accrue and cumulate until such dividends are authorized or declared. The Board intends to revisit its decision regarding the monthly dividend regularly and will assess the profitability and cash flow of the Company to determine whether and when the pause should be lifted.

During the nine months ended September 30, 2026, no dividends were declared by the Board of Directors. Dividends in arrears that have not been declared by the Board of Directors are not recorded in the condensed consolidated balance sheets but are reflected in the net income (loss) attributable to common stockholders (see Note 12). As of September 30, 2026, the Company has total undeclared dividends of approximately $18.1 million, including the cumulated (but undeclared) dividends due to Series A Preferred shareholders for the three months ended September 30, 2026 and 2025 of $2.0 million and $2.0 million, respectively, and for the nine months ended September 30, 2026 and 2025 of $6.0 million and $6.0 million, respectively.

Stock-based Compensation

As of September 30, 2026, the Company had the following equity compensation plans: 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"). As of September 30, 2026, approximately 7.0 million shares are available for issuance under the 2013 Plan, and approximately 0.9 million shares are available for issuance under the ESPP.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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The following table summarizes the stock-based compensation expense from employee stock purchase programs and restricted Common Stock awards and warrants for the periods presented:

($ in thousands)	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Fortress:				
Employee and non-employee awards	$ 665	$ 990	$ 2,432	$ 6,514
Executive awards	102	167	369	527
Partner Companies:				
Avenue	47	163	169	523
Checkpoint	—	—	—	14,097
Mustang	2	23	45	106
Journey	1,333	1,854	3,759	4,513
Other	—	—	8	—
Total stock-based compensation expense	$ 2,149	$ 3,197	$ 6,782	$ 26,280

($ in thousands)	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Research and development	$ 31	$ 152	$ 89	$ 6,245
Selling, general and administrative	2,118	3,045	6,693	20,035
Total stock-based compensation expense	$ 2,149	$ 3,197	$ 6,782	$ 26,280

Included in stock-based compensation expense for the nine months ended September 30, 2026 is a modification charge of approximately $0.6 million recognized in connection with the modification of certain outstanding equity awards to permit continued vesting.

Restricted Stock and Restricted Stock Units

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

	Number of shares	Weighted average grant price
Unvested balance at December 31, 2025	3,841,748	$ 3.62
Restricted stock granted	1,087,458	3.22
Restricted stock vested	(65,162)	17.27
Restricted stock vested - settlement deferred[1]	(236,611)	22.94
Restricted stock units granted	470,000	3.16
Restricted stock units forfeited	(150,000)	1.72
Restricted stock units vested	(399,221)	16.03
Restricted stock units vested - settlement deferred[1]	(752,874)	3.28
Unvested balance at September 30, 2026	3,795,338	$ 5.84

Note 1: The Company offers certain executives and employees the opportunity to defer settlement of vested restricted stock and vested restricted stock units as part of our deferred compensation plan.

As of September 30, 2026 and 2025, the Company had unrecognized stock-based compensation expense related to restricted stock and restricted stock unit awards of approximately $8.0 million and $5.7 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 4.8 years and 2.9 years, respectively.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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Amended and Restated Long-Term Incentive Program

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 and May 23, 2024). 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.

During the nine months ended September 30, 2026 and 2025, the Compensation Committee granted 475,424 shares and 454,163 shares, respectively, to each of Dr. Rosenwald and Mr. Weiss under the Company's LTIP. Each grant represented approximately 1% of the Company's total outstanding shares as of the respective grant dates.

The restricted shares vest upon the earlier of: (i) (A) the Company achieving a specified increase in market capitalization from the grant date and (B) the participant's continued service through, or involuntary termination prior to, July 16, 2035 (for the 2026 grant) or July 16, 2025 (for the 2025 grant); or (ii) a change in control of the Company, provided the participant remains in service through the date of such transaction.

Unvested shares are subject to repurchase by the Company at a nominal price for a period of 90 days following the earlier of (i) the applicable service date described above or (ii) the participant's voluntary termination of service.

The grant date fair value of these awards was approximately $1.5 million for the 2026 grants and $0.9 million for the 2025 grants. For the three months ended September 30, 2026 and 2025, the Company recognized stock-based compensation expense related to LTIP grants of approximately $0.1 million and $0.5 million, respectively, and for the nine months ended September 30, 2026 and 2025, the Company recognized stock-based compensation of $0.2 million and $5.4 million, respectively, in its unaudited condensed consolidated statements of operations.

Warrants

The following table summarizes Fortress warrant activities, excluding activities related to Fortress subsidiaries and partner companies:

	Number of shares	Weighted average exercise price	Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Outstanding as of December 31, 2025	13,431,502	$ 2.21	$ —	3.55
Exercised	(694,296)	1.74	—	—
Outstanding as of September 30, 2026	12,737,206	$ 2.24	$ 6,256,169	2.80
Exercisable as of September 30, 2026	12,737,206	$ 2.24	$ 6,256,169	2.80

During the nine months ended September 30, 2026, 694,296 warrants were exercised for gross proceeds of $1.2 million. As of September 30, 2026, Fortress had no unrecognized stock-based compensation expense related to warrants.

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Capital Raises

2024 Shelf

On May 17, 2024, the Company filed a shelf registration statement (File No. 333-279516) on Form S-3, which was declared effective on May 30, 2024 (the "2024 Shelf"). As of September 30, 2026, $42.1 million of securities were available for sale under the 2024 Shelf, subject to General Instruction I.B.6. of Form S-3, known as the "baby shelf rules," which limit the value of the securities that can be sold under registration statements on Form S-3. However, on July 5, 2024, the board of directors paused the payment of dividends on our Series A Preferred Stock until further notice. As a result, the Company is not currently eligible to use Form S-3 and has lost the ability to use the 2024 Shelf. The Company will regain eligibility to use the 2024 Shelf on the date it files its next Annual Report on Form 10-K, so long as it has: (i) by that date, paid all accrued but unpaid dividends at that time and (ii) timely paid all dividends accruing since the end of the fiscal year to which such Form 10-K relates.

Because the Company is not currently eligible to use Form S-3 due to the failure to pay dividends on the Series A Preferred Stock, on April 1, 2025 the Company filed a post-effective amendment to certain prior Form S-3 registration statements to continue the registration of certain previously issued warrants. This post-effective amendment was declared effective by the SEC on April 2, 2025.

At the Market Offering

During the nine months ended September 30, 2026, the Company did not issue any shares under the Company's at-the-market offering program. During the nine months ended September 30, 2025, the Company issued and sold approximately 0.5 million shares at an average price of $1.94 for gross proceeds of $1.0 million under the Company's at-the-market offering program. The at-the-market offering program is currently suspended as a result of the Company's current ineligibility to use Form S-3 registration statements.

Checkpoint 2025 Warrant Exercises

In January 2025, Checkpoint received approximately $2.1 million from the exercise of warrants for the issuance of 740,000 shares of common stock with an exercise price of $2.84 per share.

In March 2025, Checkpoint received approximately $36.0 million from the exercise of warrants for the issuance of 21,691,003 shares of common stock with an average exercise price of $1.66 per share.

In April 2025, Checkpoint received approximately $9.2 million from the exercise of warrants for the issuance of 3,256,269 shares of common stock with an average exercise price of $2.82 per share.

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 January 2025 warrant exercises noted above. Accordingly, Checkpoint issued 18,500 shares of common stock to Fortress in the five months ended May 31, 2025. Pursuant to the support agreement among Fortress, Checkpoint and Sun Pharma (see Note 3), Fortress waived its right to receive any equity fee with respect to any equity issuances by Checkpoint (including those resulting from warrant exercises) that were effected subsequent to March 9, 2025, the date on which the merger agreement was executed.

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Avenue At the Market Offering

In May 2024, Avenue entered into an At-the-Market Offering Agreement (the "Avenue ATM") under which Avenue was able to offer and sell, from time to time at its sole discretion, up to $3.9 million of shares of its common stock. The offers and sales of the shares were made pursuant to Avenue's Form S-3 registration statement declared effective in 2021, and the related prospectus supplement dated May 10, 2024. During the nine months ended September 30, 2025, Avenue issued 0.9 million shares through the Avenue ATM for net proceeds of $2.1 million. Avenue is no longer able to utilize the Avenue ATM as a result of the delisting of its stock from trading on the Nasdaq effective July 18, 2025.

Pursuant to the Company's Founders Agreement with Avenue, Avenue issued to Fortress 2.5% of the aggregate number of shares of common stock issued in the offering noted above. Accordingly, Avenue issued 23,474 shares of common stock to Fortress for the nine months ended September 30, 2025.

Mustang 2024 Shelf Registration Statement on Form S-3 and At-the-Market Offering

On May 31, 2024, Mustang filed a shelf registration statement on Form S-3 (File No. 333-279891) (the "Mustang 2024 S-3"), which was declared effective on June 12, 2024. Under the Mustang 2024 S-3, Mustang may sell up to a total of $40.0 million of its securities. As of September 30, 2026, approximately $34.2 million under the Mustang 2024 S-3 remains available for sales of securities, subject to General Instruction I.B.6. of Form S-3, known as the "baby shelf rules," which limits the amount of securities it can sell under its registration statement on Form S-3 in any 12-month period.

On May 31, 2024, Mustang entered into an At-the-Market Offering Agreement (the "Mustang ATM") relating to the sale of shares of common stock pursuant to the Mustang 2024 S-3. During the nine months ended September 30, 2026, Mustang did not issue any shares in connection with its ATM agreement. For the nine months ended September 30, 2025, Mustang issued approximately 54,000 shares through the Mustang ATM for net proceeds of approximately $0.6 million.

Mustang February 2025 Equity Offering

In February 2025, Mustang closed on an equity offering of (i) 495,000 shares of its common stock, par value $0.0001 per share (the "Shares"), (ii) pre-funded warrants to purchase up to an aggregate of 2,162,807 shares of common stock, (iii) Series C-1 warrants (the "Series C-1 Warrants") to purchase up to 2,657,807 shares of common stock, and (iv) Series C-2 warrants (the "Series C-2 Warrants") to purchase up to 2,657,807 shares of common stock. Each Share or Pre-Funded Warrant was sold together with one Series C-1 Warrant to purchase one share of common stock and one Series C-2 Warrant to purchase one share of common stock. The combined public offering price for each Share and accompanying Warrants was $3.01, and the combined public offering price for each Pre-Funded Warrant and accompanying Warrants was $3.0099. The Pre-Funded Warrants had an exercise price of $0.0001 per share, were exercisable immediately upon issuance and expired when exercised in full. Each Warrant has an exercise price of $3.01 per share and became exercisable beginning on the effective date of stockholder approval of the issuance of the Warrant Shares (the "Warrant Stockholder Approval"). The Series C-1 Warrants expire five years from the date of stockholder approval and the Series C-2 Warrants expire twenty-four months from the date of stock-holder approval. The warrants contain customary anti-dilution adjustments to the exercise price, including share splits, share dividends, rights offerings and pro rata distributions. The net proceeds of the offering, after deducting the fees and expenses of the placement agent in the transaction, and other offering expenses payable by Mustang, but excluding the net proceeds from the exercise of the Warrants, were approximately $6.8 million.

Pursuant to the Company's Founders Agreement with Mustang, Mustang issued to Fortress 2.5% of the aggregate number of shares of common stock issued in the equity offering and ATM sales noted above. Accordingly, Mustang issued 127,140 shares of common stock to Fortress for the nine months ended September 30, 2025.

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

On December 30, 2022, Journey filed a shelf registration statement on Form S-3 (File No. 333-269079) (the "Journey 2022 S-3"), which was declared effective on January 26, 2023. The Journey 2022 S-3 covered the offering, issuance and sale by Journey of up to an aggregate of $150.0 million of Journey's common stock, preferred stock, debt securities, warrants, and units.

In August 2025, Journey executed a new At Market Issuance Sales Agreement (the "Journey 2025 ATM Sales Agreement") with B. Riley Securities, Inc. and Lake Street Capital Markets, LLC (each, an "Agent" and together, the "Agents") replacing the previous December 30, 2022 At Market Issuance Sales Agreement with B. Riley (the "Journey 2022 ATM Sales Agreement"). In accordance with the terms of the Journey 2025 ATM Sales Agreement, Journey may offer and sell up to 3,750,000 shares of common stock, from time to time through or to the Agents, each acting as sales agent or principal.

On January 15, 2026, Journey filed a shelf registration statement on Form S-3 (File No. 333-292758) (the "Journey 2026 S-3"), which was declared effective by the SEC on January 21, 2026. This shelf registration statement covers the offering, issuance and sale by Journey of up to an aggregate of $150.0 million of its common stock, preferred stock, debt securities, warrants, and units. The Journey 2026 S-3 replaces the Journey 2022 S-3. Sales under the Journey 2025 ATM Sales Agreement since the effective date are made under the Journey 2026 S-3.

During the nine months ended September 30, 2026, Journey did not issue any shares in connection with its ATM agreement. For the nine months ended September 30, 2025, Journey issued approximately 1.8 million shares under the Journey 2022 ATM Sales Agreement for net proceeds of approximately $10.9 million.

AcqCorpLXII Warrant Issuance

In February 2023, the Company completed a registered direct offering of common stock priced At-the-Market under Nasdaq rules pursuant to which it issued and sold 1.1 million shares of its common stock at a purchase price of $12.53 per share for approximately $13.3 million in net proceeds after deducting estimated offering expenses. This included a concurrent private placement with investors in the registered direct offering for the pro rata rights ("Rights") to acquire securities exercisable for common stock in certain future operating subsidiaries that consummate a specified corporate development transaction within the five years following the closing of the transaction. The Company accounted for the Rights, which were liability-classified, as a contingent obligation with an immaterial fair value.

During the three months ended September 30, 2026, AcqCorpLXII entered into the CSMC license (see Note 8), triggering the issuance of the securities under the Rights. AcqCorpLXII issued warrants to purchase 347,420 shares of its common stock. The warrants are immediately exercisable, have a ten-year term and an exercise price of $0.039 per share, and permit cashless exercise.

Immediately before settlement, the Company remeasured the related contingent obligation to its fair value of approximately $12,000, recognized as a loss in other income (expense) on the condensed consolidated statement of operations. Issuance of the warrants settled the portion of the obligation attributable to AcqCorpLXII. The warrants were classified as equity at their issuance-date fair value and are not subject to subsequent fair value remeasurement.

