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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 March 31, 2025

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 May 12, 2025
Common Stock, $0.001 par value	29,569,920
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, and Exelderm. Any issues relating to the manufacture, sale, utilization, or reimbursement of Journey's products (including products liability claims) could significantly impact our operating results.
- A significant portion of Journey's sales derive from products that are without patent protection and/or are or may become subject to third party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse effect on our operating income. Four of Journey's marketed products, Emrosi, Qbrexza, Amzeeq and Zilxi, currently have patent protection. Four of Journey's marketed products, Accutane, Targadox, Exelderm, 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 our licensors may affect our ability to develop or commercialize our product candidates.

Risks Pertaining to Generic Competition and Paragraph IV Litigation

- Generic drug companies may submit applications seeking approval to market generic versions of our products.
- In connection with these applications, generic drug companies may seek to challenge the validity and enforceability of our patents through litigation and/or with the United States Patent and Trademark Office ("PTO"). Such 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)

	March 31, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 91,339	$ 57,263
Accounts receivable, net	18,025	10,231
Inventory	12,496	14,431
Other receivables - related party	309	171
Prepaid expenses and other current assets	4,734	7,110
Assets held for sale	—	1,165
Total current assets	126,903	90,371
Property, plant and equipment, net	2,796	3,260
Operating lease right-of-use asset, net	13,303	13,861
Restricted cash	1,220	1,552
Intangible assets, net	30,798	31,863
Other assets	3,051	3,316
Total assets	**$ 178,071**	**$ 144,223**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	$ 66,286	$ 65,501
Income taxes payable	952	932
Common stock warrant liabilities	261	214
Operating lease liabilities, short-term	2,159	2,623
Partner company notes payable, short-term	1,875	—
Partner company installment payments - licenses, short-term	—	625
Other current liabilities	2,141	1,504
Total current liabilities	73,674	71,399
Notes payable, long-term, net	56,382	57,962
Operating lease liabilities, long-term	13,820	14,750
Other long-term liabilities	1,709	1,756
Total liabilities	**145,585**	**145,867**
Commitments and contingencies (Note 14)		
Stockholders' equity (deficit)		
Cumulative redeemable perpetual preferred stock, $0.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 29,554,966 and 27,908,839 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	30	28
Additional paid-in-capital	773,668	763,573
Accumulated deficit	(751,451)	(740,867)
Total stockholders' equity attributed to the Company	22,250	22,737
Non-controlling interests	10,236	(24,381)
Total stockholders' equity (deficit)	32,486	(1,644)
Total liabilities and stockholders' equity (deficit)	**$ 178,071**	**$ 144,223**

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 March 31,	
	2025	2024
Revenue		
Product revenue, net	$ 13,139	$ 13,030
Operating expenses		
Cost of goods - (excluding amortization of acquired intangible assets)	4,790	6,002
Amortization of acquired intangible assets	1,065	814
Research and development	3,938	24,839
Selling, general and administrative	25,663	17,941
Total operating expenses	35,456	49,596
Loss from operations	(22,317)	(36,566)
Other income (expense)		
Interest income	490	833
Interest expense and financing fee	(2,805)	(2,602)
Loss on common stock warrant liabilities	(47)	(667)
Other income (expense)	(12)	(21)
Total other expense	(2,374)	(2,457)
Net loss	**(24,691)**	**(39,023)**
Net loss attributable to non-controlling interests	14,107	23,606
Net loss attributable to Fortress	**$ (10,584)**	**$ (15,417)**
Preferred A dividends declared and paid and/or cumulated, and Fortress' share of subsidiary deemed dividends	(2,131)	(2,442)
Net loss attributable to common stockholders	**$ (12,715)**	**$ (17,859)**
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.48)	$ (1.04)
Weighted average common shares outstanding - basic and diluted	26,450,218	17,151,945

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

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

For the Three Months Ended March 31, 2025

	Series A Perpetual Preferred Stock		Common Stock		Common Shares Issuable	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	—	—	—	—	—	6,289	—	—	6,289
Issuance of common stock related to equity plans	—	—	1,096,564	1	—	(1)	—	—	—
Redemption of partner company preferred shares	—	—	—	—	—	(150)	—	—	(150)
Issuance of common stock for at-the-market offering, net	—	—	539,563	1	—	1,008	—	—	1,009
Partner companies' offerings, net + warrant exercises	—	—	—	—	—	44,908	—	—	44,908
Partner company's at-the-market offering, net	—	—	—	—	—	6,740	—	—	6,740
Issuance of common stock under partner company's ESPP	—	—	—	—	—	99	—	—	99
Partner company's dividends declared and paid	—	—	—	—	—	(166)	—	—	(166)
Partner companies' proceeds from options	—	—	—	—	—	75	—	—	75
Exercise of warrants for cash	—	—	10,000	—	—	17	—	—	17
Non-controlling interest in partner companies	—	—	—	—	—	(48,724)	—	48,724	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	(14,107)	(14,107)
Net loss attributable to common stockholders	—	—	—	—	—	—	(10,584)	—	(10,584)
Balance as of March 31, 2025	**3,427,138**	**$ 3**	**29,554,966**	**$ 30**	**$ —**	**$ 773,668**	**$ (751,451)**	**$ 10,236**	**$ 32,486**

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

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

For the Three Months Ended March 31, 2024

	Series A Perpetual Preferred Stock		Common Stock		Common Shares Issuable	Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance as of December 31, 2023	**3,427,138**	**$ 3**	**15,093,053**	**$ 15**	**$ —**	**$ 717,396**	**$ (694,870)**	**$ (20,957)**	**$ 1,587**
Stock-based compensation expense	—	—	—	—	—	4,857	—	—	4,857
Issuance of common stock related to equity plans	—	—	461,468	—	—	—	—	—	—
Issuance of common stock for public offering, net			3,303,305	4		10,115			10,119
Issuance of common stock for at-the-market offering, net	—	—	462,200	—	—	894	—	—	894
Common shares issued for dividend on partner company's convertible preferred shares	—	—	37,817	—	—	68	—	—	68
Preferred A dividends declared and paid	—	—	—	—	—	(2,008)	—	—	(2,008)
Partner companies' offerings, net	—	—	—	—	—	12,636	—	—	12,636
Issuance of common stock under partner company's ESPP	—	—	—	—	—	133	—	—	133
Partner company's dividends declared and paid	—	—	—	—	—	(176)	—	—	(176)
Partner company's exercise of options and warrants for cash, net	—	—	—	—	—	5,461	—	—	5,461
Exercise of warrants for cash	—	—	17,500	—	—	30	—	—	30
Non-controlling interest in partner companies	—	—	—	—	—	(17,600)	—	17,600	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	(23,605)	(23,605)
Net loss attributable to common stockholders	—	—	—	—	—	—	(15,417)	—	(15,417)
Balance as of March 31, 2024	**3,427,138**	**$ 3**	**19,375,343**	**$ 19**	**$ —**	**$ 733,290**	**$ (710,287)**	**$ (26,962)**	**$ (3,937)**

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)

	Three Months Ended March 31, 2025	2024
Cash Flows from Operating Activities:		
Net loss	$ (24,691)	$ (39,023)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation expense	126	377
Bad debt expense	195	6
Amortization of debt discount	295	609
Accretion of partner company convertible preferred shares	—	45
Gain on termination of partner company lease	(394)	—
Amortization of acquired intangible assets	1,065	814
Reduction in the carrying amount of operating lease right-of-use assets	485	528
Stock-based compensation expense	6,289	4,857
Loss on partner company warrant issuance	—	574
Common shares issued for dividend on partner company's convertible preferred shares	—	68
Change in fair value of partner companies' warrant liabilities	47	93
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:		
Accounts receivable	(7,989)	5,417
Inventory	1,935	(374)
Other receivables - related party	(138)	(157)
Prepaid expenses and other current assets	2,376	(1,571)
Other assets	265	313
Accounts payable and accrued expenses	550	2,668
Income taxes payable	20	—
Lease liabilities	(589)	(585)
Other long-term liabilities	590	(46)
Net cash used in operating activities	(19,563)	(25,387)
Cash Flows from Investing Activities:		
Proceeds from sale of property and equipment	1,165	—
Net cash provided by investing activities	1,165	—

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)

	Three Months Ended March 31, 2025	2024
Cash Flows from Financing Activities:		
Payment of Series A perpetual preferred stock dividends	$ —	$ (2,008)
Proceeds from issuance of common stock for equity offerings, net	—	10,119
Proceeds from issuance of common stock for at-the-market offering, net	1,009	894
Exercise of warrants for cash	17	30
Proceeds from partner companies' ESPP	99	133
Partner company’s dividends declared and paid	(166)	(176)
Partner company’s redemption of preferred shares	(150)	—
Proceeds from partner companies' equity offerings, options and warrant exercises, net	45,218	17,383
Proceeds from partner companies' at-the-market offering, net	6,740	1,484
Repayment of partner company installment payments - licenses	(625)	—
Net cash provided by financing activities	52,142	27,859
Net increase in cash and cash equivalents and restricted cash	33,744	2,472
Cash and cash equivalents and restricted cash at beginning of period	58,815	83,365
Cash and cash equivalents and restricted cash at end of period	$ 92,559	$ 85,837
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,324	$ 1,658
Supplemental disclosure of non-cash financing and investing activities:		
Unpaid partner company’s offering cost	$ 235	$ 150

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 holding and dividend and royalty revenue streams. 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, Fred Hutchinson Cancer Center, Dana-Farber Cancer Institute, Nationwide Children's Hospital, Columbia University, the University of Pennsylvania, AstraZeneca plc, and Dr. Reddy's Laboratories, Ltd.

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

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

As used throughout this filing, the words "we", "us" and "our" may refer to Fortress individually, to one or more of its subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context. Generally, "subsidiary" refers to a private Fortress subsidiary, "partner company" refers to a public Fortress subsidiary, and "partner" refers to 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.

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. The Company is also required to comply with the financial covenants in its loan agreements as described in Note 9. Current cash and cash equivalents as of March 31, 2025 of $19.5 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 10-Q. However, the Company will need to raise additional funding through strategic relationships, public or private equity or debt financings, sale of partner companies including Checkpoint as discussed in Note 3, 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.

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

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 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, Checkpoint, Mustang and Journey. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the Company's Annual Report on Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 31, 2025 (the "2024 Form 10-K"), from which the Company derived the balance sheet data at December 31, 2024, as well as Checkpoint's Form 10-K, filed with the SEC on March 28, 2025, Mustang's Form 10-K, filed with the SEC on March 28, 2025, Avenue's Form 10-K, filed with the SEC on March 31, 2025, and Journey's Form 10-K, filed with the SEC on March 27, 2025.

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.

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 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.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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Restricted Cash

The Company records cash held in trust or pledged to secure certain debt obligations as restricted cash. As of March 31, 2025, the Company had $1.2 million of restricted cash representing pledges to secure letters of credit in connection with certain office leases. As of December 31, 2024, the Company had $1.6 million of restricted cash representing pledges to secure letters of credit in connection with certain office leases and an undertaking posted by Cyprium to secure potential damages in an injunctive proceeding.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash from the unaudited condensed consolidated balance sheets to the unaudited condensed consolidated statements of cash flows as of the dates presented:

	March 31,	
	2025	2024
Cash and cash equivalents	$ 91,339	$ 83,774
Restricted cash	1,220	2,063
Total cash and cash equivalents and restricted cash	$ 92,559	$ 85,837

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2024 Form 10-K.

Recently Issued Accounting Pronouncements

Accounting Standards Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which expands disclosures in an entity's income tax rate reconciliation table and disclosures regarding cash taxes paid both in the U.S. and foreign jurisdictions. The update will be effective for annual periods beginning after December 15, 2024. The Company is currently evaluating the impact that this guidance will have on its financial statement disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires new financial statement disclosures in tabular format, in the notes to financial statements, of specified information about certain costs and expenses. The amendments in this update do not change or remove current expense disclosure requirements. The amendments in this update are effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of the new standard on its financial statement disclosures.

3. Asset Purchase and Merger Agreements

Checkpoint

On March 9, 2025, Checkpoint entered into an Agreement and Plan of Merger (the "Merger Agreement") with Sun Pharmaceutical Industries, Inc., a Delaware corporation ("Sun Pharma" or "Parent"), and Snoopy Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent ("Merger Sub"). The Merger Agreement provides that, on the terms and subject to the conditions set forth in the Merger Agreement, Parent, Merger Sub and Checkpoint will effect a merger of Merger Sub with and into Checkpoint (the "Merger"), with Checkpoint continuing as the surviving corporation of the Merger and a wholly owned subsidiary of Parent.

On April 23, 2025, Checkpoint filed a definitive proxy statement relating to the Merger Agreement and established May 28, 2025 as the date for a special meeting of Checkpoint stockholders to vote on the Merger.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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Pursuant to the Merger Agreement, at the effective time of the Merger (the "Effective Time"), each share of common stock and each share of Class A common stock of Checkpoint (collectively, the "Shares") (including each unvested Checkpoint restricted share) outstanding immediately prior to the Effective Time will be canceled and cease to exist and be converted into the right to receive (i) $4.10 in cash, without interest (the "Common Cash Amount"), and (ii) one non-tradable contingent value right (a "CVR"), which will represent the right to receive a contingent cash payment of up to $0.70 upon the achievement of specified milestones, subject to and in accordance with the terms and conditions set forth in a Contingent Value Rights Agreement, substantially in the form attached as Exhibit B to the Merger Agreement (the "CVR Agreement"), as further described below (the foregoing clauses (i) and (ii), the "Merger Consideration"), in each case subject to applicable withholding taxes.