14. Commitments and Contingencies

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Leases

New York, NY Sublease - Fortress

On February 10, 2026, the Company entered into a sublease agreement with a third party to sublease all of its leased office space in New York, NY, consisting of approximately 23,000 square feet, under its existing lease with Sage Realty Corporation (the "Landlord"). The Company obtained the Landlord's consent to the sublease, and the sublease commenced on March 15, 2026. The sublease expires on August 31, 2031.

Pursuant to the sublease agreement, the Company expects to receive approximately $11.9 million in aggregate base rent payments over the term of the sublease. The Company remains primarily liable for the obligations under the original lease.

For the nine months ended September 30, 2026, the Company continued to recognize lease expense under the original lease agreement and recognized sublease income from the sublease commencement date of March 15, 2026. Sublease income is recognized on a straight-line basis over the sublease term. The Company has elected to present sublease income as a reduction of lease expense within the condensed consolidated statement of operations.

Lease Termination – Mustang

In February 2025, Mustang concurrently exited the lease of its manufacturing facility in Worcester, Massachusetts, relocating its corporate headquarters to 95 Sawyer Road, Waltham, Massachusetts, and divested certain fixed assets including furniture and equipment to AbbVie Bioresearch Center, Inc. for $1.0 million. In connection with the lease termination, Mustang recorded a net gain on lease termination of $0.4 million recorded in research and development expenses on the condensed consolidated statement of operations.

During the three and nine months ended September 30, 2026 and 2025, the Company recorded the following as lease costs for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2026	2025	2026	2025
Lease Cost				
Operating lease cost	$ 708	$ 728	$ 2,129	$ 2,205
Shared lease costs	(197)	(562)	(1,154)	(1,620)
Variable lease cost	58	75	200	339
Sublease income	(544)	—	(1,178)	—
Total lease expense	$ 25	$ 241	$ (3)	$ 924

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

	Nine Months Ended September 30,	
($ in thousands)	2026	2025
Cash paid for amounts included in the measurement of operating lease liabilities	$ (2,319)	$ (2,410)
Weighted-average remaining lease term – operating leases (years)	2.9	3.5
Weighted-average discount rate – operating leases	6.3 %	6.1 %

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($ in thousands)	Future Lease Liability
Remainder of 2026	$ 826
Year ended December 31, 2027	3,250
Year ended December 31, 2028	3,235
Year ended December 31, 2029	3,063
Year ended December 31, 2030	3,056
Other	2,058
Total operating lease liabilities	15,488
Less: present value discount	(2,114)
Net operating lease liabilities, short-term and long-term	$ 13,374

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.

Legal Proceedings

In the ordinary course of business, the Company and its subsidiaries and partner companies 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.

Journey Vendor Dispute

During the third quarter of 2026, Journey settled a dispute with a former vendor regarding certain service-related charges which arose in the ordinary course of business. Under the terms of the settlement, Journey paid the vendor $4.1 million during the third quarter of 2026, and the parties mutually released all claims related to the dispute. Prior to the settlement, Journey had accrued $2.4 million related to the matter. The $1.7 million difference between the settlement amount and the previously accrued amount was recognized during the three months ended September 30, 2026 in selling, general and administrative expense. As of September 30, 2026, Journey had no remaining liability related to this matter.

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15. Related Party Transactions

Founders Agreement

The Company has entered into Founders Agreements and, in some cases, exchange agreements, with certain of its subsidiaries and partner companies as described in the 2025 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' or partner companies' 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 %	Common Stock
Cellvation	October 31, 2016	2.5 %	Common Stock
Checkpoint	March 17, 2015	— %[2]	Common Stock
Cyprium	March 13, 2017	2.5 %	Common Stock
Helocyte	March 20, 2015	2.5 %	Common Stock
LemmaTx	February 11, 2026 [3]	2.5 %	Common Stock
Mustang	March 13, 2015	2.5 %	Common Stock
AcqCorpLXII	September 11, 2026 [3]	2.5 %	Common Stock
Oncogenuity	April 22, 2020 [3]	2.5 %	Common Stock
Urica	November 7, 2017 [3]	2.5 %	Common Stock

Note 1: Represents the effective date of the Founders Agreement of each subsidiary/partner company. 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: Instead of a PIK dividend, Checkpoint paid the Company an annual equity fee in shares of Checkpoint's common stock equal to 2.5% of Checkpoint's fully diluted outstanding capitalization. Due to the deconsolidation of Checkpoint in May 2025 related to the Sun Pharma transaction (see Note 3), Checkpoint no longer has this obligation to the Company.

Note 3: Represents the Trigger Date, the date that the Fortress partner company/subsidiary first acquires, whether by license or otherwise, ownership rights in a product.

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Management Services Agreements

The Company has entered into Management Services Agreements (the "MSAs") with certain of its partner companies/subsidiaries as described in the 2025 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	February 17, 2015	$ 500
Cellvation	October 31, 2016	500
Checkpoint[1]	March 17, 2015	—
Cyprium	March 13, 2017	500
Helocyte	March 20, 2015	500
LemmaTx[2]	February 11, 2026	442
Mustang	March 13, 2015	500
AcqCorpLXII[2]	September 11, 2026	152
Oncogenuity	February 10, 2017	500
Urica	November 7, 2017	500
Fortress		(4,094)
Consolidated (Income)/Expense		$ —

Note 1: Checkpoint was acquired by Sun Pharma in May 2025 (see Note 3).
Note 2: MSA fee for the year ended December 31, 2026 is pro-rated for the 2026 effective date of the subsidiary.

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.

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 also Executive Chairman and Chief Executive Officer of TGTX. Under the terms of the agreement, TGTX reimbursed 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 and nine months ended September 30, 2025, the Company invoiced TGTX $0.1 million and $0.7 million, respectively, related to this arrangement. There was no amount invoiced to TGTX under this arrangement in 2026.

Desk Share Agreement with TGTX

The Desk Share Agreement between the Company and TGTX, as amended, previously required TGTX to pay 65% of the average annual rent for the Company's New York, NY office space. For the three and nine months ended September 30, 2025, the Company had recognized $0.7 million and $2.0 million, respectively, in lease costs, recorded in selling, general and administrative expense in the condensed consolidated statement of operations, and invoiced TGTX approximately $0.5 million and $1.4 million, respectively, for TGTX's prorated share of the rent base.

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On March 15, 2026, the Company and TGTX entered into an amendment to the amended Desk Share Agreement providing for an equal allocation, during the term of the sublease, of the net cash costs associated with the New York, NY lease (see Note 14) calculated as rent and other lease costs paid by the Company less amounts received from the subtenant. For the three and nine months ended September 30, 2026, the Company invoiced TGTX approximately $0.1 million and $1.3 million, respectively, for TGTX's proportionate share of these lease costs under the amended agreement, inclusive of approximately $0.4 million invoiced to TGTX under the original Desk Share Agreement for the period January 1, 2026 through March 14, 2026. Amounts invoiced to TGTX are recorded as a reduction of selling, general and administrative expense in the condensed consolidated statement of operations. At September 30, 2026, there was $0.1 million due from TGTX, inclusive of shared costs related to commercial real estate taxes and certain operating expenses, which is recorded to other receivables – related party on the Company's condensed consolidated balance sheet.

Cyprium Debt Conversion Agreement and Promissory Note Payoff

On January 26, 2026, the Company entered into a Debt Conversion Agreement with Cyprium, whereby the Company agreed to convert $5.0 million of a total of $11.7 million owed by Cyprium under a promissory note, as amended, into approximately 2.5 million newly issued common shares of Cyprium. In March 2026, subsequent to the closing of the PRV sale (see Note 3), Cyprium made payments to the Company of the outstanding balances under the intercompany note, including accrued interest and accrued expenses owed to the Company.

Board Services Agreement

In December 2016, Checkpoint entered into an advisory agreement effective January 1, 2017 with Caribe BioAdvisors, LLC ("Caribe"), owned by Michael S. Weiss, to provide the advisory services of Mr. Weiss as Chairman of the Board. Pursuant to the agreement, Caribe will be paid an annual cash fee of $60,000, in addition to any and all annual equity incentive grants paid to members of the board. In June 2023, Mr. Weiss assigned the agreement with Checkpoint to Hawkins BioVentures, LLC, also owned by Michael Weiss. For the five months ended May 31, 2025, Checkpoint recognized $0.2 million in expense related to the advisory agreement, including expenses related to annual equity incentive grants. As Checkpoint was deconsolidated in May 2025 (see Note 3) there was no comparative expense in 2026.

In January 2017, Mustang entered into an advisory agreement effective January 1, 2017 with Caribe to provide the advisory services of Mr. Weiss as Chairman of the Board. Pursuant to the agreement, Caribe will be paid an annual cash fee of $60,000, in addition to any and all annual equity incentive grants paid to members of the board. For the three months ended September 30, 2026 and 2025, Mustang recognized approximately $15,000 and $15,000, respectively, in expenses related to the advisory agreement, and for the nine months ended September 30, 2026 and 2025, Mustang recognized approximately $45,000 and $45,000, respectively, in expense related to the advisory agreement.

Shared Services Agreement with Journey

On November 12, 2021, Journey and the Company entered into an arrangement to share the cost of certain employees. The Company's Executive Chairman and Chief Executive Officer is also the Executive Chairman of Journey. Under the terms of the arrangement, Journey reimburses 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 its 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.

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For the three months ended September 30, 2026 and 2025, the Company's employees have provided services to Journey totaling approximately $10,000 and $9,000, respectively. For the nine months ended September 30, 2026 and 2025, the Company's employees have provided services to Journey totaling approximately $35,000 and $31,000, respectively. At September 30, 2026, the Company's total related party receivable due from Journey was $0.8 million, and primarily relates to reimbursable expenses incurred by Fortress on behalf of Journey.

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

Pursuant to a private placement in August 2020, Cyprium sold 320,000 shares of Cyprium PPS. The Cyprium PPS was fully and unconditionally guaranteed by Fortress.

Pursuant to the terms of the Cyprium PPS, holders of record were entitled to receive a monthly cash dividend of $0.19531 per share, or $2.34375 per share on an annual basis. The Cyprium PPS was required to be redeemed in cash upon the first bona fide, arm's-length sale of a Priority Review Voucher (a "PPS PRV Sale") issued by the FDA in connection with the approval of CUTX-101. Upon a PPS PRV Sale, each share of Cyprium PPS would automatically be redeemed for an amount equal to twice the $25.00 liquidation preference, plus accumulated and unpaid dividends to, but excluding, the redemption date. Beginning 24 months after issuance, holders had the right to elect an exchange of the Cyprium PPS, with settlement at Fortress' election in cash or Fortress' Series A Preferred Stock. A mandatory exchange, also settleable at Fortress' election in cash or Fortress' Series A Preferred Stock, occurred on September 30, 2024 for any investors who did not opt to waive such mandatory exchange mechanism. Specifically, in September 2024, Cyprium offered holders the opportunity to waive enforcement of, and extend the mandatory exchange date to March 31, 2026, and therefore remain eligible to receive the redemption price upon a PPS PRV Sale, and waive the optional exchange right (the "PPS Extension"). Holders of 283,400 shares of Cyprium PPS opted into the PPS Extension.

The Company accounted for the Cyprium PPS as a financing obligation and recorded the carrying amount in the consolidated balance sheets as partner company redeemable perpetual preferred liability of $7.1 million as of December 31, 2025.

In addition, the Company concluded that the redemption feature associated with a PPS PRV Sale required bifurcation as an embedded derivative (partner company derivative liability), with remeasurement to fair value at each reporting date. The fair value of the embedded derivative was not material historically. As of December 31, 2025, although the NDA for CUTX-101 had been resubmitted and assigned a new PDUFA date of January 14, 2026, following the October 2024 Complete Response Letter, significant uncertainty remained regarding whether approval would be obtained, whether a PRV would be issued, and whether a PPS PRV Sale could be executed on a timely basis on agreeable terms prior to the March 31, 2026 mandatory exchange date. As a result, the fair value of the partner company derivative liability remained immaterial as of December 31, 2025.

In February 2026, the Company, Cyprium and an undisclosed buyer entered into a definitive agreement to sell Cyprium's PRV for $205 million. Cyprium recorded the increase in the fair value of the partner company derivative liability of $7.1 million. The Cyprium PPS was automatically redeemed for an amount equal to twice the $25.00 liquidation preference, pursuant to the terms of the Cyprium PPS, in the amount of $14.2 million which was comprised of the $7.1 million partner company perpetual preferred liability and the $7.1 million partner company derivative liability. In March 2026, the sale of the PRV closed (see Note 3).

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16. Segment Information

The Company's reportable segments for operating income (loss) for the three and nine months ended September 30, 2026 and 2025 consist of the following ($ in thousands):

Three Months Ended September 30, 2026	Journey	Avenue	Mustang	Fortress[1]	Consolidated
Product revenue, net	$ 18,925	$ —	$ —	$ —	$ 18,925
Other revenue	42	—	—	192	234
Net revenue	18,967	—	—	192	19,159
Cost of goods - (excluding amortization of acquired intangible assets)	5,884	—	—	—	5,884
Intangible assets amortization	969	—	—	—	969
Research and development	51	212	208	1,207	1,678
Selling, general and administrative	12,593	492	850	3,886	17,821
Total operating expenses	19,497	704	1,058	5,093	26,352
Income (loss) from operations	(530)	(704)	(1,058)	(4,901)	(7,193)
Interest income	140	13	94	1,048	1,295
Interest expense and financing fee	(919)	—	—	(1,579)	(2,498)
Gain from deconsolidation of subsidiary	—	—	—	104	104
Other expense	(6)	—	—	(12)	(18)
Total other income (expense)	(785)	13	94	(439)	(1,117)
Loss before income tax expense	(1,315)	(691)	(964)	(5,340)	(8,310)
Income tax benefit	—	—	—	(56)	(56)
Segment net loss	$ (1,315)	$ (691)	$ (964)	$ (5,284)	$ (8,254)
Attributable to non-controlling interests					2,409
Net loss attributable to Fortress					$ (5,845)

Note 1: Includes Fortress and private subsidiaries primarily funded by Fortress, including AcqCorpLXII, Cellvation, Cyprium, Helocyte, LemmaTx, Oncogenuity and Urica; and intercompany eliminations.

Three Months Ended September 30, 2026	Journey	Avenue	Mustang	Fortress[1]	Consolidated
Intersegment activity[2]:					
Research and development	$ —	$ 63	$ 63	$ (125)	$ —
Selling, general and administrative	$ —	$ 63	$ 63	$ (125)	$ —
Other Significant Items:					
Segment assets	$ 103,846	$ 1,530	$ 14,683	$ 160,155	$ 280,215
Stock-based compensation - Research & development	$ —	$ 9	$ —	$ 22	$ 31
Stock-based compensation - Selling, general and administrative	$ 1,333	$ 38	$ 2	$ 745	$ 2,118

Note 1: Includes Fortress and private subsidiaries primarily funded by Fortress, including AcqCorpLXII, Cellvation, Cyprium, Helocyte, LemmaTx, Oncogenuity and Urica; and intercompany eliminations.
Note 2: Segment activity consists of MSA fees paid by the subsidiaries to Fortress (see Note 15).

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Three Months Ended September 30, 2025	Journey	Avenue	Mustang	Fortress[1]	Consolidated
Product revenue, net	$ 17,025	$ —	$ —	$ —	$ 17,025
Other revenue	606	—	—		606
Net revenue	17,631	—	—	—	17,631
Cost of goods - (excluding amortization of acquired intangible assets)	5,755	—	—	—	5,755
Intangible assets amortization	1,064	—	—	—	1,064
Research and development	287	177	(333)	77	208
Selling, general and administrative	12,054	547	957	3,857	17,415
Total operating expenses	19,160	724	624	3,934	24,442
Loss from operations	(1,529)	(724)	(624)	(3,934)	(6,811)
Interest income	154	34	156	392	736
Interest expense and financing fee	(937)	—	—	(1,805)	(2,742)
Loss on common stock warrant liabilities	—	(2)	—	—	(2)
Other income (expense)	(3)	—	—	17,675	17,672
Total other income (expense)	(786)	32	156	16,262	15,664
Income (loss) before income tax expense	(2,315)	(692)	(468)	12,328	8,853
Income tax expense	—	—	—	26	26
Segment net income (loss)	$ (2,315)	$ (692)	$ (468)	$ 12,302	$ 8,827
Attributable to non-controlling interests					(2,977)
Net income attributable to Fortress					$ 5,850

Note 1: Includes Fortress and private subsidiaries primarily funded by Fortress, including Cellvation, Cyprium, Helocyte, Oncogenuity and Urica; and intercompany eliminations.

Three Months Ended September 30, 2025	Journey	Avenue	Mustang	Fortress[1]	Consolidated
Intersegment activity[2]:					
Research and development	$ —	$ 63	$ 63	$ (125)	$ —
Selling, general and administrative	$ —	$ 63	$ 242	$ (304)	$ —
Other Significant Items:					
Change in fair value of equity method investment held by Urica	$ —	$ —	$ —	$ 15,075	$ 15,075
Segment assets	$ 85,191	$ 3,725	$ 19,361	$ 73,131	$ 181,407
Stock-based compensation - Research & development	$ —	$ 31	$ 1	$ 120	$ 152
Stock-based compensation - Selling, general and administrative	$ 1,854	$ 132	$ 22	$ 1,037	$ 3,045

Note 1: Includes Fortress and private subsidiaries primarily funded by Fortress, including Cellvation, Cyprium, Helocyte, Oncogenuity and Urica; and intercompany eliminations.
Note 2: Segment activity consists of MSA fees paid by the subsidiaries to Fortress (see Note 15).

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Nine Months Ended September 30, 2026	Journey	Avenue	Mustang	Fortress[1]	Consolidated
Product revenue, net	$ 52,685	$ —	$ —	$ —	$ 52,685
Other revenue	753	—	—	476	1,229
Net revenue	53,438	—	—	476	53,914
Cost of goods - (excluding amortization of acquired intangible assets)	18,245	—	—	—	18,245
Amortization of acquired intangible assets	3,064	—	—	—	3,064
Research and development	105	659	610	1,649	3,023
Selling, general and administrative	33,590	1,466	2,676	16,787	54,519
Total operating expenses	55,004	2,125	3,286	18,436	78,851
Loss from operations	(1,566)	(2,125)	(3,286)	(17,960)	(24,937)
Interest income	451	48	295	2,652	3,446
Interest expense and financing fee	(2,717)	—	—	(4,625)	(7,342)
Gain on sale of priority review voucher, net of expenses	—	—	—	158,873	158,873
Change in fair value of partner company derivative liability	—	—	—	(7,085)	(7,085)
Gain on common stock warrant liabilities	—	1	—		1
Gain from deconsolidation of subsidiary	—	—	—	186	186
Other income (expense)	(10)	—	—	11,774	11,764
Total other income (expense)	(2,276)	49	295	161,775	159,843
Income (loss) before income tax expense	(3,842)	(2,076)	(2,991)	143,815	134,906
Income tax expense	15	—	—	5,380	5,395
Segment net income (loss)	$ (3,857)	$ (2,076)	$ (2,991)	$ 138,435	$ 129,511
Attributable to non-controlling interests					(25,451)
Net income attributable to Fortress					$ 104,060

Note 1: Includes Fortress and private subsidiaries primarily funded by Fortress, including AcqCorpLXII, Cellvation, Cyprium, Helocyte, LemmaTx, Oncogenuity and Urica; and intercompany eliminations.

Nine Months Ended September 30, 2026	Journey	Avenue	Mustang	Fortress[1]	Consolidated
Intersegment activity[2]:					
Research and development	$ —	$ 188	$ 188	$ (375)	$ —
Selling, general and administrative	$ —	$ 188	$ 188	$ (375)	$ —
Other Significant Items:					
Change in fair value of equity method investment held by Urica	$ —	$ —	$ —	$ 11,791	$ 11,791
Segment assets	$ 103,846	$ 1,530	$ 14,683	$ 160,155	$ 280,215
Stock-based compensation - Research & development	$ —	$ 38	$ —	$ 51	$ 89
Stock-based compensation - Selling, general and administrative	$ 3,759	$ 131	$ 45	$ 2,758	$ 6,693

Note 1: Includes Fortress and private subsidiaries primarily funded by Fortress, including AcqCorpLXII, Cellvation, Cyprium, Helocyte, LemmaTx, Oncogenuity and Urica; and intercompany eliminations.
Note 2: Segment activity consists of MSA fees paid by the subsidiaries to Fortress (see Note 15).

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Nine Months Ended September 30, 2025	Journey	Avenue	Checkpoint[1]	Mustang	Fortress[2]	Consolidated
Product revenue, net	$ 45,173	$ —	$ —	$ —	$ —	$ 45,173
Other revenue	606	1,404	—	—	—	2,010
Net revenue	45,779	1,404	—	—	—	47,183
Cost of goods - (excluding amortization of acquired intangible assets)	15,484	—	—	—	—	15,484
Intangible assets amortization	3,193	—	—	—	—	3,193
Research and development	326	780	10,775	(1,199)	1,586	12,268
Selling, general and administrative	34,505	2,955	27,263	2,961	13,986	81,670
Total operating expenses	53,508	3,735	38,038	1,762	15,572	112,615
Loss from operations	(7,729)	(2,331)	(38,038)	(1,762)	(15,572)	(65,432)
Interest income	441	96	90	379	842	1,848
Interest expense and financing fee	(2,765)	—	—	—	(5,300)	(8,065)
Gain (loss) on common stock warrant liabilities	—	14	(108)	—	(305)	(399)
Gain from deconsolidation of subsidiary	—	—	—	—	27,127	27,127
Other income (expense)	(71)	—	(3)	—	17,673	17,599
Total other income (expense)	(2,395)	110	(21)	379	40,037	38,110
Income (loss) before income tax expense	(10,124)	(2,221)	(38,059)	(1,383)	24,465	(27,322)
Income tax expense	60	—	—	—	136	196
Segment net income (loss)	$ (10,184)	$ (2,221)	$ (38,059)	$ (1,383)	$ 24,329	$ (27,518)
Attributable to non-controlling interests						38,270
Net income attributable to Fortress						$ 10,752

Note 1: Checkpoint results for five months ended May 31, 2025 due to deconsolidation as a result of acquisition by Sun Pharma (see Note 3).
Note 2: Includes Fortress and private subsidiaries primarily funded by Fortress, including Cellvation, Cyprium, Helocyte, Oncogenuity and Urica; and intercompany eliminations.

Nine Months Ended September 30, 2025	Journey	Avenue	Checkpoint[1]	Mustang	Fortress[2]	Consolidated
Intersegment activity[3]:						
Research and development	$ —	$ 188	$ —	$ 125	$ (313)	$ —
Selling, general and administrative	$ —	$ 242	$ 261	$ 519	$ (1,022)	$ —
Other Significant Items:						
Change in fair value of equity method investment held by Urica	$ —	$ —	$ —	$ —	$ 15,075	$ 15,075
Segment assets	$ 85,191	$ 3,725	$ —	$ 19,361	$ 73,131	$ 181,407
Stock-based compensation - Research & development	$ —	$ 102	$ 4,782	$ (10)	$ 1,371	$ 6,245
Stock-based compensation - Selling, general and administrative	$ 4,513	$ 421	$ 9,315	$ 116	$ 5,670	$ 20,035

Note 1: Checkpoint results for five months ended May 31, 2025 due to deconsolidation as a result of acquisition by Sun Pharma (see Note 3).
Note 2: Includes Fortress and private subsidiaries primarily funded by Fortress, including Cellvation, Cyprium, Helocyte, Oncogenuity and Urica; and intercompany eliminations.
Note 3: Segment activity consists of MSA and equity fees paid by the subsidiaries to Fortress (see Note 15).

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17. Revenues from Contracts and Significant Customers

Disaggregation of Net Revenue

Journey has the following actively marketed products: Emrosi, Qbrexza, Amzeeq, Zilxi, Accutane, Exelderm, Targadox, Luxamend, and Eurax. All of Journey's product revenues are recorded in the U.S.

The table below summarizes the Company's net revenue for the periods presented:

	Three months ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2026	2025	2026	2025
Emrosi	$ 9,002	$ 4,883	$ 23,329	$ 9,748
Qbrexza	5,590	7,361	15,732	19,470
Accutane	3,023	2,769	9,694	9,818
Foam franchise products (Amzeeq & Zilxi)	942	1,311	2,933	3,973
Eurax	105	—	225	—
Other / legacy product revenue	263	701	772	2,164
Other revenue	234	606	1,229	2,010
Total net revenue	$ 19,159	$ 17,631	$ 53,914	$ 47,183

Other revenue for the three months ended September 30, 2026 primarily consists of royalty revenue of $0.2 million recognized by Cyprium related to sales of ZYCUBO (see Note 3).

Other revenue for the nine months ended September 30, 2026 consisted of $0.8 million recognized by Journey related to the Cutia Agreement (see Note 8), including $0.1 million recognized in royalties on sales of Amzeeq by Cutia, and royalty revenue of $0.5 million recognized by Cyprium related to sales of ZYCUBO (see Note 3).

Other revenue for the three and nine months ended September 30, 2025 consisted of revenue recognized by Avenue related to the AJ201 license termination and program transfer (see Note 8) of nil and $1.4 million, respectively, and $0.6 million and $0.6 million recognized by Journey related to the Cutia Agreement (see Note 8), respectively.

Significant Customers

For the three and nine months ended September 30, 2026 and 2025, none of Journey's dermatology products customers accounted for more than 10% of its total gross product revenue.

At September 30, 2026 and December 31, 2025, none of Journey's dermatology products customers accounted for more than 10% of its total accounts receivable balance.

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.

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

The Company files a consolidated income tax return with subsidiaries in which the Company has an 80% or greater ownership interest. Subsidiaries in which the Company does not have an 80% or more ownership stake are not included in the Company's consolidated income tax group and file their own separate income tax return(s). 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, 2026 and 2025 is based on the estimated annual effective tax rate, and includes discrete tax impact primarily driven by 2026 federal and state income taxes related to the gain on sale of the PRV. For the three months ended September 30, 2026, the Company is recognizing an income tax benefit of $0.1 million on a pre-tax loss of $8.3 million, resulting in an effective tax rate of 0.7%. The effective rate for the three months ended September 30, 2026 varies from the annual estimated effective tax rate for 2026 due to low quarterly pre-tax losses relative to the expected full year pre-tax book income, driven by the gain on sale of PRV recognized in the three months ended March 31, 2026. For the nine months ended September 30, 2026, the Company is recognizing income tax expense of $5.4 million on pre-tax income of $134.9 million, resulting in an effective tax rate of 4.0%. The Company expects a net deferred tax asset with a full valuation allowance and a 4.1% estimated annual effective tax rate for 2026. For the three and nine months ended September 30, 2025 the Company recognized income tax expense of approximately $26,000 and $0.2 million respectively.

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 generally accepted accounting principles in the United States of America ("GAAP"). Statements in this Quarterly Report on Form 10-Q that are not descriptions of historical facts are "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"). The words "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "might," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology are generally intended to identify forward-looking statements. These forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include those set forth under "Item 1A. Risk 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;
- uncertainty related to the timing and amounts expected to be realized from future milestone, contingent value right, royalty or similar future revenue streams, if at all;
- 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.

We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this Quarterly Report on Form 10-Q should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

Overview

Fortress Biotech, Inc. ("Fortress" or the "Company") is a biopharmaceutical company focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holdings and dividend and royalty income. Fortress works in concert with its extensive network of key opinion leaders to identify and evaluate promising products and product candidates for potential acquisition. We have executed such arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center ("COH" or "City of Hope"), Dana-Farber Cancer Institute, Nationwide Children's Hospital, Columbia University, the University of Pennsylvania, AstraZeneca plc, Dr. Reddy's Laboratories, Ltd. ("DRL"), and Sun Pharmaceutical Industries Limited ("Sun Pharma").

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and financial expertise to help its subsidiaries and partner companies achieve their goals. Partner and subsidiary 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, three partner companies are publicly-traded, and four subsidiaries have consummated strategic partnerships with industry leaders, including AstraZeneca plc as successor-in-interest to Alexion Pharmaceuticals, Inc. ("AstraZeneca"), Sentynl Therapeutics, Inc. ("Sentynl"), Axsome Therapeutics, Inc. ("Axsome"), and Sun Pharma.

Our subsidiaries and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates are: Journey Medical Corporation (Nasdaq: DERM, "Journey"), Mustang Bio, Inc. (Nasdaq: MBIO, "Mustang"), Avenue Therapeutics, Inc. (OTCID: ATXI, "Avenue"), Cellvation, Inc. ("Cellvation"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), LemmaTx, Inc. ("LemmaTx"), Oncogenuity, Inc. ("Oncogenuity"), Urica Therapeutics, Inc. ("Urica"), and FBIO Acquisition Corp. LXII ("AcqCorpLXII"). Checkpoint Therapeutics, Inc. ("Checkpoint"), previously a partner company of ours, was acquired by Sun Pharma in May 2025. Baergic Bio, Inc. ("Baergic"), previously a subsidiary of Avenue, was acquired by Axsome in November 2025.