Consummation of the Merger is subject to customary closing conditions, including, but not limited to: (i) the adoption of the Merger Agreement and approval of the Merger by (a) the affirmative vote of the holders of at least a majority of the outstanding Shares beneficially owned by Checkpoint stockholders other than (1) Fortress and its controlled affiliates (other than Checkpoint), (2) the members of the Checkpoint board of directors (the "Checkpoint Board") (and their controlled affiliates, if any) and (3) any person that Checkpoint has determined to be an "officer" of Checkpoint within the meaning of Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") (the "Unaffiliated Checkpoint Stockholders"), and (b) the affirmative vote of the holders of a majority in voting power of the outstanding Shares; (ii) expiration or early termination of any waiting periods applicable to the consummation of the Merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, without the imposition of any burdensome condition; (iii) absence of any law or order prohibiting or making illegal the consummation of the Merger; and (iv) no Checkpoint material adverse effect having occurred that is continuing. The consummation of the Merger is also conditioned upon each of the Support Agreement, the Transition Services Agreement, the Royalty Agreement, and the CVR Agreement (in each case, as defined below) being in full force and effect.

The Merger Agreement contains customary representations, warranties and covenants made by each of Parent, Checkpoint and Merger Sub, including, among others customary covenants regarding the operation of the business of Checkpoint prior to the Effective Time, and "no-shop" restrictions regarding certain alternative acquisition proposals or discussions with third parties.

The Merger Agreement includes customary termination rights for the parties, including that, subject to certain limitations, Checkpoint or Parent may terminate the Merger Agreement prior to the Effective Time if: (i) a governmental body issues or enacts a final and non-appealable order, injunction or other legal requirement prohibiting or making illegal the consummation of the Merger, (ii) the Effective Time has not occurred on or prior to 11:59 p.m. Eastern Time on September 5, 2025, or (iii) the stockholders of Checkpoint fail to adopt the Merger Agreement by the requisite majorities at a meeting of Checkpoint's stockholders at which a vote on the Merger is conducted.

Checkpoint may terminate the Merger Agreement in certain additional limited circumstances, including to allow Checkpoint to enter into an agreement providing for an alternative acquisition transaction that constitutes a Superior Proposal (as defined in the Merger Agreement). Parent may terminate the Merger Agreement in certain additional limited circumstances, including if the Checkpoint Board, or any committee thereof, including the Special Committee of the Checkpoint Board, withdraws, withholds, amends or qualifies or modifies, in each case, in a manner adverse to Parent or Merger Sub, its recommendation that the stockholders of Checkpoint vote to adopt the Merger Agreement and approve the Merger.

Upon termination of the Merger Agreement under certain specified circumstances, Checkpoint will be required to pay Parent a termination fee (the "Checkpoint Termination Fee") of $12.5 million. Specifically, the Checkpoint Termination Fee is payable if (i) the Merger Agreement is terminated in certain circumstances; (ii) prior to such termination a bona fide proposal for an alternative acquisition transaction has been publicly disclosed or otherwise made to the Checkpoint Board and not publicly withdrawn (if made publicly); and (iii) within one year of such termination, Checkpoint subsequently consummates an alternative acquisition transaction or enters into a definitive agreement providing for an alternative acquisition transaction and such transaction is ultimately consummated. The Checkpoint Termination Fee will also be payable if the Merger Agreement is terminated: (a) by Parent, if Checkpoint Board, or any committee thereof, including the Special Committee of the Checkpoint Board, withdraws, withholds, amends or qualifies or modifies, in each case, in a manner adverse to Parent or Merger Sub, its recommendation that the stockholders of Checkpoint vote to adopt the Merger Agreement and approve the Merger; or (b) by Checkpoint in order to enter into an agreement providing for an alternative acquisition transaction that constitutes a Superior Proposal.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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On April 14, 2025, Checkpoint, Parent and Merger Sub entered into an Amendment to the Merger Agreement (the "Merger Agreement Amendment"). Pursuant to the Merger Agreement Amendment, the shareholder voting standard to approve the Merger was amended in response to recently enacted amendments to the Delaware General Corporation Law, as amended. Other than as expressly set forth in the Merger Agreement Amendment, the Merger Agreement remains unmodified and in full force and effect in accordance with its terms.

CVR Agreement

Pursuant to the Merger Agreement, as of or prior to the Effective Time, Parent and a rights agent (the "Rights Agent") will enter into the CVR Agreement governing the terms of the CVRs issued in connection with the Merger. The Rights Agent will maintain an up-to-date register of the holders of CVRs (the "Holders"). Holders shall not be permitted to transfer the CVRs (subject to certain limited exceptions as set forth in the CVR Agreement).

Each CVR represents the right to receive one of the following contingent cash payments, without interest, subject to any applicable withholding taxes (such applicable payment, the "Milestone Payment"), conditioned upon the achievement of the corresponding milestone condition within the following specified time periods:

(i) $0.70, if the Milestone (as defined below) is first achieved on or prior to the date that is 12 months prior to Milestone Deadline Date (as defined below) and the applicable regulatory approval provides for a dosing schedule of once every three weeks,

(ii) $0.45, if the Milestone is first achieved on or prior to the date that is 12 months prior to the Milestone Deadline Date and the applicable regulatory approval provides for a dosing schedule that is more frequent than once every three weeks,

(iii) $0.45, if the Milestone is first achieved after the date that is 12 months prior to the Milestone Deadline Date but on or prior to the Milestone Deadline Date, and the applicable regulatory approval provides for a dosing schedule of once every three weeks, or

(iv) $0.20, if the Milestone is first achieved after the date that is 12 months prior to the Milestone Deadline Date but on or prior to the Milestone Deadline Date, and the applicable regulatory approval provides for a dosing schedule that is more frequent than once every three weeks.

As used in the CVR Agreement, (a) the "Milestone Deadline Date" means the date that is 36 months after the date on which a marketing authorization application or equivalent for cosibelimab receives a positive validation outcome by the European Medicines Agency (the "EMA") and (b) the "Milestone" means the receipt of regulatory approval of cosibelimab in (i) the European Union pursuant to the centralized approval procedure or (ii) any of Germany, France, Italy, Spain or the United Kingdom.

Parent (directly or through its affiliates) is obligated to use, and to obligate its licensees to use, certain specified commercially reasonable efforts to (i) file a marketing authorization application for cosibelimab with the EMA within 12 months of the Closing Date or, to the extent any feedback or communications from, or expectations or requirements of, the EMA (including additional trial requirements) make it impracticable or inadvisable to file such marketing authorization application within such time period, as promptly thereafter as practicable, and (ii) achieve the Primary Milestone (as defined in the CVR Agreement) in its then-maximum value as promptly as practicable (including timely filing any appeals and curing any deficiencies identified in a relevant marketing authorization application by the relevant regulatory authority). Parent's obligations to use such commercially reasonable efforts terminates on the earlier of (a) the Milestone Deadline Date and (b) the achievement of the Milestone. There can be no assurance that the Milestone will be achieved on or before the Milestone Deadline Date, or that any Milestone Payments will be made.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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Support Agreement

Concurrently with the execution of the Merger Agreement, Checkpoint entered into a Support Agreement (the "Support Agreement") with Parent and Fortress. Under the terms of the Support Agreement, Fortress has agreed to, among other things, during the term of the Support Agreement, (i) vote its Shares in favor of the adoption of the Merger Agreement and the approval of the Merger and the other transactions contemplated by the Merger Agreement, and against any acquisition proposal or any action, proposal, agreement, transaction or arrangement that is intended, or would reasonably be expected, to result in a material breach of a covenant, representation or warranty or any obligation of Checkpoint under the Merger Agreement or any of the conditions to Checkpoint's obligations under the Merger Agreement not being fulfilled or satisfied, (ii) not transfer its Shares (subject to certain exceptions), and (iii) waive and not exercise any appraisal rights in respect of such Shares that may arise with respect to the Merger and not to commence or participate in, any class action or legal action (a) challenging the validity of, or seeking to enjoin or delay the operation of any provision of the Merger Agreement or (b) with respect to claims against the Checkpoint Board, or any committee thereof, Parent of Merger Sub relating to the Merger Agreement or the transactions contemplated thereby.

Under the Support Agreement, subject to the occurrence of the Effective Time, Fortress also agreed to forgo any further payment, dividend or distribution, or issuance or transfer of securities by Checkpoint on or after the date of the Support Agreement pursuant to the Amended and Restated Founders Agreement, dated as of July 11, 2016, between Fortress and Checkpoint and certain other agreements between Fortress and Checkpoint.

The Support Agreement also includes certain representations and warranties and covenants of Fortress to Parent, including certain restrictive covenants that apply to Fortress following the Effective Time.

As of March 31, 2025, Fortress beneficially owned an aggregate of 6,222,249 shares of common stock and 700,000 shares of Class A common stock of Checkpoint and controlled a majority of the outstanding voting power of Checkpoint's capital stock through its ownership of all outstanding shares of Checkpoint's Class A common stock. The Support Agreement will terminate upon termination of the Merger Agreement, the Effective Time and certain other specified events.

Warrant Amendment

Additionally, in connection with the Checkpoint's entry into the Merger Agreement, Checkpoint entered into a letter agreement (the "Warrant Amendment"), dated as of March 9, 2025, with Armistice Capital Master Fund Ltd., a Cayman Islands exempted company ("Armistice"). Pursuant to the Warrant Amendment, Checkpoint and Armistice agreed (i) to, immediately prior to the Effective Time, amend all outstanding Checkpoint Warrants held by or issued to Armistice or any of its affiliates other than the Specified Warrant (the "Armistice Warrants") to provide that each such Armistice Warrant that remains outstanding and unexercised as of the Effective Time will automatically be converted into the right to receive the Warrant Consideration, and (ii) that at the Effective Time, to the extent that any portion of that certain warrant to purchase 5,853,659 Shares, dated as of July 2, 2024 (the "Specified Warrant"), remains outstanding and unexercised as of the Effective Time, the Specified Warrant will be converted into the right of Armistice to receive, for each Share underlying the Specified Warrant, a cash payment equal to $3.62. The Warrant Amendment also provides that Armistice will not be entitled to transfer the Armistice Warrants prior to the Effective Time unless the Merger Agreement is validly terminated in accordance with its terms prior to the Effective Time.

Royalty Agreement

Concurrently with the execution of the Merger Agreement, Checkpoint entered into a Royalty Agreement (the "Royalty Agreement") with Parent and Fortress pursuant to which following, and subject to the occurrence of, the Effective Time, Fortress will receive a royalty interest right based on worldwide net sales of certain products of Checkpoint and Parent. The royalty interest right represents the right to receive quarterly cash payments of 2.5% of net sales of such products during the time period set forth in the Royalty Agreement.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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Transition Services Agreement

Pursuant to the Merger Agreement, as of or prior to the Effective Time, Checkpoint and Fortress will enter into a Transition Services Agreement (the "Transition Services Agreement"), pursuant to which, from and after the Effective Time, Fortress would provide Checkpoint with certain transition services as set forth in the Transition Services Agreement, for the period of time and in exchange for the compensation set forth therein.

Deconsolidation of Checkpoint

If shareholders of Checkpoint approve the Merger Agreement at the Special Meeting, and the transaction closes in the quarter ending June 30, 2025, Fortress expects to deconsolidate Checkpoint at the close of the transaction. The expected gain on deconsolidation is currently indeterminable and will depend on various factors including total net assets of Checkpoint and non-controlling interests attributable to Fortress at the time of closing.

Urica

On July 15, 2024, Urica entered into an asset purchase agreement (the "APA"), royalty agreement (the "Royalty Agreement"), and related agreements (collectively, the "Transaction Documents") with Crystalys Therapeutics, Inc. ("Crystalys"). Crystalys is a Delaware corporation incorporated in 2022 and seeded by life sciences institutional investors. Under the Transaction Documents, Urica sold the rights to its URAT1 inhibitor product candidate in development for the treatment of gout, dotinurad, and related intellectual property, licenses and agreements to Crystalys. In return, Crystalys issued to Urica shares of its common stock equal to 35% of Crystalys' outstanding equity. Urica's equity position cannot be reduced below 15% of Crystalys' fully-diluted equity capitalization until Crystalys raises $150 million in equity securities.

The Transaction Documents also granted Urica a secured three percent (3%) royalty on future net sales of dotinurad to be paid by Crystalys. Urica has the right to appoint one director to the board of directors of Crystalys, as well as an additional board observer. Crystalys is obliged to use commercially reasonable efforts to develop and commercialize dotinurad.

The APA also gives Urica the right, but not the obligation, to repurchase the sold assets for a repurchase price not to exceed $6.4 million plus accrued interest; the repurchase option expires upon the consummation by Crystalys of a qualified financing of at least $120 million by December 20, 2025. Urica has recorded a liability for the $0.6 million received as reimbursement for clinical and development expenses, which is being accreted up to the repurchase price over the term of the repurchase option, and is not recognizing an asset for its ownership interest received in Crystalys until the expiration of the repurchase option. Accordingly, for the quarters ended March 31, 2025 and 2024, Urica recorded accretion of $0.7 million and nil, respectively, of the repurchase option price, booked to interest expense and financing fee in the condensed consolidated statement of operations.