Recent Events

Revenue Portfolio

- For the three months ended September 30, 2026 and 2025, net revenue was $19.2 million and $17.6 million, respectively, and is primarily related to the sale of Journey's marketed products.
- For the three months ended September 30, 2026, net revenue included $0.2 million in Cyprium's royalty revenue from ZYCUBO. Other revenue for the three months ended September 30, 2025 consists of revenue recognized by Journey related to Journey's supply of Amzeeq to Cutia.
- For the nine months ended September 30, 2026 and 2025, net revenue was $53.9 million and $47.2 million, respectively, and is primarily related to the sale of Journey's marketed products.
- For the nine months ended September 30, 2026, net revenue included $0.8 million in royalties related to Journey's supply of Amzeeq to Cutia, inclusive of $0.1 million in royalties on sales of Amzeeq by Cutia, and $0.5 million in Cyprium's royalty revenue from sales of ZYCUBO. Other revenue for the nine months ended September 30, 2025 included $1.4 million of revenue recognized by Avenue related to the AJ201 license termination and program transfer, and $0.6 million related to Journey's supply of Amzeeq to Cutia.

Commercial and Approved Products

Emrosi* (*Minocycline Hydrochloride Modified Release Capsules, 40 mg, also known as DFD-29, for the treatment of rosacea)

- In April 2026, our partner company Journey announced that approximately 85% of all commercial lives in the United States have access to Emrosi (Minocycline Hydrochloride Modified Release Capsules, 10mg immediate release and 30mg extended release) after contracting with a third major group purchasing organization.
- In November 2024, Journey announced that the FDA approved Emrosi for the treatment of inflammatory lesions of rosacea in adults, and Journey subsequently launched Emrosi in March 2025.
- Emrosi was developed for the treatment of rosacea at our partner company, Journey, in collaboration with DRL.

ZYCUBO (copper histidinate for Menkes disease, formerly known as CUTX-101)

- On January 13, 2026, we announced the FDA approved ZYCUBO (copper histidinate, also referred to as CUTX-101) for the treatment of Menkes disease in pediatric patients. A priority review voucher ("PRV") was issued in connection with FDA approval and, pursuant to the transaction with Sentynl, was transferred to Cyprium. On February 22, 2026, Cyprium entered into a definitive asset purchase agreement pursuant to which Cyprium agreed to sell the PRV for $205 million, which was paid upon the closing of the sale as announced on March 30, 2026.
- In July 2026, the board of directors of Cyprium declared a cash dividend of approximately $118.6 million to its shareholders. Based on the Company's ownership interest in Cyprium, approximately $95.4 million of the dividend was paid to Fortress with the remaining amount paid to noncontrolling shareholders of Cyprium.
- Cyprium is eligible to receive up to $128 million in aggregate sales milestones and tiered royalties on net sales of ZYCUBO ranging from 3% to 12.5% on annual net sales. For the three and nine months ended September 30, 2026, Cyprium recognized $0.2 million and $0.5 million, respectively, in royalty revenue on net sales of ZYCUBO.
- CUTX-101 was sourced by Fortress and was developed by Cyprium until the asset transfer in December 2023.

UNLOXCYT ***(cosibelimab-ipdl, anti-PD-L1 antibody)***

- In May 2025, our partner company, Checkpoint, was acquired by Sun Pharma for $4.10 per share in cash plus a contingent value right of up to $0.70 per share upon the achievement of EU approval of Checkpoint's principal drug product candidate. Fortress received $28.0 million, and is eligible to receive up to $4.8 million upon achievement of the milestone provided for in the contingent value right.
- Sun Pharma pays Fortress a 2.5% royalty on net sales of UNLOXCYT. For the three and nine months ended September 30, 2026, Fortress recognized $0.1 million and $0.2 million, respectively, in royalty income on net sales of UNLOXCYT.

- On December 13, 2024, Checkpoint received approval from the FDA for UNLOXCYT (cosibelimab-ipdl), for the treatment of metastatic or locally advanced cutaneous squamous cell carcinoma in adults who are not candidates for curative surgery or radiation.
- Cosibelimab was sourced by Fortress and developed at Checkpoint, which was acquired by Sun Pharma in May 2025.

Late Stage Product Candidates

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 $135 million paid to Caelum shareholders, of which approximately $56.9 million was paid to Fortress. The agreement also provides for additional potential payments to Caelum shareholders totaling up to $295 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 $182 million.
- There are two ongoing global Phase 3 pivotal studies of CAEL-101 (also known as anselamimab) for Mayo Stage IIIa and Mayo Stage IIIb amyloid light-chain amyloidosis ("AL amyloidosis"), known as Cardiac Amyloid Reaching for Extended Survival ("CARES") (ClinicalTrials.gov identifiers: NCT04512235 and NCT04504825).
- On July 16, 2025, AstraZeneca announced an update from its CARES Phase 3 clinical program showing that anselamimab did not achieve statistical significance for the primary endpoint compared to placebo in patients with Mayo stages IIIa and IIIb AL amyloidosis. The primary endpoint was defined as a hierarchical combination of time to all-cause mortality ("ACM") and frequency of cardiovascular hospitalizations ("CVH"). All patients in the clinical program received background standard of care for plasma cell dyscrasia. AstraZeneca stated that anselamimab showed highly clinically meaningful improvement in time to ACM and frequency of CVH in a prespecified subgroup of patients, compared to placebo (although AstraZeneca did not further characterize this subgroup). AstraZeneca also reported that anselamimab was well tolerated, with the majority of events balanced between the anselamimab treatment arm and the placebo arm. AstraZeneca has disclosed that regulatory approval for anselamimab in Japan has been obtained.
- CAEL-101 was sourced by Fortress and developed by Caelum (founded by Fortress) until the acquisition by AstraZeneca of Caelum in October 2021.

Dotinurad (urate transporter (URAT1) inhibitor for gout)

- In July 2026, Urica announced that Crystalys Therapeutics, Inc. ("Crystalys"), in which Urica maintains an equity position, closed a $130 million Series B financing to support the late-stage global clinical development and commercialization preparation of dotinurad. After the Series B financing, as of September 30, 2026, Urica holds approximately 9% of Crystalys' fully-diluted equity.
- In May 2026, Crystalys announced the first patients were dosed in a randomized, double-blind, placebo-controlled, multicenter Phase 2 trial (ClinicalTrials.gov identifier: the AMETHYST study (NCT07535034)), evaluating dotinurad for the treatment of gout in participants who are intolerant to xanthine oxidase inhibitors or have failed uricase treatment.
- In October 2025, Urica announced that Crystalys closed a $205 million Series A financing.
- Also in October 2025, Urica announced the first patients were dosed in two randomized, double-blind, multicenter global Phase 3 trials (ClinicalTrials.gov identifiers: the RUBY study (NCT07089875) and the TOPAZ study (NCT07089888)) evaluating dotinurad for the treatment of gout.
- In July 2024, Urica entered into an asset purchase agreement, royalty agreement, and related agreements (collectively, the "Transaction Documents") with Crystalys. Under the Transaction Documents, Urica transferred substantially all intellectual property rights in dotinurad to Crystalys. In return, Crystalys issued to Urica shares of its common stock, granted certain anti-dilution rights, and also granted Urica a secured 3% royalty on future net sales of dotinurad.
- Dotinurad was approved in Japan in 2020 and has also obtained regulatory approval in China, the Philippines and Thailand.
- Dotinurad was sourced by Fortress and in development at our Urica subsidiary until the asset was acquired by Crystalys in July 2024.

Triplex (cytomegalovirus vaccine and immunotherapy)

- Triplex, a potential vaccine and immunotherapy for prevention and control of cytomegalovirus ("CMV"), is currently being studied in multiple ongoing clinical trials, including: a Phase 1/2 trial for CMV control in pediatric recipients of HSCT (NCT03354728); a Phase 1 trial of Triplex in combination with a bi-specific CMV/CD19 CAR T cell therapy for the treatment of non-Hodgkin lymphoma (NCT05432635); a Phase 2 trial for safety and effectiveness in reducing CMV complications in patients previously infected with CMV and undergoing donor hematopoietic cell transplant (NCT02506933); a Phase 1 trial of Triplex in combination with CAR T cell therapy for adults with non-Hodgkin lymphoma (NCT05801913); and a Phase 1 trial

of Triplex in combination with an allogeneic anti-CD19-CAR CMV-specific T cell therapy for adults with high-risk acute lymphoblastic leukemia (NCT06735690).
- Triplex was sourced by Fortress and is currently in development at our subsidiary, Helocyte.

Early Stage Product Candidates

FB-607 (combination therapy for irritable bowel syndrome with diarrhea)
- In September 2026, AcqCorpLXII, a majority-owned and controlled subsidiary of the Company, entered into a license agreement with Cedars-Sinai Medical Center and other named parties, pursuant to which AcqCorpLXII obtained an exclusive worldwide license to rifaximin combined with N-acetylcysteine, referred to as FB-607 or RNIB21, for indications including irritable bowel syndrome with diarrhea ("IBS-D").
- FB-607 is currently being evaluated in a randomized, double-blind, placebo-controlled, multicenter Phase 2 clinical study assessing safety, efficacy and pharmacokinetics in adults with IBS-D (NCT06727422).
- FB-607 was sourced by Fortress and is currently in development at our subsidiary, AcqCorpLXII.

MB-109 (IL13Rα2-targeted CAR T Cells (MB-101) + HSV-1 oncolytic virus (MB-108))
- In November 2024, Mustang announced that the FDA granted Orphan Drug Designation to Mustang for MB-108, an HSV-1 oncolytic virus, for the treatment of malignant glioma. In July 2025, we announced that the FDA granted Orphan Drug Designation to Mustang for MB-101 for the treatment of recurrent diffuse and anaplastic astrocytoma (astrocytomas) and glioblastoma.
- In March 2024, data from the Phase 1 trial evaluating MB-101 IL13Rα2-targeted CAR T-cells in high-grade glioma were published in Nature Medicine. MB-101 was well tolerated, and 50% of patients achieved stable disease or better, with two partial responses and two complete responses in high-grade glioma patients. The two patients who achieved complete response both had high levels of intratumoral CD3+ T-cells pre-therapy (i.e., "hot" tumors), and their responses lasted 7.5 and 66+ months, respectively. In the cohort with dual intratumoral (ICT)/intraventricular (ICV) delivery and an optimized manufacturing process there was a ~70% improvement in median overall survival (10.2 months) compared to the expected survival rate of six months in this patient population.
- Mustang is currently exploring with COH an investigator-sponsored single-institution trial under the COH IND to treat patients with IL13Rα2+ recurrent GBM and high-grade astrocytoma with MB-109 that could potentially be initiated in the first quarter of 2027.
- MB-101, MB-108, and MB-109 are currently in development at our partner company, Mustang.

ATX-04 (selective β2-adrenergic agonist for Pompe disease)
- In February 2026, Avenue entered into a license agreement with Duke University, whereby Avenue obtained an exclusive worldwide license from Duke to certain patents and know-how pertaining to ATX-04 for the treatment of lysosomal storage diseases.
- Avenue intends to advance ATX-04 through a late-stage clinical development program leveraging existing human safety and efficacy data, with an initial focus on treating Pompe disease as an adjunct to enzyme replacement therapy.
- ATX-04 is currently in development at our partner company, Avenue.

FB-606 (sarcolemmal membrane stabilizer for Duchenne Muscular Dystrophy)
- In February 2026, Fortress contributed internally developed intellectual property for FB-606 to LemmaTx, a controlled subsidiary of Fortress, to advance the development of FB-606 as a potential membrane stabilizer for patients with Duchenne muscular dystrophy.
- FB-606 was sourced by Fortress and is currently in development at our subsidiary company, LemmaTx.

Other Product Candidates

AJ201 (Nrf1 and Nrf2 activator, androgen receptor degradation enhancer)
- In April 2025, Avenue and AnnJi entered into a License Termination and Program Transfer Agreement, pursuant to which the license agreement and related agreements were terminated and the program was returned to AnnJi, with AnnJi paying $1.6 million net of withholding to Avenue. Avenue is eligible to receive milestone payments, royalties on AJ201, and sublicensing revenue from AnnJi.
- AJ201 was sourced by Fortress and was previously in development at our partner company, Avenue.

BAER-101 (GABAA α2/3 positive allosteric modulator)

- In November 2025, Avenue announced it had entered into an agreement for Baergic to be acquired by Axsome Therapeutics, Inc. ("Axsome"), including the global rights to BAER-101 (also known as AZD7325), a novel oral GABAA α2,3 subtype-selective receptor positive allosteric modulator. BAER-101 was originally licensed by Baergic from AstraZeneca AB and will be referred to as AXS-17 by Axsome going forward. Axsome intends to evaluate AXS-17 as a potential treatment for epilepsy.
- Avenue is eligible to receive approximately 74% of all future payments and royalties payable to the former stockholders of Baergic including development and commercial milestones and a tiered mid-to-high single-digit royalty on potential global net sales of AXS-17.
- BAER-101 was sourced by Fortress and was in development at Baergic, a majority-owned subsidiary of Avenue, until its sale to Axsome in November 2025.

General Corporate

- On September 30, 2026, the $50.0 million senior secured credit agreement with Oaktree Fund Administration, LLC ("Oaktree"), as amended, was terminated upon the receipt by Oaktree of a payoff amount of $15.6 million from the Company comprising principal, interest and yield protection premium.
- In March 2026, the Company and Cyprium announced the closing of the sale of Cyprium's PRV for $205 million in gross proceeds. In connection with the sale of the PRV, the Company made payments to Oaktree comprising: $14.5 million in principal and $0.1 million in Yield Protection Premium.
- In February 2026, Fortress entered into a sublease agreement for all of its leased office space in New York, NY expiring in August 2031 concurrent with the base lease. Under the sublease agreement the Company expects to receive approximately $11.9 million in aggregate base rent payments over the term of the sublease. For the three and nine months ended September 30, 2026, the Company recognized sublease income of $0.5 million and $1.2 million, respectively. The Company remains primarily liable for the obligations under the original lease.

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 for the year ended December 31, 2025, which was filed with the United States Securities and Exchange Commission ("SEC") on March 31, 2026 (the "2025 Form 10-K"). There were no material changes in our critical accounting estimates or accounting policies from December 31, 2025 other than the following:

Contingent Consideration

The Company accounts for rights to contingent consideration received in connection with the disposal of a business as contingencies that are not recognized before realization. Sales-based contingent consideration is recognized when the underlying qualifying sales have occurred, the Company has an enforceable right to payment, and the amount is realized or realizable and determinable. Amounts recognized are presented as other income because they represent additional consideration from the disposal.

Accounting Pronouncements

See Note 2, "Summary of Significant Accounting Policies", to our unaudited condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

Smaller Reporting Company Status

We are a "smaller reporting company," meaning that either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) 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 (x) the market value of our shares held by non-affiliates is less than $250 million or (y) 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 2025 Form 10-K, have reduced disclosure obligations regarding executive compensation and utilize certain other accommodations available to smaller reporting companies.

Basis of Presentation and Principles of Consolidation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America. The Company's 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 income (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.

The following table summarizes the Company's ownership of the issued and outstanding common and preferred shares in certain consolidated Fortress subsidiaries as of the date indicated:

Partner Company/Subsidiary	September 30, 2026
Avenue (OTCID: ATXI)	13.4 %
Cellvation	80.0 %
Checkpoint[1]	— %
Cyprium	80.4 %
Helocyte	83.8 %
Journey (Nasdaq: DERM)	34.9 %
LemmaTx	100.0 %
Mustang (Nasdaq: MBIO)	8.0 %
AcqCorpLXII	70.6 %
Oncogenuity	74.4 %
Urica	70.4 %

Note 1: Checkpoint was acquired in May 2025 by Sun Pharma.

Results of Operations

Comparison of the three months ended September 30, 2026 and 2025

($ in thousands)	Three Months Ended September 30, 2026	2025	Change $	Change %
Revenue				
Product revenue, net	$ 18,925	$ 17,025	$ 1,900	11 %
Other revenue	234	606	(372)	(61)%
Net revenue	19,159	17,631	1,528	9 %
Operating expenses				
Cost of goods sold – (excluding amortization of acquired intangible assets)	5,884	5,755	129	2 %
Amortization of acquired intangible assets	969	1,064	(95)	(9)%
Research and development	1,678	208	1,470	707 %
Selling, general and administrative	17,821	17,415	406	2 %
Total operating expenses	26,352	24,442	1,910	8 %
Loss from operations	(7,193)	(6,811)	(382)	6 %
Other income (expense)				
Interest income	1,295	736	559	76 %
Interest expense and financing fee	(2,498)	(2,742)	244	9 %
Gain on common stock warrant liabilities	—	(2)	2	100 %
Gain from deconsolidation of subsidiary	104	—	104	100 %
Other income (expense)	(18)	17,672	(17,690)	(100)%
Total other income (expense)	(1,117)	15,664	(16,781)	(107)%
Income (loss) before income tax expense	(8,310)	8,853	(17,163)	(194)%
Income tax (benefit) expense	(56)	26	(82)	(315)%
Net income (loss)	**(8,254)**	**8,827**	**(17,081)**	**(194)%**
Attributable to non-controlling interests	2,409	(2,977)	5,386	181 %
Net income (loss) attributable to Fortress	**$ (5,845)**	**$ 5,850**	**$ (11,695)**	**(200)%**

($ in thousands)	Three Months Ended September 30, 2026	2025	Change $	Change %
Revenue				
Product revenue, net	$ 18,925	$ 17,025	$ 1,900	11 %
Other revenue	234	606	(372)	(61)%
Net revenue	**$ 19,159**	**$ 17,631**	**$ 1,528**	**9 %**

For the three months ended September 30, 2026, we generated $18.9 million of net product revenue related to the sale of Journey's branded and generic products as compared to $17.0 million for the three months ended September 30, 2025. The $1.9 million, or 11%, increase is primarily driven by sales of Emrosi in the third quarter of 2026 of $9.0 million compared to $4.9 million in the third quarter of 2025. Journey launched Emrosi in the first quarter of 2025. This increase is partially offset by a decrease in sales of Qbrexza of $1.8 million primarily due to coverage mix and a decrease in sales of Journey's legacy products of $0.4 million due to continued generic competition.

Other revenue for the three months ended September 30, 2026 of $0.2 million consists of royalties recognized by Cyprium on net sales of ZYCUBO. Other revenue for the three months ended September 30, 2025 of $0.6 million consists of revenue recognized by Journey related to the supply of Amzeeq to Cutia for Cutia's commercial use.

Cost of Goods Sold – (excluding amortization of acquired intangible assets)

($ in thousands)	Three Months Ended September 30, 2026	2025	Change $	Change %
Cost of goods sold – (excluding amortization of acquired intangible assets)	$ 5,884	$ 5,755	$ 129	2 %

We incurred $5.9 million and $5.8 million of costs of goods sold in connection with the sale of Journey's branded and generic products for the three months ended September 30, 2026 and 2025, respectively. Cost of goods sold increased by $0.1 million, or 2%, period over period driven primarily by an increase in royalty expense from the incremental net revenue recognized for Emrosi during the third quarter of 2026 as compared to the third quarter of 2025.

Amortization of acquired intangible assets

Amortization of acquired intangible assets decreased $0.1 million, or 9%, to $1.0 million for the three months ended September 30, 2026, from $1.1 million for the three months ended September 30, 2025, driven by the completion of amortization on the Accutane intangible asset partially offset by the start of amortization on the Eurax acquired intangible asset during the first quarter of 2026.

Research and Development Expenses

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

For the three months ended September 30, 2026 and 2025, R&D expenses were approximately $1.7 million and $0.2 million, respectively, an increase of $1.5 million, or 707%. The table below provides a summary of research and development by entity, for the periods presented:

($ in thousands)	Three Months Ended September 30, 2026	2025	Change $	Change %
Research & development				
Fortress[1]	$ 1,207	$ 77	$ 1,130	1468 %
Avenue	212	177	35	20 %
JMC	51	287	(236)	(82)%
Mustang	208	(333)	541	162 %
Total research and development expense	**$ 1,678**	**$ 208**	**$ 1,470**	**707 %**

Note 1: Includes Fortress and private subsidiaries as applicable.

The increase at Fortress in R&D expenses of $1.1 million, or 1468%, is primarily related to license costs of $1.0 million incurred at AcqCorpLXII for the license acquisition of FB-607. The increase in R&D expenses of $0.5 million, or 162%, at Mustang is attributed to the settlement of aged payables in 2025. The decrease at Journey in R&D expenses of $0.2 million, or 82%, is due to a reduction in costs incurred related to Eurax.

The table below provides a summary by entity of noncash, stock-based compensation expense included in R&D expense for the periods presented:

	Three Months Ended September 30,		Change	
($ in thousands)	2026	2025	$	%
Stock-based compensation - research & development				
Fortress[1]	$ 22	$ 120	$ (98)	(82)%
Avenue	9	31	(22)	(71)%
Mustang	—	1	(1)	(100)%
Total stock-based compensation expense - research and development	**$ 31**	**$ 152**	**$ (121)**	**(80)%**

Note 1: Includes Fortress and private subsidiaries as applicable.

The decrease in stock-based compensation recorded in R&D expense of $0.1 million, or 80%, for the three months ended September 30, 2026 as compared to the three months ended September 30, 2025 is attributed to the vesting of grants in the prior year at both Fortress and Avenue.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist principally of personnel-related costs, costs required to support the marketing and sales of our commercialized products, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in R&D expenses.

The table below provides a summary by entity of selling, general and administrative expenses for the periods presented:

	Three Months Ended September 30,		Change	
($ in thousands)	2026	2025	$	%
Selling, general & administrative				
Fortress[1]	$ 3,886	$ 3,857	$ 29	1 %
Avenue	492	547	(55)	(10)%
JMC	12,593	12,054	539	4 %
Mustang	850	957	(107)	(11)%
Total selling, general & administrative expense	**$ 17,821**	**$ 17,415**	**$ 406**	**2 %**

Note 1: Includes Fortress and private subsidiaries as applicable.

For the three months ended September 30, 2026, the increase in selling, general and administrative expenses of $0.4 million, or 2%, is primarily attributable to the increase at Journey of $0.5 million, or 4%, due to the incremental expense of $1.7 million recognized upon the settlement of a dispute with a vendor, offset by a reduction in Emrosi launch costs from the prior period. The decrease at Mustang of $0.1 million, or 11%, is primarily attributed to a $0.2 million decrease in the equity fee to Fortress related to financing activity in the prior year, partially offset by a $0.1 million increase in personnel-related expenses. The decrease at Avenue of $0.1 million, or 10%, was primarily due to a $0.1 million decrease in personnel-related costs.

The table below provides a summary by entity of noncash, stock-based compensation expense included in selling, general and administrative expense for the periods presented:

($ in thousands)	Three Months Ended September 30, 2026	2025	Change $	Change %
Stock-based compensation - Selling, general and administrative				
Fortress[1]	$ 745	$ 1,037	$ (292)	(28)%
Avenue	38	132	(94)	(71)%
JMC	1,333	1,854	(521)	(28)%
Mustang	2	22	(20)	(91)%
Total stock-based compensation expense - selling, general and administrative	**$ 2,118**	**$ 3,045**	**$ (927)**	**(30)%**

Note 1: Includes Fortress and private subsidiaries as applicable.

The decrease in stock-based compensation recorded in selling, general and administrative expenses of $0.9 million, or 30%, for the three months ended September 30, 2026 as compared to the three months ended September 30, 2025, is primarily attributed to the decrease at Journey of $0.5 million, or 28%, due to the vesting of grants in the prior year, and the decrease at Fortress of $0.3 million, or 28%, is due to the vesting of grants under the Amended and Restated Long-Term Incentive Program ("LTIP") in 2025.

Other income (expense)

($ in thousands)	Three Months Ended September 30, 2026	2025	Change $	Change %
Other income (expense)				
Interest income	$ 1,295	$ 736	$ 559	76 %
Interest expense and financing fee	(2,498)	(2,742)	244	9 %
Loss on common stock warrant liabilities	—	(2)	2	100 %
Gain from deconsolidation of subsidiary	104	—	104	100 %
Other income (expense)	(18)	17,672	(17,690)	(100)%
Total other income (expense)	$ (1,117)	$ 15,664	$ (16,781)	(107)%

Total other income decreased $16.8 million, or 107%, from $15.7 million for the three months ended September 30, 2025 to expense of $1.1 million for the three months ended September 30, 2026. Interest expense and financing fees for the three months ended September 30, 2026 includes $1.0 million loss on debt extinguishment related to the payoff of the Oaktree debt (see Note 9 to the unaudited condensed consolidated financial statements). Included in income for the three months ended September 30, 2025 is an increase in the fair value of Urica's investment in Crystalys of $15.1 million. Interest income increased $0.6 million or 76% for the three months ended September 30, 2026 as compared to the three months ended September 30, 2025 due to higher cash balances in the current period.

Comparison of the nine months ended September 30, 2026 and 2025

($ in thousands)	Nine Months Ended September 30, 2026	2025	Change $	Change %
Revenue				
Product revenue, net	$ 52,685	$ 45,173	$ 7,512	17 %
Other revenue	1,229	2,010	(781)	(39)%
Net revenue	53,914	47,183	6,731	14 %
Operating expenses				
Cost of goods - (excluding amortization of acquired intangible assets)	18,245	15,484	2,761	18 %
Amortization of acquired intangible assets	3,064	3,193	(129)	(4)%
Research and development	3,023	12,268	(9,245)	(75)%
Selling, general and administrative	54,519	81,670	(27,151)	(33)%
Total operating expenses	78,851	112,615	(33,764)	(30)%
Loss from operations	(24,937)	(65,432)	40,495	62 %
Other income (expense)				
Interest income	3,446	1,848	1,598	86 %
Interest expense and financing fee	(7,342)	(8,065)	723	9 %
Gain on sale of priority review voucher, net of expenses	158,873	—	158,873	100 %
Change in fair value of partner company derivative liability	(7,085)	—	(7,085)	100 %
Gain (loss) on common stock warrant liabilities	1	(399)	400	100 %
Gain from deconsolidation of subsidiary	186	27,127	(26,941)	(99)%
Other income	11,764	17,599	(5,835)	(33)%
Total other income	159,843	38,110	121,733	319 %
Income (loss) before income tax expense	134,906	(27,322)	162,228	594 %
Income tax expense	5,395	196	5,199	2653 %
Net income (loss)	**129,511**	**(27,518)**	**157,029**	**571 %**
Attributable to non-controlling interests	(25,451)	38,270	(63,721)	(167)%
Net income attributable to Fortress	**$ 104,060**	**$ 10,752**	**$ 93,308**	**868 %**

($ in thousands)	Nine Months Ended September 30, 2026	2025	Change $	Change %
Revenue				
Product revenue, net	$ 52,685	$ 45,173	$ 7,512	17 %
Other revenue	1,229	2,010	(781)	(39)%
Net revenue	**$ 53,914**	**$ 47,183**	**$ 6,731**	**14 %**

For the nine months ended September 30, 2026 we generated $52.7 million of net product revenue related to the sale of Journey's branded and generic products as compared to $45.2 million for the nine months ended September 30, 2025. The $7.5 million, or 17%, increase is primarily driven by sales of Emrosi for the nine months ended September 30, 2026 of $23.3 million compared to $9.7 million for the nine months ended September 30, 2025. Journey launched Emrosi in the first quarter of 2025. This is partially offset by a decrease in sales of Qbrexza of $3.7 million primarily due to coverage mix and a decrease in sales of Journey's legacy products of $1.4 million due to continued generic competition.

Other revenue for the nine months ended September 30, 2026 of $1.2 million consists of $0.8 million recognized by Journey for the supply of Amzeeq to Cutia as well as sales-based royalties on Cutia's net sales of Amzeeq, in each case pursuant to the Cutia Agreement, and royalties recognized by Cyprium on net sales of ZYCUBO of $0.5 million. Other revenue for the nine months ended September 30, 2025 of $2.0 million consists of revenue recognized by Avenue related to the AJ201 license termination and program transfer of $1.4 million and revenue recognized by Journey related to the supply of Amzeeq to Cutia of $0.6 million.