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, until $4.0 million in the aggregate is paid to InvaGen. In connection with equity financings in the three months ended March 31, 2025 and 2024, Avenue made payments totaling $0.2 and $0.3 million, respectively, to InvaGen. Approximately $1.4 million in aggregate has been paid to InvaGen under the share repurchase agreement through the three months ended March 31, 2025.

4. Inventory

($ in thousands)	March 31, 2025	December 31, 2024
Raw materials	$ 2,808	$ 3,196
Work-in-process	435	367
Finished goods	10,026	11,381
Inventory reserve	(773)	(513)
Total inventories	$ 12,496	$ 14,431

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5. Property and Equipment

($ in thousands)	Useful Life (Years)	March 31, 2025	December 31, 2024
Computer equipment	3	$ 594	$ 595
Furniture and fixtures	5	1,017	1,017
Leasehold improvements	15	5,481	13,175
Buildings	40	581	581
Total property and equipment		7,673	15,368
Impairment - Leasehold Improvements		(2,176)	(2,176)
Less: Accumulated depreciation		(2,701)	(9,932)
Property and equipment, net		$ 2,796	$ 3,260

Fortress' depreciation expense for the three months ended March 31, 2025 and 2024 was approximately $0.1 million and $0.4 million, respectively. Fortress' depreciation expense is recorded in both research and development expense and general and administrative expense in the condensed consolidated statement of operations.

In February 2025, Mustang terminated the lease of its manufacturing facility. The remaining Mustang lease liability of approximately $0.8 million was reversed, and the remaining leasehold improvements of approximately $0.3 million and right of use assets of approximately $0.1 million were written off resulting in a net gain of $0.4 million recorded in research and development expense in the unaudited condensed consolidated statements of operations. In conjunction with the termination of the lease, the Company also completed the sale of the remaining equipment held for sale for approximately $1.2 million, which had been classified as held for sale at December 31, 2024.

6. Fair Value Measurements

Common Stock Warrant Liabilities

($ in thousands)	Warrants 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	62
Balance at March 31, 2025	$ 261

Checkpoint

Checkpoint deemed the placement agent warrants it issued in connection with a registered direct offering (the "December 2022 Placement Agent Warrants") to be classified as liabilities on the balance sheet as they contain terms for redemption of the underlying security that are outside its control. The December 2022 Placement Agent Warrants were recorded at the time of closing at a fair value determined by using the Black-Scholes model. Checkpoint will revalue the December 2022 Placement Agent Warrants at each reporting period thereafter for as long as they remain outstanding. At March 31, 2025 and December 31, 2024, the liability associated with the December 2022 Placement Agent Warrants was $0.3 million and $0.2 million, respectively.

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

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Checkpoint Warrants	March 31, 2025	December 31, 2024
Exercise price	$ 5.41	$ 5.41
Volatility	114.9 %	111.1 %
Expected life in years	2.7	3.0
Risk-free rate	3.9 %	4.3 %

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 of its control. In connection with the Avenue January 2023 registered direct offering in January 2023, the down-round price protection feature was triggered and the exercise price for the October 2022 Warrants was permanently adjusted to $116.25, which was the offering price for the Avenue registered direct offering in January 2023. The Black-Scholes model was used to value the October 2022 Warrants as of March 31, 2025 and December 31, 2024. At March 31, 2025 and December 31, 2024, the liability associated with the October 2022 Warrants was approximately $1,000 and $16,000, respectively.

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:

	March 31, 2025	December 31 2024
Stock price	$ 0.30	$ 2.00
Risk-free interest rate	4.35 %	4.27 %
Expected dividend yield	—	—
Expected term in years	2.5	2.8
Expected volatility	159.75 %	154.94 %

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)	March 31, 2025	December 31, 2024
Intangible assets – product licenses	3 to 15	$ 52,925	$ 52,925
Accumulated amortization		(18,984)	(17,919)
Accumulated Impairment loss		(3,143)	(3,143)
Net intangible assets		$ 30,798	$ 31,863

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For the three months ended March 31, 2025 and 2024, Journey's amortization expense related to its product licenses was $1.1 million and $0.8 million, respectively.

The future amortization of these intangible assets is as follows:

For the year ended December 31, ***($ in thousands)***	**Total Amortization**
2025	$ 3,192
2026	3,471
2027	2,775
2028	2,595
2029	2,595
Thereafter	12,228
Sub-total	$ 26,856
Asset not yet placed in service	3,942
Total	$ 30,798

8. License Agreements

In accordance with ASC 730-10-25-1, *Research and Development*, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future use. The licenses purchased by 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. The purchase price of the licenses acquired is classified as research and development-licenses acquired in the unaudited condensed consolidated statement of operations. For the three months ended March 31, 2025 and 2024, there was no expense recognized for license acquisitions.

Journey

In June 2021, Journey entered a license, collaboration, and assignment agreement (the "Emrosi Agreement") to obtain global rights for the development and commercialization of EmrosiTM (Minocycline Hydrochloride Extended-Release Capsules, 40mg), for the treatment of rosacea with Dr. Reddy's Laboratories, Ltd ("DRL"); provided, that DRL retained certain rights to the program in select markets, namely in Armenia, Azerbaijan, Belarus, Brazil, Georgia, India Kazakhstan, Kyrgyzstan, Moldova, the People's Republic of China, Russia, Taiwan, Tajikistan, Turkmenistan, Ukraine and Uzbekistan. Pursuant to the terms and conditions of the Emrosi Agreement, Journey paid $10.0 million. In addition, Journey made two developmental milestone payments in 2024. In April 2024, Journey made a $3.0 million milestone payment to DRL, based on FDA acceptance of the NDA application for Emrosi, and in December of 2024 Journey made a $15.0 million milestone payment to DRL, which was triggered by the FDA marketing approval of Emrosi. Upon the $15.0 million milestone payment, the assets that had been the subject of the exclusive license related to Emrosi, including the NDA itself, the patents and other intellectual property, were assigned to Journey. Pursuant to the Emrosi Agreement, Journey may be required to make additional contingent regulatory, commercial, and corporate-based milestone payments to DRL, totaling up to $150.0 million. Journey is required to pay royalties ranging from approximately ten percent to fourteen percent on net sales of Emrosi, subject to certain possible reductions. Journey launched Emrosi in March 2025, and recognized net revenue of $2.1 million related to Emrosi in the quarter ended March 31, 2025.

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Avenue

On February 28, 2023, Avenue entered into a license agreement with AnnJi Pharmaceutical Co. Ltd. ("AnnJi"), whereby Avenue obtained an exclusive license (the "AnnJi License Agreement") from AnnJi to the intellectual property rights pertaining to the molecule known as JM17, which activates Nrf1 and Nrf2, enhances androgen receptor degradation and underlies AJ201, a clinical product candidate currently in a Phase 1b/2a clinical trial in the U.S. for the treatment of SBMA, also known as Kennedy's Disease. Under the AnnJi License Agreement, in exchange for exclusive rights to the intellectual property underlying the AJ201 product candidates, Avenue paid $3.0 million, issued shares of Avenue stock in two tranches, and agreed to make additional payments including: reimbursement of payments up to $10.8 million in connection with the product's Phase 1b/2a clinical trial, up to $14.5 million in connection with certain development milestones pertaining to the first indication in the U.S., up to $27.5 million in connection with certain drug development milestones pertaining to additional indications and development outside the U.S., up to $165 million upon the achievement of certain net sales milestones ranging from $75 million to $750 million in annual net sales, and royalty payments based on a percentage of net sales ranging from mid-single digits to the low-double digits, which were subject to potential diminution in certain circumstances. On March 3, 2025, Avenue received a notice of AnnJi's intent to terminate the AnnJi License Agreement, in which AnnJi asserted several bases for its right to terminate the AnnJi License Agreement.

On April 24, 2025 (the "Termination Effective Date"), Avenue and AnnJi entered into a License Termination and Program Transfer Agreement (the "Termination and Transfer Agreement"), pursuant to which: (i) the AnnJi License Agreement and related agreements were terminated with immediate effect; (ii) the parties dismissed all pending dispute resolution proceedings between them and provided mutual releases of claims; (iii) Avenue transferred to AnnJi all of its rights, title and interest to and under the assets arising under the AnnJi License Agreement and otherwise related to AJ201 and (iv) Avenue agreed not to, for 48 months following the date of the Termination and Transfer Agreement, develop, commercialize, manufacture or sell any product competing with AJ201 in the US, Canada, the European Union, Great Britain or Israel. Under the Termination and Transfer Agreement, Avenue will repurchase all shares of common stock held by AnnJi for an aggregate payment of $1.00, and Avenue also made a payment of $0.2 million to AnnJi for legal expense reimbursement.

AnnJi agreed to make payments to Avenue of $2.0 million, with $1.0 million due within 30 days after the Termination Effective Date and $1.0 million due within 90 days after the Termination Effective Date. Additionally, Avenue will be eligible to receive from AnnJi:

- payments totaling up to $5 million in the aggregate upon the occurrence of certain development and regulatory milestone events pertaining to AJ201;
- payments totaling up to $17 million in the aggregate upon AJ201 experiencing certain commercial sales milestone events;
- a 1.75% royalty on net sales of AJ201, which royalty percentage is subject to potential diminution in certain circumstances; and
- in the event that AnnJi enters into one or more subsequent licenses of rights to AJ201 with third party licensee(s), 15% of payments received by AnnJi from such licensee(s), up to a cap of $7.5 million, and with a minimum of $4 million owing under certain mechanism in the event of an approval of a New Drug Application in the U.S. with respect to AJ201.

The Termination and Transfer Agreement also contains customary representations and warranties and provisions related to confidentiality and indemnification.

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9. Debt and Interest

Debt

Total debt consists of the following:

($ in thousands)	March 31, 2025	December 31, 2024	Interest rate at March 31, 2025	Maturity
2024 Oaktree Note	$ 35,350	$ 35,350	11.95 %	July 2027
SWK Term Loan	25,000	25,000	14.60 %	December 2027
Less: Discount on notes payable	(2,093)	(2,388)		
Current portion of SWK Term Loan	(1,875)	—		
Total notes payable, long term, net	$ 56,382	$ 57,962		

As of March 31, 2025, the carrying value of the notes payable approximates their fair value as the interest rate is variable and approximates the market rate for loans with similar terms and risk characteristics.

2024 Oaktree Note

On July 25, 2024, Fortress entered into the $50.0 million senior secured credit agreement (the "New Oaktree Agreement") with a maturity date of July 25, 2027 with Oaktree Fund Administration, LLC and the lenders from time-to-time party thereto (collectively, "Oaktree"). The Company borrowed $35.0 million under the New Oaktree Agreement on the Closing Date (the "2024 Oaktree Note") and is eligible to draw up to an additional $15.0 million at the lenders' discretion to support future business development activities. The 2024 Oaktree Note replaces the 2020 Oaktree Note (as defined below) with respect to which the remaining $50.0 million balance was repaid in full.

Under the terms of the New Oaktree Agreement, the loans have a 30-month interest-only period with a maturity date of July 25, 2027, and bear interest at an annual rate equal to the 3-month Secured Overnight Financing Rate (SOFR) plus 7.625% (subject to a 2.50% SOFR floor and a 5.75% SOFR cap). For the quarter ended March 31, 2025, the interest rate applicable to the 2024 Oaktree Note was 11.95%. The Company is required to make quarterly interest-only payments until the maturity date, except fifty percent of the then-outstanding principal balance of the loans is due on March 31, 2027, with the remaining principal amount due on the maturity date.

The Company may voluntarily prepay, in whole or in part, the amounts due under the New Oaktree Agreement at any time subject to a prepayment fee. Subject to prior written notice by the Company, to repay any amounts due prior to the maturity date, the Company must pay the sum of (A) the aggregate principal amount of the Loans being prepaid, (B) any accrued but unpaid interest on the principal amount of the Loans being prepaid, (C) any applicable Yield Protection Premium (as defined in the New Oaktree Agreement) and (D) if applicable, other unpaid amounts then due and owing pursuant to the New Oaktree Agreement and the other loan documents (such aggregate amount, the "Prepayment Price"); provided that each partial prepayment of the principal amount of the Loans shall be in an aggregate amount of at least $5.0 million and integral multiples of $1.0 million in excess thereof. The Company is required to make mandatory prepayments of the Loans with net cash proceeds from (i) certain casualty events, (ii) certain monetization events, including, among other things, certain asset sales and the sale(s) of priority review vouchers by certain subsidiaries of the Company, and the receipt by the Company of any dividend or other distributions in cash from any of its subsidiaries in excess of $5.0 million other than in connection with certain monetization events, (iii) debt issuances that are not permitted, and (iv) failure to comply with certain covenants. The lenders may elect to receive warrant
s to purchase common stock of the Company as an alternative to cash prepayments in some situations where a mandatory prepayment would otherwise be required. No mandatory prepayments were required in the quarter ended March 31, 2025.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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The New Oaktree Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions. In addition, the New Oaktree Agreement contains certain financial covenants, including, (i) a requirement that the Company maintain a minimum liquidity of $7.0 million, which may be reduced or increased as described in the New Oaktree Agreement ("the "Liquidity Requirement"), and (ii) that product net sales of Journey meet a consolidated minimum net sales amount of $50.0 million on a trailing 12-month basis, tested quarterly, which may be reduced or increased as described in the New Oaktree Agreement (the "Minimum Net Sales Test"), subject to certain exclusions. Due to the approval of Emrosi, the minimum net sales amount will increase by $7.5 million each quarter, beginning in the third quarter of 2025, provided that the minimum net sales amount will in no event exceed $80.0 million. Both the Minimum Net Sales Test and the Liquidity Requirement will be reduced to $0 while the outstanding principal balance is less than or equal to $10.0 million. The Liquidity Requirement decreases to $5.0 million while the outstanding principal balance is between $10.0 million and $25.0 million. Failure by the Company to comply with the financial covenants will result in an event of default, subject to certain cure rights of the Company with respect to the Minimum Net Sales Test.