Cost of Goods Sold – (excluding amortization of acquired intangible assets)

($ in thousands)	Nine Months Ended September 30, 2026	2025	Change $	Change %
Cost of goods sold – (excluding amortization of acquired intangible assets)	$ 18,245	$ 15,484	$ 2,761	18 %

We incurred $18.2 million and $15.5 million of costs of goods sold in connection with the sale of Journey's branded and generic products, excluding amortization of acquired intangible assets, for the nine months ended September 30, 2026 and 2025, respectively. Cost of goods sold increased by $2.8 million, or 18%, driven primarily by a $1.3 million non-cash charge related to inventory acquired in the 2021 Qbrexza asset acquisition as well as an increase in product royalties payable driven by the incremental net revenue recognized for Emrosi.

Amortization of acquired intangible assets

Amortization of acquired intangible assets decreased by $0.1 million, or 4%, to $3.1 million for the nine months ended September 30, 2026, from $3.2 million for the nine months ended September 30, 2025, driven by driven by the completion of amortization on the Accutane intangible asset partially offset by the start of amortization on the Eurax acquired intangible asset during the same period.

Research and Development Expenses

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

For the nine months ended September 30, 2026 and 2025, R&D expenses were approximately $3.0 million and $12.3 million, respectively, a decrease of $9.2 million, or 75%. The table below provides a summary of research and development by entity, for the periods presented:

($ in thousands)	Nine Months Ended September 30, 2026	2025	Change $	Change %
Research & development				
Fortress[1]	$ 1,649	$ 1,586	$ 63	4 %
Avenue	659	780	(121)	(16)%
Checkpoint[2]	—	10,775	(10,775)	(100)%
Journey	105	326	(221)	(68)%
Mustang	610	(1,199)	1,809	151 %
Total research & development expense	**$ 3,023**	**$ 12,268**	**$ (9,245)**	**(75)%**

Note 1: Includes Fortress and private subsidiaries as applicable.
Note 2: Checkpoint was deconsolidated as of May 2025 related to the Sun Pharma transaction (see Note 3 to the unaudited condensed consolidated financial statements).

R&D expense at Checkpoint decreased $10.8 million, or 100%, due to the deconsolidation of that entity as of May 2025 as a result of its acquisition by Sun Pharma. The decrease at Journey in R&D expenses of $0.2 million, or 68%, is due to a reduction in costs incurred related to Eurax. The increase in R&D expenses of $1.8 million, or 151%, at Mustang is attributed to actions taken in 2025, including $1.4 million in one-time non-cash savings from the settlement of aged payables and the $0.4 million gain recognized on the termination of the Worcester facility lease during the first quarter of 2025, which did not reoccur to similarly offset R&D expense in 2026. The increase at Fortress of $0.1 million, or 4%, is primarily related to the increase at AcqCorpLXII of $1.0 million related to the license acquisition of FB-607, and the increase in R&D expense incurred by LemmaTx related to FB-606 of $0.6 million, partially offset by a decrease in stock compensation of $1.3 million related to fully vested LTIP grants and the increase in MSA income of $0.2 million related to LemmaTx and AcqCorpLXII.

The table below provides a summary by entity of noncash, stock-based compensation expense included in R&D expense for the periods presented:

	Nine Months Ended September 30,		Change	
($ in thousands)	2026	2025	$	%
Stock-based compensation - research & development				
Fortress[1]	$ 51	$ 1,371	$ (1,320)	(96)%
Avenue	38	102	(64)	(63)%
Checkpoint[2]	—	4,782	(4,782)	(100)%
Mustang	—	(10)	10	100 %
Total stock-based compensation expense - research and development	**$ 89**	**$ 6,245**	**$ (6,156)**	**(99)%**

Note 1: Includes Fortress and private subsidiaries as applicable.
Note 2: Checkpoint was deconsolidated as of May 2025 related to the Sun Pharma transaction (see Note 3 to the unaudited condensed consolidated financial statements).

The decrease in stock-based compensation recorded in R&D expense of $6.2 million, or 99%, for the nine months ended September 30, 2026 as compared to the nine months ended September 30, 2025 is attributed to the decrease at Checkpoint of $4.8 million, or 100%, due to the deconsolidation of that entity as of May 2025 as a result of its acquisition by Sun Pharma. The decrease in stock compensation at Fortress of $1.3 million, or 96%, is due to vesting of grants under the LTIP in 2025.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist principally of personnel-related costs, costs required to support the marketing and sales of our commercialized products, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in R&D expenses.

The table below provides a summary by entity of selling, general and administrative expenses for the periods presented:

	Nine Months Ended September 30,		Change	
($ in thousands)	2026	2025	$	%
Selling, general & administrative				
Fortress[1]	$ 16,787	$ 13,986	$ 2,801	20 %
Avenue	1,466	2,955	(1,489)	(50)%
Checkpoint[2]	—	27,263	(27,263)	(100)%
Journey	33,590	34,505	(915)	(3)%
Mustang	2,676	2,961	(285)	(10)%
Total selling, general & administrative expense	**$ 54,519**	**$ 81,670**	**$ (27,151)**	**(33)%**

Note 1: Includes Fortress and private subsidiaries as applicable.
Note 2: Checkpoint was deconsolidated as of May 2025 related to the Sun Pharma transaction (see Note 3 to the unaudited condensed consolidated financial statements).

For the nine months ended September 30, 2026, the decrease in selling, general and administrative expenses of $27.2 million, or 33%, is primarily attributable to the decrease of $27.3 million, or 100%, at Checkpoint due to the deconsolidation of that entity as of May 2025 as a result of its acquisition by Sun Pharma. The decrease at Journey of $0.9 million, or 3%, is due to a reduction in Emrosi launch costs from the prior period, offset by the incremental expense of $1.7 million recognized upon the settlement of a dispute with a vendor. The decrease at Avenue of $1.5 million, or 50%, is primarily due to a decrease of $0.8 million in legal expenses incurred in connection with the AJ201 license termination in 2025 (see Note 8 to the unaudited condensed consolidated financial statements), a $0.5 million decrease in personnel-related costs, a $0.1 million decrease in equity fees to Fortress associated with financing activities in the prior year, and a $0.1 million decrease in consulting costs. The decrease at Mustang of $0.3 million, or 10%, is primarily attributed to a $0.4 million decrease in non-cash stock-based compensation expense, primarily related to the equity fee to Fortress, and a $0.2 million decrease in professional and outside services, partially offset by a $0.3 million increase in personnel-related expenses. The increase of $2.8 million, or 20%, at Fortress is due to increased personnel and severance expenses of $2.5 million, Cyprium's increased personnel-related expenses of $3.0 million and increased legal expense of $0.5 million, partially offset by decreased stock-based compensation at Fortress of $2.9 million related to fully vested LTIP grants in 2025, and $0.4 million in decreased legal costs associated with the Checkpoint transaction in 2025.

The table below provides a summary by entity of noncash, stock-based compensation expense included in selling, general and administrative expense for the periods presented:

	Nine Months Ended September 30,		Change	
($ in thousands)	2026	2025	$	%
Stock-based compensation - Selling, general and administrative				
Fortress[1]	$ 2,758	$ 5,670	$ (2,912)	(51)%
Avenue	131	421	(290)	(69)%
Checkpoint[2]	—	9,315	(9,315)	(100)%
Journey	3,759	4,513	(754)	(17)%
Mustang	45	116	(71)	(61)%
Total stock-based compensation expense - selling, general and administrative	**$ 6,693**	**$ 20,035**	**$ (13,342)**	**(67)%**

Note 1: Includes Fortress and private subsidiaries as applicable.
Note 2: Checkpoint was deconsolidated as of May 2025 related to the Sun Pharma transaction (see Note 3 to the unaudited condensed consolidated financial statements).

The decrease in stock-based compensation recorded in selling, general and administrative expenses of $13.3 million, or 67%, for the nine months ended September 30, 2026 as compared to the nine months ended September 30, 2025 is primarily attributed to the decrease at Checkpoint of $9.3 million, or 100%, due to the deconsolidation of that entity as of May 2025 as a result of its acquisition by Sun Pharma, and the decrease at Fortress of $2.9 million, or 51%, due to the vesting of grants under the LTIP in 2025. The decrease at Journey of $0.8 million, or 17%, is due to grants that fully vested in the comparable prior period.

Other income (expense)

	Nine Months Ended September 30,		Change	
($ in thousands)	2026	2025	$	%
Other expense				
Interest income	$ 3,446	$ 1,848	$ 1,598	86 %
Interest expense and financing fee	(7,342)	(8,065)	723	9 %
Gain on sale of priority review voucher, net of expenses	158,873	—	158,873	100 %
Change in fair value of partner company derivative liability	(7,085)	—	(7,085)	100 %
Loss on common stock warrant liabilities	1	(399)	400	100 %
Gain from deconsolidation of subsidiary	186	27,127	(26,941)	(99)%
Other income	11,764	17,599	(5,835)	(33)%
Total other income	**$ 159,843**	**$ 38,110**	**$ 121,733**	**319 %**

Total other income increased $121.7 million, or 319%, from income of $38.1 million for the nine months ended September 30, 2025 to income of $159.8 million for the nine months ended September 30, 2026. As a result of Cyprium's sale of its PRV in March 2026 for $205 million, Cyprium recorded a gain of approximately $158.9 million (see Note 3 to the unaudited condensed consolidated financial statements), and recognized the fair value increase of the embedded derivative liability of $7.1 million associated with the Cyprium perpetual preferred stock redemption due to the PRV sale. We also recognized an increase in the fair value of Urica's equity interest in Crystalys of $11.8 million for the nine months ended September 30, 2026 (see Note 3 to the unaudited condensed consolidated financial statements), and $0.2 million in UNLOXCYT royalties recognized by Fortress as royalty income (contingent consideration). These gains were partially offset by interest expense and financing fee expenses related to Fortress' debt outstanding with Oaktree, including $1.0 million loss on the extinguishment of the Oaktree debt, and Journey's debt outstanding with SWK Funding LLC. The increase in interest income of $1.6 million, or 86%, is due to increased cash balances period over period.

Liquidity and Capital Resources

Sources of Liquidity

At September 30, 2026, we had an accumulated deficit of $630.0 million, primarily as a result of R&D expenses, and selling, general and administrative expenses.

We fund our operations through cash on hand, the sale of debt and equity securities, third-party financings, out-licensing of drug product and drug product candidates and the sale of subsidiaries and partner companies. At September 30, 2026, we had cash and cash equivalents of $152.2 million, of which $114.1 million relates to Fortress and private subsidiaries primarily funded by Fortress, $14.3 million relates to Mustang, $22.3 million relates to Journey, and $1.5 million relates to Avenue. Restricted cash at September 30, 2026, was $1.2 million, which relates to pledges to secure letters of credit in connection with certain office leases held by Fortress.

We may require significant 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, third-party financings, out-licensing of drug product and drug product candidates and the sales of subsidiaries and partner companies. We believe that our current cash and cash equivalents are sufficient to fund operations for at least the twelve months following the date of filing of this Quarterly Report on Form 10-Q. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We may seek funds through equity or debt financings, joint venture or similar development collaborations, the sale of partner companies, royalty financings, or through other sources of financing. See "Item 1A. Risk Factors—Risks Pertaining to the Need for and Impact of Existing and Additional Financing Activities."

Stock Offerings and At-The-Market Share Issuances

On May 17, 2024, the Company filed a shelf registration statement (File No. 333-279516) on Form S-3, which was declared effective on May 30, 2024 (the "2024 Shelf"). As of September 30, 2026, $42.1 million of securities were available for sale under the 2024 Shelf, subject to General Instruction I.B.6. of Form S-3, known as the "baby shelf rules," which limit the number of securities that can be sold under registration statements on Form S-3. However, on July 5, 2024, the board of directors paused the payment of dividends on our Series A Preferred Stock until further notice. As a result, the Company is not currently eligible to use Form S-3 and has lost the ability to use the 2024 Shelf. The Company will regain eligibility to use the 2024 Shelf on the date it files its next Annual Report on Form 10-K, so long as it has: (i) by that date, paid all accrued but unpaid dividends at that time and (ii) timely paid all dividends accruing since the end of the fiscal year to which such Form 10-K relates.

Because the Company is not currently eligible to use Form S-3 due to the failure to pay dividends on the Series A Preferred Stock, on April 1, 2025 the Company filed a post-effective amendment to certain prior Form S-3 registration statements to continue the registration of the offer and sale of shares underlying certain previously issued warrants. This post-effective amendment was declared effective by the SEC on April 2, 2025.

Journey

On December 30, 2022, Journey filed a shelf registration statement on Form S-3 (File No. 333-269079) (the "Journey 2022 S-3"), which was declared effective on January 26, 2023. The Journey 2022 S-3 covered the offering, issuance and sale by Journey of up to an aggregate of $150.0 million of Journey's common stock, preferred stock, debt securities, warrants, and units.

In August 2025, Journey entered into a new At Market Issuance Sales Agreement (the "Journey 2025 ATM Sales Agreement") with B. Riley Securities, Inc. and Lake Street Capital Markets, LLC (each, an "Agent" and together, the "Agents"). In accordance with the terms of the Journey 2025 ATM Sales Agreement, Journey may offer and sell up to 3,750,000 shares of common stock, from time to time through or to the Agents, each acting as sales agent or principal.

On January 15, 2026, Journey filed a shelf registration statement on Form S-3 (File No. 333-292758) (the "Journey 2026 S-3"), which was declared effective by the SEC on January 21, 2026. This shelf registration statement covers the offering, issuance and sale by Journey of up to an aggregate of $150.0 million of its common stock, preferred stock, debt securities, warrants, and units. The Journey 2026 S-3 replaces the Journey 2022 S-3. Sales under the Journey 2025 ATM Sales Agreement after the effective date of the Journey 2026 S-3 are made under the Journey 2026 S-3.

Mustang

On May 31, 2024, Mustang filed a shelf registration statement on Form S-3 (File No. 333-279891) (the "Mustang 2024 S-3"), which was declared effective on June 12, 2024. Under the Mustang 2024 S-3, Mustang may sell up to a total of $40.0 million of its securities. As of September 30, 2026, approximately $34.2 million under the Mustang 2024 S-3 remains available for sales of securities, subject to General Instruction I.B.6. of Form S-3, known as the "baby shelf rules," which limits the amount of securities it can sell under its registration statement on Form S-3 in any 12-month period.

Cyprium

In July 2026, Cyprium declared a cash dividend of approximately $118.6 million, of which approximately $95.4 million was paid to Fortress.

Cash Flows

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

	For the Nine Months Ended September 30, 2026				
($ in thousands)	Fortress[1]	Avenue	Journey	Mustang	Total
Statement of cash flows data:					
Total cash (used in)/provided by:					
Operating activities	$ 144,825	$ (1,335)	$ (2,262)	$ (2,851)	$ 138,377
Investing activities	(86)	—	—	—	(86)
Financing activities	(65,842)	—	495	(139)	(65,486)
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 78,897	$ (1,335)	$ (1,767)	$ (2,990)	$ 72,805

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

	For the Nine Months Ended September 30, 2025					
($ in thousands)	Fortress[1]	Avenue	Checkpoint[2]	Journey	Mustang	Total
Statement of cash flows data:						
Total cash (used in)/provided by:						
Operating activities	$ 10,603	$ (979)	$ (53,154)	$ (6,157)	$ (3,546)	$ (53,233)
Investing activities	8,956	—	—	—	1,165	10,121
Financing activities	(2,995)	2,094	47,310	10,800	14,526	71,735
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 16,564	$ 1,115	$ (5,844)	$ 4,643	$ 12,145	$ 28,623

Note 1: Includes Fortress, non-public subsidiaries and elimination entries.
Note 2: Checkpoint was deconsolidated as of May 2025 related to the Sun Pharma transaction (see Note 3 to the unaudited condensed consolidated financial statements).

The following table summarizes our consolidated cash flows during the periods indicated:

($ in thousands)	Nine Months Ended September 30, 2026	2025	Change
Total cash (used in)/provided by:			
Operating activities	$ 138,377	$ (53,233)	$ 191,610
Investing activities	(86)	10,121	(10,207)
Financing activities	(65,486)	71,735	(137,221)
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 72,805	$ 28,623	$ 44,182

Operating Activities

Net cash provided by operating activities increased $191.6 million for the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025. The increase is due to net income of $129.5 million for the nine months ended September 30, 2026 as compared to the net loss of $27.5 million for the same period in 2025, a decrease in the gain recognized on the deconsolidation of Checkpoint of $26.9 million, and an increase of $13.8 million resulting from changes in operating assets and liabilities.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2026 was $0.1 million, compared to net cash provided by investing activities for the nine months ended September 30, 2025 of $10.1 million, a decrease of $10.2 million, due to the cash increase in 2025 as a result of the deconsolidation of Checkpoint, and Mustang's $1.2 million proceeds from the sale of its held-for-sale assets related to the exit of its manufacturing facility in 2025.

Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2026 was $65.5 million, compared to net cash provided by financing activities for the nine months ended September 30, 2025 of $71.7 million, a decrease of $137.2 million. The decrease is attributable to a decrease in proceeds from partner companies' equity offerings and option and warrant exercises of $61.6 million, an increase in partner company dividends declared and paid of $22.7 million, an increase in the payments made to Oaktree of $24.0 million, and an increase of $14.2 million in payments made for the redemption of partner company preferred shares.

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 for convenience. 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, 2026, there were no material changes in our contractual obligations and commitments, except (i) our lease obligation, as described in our 2025 Form 10-K and (ii) the extinguishment of our debt obligation to Oaktree Fund Administration, LLC being terminated upon full payment in September 2026, resulting in no future payments or obligations, as described in Note 9. On February 10, 2026, the Company became party to a sublease agreement with a third party to sublease all of its leased office space in New York, NY, consisting of approximately 23,000 square feet, under its existing lease with Sage Realty Corporation (the "Landlord"). The Company obtained the Landlord's consent to the sublease, and the sublease commenced on March 15, 2026. The sublease expires on August 31, 2031.

Pursuant to the sublease agreement, the Company expects to receive approximately $11.9 million in aggregate base rent payments over the term of the sublease. The Company remains primarily liable for the obligations under the original lease.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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, 2026, 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 that materially affected, or is reasonably 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, 2026. 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, that are 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 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, 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, 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 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 can take many 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 product candidates, 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 Administration ("DEA"), or foreign equivalent, may schedule one or more of our product candidates under the Controlled Substances Act (the "CSA"), 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 or unanticipated delays, and/or prevent the receipt of the required approvals for commercialization.

The research and clinical development, testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of any product candidate, including our product candidates, is subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market a product candidate until the FDA approves such product candidate's Biologics License Application or New Drug Application ("NDA"). The approval process is uncertain, expensive, often spans many years, and can vary substantially based upon the type, complexity and novelty of the product candidates 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, including changes that may be taken by the current presidential administration.

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.

Additionally, over the last several years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to review and process our regulatory submissions in a timely manner, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 or resume a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching and maintaining agreements on acceptable terms with 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 candidates, if approved, 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 candidate 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 or chemistry, manufacturing and control issues, or other 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 making, use, sale, importation, exportation and distribution of controlled substances are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies.

Controlled substances are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Controlled substances are regulated under the CSA and regulations of the DEA. IV tramadol, under development by our partner company Avenue, will be subject to these regulations.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse and no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Various states also independently regulate controlled substances. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

For any of our products classified as controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in clinical trials for our product candidates and the ability to produce and distribute our products in the volume needed to both meet commercial demand and build inventory to mitigate possible supply disruptions.

Regulations associated with controlled substances govern manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product candidates including controlled substances. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our product candidates that are classified as controlled substances, which 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 Securities to decline.

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, 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 or Untitled 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.

If the FDA does not conclude that a product candidate satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidate under Section 505(b)(2) are not as we expect, the approval pathway for the product candidate will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act (the "FDCA"). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization in a timely manner, or at all.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Changes in U.S. government policy, regulation, enforcement priorities, and funding decisions could adversely affect our business, financial condition and results of operations.

The current presidential administration has signaled, and may further implement, significant shifts in policies that directly impact the life sciences industry, including policies relating to FDA regulation and enforcement, drug approval and review processes, reimbursement and pricing (including Medicare, Medicaid and other government programs), healthcare reform, intellectual property protection, trade and tariffs, and federal research and public health funding. The administration's approach, together with actions by Congress and federal agencies such as the FDA, PTO, Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services ("HHS"), National Institutes of Health and the Centers for Disease Control and Prevention, is inherently uncertain and may materially differ from historical norms or from our current expectations.

Potential changes may include, among others: (i) modifications to standards, procedures or timelines for the review, clearance, approval or post-market oversight of drugs; (ii) changes to policies on real-world evidence, accelerated approval, emergency use authorizations, and clinical trial requirements; (iii) reforms or restrictions affecting drug pricing, reimbursement levels, coverage decisions and formulary placement for products paid for by federal healthcare programs; (iv) increased or decreased enforcement of laws and regulations relating to manufacturing, promotion, fraud, abuse, data integrity, privacy and cybersecurity; (v) changes in federal funding priorities for biomedical research and public health programs that may impact key customers, collaborators and research partners; and (vi) trade, tariff and supply-chain measures that could affect our access to critical materials, components, contract manufacturers, or international markets.

Any such actions, or uncertainty regarding potential actions, could increase development, regulatory, compliance, and commercialization costs; delay, limit or prevent the development, approval, launch or commercial success of future product candidates or marketed products; affect pricing, reimbursement and market access; disrupt our supply chain; alter the behavior and financial condition of our customers, clinical sites, collaborators and payors; and contribute to volatility in capital markets that could affect our ability to raise additional financing on acceptable terms or at all. Because we cannot predict the timing, scope, direction, or ultimate impact of policy or regulatory changes under the current presidential administration, we may not be able to anticipate or fully mitigate their effects. Any of the foregoing could materially and adversely affect our business, financial condition, and results of operations.

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.

At September 30, 2026, after giving effect to our repayment in full of the remaining amounts due under our prior facility with Oaktree Fund Administration, LLC and the lenders from time-to-time party to such facility, the total amount of debt outstanding, net of the debt discount, was $25.6 million. If we default on any future debt 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 future 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, 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.

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 $24.9 million and $65.4 million for the nine months ended September 30, 2026 and 2025, respectively and $70.2 million and $110.4 million for the years ended December 31, 2025 and 2024, respectively. At September 30, 2026, we had an accumulated deficit of approximately $630.0 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 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 achieve profitability will depend upon our ability to generate and sustain revenue. To date: (i) Journey generates revenue from product sales (and in some cases royalties); (ii) Cyprium receives royalty payments from sales of ZYCUBO; and (iii) Fortress is eligible to receive royalty payments from sales of UNLOXCYT. Aside from these sources, we have not generated any sales revenue from our development stage products, and we do not know when, or if, we will generate any sales revenue from such development-stage products. Our ability to do so 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, which 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 Securities to decline. 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 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 trading 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 nine months ended September 30, 2026 and 2025, we incurred R&D expenses of approximately $3.0 million and $12.3 million, respectively, and during the years ended December 31, 2025 and 2024, we incurred R&D expenses of approximately $11.9 million and $56.9 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, 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, which 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 Securities to decline. The terms of our existing debt arrangements 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, have 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, which 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 Securities to decline.

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 Securities that are convertible into or exercisable for shares of 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 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 impose covenants that restrict our operations, including by limiting 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.

We have paused dividend payments on our Series A Preferred Stock and may not be able to resume payment of dividends on our Series A Preferred Stock in the future if, inter alia, we have insufficient cash or available "surplus" as defined under Delaware law to make such dividend payments.

On July 5, 2024, our board of directors paused the payment of dividends on our Series A Preferred Stock until further notice. However, dividends on our Series A Preferred Stock accrue daily, are payable monthly and will continue to accrue from the last date of payment. Our board of directors deemed the foregoing to be in the best interests of the Company and its common stockholders in light of the Company's current and anticipated financial condition and outlook, and after considering its fiduciary duties to the Company's common stockholders and other relevant factors. Our ability to pay cash dividends on our Series A Preferred Stock in the future requires us to have either net profits or positive net assets (total assets less total liabilities) over our capital, and that we have sufficient working capital in order to be able to pay our debts as they become due in the usual course of business. Our ability to pay dividends may also be impaired if any of the risks described in this report were to occur. Also, payment of our dividends depends upon our financial condition and other factors as our board of directors may deem relevant from time to time. We cannot assure you that we will have sufficient cash or "surplus" to resume payment of the cash dividends on the Series A Preferred Stock in a timely manner, or at all.

Because we have paused dividend payments on our Series A Preferred Stock, we are currently ineligible to file new short-form registration statements on Form S-3, which may impair our ability to raise capital on terms favorable to us, in a timely manner or at all.

Form S-3 permits eligible issuers to conduct registered offerings using a short-form registration statement that allows the issuer to incorporate by reference its past and future filings and reports made under the Exchange Act. In addition, Form S-3 enables eligible issuers to conduct primary offerings "off the shelf" under Rule 415 of the Securities Act. The shelf registration process, combined with the ability to forward incorporate information, allows issuers to avoid delays and interruptions in the offering process and to access the capital markets in a more expeditious and efficient manner than raising capital in a standard registered offering pursuant to a registration statement on Form S-1.

As a result of our decision to pause dividend payments on our Series A Preferred Stock, we will not be eligible to register the offer and sale of our securities using a registration statement on Form S-3 until we pay all accumulated dividends on our Series A Preferred Stock, resume payments of newly accruing dividends on our Series A Preferred Stock and enter a fiscal year during which we missed no such dividend payments. Should we wish to register the offer and sale of our securities to the public prior to the time we are eligible to use Form S-3, both our transaction costs and the amount of time required to complete the transaction could increase, making it more difficult to execute any such transaction successfully and thereby potentially adversely affecting our financial condition.

We have never paid and currently do not intend to pay cash dividends in the near future, except for the dividend we previously paid 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 previously paid 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 partner companies and subsidiaries 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.

We have historically relied in part on sales of our Common Stock and other securities to fund our operations, and our future ability to obtain additional capital through stock sales or other securities offerings may be more costly than in the past, or may not be available to us at all.

We have historically relied in part on sales of our Common Stock to fund our operations. For example, we raised an aggregate of approximately $36.6 million in net proceeds in fiscal years 2023 and 2024 and $1.0 million in net proceeds through the sale of shares of our Common Stock in offerings made under a Form S-3 "shelf" registration statement and $2.6 million from warrant exercises in fiscal year 2025. For the nine months ended September 30, 2026 we raised $1.2 million in net proceeds from warrant exercises. Using a shelf registration statement to conduct an equity offering to raise capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. We are no longer eligible to file any new shelf registration statements due to non-payment of dividends on our Series A Preferred Stock since July 5, 2024 and because we have not resumed payment of dividends on our Series A Preferred Stock or paid all accumulated dividends, we have lost the ability to use our currently effective "shelf" registration statement on Form S-3. Accordingly, we are only able to conduct additional offerings of our securities under an exemption from registration under the Securities Act or under a Form S-1 registration statement. We would expect either of these alternatives to be a more expensive method of raising additional capital and may be more dilutive to our stockholders relative to using a Form S-3 shelf registration statement.

Risks Pertaining to Our Existing Revenue Stream from Journey Medical Corporation

Future revenue based on sales of our dermatology products, Qbrexza, Accutane, Amzeeq, Zilxi, Targadox, Exelderm, Luxamend, Eurax and Emrosi, 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 financial condition, cash flows and/or operating results and/or reduce 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 our products face generic competition and/or losses of exclusivity.

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

A significant portion of our sales derive from products that are without patent protection and/or are or may become subject to third-party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse impact on our operating income. Four of our marketed products, Qbrexza, Amzeeq, Zilxi, and Emrosi, currently have patent protection. Five of our marketed products, Accutane, Targadox, Exelderm, Eurax, and Luxamend 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/B rated products. Targadox currently competes with one therapeutically equivalent A/B rated generic product. Exelderm may face A/B 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 by third-party payors, 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 reduction in sales of our products, or the prices we receive for our products as a result of generic competition 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 Securities to decline.

On February 25, 2026, Journey filed a patent infringement lawsuit in the District Court for the District of Delaware against Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. (collectively "Lupin"). This lawsuit was filed following receipt of a "paragraph IV certification" notice from Lupin regarding its filing of an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to engage in the commercial manufacture, use, or sale of a generic version of Emrosi in the U.S. prior to the expiration of certain of Journey's U.S. patents. The notice alleged that certain of Journey's patents related to Emrosi, which expire in January 2039, are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the proposed generic products. Journey intends to vigorously defend its intellectual property. The filing of a lawsuit within 45 days of receipt of Lupin's paragraph IV notice triggered a stay of FDA approval of Lupin's ANDA for up to 30 months in accordance with the Hatch-Waxman Act.

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 and for which we receive marketing authorization, 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, cash flows and results of operations and could cause the market value of our Securities to decline.

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, if approved, 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 product candidates 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.