The New Oaktree Agreement contains events of default that are customary for financings of this type, in certain circumstances subject to customary cure periods. In addition, the Company is also required to (i) raise cash proceeds from the sale of common stock, or receive monetizations or distributions, by the end of each calendar year prior to the maturity date, in an aggregate amount equal to the greater of $20 million or 50% of an amount set forth in an annual budget delivered to the lenders and (ii) maintain a specified minimum equity stake in Journey. These capital raise and minimum stake covenants and financial covenants will not apply if the outstanding principal balance of the loan is less than or equal to $10 million. Following an event of default and any cure period, if applicable, the Agent will have the right upon notice to accelerate all amounts outstanding under the New Oaktree Agreement, in addition to other remedies available to the lenders as secured creditors of the Company.

In connection with the New Oaktree Agreement, the Company granted a security interest in favor of Oaktree, for the benefit of the lenders, in substantially all of the Company's assets, subject to customary exceptions, as collateral securing the Company's obligations under the New Oaktree Agreement. Also in connection with the New Oaktree Agreement, the Company granted warrants to the lenders to purchase up to 506,390 shares of the Company's common stock at a purchase price of $2.0735 per share (the "Warrants"). The Warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offerings and pro rata distributions. The exercise price of the Warrants will also be adjusted if, while the Warrants are outstanding, the Company engages in any transaction involving the issuance or sale of shares of Common Stock or equivalent securities at an effective price per share less than the exercise price of the Warrant then in effect (such lower price, the "Base Share Price"). In such case, the exercise price of the Warrants will be reduced to equal the Base Share Price. The Warrants are exercisable from July 25, 2024, will expire on July 25, 2031 and may be net exercised for no cash payment at the holder's election. The Company filed a registration statement to register the resale of the shares of Company common stock issuable upon exercise of the Warrants (see Note 13).

The Company was in compliance with all applicable financial covenants under the New Oaktree Agreement as of March 31, 2025.

2020 Oaktree Note

On July 25, 2024, the Company's $50.0 million outstanding balance of the senior secured credit agreement with Oaktree (the "Prior Oaktree Agreement") and the debt thereunder, the "2020 Oaktree Note") was terminated upon receipt by Oaktree of a payoff amount of $51.4 million from the Company comprised of principal, interest and the applicable final payment amount. The payoff of the 2020 Oaktree Note was treated as a debt extinguishment, as the 2024 Oaktree Note originated from a fund group different from the Prior Oaktree Agreement. The Company recorded a loss on extinguishment of debt of approximately $3.6 million, representing unamortized debt issuance costs and inclusive of a $1.0 million prepayment fee; the loss on extinguishment was recorded to interest expense in the Consolidated Statement of Operations for the year ended December 31, 2024.

The Company had entered the Prior Oaktree Agreement in August 2020. The Prior Oaktree Agreement contained customary representations and warranties and customary affirmative and negative covenants as well as certain financial covenants, including, among other things, (i) maintenance of minimum liquidity and (ii) a minimum revenue test that required Journey's annual revenue to be equal to or to exceed annual revenue projections set forth in the Prior Oaktree Agreement. Failure by the Company or Journey, as applicable, to have complied with the Prior Oaktree Agreement covenants would have resulted in an event of default, subject to certain cure rights of the Company.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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The Company was required to make quarterly interest-only payments until the fifth anniversary of the closing date of the 2020 Oaktree Note, August 27, 2025, at which point the outstanding principal amount would have been due. The Company could have voluntarily prepaid the 2020 Oaktree Note at any time subject to a prepayment fee. The Company was required to make mandatory prepayments of the 2020 Oaktree Note under various circumstances as defined in the Prior Oaktree Agreement.

SWK Term Loan

On December 27, 2023 (the "SWK Closing Date"), Journey entered into a credit agreement (the "SWK Credit Agreement") with SWK Funding LLC ("SWK"). The SWK Credit Agreement provides for a term loan facility (the "SWK Credit Facility") in the original principal amount of up to $20.0 million. On the SWK Closing Date, Journey drew $15 million. On June 26, 2024, Journey drew the remaining $5.0 million under the SWK Credit Facility. On July 9, 2024, Journey entered into the amendment to the SWK Credit Agreement with SWK. The amendment increased the original principal amount of the SWK Credit Facility from $20.0 million to $25.0 million. The $5.0 million of additional principal added in the amendment was contractually required to be drawn upon FDA approval of Emrosi, subject to Journey receiving approval on or before June 30, 2025. Journey drew on the remaining $5.0 million relating to the FDA approval of Emrosi on November 25, 2024.

Loans under the SWK Credit Facility (the "Term Loans") mature on December 27, 2027. The Term Loans accrue interest at a rate per annum equal to the three-month term SOFR (subject to a SOFR floor of 5%) plus 7.75% and interest is payable quarterly and resets quarterly.

Beginning in February 2026, Journey is required to repay a portion of the outstanding principal of the Term Loans quarterly in an amount equal to 7.5% of the principal amount of funded Term Loans, with any remaining principal balance due on the maturity date. If the total revenue of Journey, measured on a trailing twelve-month basis, is greater than $70.0 million as of December 31, 2025, the principal repayment start date is extended from February 2026 to February 2027, at which point Journey is required to repay a portion of the outstanding principal of the Term Loans quarterly in an amount equal to 15% of the principal amount of funded Term Loans, with any remaining principal balance due on the maturity date.

Journey may at any time prepay the outstanding principal balance of the Term Loans in whole or in part. Prepayment of the Term Loans is subject to payment of a prepayment premium equal to (i) 1% of the Term Loans prepaid if the Term Loans are prepaid on or after the first anniversary of the SWK Closing Date but prior to the second anniversary of the SWK Closing Date, or (ii) 0% if prepaid thereafter.

Upon repayment in full of the Term Loans, Journey will pay an exit fee equal to 5% of the original principal amount of the Term Loans. Additionally, Journey paid an origination fee of $0.2 million on the SWK Closing Date 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 Loan 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 in the Consolidated Statement of Operations. The effective interest rate on the SWK Term Loan as of March 31, 2025 was 14.6%.

The SWK 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 March 31, 2025, Journey was in compliance with the financial covenants under the SWK Credit Facility.

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:

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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	Three Months Ended March 31,					
	2025			2024		
($ in thousands)	*Interest*	*Fees*	Total	*Interest*	*Fees*	Total
2024 Oaktree Note	$ 1,046	$ 193	$ 1,239	$ —	$ —	$ —
2020 Oaktree Note	—	—	—	1,390	502	1,892
Partner company convertible preferred shares	—	—	—	113	45	158
Partner company notes payable	789	102	891	486	62	548
Partner company contingent call option accretion[1]	677	—	677	—	—	—
Other	(2)	—	(2)	4	—	4
Total Interest Expense and Financing Fee	$ 2,510	$ 295	$ 2,805	$ 1,993	$ 609	$ 2,602

Note 1: Relates to Urica's optional repurchase obligation to Crystalys (see Note 3)

10. Accounts Payable and Accrued Expenses and Partner Company Installment Payments

Accounts payable and accrued expenses consisted of the following:

($ in thousands)	March 31, 2025	December 31, 2024
Accounts payable	$ 27,818	$ 31,636
Accrued expenses:		
Professional fees	5,673	3,147
Salaries, bonus and related benefits	6,108	6,596
Research and development	6,235	8,509
Accrued royalties payable	1,406	1,374
Accrued coupon and rebates	12,869	6,200
Return reserve	2,601	3,124
Other	3,576	4,915
Total accounts payable and accrued expenses	$ 66,286	$ 65,501

11. Non-Controlling Interests

The Company's ownership interests in its consolidated subsidiaries at March 31, 2025 was similar to December 31, 2024.

12. Net Loss per Common Share

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

For the three months ended March 31, 2025 and 2024, the effect on the net loss per share calculation from Series A Preferred dividends (paid and cumulated but undeclared) (see Note 13) was $2.0 million and $2.0 million, respectively, and partner company preferred and deemed dividends were $0.1 million and $0.4 million, respectively.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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For the three months ended March 31, 2025 and 2024, diluted and basic net loss per share attributable to common stockholders of the Company were identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive. The following potentially dilutive securities were excluded from the computation of net loss per common share as of the dates presented:

	March 31,	
	2025	2024
Warrants to purchase Common Stock	14,396,201	5,769,788
Options to purchase Common Stock	18,896	18,896
Unvested Restricted Stock and deferred Restricted Stock	3,093,923	1,902,386
Unvested Restricted Stock units and deferred Restricted Stock units	2,436,705	373,933
Total	19,945,725	8,065,003

13. Stockholders' Equity

9.375% Series A Cumulative Redeemable Perpetual Preferred Stock Dividends

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 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 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 three months ended March 31, 2025, no dividends were declared by the Board of Directors. At March 31, 2025, the Company had total undeclared dividends of approximately $6.0 million, which represents the cumulated (but undeclared) dividends due to Series A Preferred shareholders. 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 loss attributable to common shareholders (see Note 12).

Stock-based Compensation

As of March 31, 2025, 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 March 31, 2025, approximately 10.0 million shares are available for issuance under the 2013 Plan, and approximately 1.0 million shares are available for issuance under the ESPP.

The following table summarizes the stock-based compensation expense from stock option, employee stock purchase programs and restricted Common Stock awards and warrants for the periods presented:

	Three Months Ended March 31,	
($ in thousands)	**2025**	**2024**
Fortress:		
Employee and non-employee awards	$ 2,607	$ 2,193
Executive awards	180	224
Partner Companies:		
Avenue	185	191
Checkpoint	1,956	709
Mustang	38	77
Journey	1,323	1,406
Other	—	57
Total stock-based compensation expense	$ 6,289	$ 4,857

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

For the three months ended March 31, 2025 and 2024, approximately $1.3 million and $1.1 million, respectively, of stock-based compensation expense was included in research and development expenses in connection with equity grants made to employees and consultants, and approximately $4.9 million and $3.7 million, respectively, was included in general and administrative expenses in connection with grants made to employees, members of the board of directors and consultants.

Stock Options

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

	Number of shares	Weighted average exercise price	Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Options vested and expected to vest at December 31, 2024	558,896	$ 2.32	$ 186,300	6.02
Forfeited	(540,000)	1.68	—	—
Options vested and expected to vest at March 31, 2025	18,896	$ 20.55	$ —	0.52
Options vested and exercisable at March 31, 2025	18,896	$ 20.55	$ —	0.52

As of March 31, 2025, Fortress had no unrecognized stock-based compensation expense related to options. As of March 31, 2024, Fortress had $0.4 million in unrecognized stock-based compensation expense related to options which were forfeited in the first quarter of 2025.

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, 2024	4,414,724	$ 12.87
Restricted stock granted	1,204,360	2.03
Restricted stock vested	(11,331)	34.12
Restricted stock units vested	(77,124)	29.17
Unvested balance at March 31, 2025	5,530,629	$ 10.24

As of March 31, 2025 and 2024, the Company had unrecognized stock-based compensation expense related to restricted stock and restricted stock unit awards of approximately $8.3 million and $13.2 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 2.1 years and 1.4 years, respectively.

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, 2024	14,406,201	$ 2.15	$ 2,933,774	4.46
Exercised	(10,000)	1.68	—	—
Outstanding as of March 31, 2025	14,396,201	$ 2.16	$ —	4.22
Exercisable as of March 31, 2025	14,396,201	$ 2.16	$ —	4.22

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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Amended and Restated Long-Term Incentive Program ("LTIP")

On July 15, 2015, the Company's stockholders approved the LTIP for the Company's Chairman, President and Chief Executive Officer, Dr. Rosenwald, and Executive Vice Chairman, Strategic Development, Mr. Weiss (amended and restated with stockholder approval on June 7, 2017 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.

On January 1, 2025 and 2024, the Compensation Committee granted 454,163 shares and 216,465 shares each to Dr. Rosenwald and Mr. Weiss, respectively. These equity grants, made in accordance with the LTIP, represent 1% of total outstanding shares of the Company as of the dates of such grants. Restricted shares granted under the LTIP vest upon (i)(A) the Company achieving a specified increase in market capitalization since the grant date and (B) the participant remaining in service with the Company until (or being involuntarily terminated prior to) July 16, 2025, or (ii) a change in control of the Company, provided the eligible participant remains in service with the Company until the date of such transaction. If the restricted shares have not vested in accordance with the preceding sentence, they will be subject to a repurchase option by the Company at a nominal price for 90 days following the earlier of July 16, 2025 or the participant's voluntary separation from service with the Company. The fair value of each grant on the grant date was approximately $0.9 million for the 2025 grant and $0.7 million for the 2024 grant. For the three months ended March 31, 2025 and 2024, the Company recorded stock compensation expense related to LTIP grants of approximately $2.5 million and $1.7 million, respectively, on the unaudited condensed consolidated statement of operations.

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 March 31, 2025, $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 notices. As a result, the Company is no longer 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 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 no longer 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 by certain selling stockholders who were previously holders of shares of 8% Cumulative Redeemable Perpetual Class B Preferred Stock of Urica, of an aggregate of up to 1,987,250 shares of the Company's common stock;
- the offer and sale of up to 5,885,000 shares underlying warrants originally issued as part of units, each consisting of one share of Common Stock and one warrant, originally registered pursuant to the prospectus filed with the SEC under November 10, 2023;
- the offer and sale of up to 3,303,305 shares underlying warrants originally issued as part of units, each consisting of one share of Common Stock and one warrant, originally registered pursuant to the prospectus filed with the SEC on December 29, 2023; and
- the offer and sale by certain selling stockholders of up to 116,637 shares of Common Stock issuable upon the exercise of warrants, as amended, granted to Oaktree and its affiliates under the Prior Oaktree Agreement.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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This post-effective amendment was declared effective by the SEC on April 2, 2025.

At the Market Offering

During the three months ended March 31, 2025, the Company issued and sold approximately 0.5 million shares at an average price of $1.94 per share for gross proceeds of $1.0 million under the Company's at-the-market offering program. During the three months ended March 31, 2024, the Company issued and sold approximately 0.5 million shares at an average price of $1.99 for gross proceeds of $0.9 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 2023 Shelf Registration Statement

In March 2023, Checkpoint filed a shelf registration statement (File No. 333-270843) on Form S-3 (the "Checkpoint 2023 S-3"), which was declared effective May 5, 2023. Under the Checkpoint 2023 S-3, Checkpoint may sell up to a total of $150 million of its securities. As of March 31, 2025, approximately $65.7 million of the securities remains available for sale through the Checkpoint 2023 S-3.

Checkpoint 2025 Warrant Exercises

In January 2025, Checkpointo 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.

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 for the three months ended March 31, 2025. Pursuant to the Support Agreement between Fortress, Checkpoint and Sun Pharma, Fortress waived its right to receive any equity fee with respect to any equity issuances by Checkpoint (including those resulting from warrant exercise) that are effected subsequent to the date on which the Merger Agreement was executed; such waiver will be null and void ab initio if the Merger Agreement is terminated before Merger consummation.

Avenue 2021 Shelf Registration Statement

In December 2021, Avenue filed a shelf registration statement (File No. 333-261520) on Form S-3 (the "Avenue 2021 S-3"), which was declared effective on December 10, 2021. Avenue filed a replacement shelf registration on Form S-3 on December 4, 2024 (the "Avenue Replacement Shelf"), which has not yet become effective under the Securities Act of 1933, as amended. However, upon Avenue's formal delisting from Nasdaq, effective upon Nasdaq's filing of a Form 25 with the SEC, Avenue will be ineligible to use Form S-3 and therefore unable to use the Avenue 2021 S-3 or the Avenue Replacement Shelf.

Avenue At the Market Offering

In May 2024, Avenue entered into an At-the-Market Offering Agreement (the "Avenue ATM") under which Avenue may 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 are made pursuant the Avenue 2021 S-3, and the related prospectus supplement dated May 10, 2024. During the three months ended March 31, 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 suspension of its stock from trading on the Nasdaq.

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 three-month period ended March 31, 2025.

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

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 March 31, 2025, 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.

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 three months ended March 31, 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 (the "Pre-Funded Warrant Shares), (iii) Series C-1 warrants to purchase up to 2,657,807 shares of common stock, and (iv) 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 have an exercise price of $0.0001 per share, were exercisable immediately upon issuance and will expire 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 will expire five years from the date of stockholder approval and the Series C-2 warrants will 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, if any, from the exercise of the Warrants, was approximately $6.8 million. 670,000 of the 2,162,807 pre-funded warrants have since been exercised as of the date of the filing of this Form 10-Q.

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 67,806 shares of common stock to Fortress for the three-month period ended March 31, 2025.

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 covers 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 connection with the Journey 2022 S-3, Journey entered into a sales agreement relating to the sale of shares of Journey's common stock in an at-the-market offering (the "Journey ATM Sales Agreement"). In accordance with the terms of the Journey ATM Sales Agreement, Journey may offer and sell up to 4,900,000 shares of its common stock, par value $0.0001 per share, from time to time. For the three months ended March 31, 2025, Journey issued and sold approximately 0.8 million shares of common stock for gross proceeds of $4.1 million under the Journey ATM Sales Agreement. At March 31, 2025, 1.8 million shares remain available for issuance under the Journey ATM Sales Agreement.

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

14. Commitments and Contingencies

Leases

Lease Amendment – 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 unaudited condensed consolidated statement of operations for the three months ended March 31, 2025.

During three months ended March 31, 2025 and 2024, the Company recorded the following as lease costs for the periods presented:

($ in thousands)	Three Months Ended March 31, 2025	2024
Operating lease cost	$ 748	$ 640
Shared lease costs	(533)	(523)
Variable lease cost	189	216
Total lease expense	$ 404	$ 333

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

($ in thousands)	Three Months Ended March 31, 2025	2024
Operating cash flows from operating leases	$ (852)	$ (920)
Weighted-average remaining lease term – operating leases (years)	3.7	4.1
Weighted-average discount rate – operating leases	6.1 %	6.5 %

($ in thousands)	Future Lease Liability
Nine months ended December 31, 2025	2,461
Year ended December 31, 2026	2,937
Year ended December 31, 2027	2,940
Year ended December 31, 2028	2,967
Year ended December 31, 2029	3,011
Other	5,114
Total operating lease liabilities	19,430
Less: present value discount	(3,451)
Net operating lease liabilities, short-term and long-term	$ 15,979

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.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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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 seeing resulting alleged damages.

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 2024 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
Mustang	March 13, 2015	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 pays the Company an annual equity fee in shares of Checkpoint's common stock equal to 2.5% of Checkpoint's fully diluted outstanding capitalization.
Note 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.

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

Management Services Agreements

The Company has entered into Management Services Agreements (the "MSAs") with certain of its partner companies/subsidiaries as described in the 2024 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	March 17, 2015	500
Cyprium	March 13, 2017	500
Helocyte	March 20, 2015	500
Mustang	March 13, 2015	500
Oncogenuity	February 10, 2017	500
Urica	November 7, 2017	500
Fortress		(4,000)
Consolidated (Income)/Expense		$ —

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 Interim Chief Executive Officer of TGTX. Under the terms of the Agreement, TGTX reimburses the Company for the salary and benefit costs associated with these employees based upon actual hours worked on TGTX-related projects. In connection with the shared services agreement, for the three months ended March 31, 2025 and 2024 the Company invoiced TGTX $0.1 million and $0.6 million, respectively. At March 31, 2025, approximately $0.1 was due from TGTX related to this arrangement.

Desk Share Agreement with TGTX

The Desk Share Agreement between the Company and TGTX, as amended, requires TGTX to pay 65% of the average annual rent for the Company's New York, NY office space. Additionally, the Company has reserved the right to execute desk share agreements with other third parties and those arrangements will affect the cost of the lease actually borne by the Company. Each initial desk share agreement has a term of five years. In connection with the Company's Desk Share Agreement with TGTX for the New York, NY office space, for the three months ended March 31, 2025 and 2024, the Company had paid $0.7 million and $0.7 million in rent, respectively, and invoiced TGTX approximately $0.5 million and $0.5 million, respectively, for their prorated share of the rent base. At March 31, 2025, approximately $0.2 million was due from TGTX related to this arrangement.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
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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 three months ended March 31, 2025 and 2024, Checkpoint recognized $32,000 and $27,000 in expenses, respectively, related to the advisory agreement, including approximately $17,000 and $12,000, respectively, in expenses related to annual equity incentive grants.
In January 2017, Mustang entered into an advisory agreement effective January 1, 2017 with Caribe BioAdvisors, LLC, 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. For the three months ended March 31, 2025 and 2024, Mustang recognized approximately $15,000 and $15,000 in expenses related to the advisory agreement, respectively.

Shared Services Agreement with Journey

On November 12, 2021, Journey and the Company entered into an arrangement to share the cost of certain legal, finance, regulatory, and research and development employees. The Company's Executive Chairman and Chief Executive Officer is also the Executive Chairman of Journey. Under the terms of the arrangement, Journey began reimbursing the Company for the salary and benefit costs associated with these employees based upon actual hours worked on Journey-related projects following the completion of 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. For the three months ended March 31, 2025 and 2024, the Company's employees have provided services to Journey totaling approximately $12,000 and $9,000, respectively. At March 31, 2025, the total related party receivable was $0.4 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 its 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock ("Cyprium PPS"); as of March 31, 2025, there remain 320,000 shares of Cyprium PPS outstanding. The Cyprium PPS is fully and unconditionally guaranteed by Fortress.

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

If a PRV Sale has not occurred by March 31, 2026 (the "Exchange Date"), the Cyprium PPS will automatically be exchanged for Fortress Series A Preferred Stock or cash, at the discretion of Fortress.

16. Segment Information

The Company's reportable segments for operating income (loss) for the three months ended March 31, 2025 and 2024 consist of the following ($ in thousands):

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

Three Months Ended March 31, 2025	Journey	Avenue	Checkpoint	Mustang	Fortress[1]	Consolidated
Product revenue, net	$ 13,139	$ —	$ —	$ —	$ —	$ 13,139
Cost of goods	4,790	—	—	—	—	4,790
Intangible assets amortization	1,065	—	—	—	—	1,065
Research and development	39	411	3,788	(964)	664	3,938
Selling, general and administrative	10,569	1,494	7,361	1,217	5,022	25,663
Total operating expenses	16,463	1,905	11,149	253	5,686	35,456
Loss from operations	(3,324)	(1,905)	(11,149)	(253)	(5,686)	(22,317)
Interest income	149	32	1	100	208	490
Interest expense and financing fee	(891)	—	—	—	(1,914)	(2,805)
(Gain) loss on common stock warrant liabilities	—	15	(62)	—	—	(47)
Other income (expense)	(7)	—	(2)	—	(3)	(12)
Total other income (expense)	(749)	47	(63)	100	(1,709)	(2,374)
Segment net loss	$ (4,073)	$ (1,858)	$ (11,212)	$ (153)	$ (7,395)	$ (24,691)
Net loss attributable to NCI						14,107
Net loss attributable to Fortress						$ (10,584)
Intersegment activity[2]:						
Research and development	$ —	$ 63	$ —	$ 63	$ (125)	$ —
Selling, general and administrative	$ —	$ 117	$ 178	$ 279	$ (573)	$ —
Other Significant Items:						
Segment assets	$ 84,963	$ 3,593	$ 34,165	$ 14,909	$ 40,440	$ 178,071
Stock-based compensation - Research & development	$ —	$ 40	$ 689	$ (11)	$ 625	$ 1,343
Stock-based compensation - Selling, general and administrative	$ 1,323	$ 145	$ 1,267	$ 50	$ 2,161	$ 4,946

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 PIK Dividends and MSA and equity fees paid by the subsidiaries to Fortress, see Note 15.

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

Three Months Ended March 31, 2024	Journey	Avenue	Checkpoint	Mustang	Fortress[1]	Consolidated
Product revenue, net	$ 13,030	$ —	$ —	$ —	$ —	$ 13,030
Cost of goods	6,002	—	—	—	—	6,002
Intangible assets amortization	814	—	—	—	—	814
Research and development	7,884	2,392	8,497	3,804	2,262	24,839
Selling, general and administrative	8,420	1,316	2,451	1,427	4,327	17,941
Asset impairment	—	—	—	—	—	—
Total operating expenses	23,120	3,708	10,948	5,231	6,589	49,596
Loss from operations	(10,090)	(3,708)	(10,948)	(5,231)	(6,589)	(36,566)
Interest income	217	49	4	40	523	833
Interest expense and financing fee	(548)	—	—	—	(2,054)	(2,602)
(Gain) loss on common stock warrant liabilities	—	(690)	—	—	23	(667)
Other income (expense)	(21)	—	(1)	—	1	(21)
Total other income (expense)	(352)	(641)	3	40	(1,507)	(2,457)
Segment net loss	$ (10,442)	$ (4,349)	$ (10,945)	$ (5,191)	$ (8,096)	$ (39,023)
Net loss attributable to NCI						23,606
Net loss attributable to Fortress						$ (15,417)
Intersegment activity[2]:						
Research and development	$ —	$ 63	$ —	$ 63	$ (125)	$ —
Selling, general and administrative	$ —	$ 71	$ 521	$ 63	$ (654)	$ —
Other Significant Items:						
Segment assets	$ 66,571	$ 3,309	$ 11,975	$ 14,592	$ 68,198	$ 164,645
Stock-based compensation - Research & development	$ 145	$ 45	$ 490	$ 29	$ 408	$ 1,117
Stock-based compensation - Selling, general and administrative	$ 1,261	$ 146	$ 220	$ 47	$ 2,066	$ 3,740

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 PIK Dividends and MSA and equity fees paid by the subsidiaries to Fortress, see Note 15.