Our products and future product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to successfully commercialize any product candidate that receives marketing authorization depends in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the healthcare industry in the United States and elsewhere is cost containment.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system, including implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "Affordable Care Act"), was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, may result in more rigorous coverage criteria and in additional downward pressure on the price that can be charged for drug products. In addition, on May 12, 2025, President Trump issued an executive order implementing the concept of most-favored nation pricing. Under this order, the HHS, in coordination with other federal agencies, is directed to take actions to ensure that the price of prescription drugs paid by federal health insurers, including Medicare and Medicaid, is in line with the prices paid in comparably developed nations. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers.

The Inflation Reduction Act of 2022 (the "IRA") contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the HHS that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Orphan drugs that treat only one rare disease are exempt from the IRA's drug negotiation program. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA.

As an alternative to the Affordable Care Act, President Trump recently announced the Great Healthcare Plan. As presented, the plan is intended to lower drug prices by increasing competition and benchmarking U.S. drug prices to other countries, reduce insurance premiums by redirecting subsidies from insurers to individuals, increase accountability and transparency from insurers, and promote consumer choice by giving individuals more direct control over how healthcare dollars are spent. Legislative and regulatory action will be required to fully implement the plan. It is unclear how these proposed changes will impact our business and the pharmaceutical industry in general.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Additional federal, state and foreign healthcare reform measures will be adopted in the future.

The implementation of any of the cost containment measures or other healthcare reforms discussed above may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. It is uncertain whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such may be. In addition, increased Congressional scrutiny of the FDA's approval process, as well as staffing cuts effected at the FDA in early 2025, may significantly delay or prevent marketing approval, and the industry could become subject to more stringent product labeling and post-marketing testing and other requirements, any of which could have a material adverse impact on the development and commercialization of drug products.

Over the last several years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to review and process any regulatory submissions we submit in a timely manner, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The Company's business may be materially adversely affected by the imposition of duties and tariffs and other trade barriers and retaliatory countermeasures implemented by the U.S. and other governments.

Recently there have been significant changes to United States trade policies, sanctions and tariffs, including, but not limited to, trade policies and imposition of tariffs affecting products imported from outside of the U.S., including pharmaceutical products. This could have negative impacts on our business operations. These changes to trade policies, sanctions, and tariffs have led to increased trade and political tensions between the U.S. and other countries in the international community. In response to the U.S. tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Currently, we import a large portion of our finished products from countries outside of the U.S., including, most significantly, from India. These tariffs or any new or additional tariffs on goods imported to the U.S. from India, or other countries, could increase the cost of sourcing of our products and therefore reduce our margins, reduce our net sales and/or cause us to increase prices. Further, the continued threats of tariffs, trade restrictions and trade barriers could have a generally disruptive impact on the global economy and, therefore, negatively impact our sales, overall business and results of operations. The impact of any adopted, new or proposed tariffs, trade restrictions or domestic sourcing requirements on our business is subject to a number of factors that we cannot predict, including, but not limited to, the scope, nature, amount, effective date and duration of any such measures. Such tariffs, trade restrictions or domestic sourcing requirements could have a material adverse effect on our business, prospects, financial condition or results of operations.

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 several collaborations and/or contingent sale agreements in respect of certain of our assets and subsidiaries, and the acquisition component of these transactions has been consummated. These arrangements include the acquisition of Checkpoint by Sun Pharma, which closed in May 2025, an equity investment and contingent acquisition between Caelum and AstraZeneca, and a development funding and contingent asset purchase between Cyprium and Sentynl. Each of these arrangements has been time-consuming and has diverted management's attention. As a result of these consummated/contingent sales, as with other similar transactions that we may complete, we may experience a reduction in the size or scope of our business, our market share in particular markets, our opportunities with respect to certain markets, products or therapeutic categories or our ability to compete in certain markets and therapeutic categories.

In addition, in connection with any transaction involving a (contingent or non-contingent) sale of one of our 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 Securities.

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 capital 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 capital 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, Preferred Stock and/or debt securities may be materially adversely affected.

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 subsidiaries and partner companies, pursuant to which we may become obligated either to pay what could be a significant amount of cash or issue what could be a significant number of shares of Common Stock or Preferred Stock if certain events occur or do not occur, which could lead to a depletion of resources or dilution to our Common Stock, or both.

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

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

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

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger biopharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors may have access to greater financial resources than we do 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, 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 subsidiaries, partner companies, related parties 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 conflict 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 financial condition, cash flows and/or 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, enter into joint ventures with or obtain a controlling interest in, companies in the future, our financial condition, 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.

Our results of operations could be adversely affected by economic and political conditions and the effects of these conditions on our business activities.

Any terrorist attack, other act of violence or war, including military conflicts, could result in increased volatility in, or damage to, the worldwide financial markets and economy. This includes military conflict between Russia and Ukraine, military conflict in the Middle East, military conflicts between the United States and Iran, and tensions across the Taiwan Strait. For instance, the United States or other countries may impose sanctions that restrict doing business in the affected countries and increased military conflict may affect third-party vendors and cause delays.

This risk may be magnified in the case of the recent and ongoing military conflicts between the United States and Iran, Israel and Hamas and Hezbollah and Russia and Ukraine. These conflicts may disrupt our partner companies' ability to conduct clinical trials in a number of areas of the world, and accordingly, certain clinical trial sites may be affected. 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.

Additionally, trade policies and geopolitical disputes and other international conflicts can result in tariffs, sanctions and other measures that restrict international trade, and can materially adversely affect our business, particularly if these measures occur in regions where drug products are manufactured or raw materials are sourced. Under the current presidential administration in the U.S., additional and higher tariffs and sanctions have been imposed on goods imported from China and other countries which could increase the cost of goods needed to commercialize our products and continue development of our current and any future product candidates. Further, such actions by the U.S. could result in retaliatory action by those countries which could impact our ability to profitably commercialize our products in those jurisdictions. As a result, our business, operations, and financial condition could be materially harmed.

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 rely heavily on such third parties and other contractors to produce commercial supplies of our product candidates and products, if approved. 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 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. Finally, in light of our partner company Mustang's recent exit from its leased manufacturing facility and reduction in force in April 2024, we may increase our reliance at Mustang on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of one or more product candidates for which our collaborators or we obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms, and even if we are able to establish such agreements with third-party manufacturers, reliance entails additional risks.

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 product candidates 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, particularly in the development and manufacture of gene therapy products, 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 to 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.

New environmental laws or regulations in the various jurisdictions in which we operate may also impose additional requirements that impact the way our products and product candidates are manufactured or packaged. Complying with such changes could be costly, and a failure to comply in a timely manner could lead to fines, penalties or the inability to pursue our development and commercialization activities in such jurisdictions, materially impacting our business and financial condition.

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 September 30, 2026, we had an accumulated deficit of approximately $630.0 million, and as of December 31, 2025 and 2024, we had an accumulated deficit of approximately $734.1 million and $740.9 million, respectively. 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 is 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 GLPs as appropriate. Moreover, the FDA requires us to comply with 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 third party on which we rely 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 certain 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, not acceptable by regulatory authorities 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, if approved, 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 have 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 indemnitees (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 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 a 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 Approved

If any of our product candidates are successfully developed and receive regulatory approval but do not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that any such product candidates, if approved, 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, if approved 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 products 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 such products over alternative treatments;
- the safety of such products 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 such products;
- 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 candidates 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 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, if approved.

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 candidate or product we develop, license, or acquire 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 candidate or 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, license or acquire;

- 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 ability to commercialize our product candidates or future product candidates.

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 adverse events. 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 letters, untitled letters, or Form 483s;
- 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 product candidates when and if any of them are approved, resulting in decreased revenue from milestones, product sales or royalties, which 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 Securities to decline.

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 could 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, chiropractors, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives 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;

- U.S. Foreign Corrupt Practices Act, or FCPA, which prohibit us and third parties working on our behalf from making payments to foreign government officials to assist in obtaining or retaining business. Specifically, the anti- bribery provisions of the FCPA prohibit the willful use of the mails or any means of instrumentality of interstate commerce corruptly in furtherance of any offer, payment, promise to pay, or authorization of the payment of money or anything of value to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to a foreign official to influence the foreign official in his or her official capacity, induce the foreign official to do or omit to do an act in violation of his or her lawful duty, or to secure any improper advantage in order to assist in obtaining or retaining business for or with, or directing business to, any person; enforcement actions may be brought by the Department of Justice or the SEC; legislation has expanded the SEC's power to seek disgorgement in all FCPA cases filed in federal court and extended the statute of limitations in SEC enforcement actions in intent-based claims, such as those under the FCPA, from five years to ten years; 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.

Recent U.S. Supreme Court decisions could create uncertainty in the life sciences space that could negatively impact our business.

Three decisions from the U.S. Supreme Court in July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. These cases may result in increased litigation by industry against regulatory agencies and impact how such agencies choose to pursue enforcement and compliance actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and SEC regulations, policies, and decisions may become subject to increasing legal challenges, delays, and changes.

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 was able to trace and seize the fraudulently transferred cryptocurrency associated with the breach. On September 19, 2024, the United States District Court Southern District of New York through the United States Marshals notified the Company that it has recovered and would be returning to the Company a portion of the misappropriated cash, and in December of 2024 Journey received $4.6 million in connection with the recovery of funds related to the cybersecurity incident.

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.

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 of 1933, as amended (the "Securities Act"), or an effective registration statement. 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 Series A 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, 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, including climate-related initiatives. 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.

The use of artificial intelligence in the healthcare industry and challenges with properly managing its use could adversely affect our business.

We may incorporate artificial intelligence ("AI") solutions into our business, and applications of AI may become important in our operations over time. Our competitors or other third parties may incorporate AI into their businesses more quickly or more successfully than us, which could impair our ability to compete effectively and adversely affect our results of operations. There are also significant risks involved in developing and deploying AI, and there can be no assurance that the usage of AI will enhance our products or the development of our product candidates or be beneficial to our business, including our efficiency or profitability. For example, any AI-related efforts, particularly those related to generative AI, could subject us to risks related to harmful content, inaccuracies, bias, discrimination, intellectual property infringement or misappropriation, defamation, data privacy, cybersecurity, and sanctions and export controls, among others. It is also uncertain how various laws will apply to content generated by AI. We are subject to the risks of new or enhanced governmental or regulatory scrutiny, litigation, or other legal liability, ethical concerns, negative consumer perceptions as to automation and AI, or other complications that could adversely affect our business, reputation, or financial results.

AI's rapid development is the subject of evolving review by various U.S. governmental and regulatory agencies, and other foreign jurisdictions are applying, or are considering applying, their intellectual property, cybersecurity, data protection and other laws to AI, and/or are considering general legal frameworks on AI. We may not be able to timely comply with these frameworks and, if such regulatory actions are contrary to our use of AI, would require us to expend our limited resources to adjust our use accordingly.

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 and staffing cuts effected at the FDA in early 2025 may significantly delay or prevent marketing approval. 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. We do not know what impact any changes by the current presidential administration will have on our business or the business of our partners.

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

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

We will 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 Market. 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.

We have previously failed to satisfy certain continued listing rules of the Nasdaq, including rules requiring that the minimum trading price of our Common Stock not close below $1.00 per share for 30 consecutive business days. If we again are unable to meet the continued listing requirements, our Common Stock and Preferred Stock may be subject to delisting from The Nasdaq Capital Market if we are unable to regain compliance with such rules. The delisting of our Securities from the Nasdaq may decrease the market liquidity and market price of our Common Stock and Preferred Stock.

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. For example, the United States recently passed the Inflation Reduction Act, which provides for a minimum tax equal to 15% of the adjusted financial statement income of certain large corporations, as well as a 1% excise tax on certain share buybacks by public corporations that would be imposed on such corporations. In addition, it is uncertain if and to what extent various states will conform to newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Fluctuations in interest rates may negatively impact the rate of return that we realize on the investment securities that we hold.

We customarily invest a significant portion of our cash in Insured Cash Sweeps ("ICS") and/or Certificate of Deposit Account Registry Service ("CDARS") accounts, each of which bears interest income to us that fluctuates according to adjustments in the target federal funds rate effected by the U.S. Federal Reserve's Federal Open Market Committee ("FOMC"). The FOMC recently lowered the target federal funds rate and is anticipated by some to effect further decreases over the coming weeks and months, actions which have decreased, and could further decrease, the amount of interest income that we generate on our ICS, CDARS, and other short-term cash equivalent investment securities that we may hold.

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

On October 11, 2026, the Company issued 237,733 shares of its common stock, par value $0.001 per share, to Cedars-Sinai Intellectual Property Company as consideration for an exclusive worldwide license under certain patent rights and technical information relating to rifaximin combined with N-acetylcysteine, also known as FB-607, for the prevention, treatment, diagnosis, detection and monitoring of diseases and conditions in humans and animals, including irritable bowel syndrome with diarrhea. The aggregate value of the consideration received was $0.5 million. The Company received no cash proceeds from the issuance, and no underwriting discounts or commissions were paid.

The shares were issued in reliance on Section 4(a)(2) of the Securities Act of 1933, as amended, because the issuance involved a privately negotiated transaction with Cedars-Sinai Medical Center and did not involve a public offering.

Item 3. Defaults Upon Senior Securities

On July 5, 2024, Fortress announced that the Company's Board of Directors had decided to pause the monthly dividend of $0.1953125 per share of the Company's Series A Preferred Stock. In accordance with the terms of the Series A Preferred Stock, dividends on the Series A Preferred Stock will continue to accrue and cumulate until such dividends are authorized or declared. The pausing of these dividends will defer approximately $0.7 million in cash dividend payments each month. The Board intends to revisit its decision regarding the monthly dividend regularly and will assess the profitability and cash flow of the Company to determine whether and when the pause should be lifted.

During the nine months ended September 30, 2026, no dividends were declared by the Board of Directors. At September 30, 2026, the Company had total undeclared dividends of approximately $18.1 million, which represents the cumulated (but undeclared) dividends due to Series A Preferred shareholders on September 30, 2026.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended) adopted, modified or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K of the Securities Act of 1933).

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, as amended, 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, as amended, 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 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 8-K (file No. 001-35366) filed with SEC on June 23, 2021).
3.7	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).
3.8	Certificate of Amendment of the Amended and Restated Certificate of Incorporation 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).
3.9	Fourth Amended and Restated Bylaws of the Company (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 June 25, 2024).
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.
** Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

November 13, 2026

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 13, 2026

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 fiscal 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 13, 2026

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 fiscal 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 13, 2026

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, 2026, 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 13, 2026

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, 2026, 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 13, 2026

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