17. Revenues from Contracts and Significant Customers

Disaggregation of Total Revenue

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

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

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

($ in thousands)	Three Months Ended March 31, 2025	2024
Qbrexza	$ 5,161	$ 5,017
Accutane	3,655	5,819
Emrosi	2,070	—
Amzeeq	1,100	755
Zilxi	426	273
Other / legacy product revenue	727	1,166
Total net revenue	$ 13,139	$ 13,030

Significant Customers

For the three-month periods ending March 31, 2025 and 2024, none of Journey's dermatology products customers accounted for more than 10% of its total gross product revenue.

At March 31, 2025, none of Journey's dermatology products customers accounted for more than 10% of its total accounts receivable balance. At December 31, 2024, one of the Company's dermatology products customers accounted for more than 10% of its total accounts receivable balance at 10.3%.

18. Income taxes

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

The Company files a consolidated income tax return with subsidiaries for which the Company has an 80% or greater ownership interest. Subsidiaries 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 months ended March 31, 2025 and 2024 is based on the estimated annual effective tax rate, and includes interest related to unrecognized tax benefits. The Company expects a net deferred tax asset with a full valuation allowance and 0% estimated annual effective tax rate for 2024. No income tax expense was recognized for the three months ended March 31, 2025 or 2024.

19. Subsequent Events

Checkpoint

On April 14, 2025, Checkpoint, Parent and Merger Sub entered into an Amendment to the Original Merger Agreement (the "Merger Agreement Amendment") (see Note 3).

On April 23, 2025, Checkpoint filed a definitive proxy statement relating to the Merger Agreement and established May 28, 2025 as the date for a special meeting of Checkpoint stockholders to vote on the Merger (see Note 3).

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 exercise price of $2.821 per share.

Avenue

On April 24, 2025, Avenue and AnnJi entered into the Termination and Transfer Agreement (see Note 8).

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our condensed consolidated financial statements and the related notes included elsewhere in this Form 10-Q. Our condensed consolidated financial statements have been prepared in accordance with U.S. GAAP. 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;
- 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 holding and dividend and royalty revenue streams. 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"), Fred Hutchinson Cancer Center, Dana-Farber Cancer Institute, Nationwide Children's Hospital, Columbia University, the University of Pennsylvania, AstraZeneca plc and Dr. Reddy's Laboratories, Ltd.

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

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

Recent Events

Revenue

- For the three months ended March 31, 2025 and 2024, net revenue was $13.1 million and $13.0 million, respectively, and is related to the sale of Journey's marketed products.

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

- In March 2025, our partner company Journey launched Emrosi™ (Minocycline Hydrochloride Extended-Release Capsules, 40mg).
- In November 2024, Journey announced that the FDA approved Emrosi for the treatment of inflammatory lesions of rosacea in adults.
- Emrosi was developed for the treatment of rosacea at our partner company, Journey, in collaboration with Dr. Reddy's Laboratories Ltd.

Late Stage Product Candidates

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

- In March 2025, we announced that our partner company, Checkpoint, entered into an agreement to be acquired by Sun Pharmaceutical Industries, Inc. ("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. The closing of the transaction is subject to various conditions including the approval by requisite majorities of holders of Checkpoint's shares at a meeting of Checkpoint's stockholders on May 28, 2025. We expect the transaction to close shortly after the stockholder meeting, assuming the requisite votes are received, although there can be no assurance that the transaction closes in a timely manner, or at all.
- 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 ("cSCC") in adults who are not candidates for curative surgery or radiation.
- Cosibelimab was sourced by Fortress and developed at Checkpoint.

Triplex (cytomegalovirus vaccine and immunotherapy)

- Triplex, a potential vaccine and immunotherapy for prevention and control of cytomegalovirus ("CMV"), is currently being studied in a Phase 2 clinical trial for adults co-infected with HIV and CMV that is now fully enrolled with topline data anticipated in the third quarter of 2025. The study aims to show that vaccination with Triplex can safely elicit a CMV-specific immune response and reduce asymptomatic CMV replication in a population of people with HIV on suppressive antiretroviral therapy. The study will also evaluate whether this intervention might reduce chronic inflammation and immune activation, as compared to placebo, and thus, potentially reduce related mortality and morbidity (NCT05099965).
- In January 2025, we announced that the first patient was dosed in a multi-center, placebo-controlled, randomized Phase 2 clinical trial to evaluate Triplex when administered to human leukocyte antigen ("HLA") matched related stem cell donors to reduce CMV events in patients undergoing hematopoietic stem cell transplantation ("HSCT"). The trial is funded by a grant from the National Cancer Institute ("NCI") (NCT06059391).
- Triplex is currently also the subject of multiple other 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.

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

- On October 5, 2021, AstraZeneca acquired Caelum Biosciences, Inc. ("Caelum"), a former subsidiary of Fortress for an upfront payment of approximately $150 million paid to Caelum shareholders, of which approximately $56.9 million was paid to Fortress. 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 for Mayo Stage IIIa and Mayo Stage IIIb amyloid light-chain amyloidosis ("AL amyloidosis") and based on statements made by AstraZeneca, we expect topline data readouts from both trials in the second half of 2025 (ClinicalTrials.gov identifiers: NCT04512235 and NCT04504825). (Information on clinicaltrials.gov does not constitute part of this Quarterly Report on Form 10-Q.).
- CAEL-101 (also known as anselamimab) was sourced by Fortress and was developed by Caelum (founded by Fortress) until the acquisition by AstraZeneca of Caelum in October 2021.

CUTX-101 (copper histidinate for Menkes disease)

- In January 2025, our subsidiary Cyprium announced that the FDA had accepted the NDA for CUTX-101 (copper histidinate for Menkes disease) for priority review with a target action date of September 30, 2025.
- In December 2023, Cyprium completed the asset transfer of CUTX-101 to Sentynl, a wholly owned subsidiary of Zydus Lifesciences Ltd. Sentynl is obligated under the applicable agreement to use commercially reasonable efforts to develop and commercialize CUTX-101, including the funding of the same. Additionally, Cyprium remains eligible to receive up to $129 million in aggregate development and sales milestones under the Agreement and royalties on net sales of CUTX-101 ranging from 3% to 12.5% on tiered annual net sales. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at the New Drug Application ("NDA") approval for CUTX-101.
- CUTX-101 was sourced by Fortress and was developed by Cyprium until the asset transfer in December 2023.

Early Stage Product Candidates

Dotinurad (urate transporter (URAT1) inhibitor for gout)

- In July 2024, Urica entered into an asset purchase agreement, royalty agreement, and related agreements (collectively, the "Transaction Documents") with Crystalys Therapeutics, Inc. ("Crystalys"). Crystalys is a Delaware corporation founded in 2023 and seeded by leading life sciences institutional investors. Under the Transaction Documents, Urica transferred substantially all intellectual property rights in dotinurad, its URAT1 inhibitor product candidate that is in development for the treatment of gout, to Crystalys. In return, Crystalys issued to Urica shares of its common stock equal to 35% of Crystalys' outstanding equity including certain anti-dilution provisions through the raise of $150 million in equity securities. The Transaction Documents also granted Urica a secured 3% royalty on future net sales of dotinurad, as well as a right to receive nominal cash reimbursement payments for certain clinical and development costs incurred by Urica related to dotinurad.
- Dotinurad was approved in Japan in 2020 as a once-daily oral therapy for gout and hyperuricemia. Dotinurad was efficacious and well-tolerated in more than 500 Japanese patients treated for up to 58 weeks in Phase 3 clinical trials.
- Dotinurad was sourced by Fortress and was in development at our Urica subsidiary until the asset was acquired by Crystalys in July 2024.

MB-109 (IL13Rα2-targeted CAR T Cells (MB-101) + HSV-1 oncolytic virus (MB-108))

- We are currently exploring with COH to conduct 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 2026.
- MB-101 has completed the treatment phase of the Phase 1 study in patients with IL13Rα2 recurrent/refractory malignant glioma sponsored by City of Hope (ClinicalTrials.gov identifier: NCT02208362) and is currently in three ongoing clinical trials sponsored by City of Hope for glioblastoma in adults and children (ClinicalTrials.gov identifiers: NCT04003649, NCT04661384, NCT04510051)
- MB-108 has completed a Phase 1 clinical trial in patients with recurrent GBM sponsored by the University of Alabama at Birmingham ("UAB") (ClinicalTrials.gov identifier: NCT03657576) and UAB is planning to initiate a Phase 1b study in early 2026 for the treatment of patients with recurrent malignant glioma (ClinicalTrials.gov identifier: NCT06614855).
- MB-101, MB-108, and MB-109 are currently in development at our partner company, Mustang.

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

- Mustang is currently assessing plans for studying autoimmune diseases with MB-106, a personalized CD20-targeted, 3rd-generation autologous CAR T-cell therapy. Planning for a proof-of concept Phase 1 investigator-sponsored clinical trial evaluating MB-106 in autoimmune diseases is underway and could potentially be initiated in the first quarter of 2026.
- In June 2024, we announced that updated data for MB-106 showed a favorable safety and efficacy profile in patients with Waldenstrom macroglobulinemia ("WM"), a rare form of blood cancer. There was an ORR of 90% in the cohort with durable responses observed, including three complete responses ("CR"), two very good partial responses ("VGPR"), and four partial responses, and one patient remaining in complete remission at 31 months.
- MB-106 was sourced by Fortress and is currently in development at our partner company, Mustang.

General Corporate and Other – Public Subsidiaries

- In March 2025, Avenue (ATXI) received a notice from The Nasdaq Stock Market LLC that Avenue's common stock would be suspended at the open of trading on March 19, 2025. Avenue's common stock began trading under the symbol "ATXI" on the OTC Markets system on March 19, 2025. Avenue currently plans to continue to file its required periodic reports and other filings with the SEC.
- In February 2025, Mustang announced it had concurrently exited the lease for its manufacturing facility in Worcester, Massachusetts and sold certain fixed assets including furniture and equipment to AbbVie Bioresearch Center, Inc. for $1.0 million.
- In January 2025, Mustang effected a 1-for-50 reverse stock split to achieve compliance with the minimum bid price listing requirement of the Nasdaq Capital Market.

Critical Accounting Policies and Use of Estimates

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

For a discussion of our critical accounting estimates, see the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 31, 2025 (the "2024 Form 10-K"). There were no material changes in our critical accounting estimates or accounting policies from December 31, 2024.

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 2024 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 ("GAAP"). 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 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	March 31, 2025
Avenue (OTC: ATXI)	10.3 %
Cellvation	79.6 %
Checkpoint (Nasdaq: CKPT)	8.3 %
Cyprium	73.8 %
Helocyte	83.4 %
Journey (Nasdaq: DERM)	42.7 %
Mustang (Nasdaq: MBIO)	7.9 %
Oncogenuity	73.5 %
Urica	69.6 %

Results of Operations

Comparison of Three Months Ended March 31, 2025 and 2024

($ in thousands)	Three Months Ended March 31, 2025	2024	Change $	Change %
Revenue				
Product revenue, net	$ 13,139	$ 13,030	$ 109	1 %
Operating expenses				
Cost of goods sold – (excluding amortization of acquired intangible assets)	4,790	6,002	(1,212)	(20)%
Amortization of acquired intangible assets	1,065	814	251	31 %
Research and development	3,938	24,839	(20,901)	(84)%
Selling, general and administrative	25,663	17,941	7,722	43 %
Total operating expenses	35,456	49,596	(14,140)	(29)%
Loss from operations	(22,317)	(36,566)	14,249	(39)%
Other income (expense)				
Interest income	490	833	(343)	(41)%
Interest expense and financing fee	(2,805)	(2,602)	(203)	8 %
Loss on common stock warrant liabilities	(47)	(667)	620	(93)%
Other income	(12)	(21)	9	(43)%
Total other expense	(2,374)	(2,457)	83	(3)%
Net Loss	**(24,691)**	**(39,023)**	**14,332**	**(37)%**
Less: net loss attributable to non-controlling interest	14,107	23,606	(9,499)	(40)%
Net loss attributable to Fortress	**$ (10,584)**	**$ (15,417)**	**$ 4,833**	**(31)%**

Revenue

($ in thousands)	Three Months Ended March 31, 2025	2024	Change $	Change %
Revenue				
Product revenue, net	$ 13,139	$ 13,030	$ 109	1 %

For the three months ended March 31, 2025 we generated $13.1 million of net revenue related to the sale of Journey's branded and generic products as compared to $13.0 million for the three months ended March 31, 2024. The first quarter of 2025 includes $2.0 million of net product revenue related to the U.S. commercial launch of Emrosi, offset by a decrease in Accutane revenue as a result of lower sales volume driven by recent market competition.

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

($ in thousands)	Three Months Ended March 31, 2025	2024	Change $	Change %
Cost of goods sold – (excluding amortization of acquired intangible assets)	$ 4,790	$ 6,002	$ (1,212)	(20)%

We incurred $4.8 million and $6.0 million of costs of goods sold in connection with the sale of Journey's branded and generic products for the quarters ended March 31, 2025 and 2024, respectively. Cost of goods sold decreased by $1.2 million, or 20% quarter-over-quarter, related to product sales mix, driven mainly by the decrease in Accutane revenue.

Amortization of acquired intangible assets

Amortization of acquired intangible assets increased by $0.3 million, or 31%, to $1.1 million for the three-month period ended March 31, 2025, from $0.8 million for the three-month period ended March 31, 2024, driven by the addition of the Emrosi acquired intangible asset upon Journey's payment to DRL of the milestone payment triggered by the FDA's approval of Emrosi in November 2024.

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.

The table below provides a summary of research and development by entity, for the periods presented:

($ in thousands)	Three Months Ended March 31, 2025	2024	Change $	Change %
Research & development				
Fortress[1]	$ 664	$ 2,262	$ (1,598)	(71)%
Avenue	411	2,392	(1,981)	(83)%
Checkpoint	3,788	8,497	(4,709)	(55)%
Journey	39	7,884	(7,845)	(100)%
Mustang	(964)	3,804	(4,768)	(125)%
Total research & development expense	**$ 3,938**	**$ 24,839**	**$ (20,901)**	**(84)%**

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

The decrease in R&D spending at Mustang of $4.8 million is primarily attributed to actions taken in 2024, including Mustang's reduction in workforce, closing the MB-106 clinical trial, and the termination of their transaction with uBriGene (Boston) Biosciences, Inc. These activities resulted in decreased expenses of $0.6 million for personnel related costs, a $1.7 million reduction in clinical trial related costs, a $1.3 million decrease in expenses related to outside services, a $0.7 million decrease in consulting expenses, and a $0.4 million gain on the termination of the lease on its manufacturing facility. Journey's decrease of $7.8 million is primarily driven by lower Emrosi costs related to pre-approval expenses, milestones and fees. Avenue's decrease in R&D expense of $2.0 million in the quarter ended March 31, 2025 is primarily attributable to a decrease in pre-clinical and clinical development costs for AJ201, prior to its sale to AnnJi, and a $0.1 million decrease in IV tramadol supply costs. Checkpoint's decreased R&D expense of $4.7 million is due to decreased manufacturing-related costs for cosibelimab of $4.0 million, and a $0.7 million decrease in clinical costs for product candidates, primarily the CK-301-101 study.

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 March 31,		Change	
($ in thousands)	2025	2024	$	%
Stock-based compensation - research & development				
Fortress[1]	$ 625	$ 408	$ 217	53 %
Avenue	40	45	(5)	(11)%
Checkpoint	689	490	199	41 %
Journey	—	145	(145)	(100)%
Mustang	(11)	29	(40)	(139)%
Total stock-based compensation expense - research and development	**$ 1,343**	**$ 1,117**	**$ 226**	**20 %**

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

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 March 31,		Change	
($ in thousands)	2025	2024	$	%
Selling, general & administrative				
Fortress[1]	$ 5,022	$ 4,327	$ 695	16 %
Avenue	1,494	1,316	178	14 %
Checkpoint	7,361	2,451	4,910	200 %
Journey	10,569	8,420	2,149	26 %
Mustang	1,217	1,427	(210)	(15)%
Total selling, general & administrative expense	**$ 25,663**	**$ 17,941**	**$ 7,722**	**43 %**

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

For the three months ended March 31, 2025, the increase in selling, general and administrative expenses of $7.7 million, or 43%, is primarily attributable to an increase of $4.9 million at Checkpoint due to primarily to an increase in legal and accounting fees of $2.5 million and an increase of $1.5 million for costs related to the pending transaction with Sun Pharma, including fees to financial advisors, and an increase in stock-based compensation of $1.1 million, and to an increase of $2.1 million at Journey due to incremental operating activities related to the launch and commercialization of Emrosi.

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 March 31, 2025	2024	Change $	Change %
Stock-based compensation - Selling, general and administrative				
Fortress[1]	$ 2,161	$ 2,066	$ 95	5 %
Avenue	145	146	(1)	(1)%
Checkpoint	1,267	220	1,047	476 %
Journey	1,323	1,261	62	5 %
Mustang	50	47	3	6 %
Total stock-based compensation expense - selling, general and administrative	**$ 4,946**	**3,740**	**$ 1,206**	**32 %**

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

Other income (expense)

($ in thousands)	Three Months Ended March 31, 2025	2024	Change $	Change %
Other income (expense)				
Interest income	$ 490	$ 833	$ (343)	(41)%
Interest expense and financing fee	(2,805)	(2,602)	(203)	8 %
Loss on common stock warrant liabilities	(47)	(667)	620	(93)%
Other income	(12)	(21)	9	(43)%
Total other expense	$ (2,374)	(2,457)	$ 83	(3)%

Total other income (expense) decreased $0.1 million, or 3%, from expense of $2.5 million for the quarter ended March 31, 2024 to expense of $2.4 million for the quarter ended March 31, 2025, primarily due to the decrease in the loss on common stock warrant liabilities of $0.6 million, partially offset by the decrease in interest income of $0.3 million and an increase in interest expense and financing fees of $0.2 million.

Liquidity and Capital Resources

Sources of Liquidity

At March 31, 2025, we had an accumulated deficit of $751.5 million, primarily as a result of R&D expenses, purchases of in-process research and development and selling, general and administrative expenses.

We fund our operations through cash on hand, the sale of debt, third-party financings, and the sale of subsidiaries and partner companies. securities. At March 31, 2025, we had cash and cash equivalents of $91.3 million, of which $19.5 million relates to Fortress and private subsidiaries primarily funded by Fortress, $33.0 million relates to Checkpoint, $14.2 million relates to Mustang, $21.1 million relates to Journey, and $3.5 million relates to Avenue. Restricted cash at March 31, 2025 was $1.2 million, which relates to 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. We believe that our current cash and cash equivalents is sufficient to fund operations for at least the next twelve months. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We may seek funds through equity or debt financings, joint venture or similar development collaborations, the sale of partner companies, 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 March 31, 2025, $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 notices. As a result, the Company is no longer 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 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 no longer 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 by certain selling stockholders who were previously holders of shares of 8% Cumulative Redeemable Perpetual Class B Preferred Stock of Urica, of an aggregate of up to 1,987,250 shares of the Company’s common stock;
- the offer and sale of up to 5,885,000 shares underlying warrants originally issued as part of units, each consisting of one share of Common Stock and one warrant, originally registered pursuant to the prospectus filed with the SEC under November 10, 2023;
- the offer and sale of up to 3,303,305 shares underlying warrants originally issued as part of units, each consisting of one share of Common Stock and one warrant, originally registered pursuant to the prospectus filed with the SEC on December 29, 2023; and
- the offer and sale by certain selling stockholders of up to 116,637 shares of Common Stock issuable upon the exercise of warrants, as amended, granted to Oaktree and its affiliates under the Prior Oaktree Agreement.

This post-effective amendment was declared effective by the SEC on April 2, 2025.

During the three months ended March 31, 2025, the Company issued and sold approximately 0.5 million shares at an average price of $1.94 per share for gross proceeds of approximately $1.0 million under the Company’s at-the-market offering program.

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 covers 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 connection with the Journey 2022 S-3, Journey entered into a sales agreement relating to the sale of shares of Journey's common stock in an at-the-market offering (the "Journey ATM Sales Agreement"). In accordance with the terms of the Journey ATM Sales Agreement, Journey may offer and sell up to 4,900,000 shares of its common stock, par value $0.0001 per share, from time to time. For the three months ended March 31, 2025, Journey issued and sold approximately 0.8 million shares of common stock for gross proceeds of $4.1 million under the Journey ATM Sales Agreement. At March 31, 2025, 1.8 million shares remain available for issuance under the Journey ATM Sales Agreement.

Checkpoint

In March 2023, Checkpoint filed a registration statement on Form S-3 (File No. 333-270843), which was declared effective May 5, 2023 (the "Checkpoint 2023 S-3"). Under the Checkpoint 2023 S-3, Checkpoint may sell up to a total of $150 million of its securities. As of March 31, 2025, approximately $65.7 million of the securities remain available for sale through the Checkpoint 2023 S-3.

In January 2025, Checkpointo 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.

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 March 31, 2025, 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.

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 three months ended March 31, 2025, Mustang issued and sold approximately 54,000 shares through the Mustang ATM for net proceeds of approximately $0.6 million.

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 (the "Pre-Funded Warrant Shares), (iii) Series C-1 warrants to purchase up to 2,657,807 shares of common stock, and (iv) 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 have an exercise price of $0.0001 per share, were exercisable immediately upon issuance and will expire 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 will expire five years from the date of stockholder approval and the Series C-2 warrants will 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, if any, from the exercise of the Warrants, was approximately $6.8 million. 670,000 of the 2,162,807 pre-funded warrants have since been exercised as of the date of the filing of this Form 10-Q.

Avenue

In December 2021, Avenue filed a shelf registration statement (File No. 333-261520) on Form S-3 (the "Avenue 2021 S-3"), which was declared effective on December 10, 2021. Avenue filed a replacement shelf registration on Form S-3 on December 4, 2024 (the "Avenue Replacement Shelf"), which has not yet become effective under the Securities Act of 1933, as amended. However, upon Avenue's formal delisting from Nasdaq, effective upon Nasdaq's filing of a Form 25 with the SEC, Avenue will be ineligible to use Form S-3 and therefore unable to use the Avenue 2021 S-3 or the Avenue Replacement Shelf.

In May 2024, Avenue entered into an At-the-Market Offering Agreement (the "Avenue ATM") under which Avenue may 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 are made pursuant the Avenue 2021 S-3, and the related prospectus supplement dated May 10, 2024. During the three months ended March 31, 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 suspension of its stock from trading on the Nasdaq.

Cash Flows

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

	For the Three Months Ended March 31, 2025					
($ in thousands)	Fortress[1]	Avenue	Checkpoint	Journey	Mustang	Total
Statement of cash flows data:						
Total cash (used in)/provided by:						
Operating activities	$ (2,470)	$ (1,186)	$ (11,686)	$ (2,832)	$ (1,389)	$ (19,563)
Investing activities	—	—	—	—	1,165	1,165
Financing activities	711	2,094	38,124	3,597	7,616	52,142
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (1,759)	$ 908	$ 26,438	$ 765	$ 7,392	$ 33,744

	For the Three Months Ended March 31, 2024					
($ in thousands)	Fortress[1]	Avenue	Checkpoint	Journey	Mustang	Total
Statement of cash flows data:						
Total cash (used in)/provided by:						
Operating activities	$ (5,453)	$ (3,120)	$ (6,474)	$ (5,019)	$ (5,321)	$ (25,387)
Investing activities	—	—	—	—	—	—
Financing activities	8,855	4,531	12,787	1,637	49	27,859
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 3,402	$ 1,411	$ 6,313	$ (3,382)	$ (5,272)	$ 2,472

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

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

	Three Months Ended March 31,		
($ in thousands)	2025	2024	Change
Total cash (used in)/provided by:			
Operating activities	$ (19,563)	$ (25,387)	$ 5,824
Investing activities	1,165	—	1,165
Financing activities	52,142	27,859	24,283
Net decrease in cash and cash equivalents and restricted cash	$ 33,744	$ 2,472	$ 31,272

Operating Activities

Net cash used in operating activities decreased $5.8 million from the three months ended March 31, 2024, as compared to the three months ended March 31, 2025. The decrease is due to the decrease of $14.3 million in net loss offset by the $8.4 million decrease resulting from changes in operating assets and liabilities.

Investing Activities

Net cash provided by investing activities for the three months ended March 31, 2025 as compared to the three months ended March 31, 2024 increased by $1.2 million, due to Mustang's $1.2 million proceeds from the sale of its held-for-sale assets related to the exit of its manufacturing facility.

Financing Activities

Net cash provided by financing activities was $27.9 million for the three months ended March 31, 2024, compared to $52.1 million of net cash provided by financing activities for the three months ended March 31, 2025, an increase of $24.3 million. The increase is attributable to proceeds from partner companies' equity offerings and warrant exercises, partially offset by decreased proceeds from the issuance of common stock for equity offerings of the Company in the current period.

Contractual Obligations

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

During the three months ended March 31, 2025, there were no material changes in our contractual obligations and commitments, including our lease obligations, as described in our 2024 Form 10-K.

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 March 31, 2025, 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, which materially affected, or is reasonable likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

There are no reportable events or material developments with respect to previously disclosed proceedings for the quarter ended March 31, 2025. 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, Checkpoint, Journey and Mustang with the SEC, before deciding to invest in our Securities. If any of the following risks or the risks included in the public filings of Avenue, Checkpoint, Journey or Mustang were to materialize, our business, financial condition, results of operations, and future growth prospects could be materially and adversely affected. In that event, the market price of our Securities could decline, and you could lose part of or all of your investment in our Securities. In addition, you should be aware that the below stated risks should be read as being applicable to our subsidiaries and partner companies such that, if any of the negative outcomes associated with any such risk is experienced by one of our subsidiaries or partner companies, the value of Fortress' holdings in such entity may decline. As used throughout this filing, the words "we", "us" and "our" may refer to Fortress individually, to one or more subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context.

Risks Inherent in Drug Development

Most of our 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 Agency ("DEA"), or foreign equivalent, may schedule one or more of our product candidates under the Controlled Substances Act, or its foreign equivalent, which could impede such product's commercial viability. Any of these scenarios could impact the commercial prospects for one or more of our current or future product candidates.

The extensive regulation to which our product candidates are subject may be costly and time consuming, cause anticipated 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 BLA or NDA. The approval process is uncertain, expensive, often spans many years, and can vary substantially based upon the type, complexity and novelty of the 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.

Foreign approval procedures vary by country and may, in addition to the aforementioned risks, involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, rapid drug and biological development during the COVID-19 pandemic has raised questions about the safety and efficacy of certain marketed pharmaceuticals and may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals may prevent us from commercializing our product candidates.

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

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

- obtaining regulatory approval to commence 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, 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 Federal Controlled Substances Act of 1970 ("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 ("off label uses"), our ability to promote the products is limited to those indications that are specifically approved by the FDA. Such off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the practice of medicine or behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies regarding the promotion of off-label use.

If our promotional activities fail to comply with these regulations or guidelines, we may be subject to compliance or enforcement actions, including Warning Letters 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 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.

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

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

At March 31, 2025, the total amount of debt outstanding, net of the debt discount, was $58.3 million. If we default on our obligations, the holders of our debt may declare the outstanding amounts immediately payable together with accrued interest, and/or take possession of any pledged collateral. If an event of default occurs, we may be unable to cure it within the applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment and we may be unable to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. In addition, current or future debt obligations may limit our ability to finance future operations, satisfy capital needs, or to engage in, expand or pursue our business activities. Such restrictions may also prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding debt, which may not be desirable or possible.

On July 25, 2024, we, as borrower, entered into a $50.0 million senior secured credit agreement (the "Oaktree Agreement") with Oaktree Fund Administration, LLC and the lenders from time-to-time party thereto (collectively, "Oaktree"). We borrowed $35.0 million under the Oaktree Agreement on the date of the agreement and are eligible to draw up to an additional $15.0 million with the lenders' consent. The Oaktree Agreement contains customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions. In addition, the Oaktree Agreement contains certain financial covenants, including, (i) a requirement that we maintain a minimum liquidity of $7.0 million, which may be reduced or increased as described in the Oaktree Agreement, and (ii) that product net sales of Journey meet a consolidated minimum net sales amount of $50.0 million on a trailing 12-month basis, tested quarterly, which may be reduced or increased as described in the Oaktree Agreement (the "Minimum Net Sales Test"), subject to certain exclusions. Failure by the Company to comply with the financial covenants will result in an event of default, subject to certain cure rights with respect to the Minimum Net Sales Test. The Oaktree Agreement contains events of default that are customary for financings of this type, in certain circumstances subject to customary cure periods. In addition, the Company is also required to (i) raise common equity, or receive in monetizations or distributions, by the end of each calendar year prior to the maturity date, in an aggregate amount equal to the greater of $20 million or 50% of an amount set forth in an annual budget delivered to the lenders and (ii) maintain a specified minimum equity stake in Journey. The breach of any other such provisions (even, potentially, in an immaterial manner) could result in an event of default under the Oaktree Agreement, the announcement and impact of which could have a negative impact on the trading prices of our securities. The restrictions imposed by such provisions may also inhibit our and certain of our subsidiaries and partner companies' ability to enter into certain transactions or arrangements that management otherwise believes would be in our or such partner companies' best interests, such as dispositions that would result in cash inflows to Fortress and/or our subsidiaries and partner companies, or acquisitions or financings that would promote future growth.

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

We continue to generate operating losses in all periods including losses from operations of approximately $22.7 million and $36.6 million for the three months ended March 31, 2025 and 2024, respectively and $110.4 million and $142.3 million for the years ended December 31, 2025 and 2024, respectively. At March 31, 2025, we had an accumulated deficit of approximately $751.5 million. We expect to make substantial expenditures and incur increasing operating costs and interest expense in the future, and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates and finance investments in certain of our existing and new 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 become profitable depends upon our ability to generate revenue. To date, other than from Journey, we have not generated any revenue from our development stage products, and we do not know when, or if, we will generate any revenue from such development-stage products. Our ability to generate revenue from such development-stage products depends on a number of factors, including, but not limited to, our ability to:

- obtain regulatory approval for one or more of our product candidates, or any future product candidate that we may license or acquire in the future;
- manufacture commercial quantities of one or more of our product candidates or any future product candidate, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell one or more of our product candidates or any future product candidate, if approved.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations, 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 three months ended March 31, 2025 and 2024, we incurred R&D expenses of approximately $4.3 million and $24.8 million, respectively, and during the years ended December 31, 2025 and 2024, we incurred R&D expenses of approximately $56.6 million and $101.7 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, including that with Oaktree, have and will continue to inhibit our and our subsidiaries' abilities to raise capital.

We may be unable to generate returns for our investors if our partner companies and subsidiaries, several of which have limited or no operating history, have no commercialized revenue generating products or, if not yet profitable, cannot obtain additional third-party financing.

As part of our growth strategy, we have made and will likely continue to make substantial financial and operational commitments in our subsidiaries, which often have limited or no operating history, 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 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 in fiscal 2025 to date through the sale of shares of our common stock and other securities in offerings made under a Form S-3 "shelf" registration statement. 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 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 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, for which we recently received FDA approval, currently have patent protection. Four of our marketed products, Accutane, Targadox, Luxamend and Exelderm, do not have patent protection or otherwise are not eligible for patent protection.

Accutane currently competes in the Isotretinoin market with five other therapeutically equivalent A/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.

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 our products, or any product candidate for which we receive marketing authorization, will depend 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. It is currently unknown what impact, if any, proposed changes by the federal and state governments in the U.S. and similar changes in foreign countries may have on pricing and reimbursement, particularly with respect to government programs such as Medicare and Medicaid.

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 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 healthcare 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 we receive for our products and any future product candidates, if approved. In addition, on May 12, 2025, President Trump issued an executive order implementing the concept of most-favored nation pricing. Under this order, the Department of Health and Human Services, 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 U.S. Department of Health and Human Services 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. The effects of the IRA on the pharmaceutical industry in general are not yet known.

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. We expect that 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 changes 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.

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 tariffs affecting products imported from outside of the U.S. that could have negative impacts on our business operations. In this respect, on February 1, 2025, the U.S. government imposed a 25% tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and imposed substantial additional blanket tariffs on imports from China. In April 2025, the U.S. government announced additional 10% blanket tariffs on all imported goods. On April 14, 2025, the U.S. Department of Commerce Bureau of Industry and Security launched an investigation into the effects on U.S. national security as a result of imports of pharmaceuticals and pharmaceutical ingredients, and on May 5, 2025, the U.S. government announced plans to impose tariffs on pharmaceutical imports to the U.S. Historically, 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, if implemented, 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 and consummated several partnerships and/or contingent sales of our assets and subsidiaries, including an agreement under which Checkpoint will be acquired by Sun Pharma, an equity investment and contingent acquisition agreement between Caelum and AstraZeneca and a development funding and contingent asset purchase between Cyprium and Sentynl, of which the acquisition components of each such transaction have not yet been consummated. Each of these arrangements has been time-consuming and has diverted management's attention, and there can be no assurance that any of these transactions closes in a timely manner, or at all. With respect to the Checkpoint acquisition in particular, due to uncertainties as to the timing of the completion of the transaction, uncertainties as to whether Checkpoint's stockholders will vote to approve the transaction, the possibility that competing offers will be made and the possibility that various closing conditions for the transaction may not be satisfied or waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the transaction (or only grant approval subject to adverse conditions or limitations), Fortress may not realize the anticipated benefits of the proposed transaction in the time frame expected, or at all. 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 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 us and/or may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

Certain of our officers and directors serve in similar roles at our partner companies, subsidiaries, 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 Russia's February 2022 invasion of Ukraine, the conflict between Israel and the Hamas and Hezbollah extremist groups, attacks by armed groups on cargo ships in the Red Sea, and tensions across the Taiwan Strait. For instance, the United States or other countries may impose sanctions that restrict doing business in the effected countries and increased military conflict may affect third-party vendors and cause delays.

This risk may be magnified in the case of the conflict between Russia and Ukraine. Russia's invasion and the ensuing response by Ukraine may disrupt our partner companies' ability to conduct clinical trials in Russia, Ukraine, Belarus, and Georgia, and potentially other neighboring countries. Although the impact of Russia's military action is highly unpredictable, certain clinical trial sites may be affected, including those of our partner company Checkpoint in Russia, Ukraine, Belarus, and Georgia. Those clinical trial sites may suspend or terminate trials, and patients could be forced to evacuate or choose to relocate, making them unavailable for initial or further participation in clinical trials. For instance, Checkpoint had to terminate their Phase 3 NSCLC trial in the first quarter of 2023 as a result of such conflicts. 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. With the new presidential administration in the U.S., additional and higher tariffs and sanctions may be 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 continue 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 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 March 31, 2025, we had an accumulated deficit of approximately $751.5 million, and as of December 31, 2024 and 2023, we had an accumulated deficit of approximately $740.9 million and $694.9 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 are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with 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 of our clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may refuse to accept such data, or require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP in strict conformity to cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

We also are required to register 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've been compelled to agree to such language, it is conceivable that we will be liable to third parties for liabilities in excess of such caps that are attributable to the actions, forbearances and/or culpability of such service providers and their 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 candidate or future product candidates, which could reduce the marketing impact of any labeling or marketing claims that we could make following FDA approval;
- relative convenience and ease of administration;
- the prevalence and severity of side effects and adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and in turn we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

Even if approved, any product candidates that we may develop and market may be later withdrawn from the market or subject to promotional limitations.

We may not be able to obtain the desired labeling claims or scheduling classifications necessary or desirable for the promotion of our marketed products (or our product candidates if approved). We may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory or if adverse events or other safety issues arise after approval while our products are on the market, the FDA or a comparable regulatory authority in another jurisdiction may withdraw marketing authorization or may condition continued marketing on commitments from us that may be expensive and/or time consuming to complete. In addition, if manufacturing problems occur, regulatory approval may be impacted or withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of such products if approved.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for one or more of our product candidates or a future product candidate we may license or acquire and may have to limit their commercialization, 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 candidate 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 side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

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

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

- restrictions on product manufacturing, distribution or use;
- restrictions on the labeling or marketing of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning 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 Stated District Court Southern District of New York through the United States Marshalls 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. 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 new 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 Exchange. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

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

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

- the inability of stockholders to call special meetings; and

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

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

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

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

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 bear 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

None.

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 three months ended March 31, 2025, no dividends were declared by the Board of Directors. At March 31, 2025, the Company had total undeclared dividends of approximately $6.0 million, which represents the cumulated (but undeclared) dividends due to Series A Preferred shareholders on March 31, 2025.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

During the three months ended March 31, 2025, 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 of Fortress Biotech, Inc. dated May 20, 2011 (incorporated by reference to Exhibit 3.2 of the Registrant's Form 10 (file No. 000-54463) filed with SEC on July 15, 2011).
3.3	Second Certificate of Amendment of Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated October 1, 2013 (incorporated by reference to Exhibit 3.8 of the Registrant's Annual Report on Form 10-K (file No. 001-35366) filed with SEC on March 14, 2014).
3.4	Third Certificate of Amendment of Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated April 22, 2015 (incorporated by reference to Exhibit 3.9 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with SEC on April 27, 2015).
3.5	Certificate of Designation of Rights and Preferences of the Fortress Biotech, Inc. 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on November 7, 2017).
3.6	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).
3.7	Certificate of Amendment to the Certificate of Designations and Rights and Preferences of the Fortress Biotech, Inc. 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock under the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated June 18, 2020 (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on June 19, 2020).
3.8	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated June 23, 2021 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 10-K (file No. 001-35366) filed with SEC on June 23, 2021).

3.9	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).
3.10	Certificate of Amendment of the Amended and Restated Certificate of Incorporation, as Amended, of Fortress Biotech, Inc. dated October 9, 2023 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K (file No. 001-35366) filed with SEC on October 10, 2023.
3.11	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).
10.1	Agreement and Plan of Merger, dated as of March 9, 2025, by and among Checkpoint Therapeutics, Inc., Sun Pharmaceutical Industries, Inc., and Snoopy Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on March 10, 2025).
10.2	Support Agreement, dated as of March 9, 2025, by and among Checkpoint Therapeutics, Inc., Sun Pharmaceutical Industries, Inc., and Fortress Biotech, Inc. (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on March 10, 2025).
10.3	Royalty Agreement, dated as of March 9, 2025, by and among Checkpoint Therapeutics, Inc., Sun Pharmaceutical Industries, Inc., and Fortress Biotech, Inc. (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on March 10, 2025).
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.
*** Certain portions of this exhibit have been omitted pursuant to Item 60(b)(10) of Regulation S-K.

SIGNATURES

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

May 15, 2025

FORTRESS BIOTECH, INC.

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

May 15, 2025

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: May 15, 2025

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: May 15, 2025

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 March 31, 2025, 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: May 15, 2025

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 March 31, 2025, 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: May 15, 2025

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