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

## FORM 10-K

$\times$	ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SEC	URITIES EXCHANGE ACT OF 1934	
	For the Fisc	cal Year Ended December 31, 2024	
		or	
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE	SECURITIES EXCHANGE ACT OF 1934	
	For the Tra	nsition Period from to	
	Com	mission File No. 001-35366	
		RESS BIOTECH, INC. Registrant as Specified in its Charter)	
	Delaware (State or Other Jurisdiction of Incorporation or Organization)	(I.I	20-5157386 R.S. Employer ntification No.)
	1111 Kane Concourse Suite 301 Bay Harbor Islands, FL 33154 (Address of Principal Executive Offices)		33154 (Zip Code)
	Registrant's telephone	number, including area code: (781) 652-4500	
	Securities register	red pursuant to Section 12(b) of the Act:	
	Title of Class	Trading Symbol(s)	Exchange Name
	mon Stock 5% Series A Cumulative Redeemable Perpetual Preferred Stock	FBIO FBIOP	Nasdaq Capital Market Nasdaq Capital Market
	•	pursuant to section 12(g) of the Act: None.	4 - F
Indic	rate by check mark if the registrant is a well-known seasoned issuer, as defined in Ru	ule 405 of the Securities Act. Yes  No  \text{\texts}	
Indic	ate by check mark if the registrant is not required to file reports pursuant to Section	13 or Section 15(d) of the Act. Yes □ No ☒	
	ate by check mark whether the registrant (1) has filed all reports required to be file er period that the registrant was required to file such reports), and (2) has been subje		
	ate by check mark whether the registrant has submitted electronically every Inter- ng the preceding 12 months (or for such shorter period that the registrant was require		ule 405 of Regulation S-T (§ 232.405 of this chapter)
Indic "larg	ate by check mark whether the registrant is a large accelerated filer, an accelerated e accelerated filer," "accelerated filer," "smaller reporting company," and "emerging	d filer, a non-accelerated filer, a smaller reporting compa g growth company" in Rule 12b-2 of the Exchange Act.	any, or an emerging growth company. See definition of
	e accelerated filer   \( \square\) accelerated filer   \( \square\)		Accelerated filer  Smaller reporting company  Emerging growth company
	emerging growth company, indicate by check mark if the registrant has elected n ided pursuant to Section 13(a) of the Exchange Act. $\hfill\Box$	ot to use the extended transition period for complying w	with any new or revised financial accounting standards
	ate by check mark whether the registrant has filed a report on and attestation to it b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting		internal control over financial reporting under Section
	curities are registered pursuant to Section 12(b) of the Act, indicate by check manously issued financial statements. $\Box$	rk whether the financial statements of the registrant incl	luded in the filing reflect the correction of an error to
	tate by check mark whether any of those error corrections are restatements that require the relevant recovery period pursuant to §240.10D-1(b). $\Box$	uired a recovery analysis of incentive-based compensation	n received by any of the registrant's executive officers
Indic	ate by check mark whether the registrant is a shell company (as defined in Rule 12b	o-2 of the Act). Yes □ No ☒	
The a	aggregate market value of the common stock held by non-affiliates of the registrant	as of the last business day of the registrant's most recently	y completed second fiscal quarter: \$30,782,670.
	Class of Stock	Outstanding S	hares as of March 27, 2025
	Common Stock, \$0.001 par value 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock, \$0.001 par v	value	29,533,840 3,427,138

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#### CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Statements in this Annual Report on Form 10-K 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, as amended. 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;
- our ability to obtain regulatory approval for products under development;
- our ability to successfully commercialize products for which we receive regulatory approval or receive royalties or other distributions from third parties;
- 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 Annual Report on Form 10-K should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

#### 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 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 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
  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.

#### 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

#### Item 1. Business.

#### 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 our extensive network of key opinion leaders to identify and evaluate promising products and product candidates for potential acquisition. We have executed arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center, Fred Hutchinson Cancer Center, 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 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.

## **Recent Developments**

## Checkpoint and UNLOXCYT (cosibelimab-ipdl)

In December 2024, we announced that Checkpoint had received approval for UNLOXCYT, which is the first and only programmed death-ligand 1 ("PD-L1") blocking antibody to receive U.S. Food and Drug Administration ("FDA") marketing approval for the treatment of adults with metastatic cutaneous squamous cell carcinoma ("cSCC") or locally advanced cSCC who are not candidates for curative surgery or curative radiation.

In March 2025, we announced that 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. We expect the transaction to close in the second quarter of 2025, although there can be no assurance that the transaction closes in a timely manner, or at all.

As of the announcement date, Fortress owned approximately 6.9 million shares of Checkpoint (including Class A Common Stock on an asconverted basis to Common Stock). Fortress also entered into a royalty agreement with Checkpoint and Sun Pharma pursuant to which Fortress is eligible to receive a royalty of 2.5% on worldwide net sales of UNLOXCYT. Due to uncertainties as to the timing of the completion of the acquisition, 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.

## Journey and EMROSI (Minocycline Hydrochloride Extended-Release Capsules, 40mg)

In November 2024, we announced that partner company Journey received approval of Emrosi (also referred to as DFD-29), a 40mg minocycline hydrochloride extended release capsule for oral use indicated to treat inflammatory lesions (papules and pustules) of rosacea in adults.

## Cyprium and CUTX-101 (copper histidinate)

In January 2025, we announced that the FDA had accepted the NDA for CUTX-101, a copper histidinate injection, for priority review for the treatment of Menkes disease. The Prescription Drug User Fee Act ("PDUFA") target action date is September 30, 2025 and the candidate has been granted Rare Pediatric Disease Designation by the FDA for the treatment of Menkes disease, Fast Track Designation for classic Menkes disease in patients who have not demonstrated significant clinical progression, and Breakthrough Therapy Designation.

Cyprium is eligible to receive up to \$129 million in aggregate development and sales milestones from its partner Sentynl Therapeutics, Inc. ("Sentynl"), as well as royalties on net sales of CUTX-101 as follows: (i) 3% of annual net sales up to \$75 million; (ii) 8.75% of annual net sales between \$75 million and \$100 million; and (iii) 12.5% of annual net sales in excess of \$100 million. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued if the NDA for CUTX-101 is approved.

#### **Commercial Products and Product Candidates**

## Commercial and Approved Products

Through our partner company Journey we market the following branded dermatology products approved by the FDA for sale in the United States:

- Emrosi<sup>TM</sup> (Minocycline Hydrochloride Extended-Release Capsules, 40mg for the treatment of inflammatory lesions of rosacea in adults): approved by the FDA in November 2024, which launched in March 2025;
- Qbrexza®: a medicated cloth towelette for the treatment of primary axillary hyperhidrosis;
- Accutane®: an oral isotretinoin drug for the treatment of severe recalcitrant nodular acne;
- Amzeeq® (minocycline topical foam, 4%): a topical formulation of minocycline for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and children nine years and older;
- Zilxi® (minocycline topical foam, 1.5%): a topical minocycline treatment for inflammatory lesions of rosacea in adults;
- Exelderm® Cream and Solution: a broad-spectrum antifungal intended for topical use;
- Targadox®: an oral doxycycline drug for adjunctive therapy for severe acne; and
- Luxamend®: a water-based emulsion formulated to provide an optimally moist healing environment for superficial wounds; minor cuts or scrapes; dermal ulcers; donor sites; first- and second-degree burns, including sunburns; and radiation dermatitis.

#### EMROSI (Minocycline Hydrochloride Extended-Release Capsules, 40mg)

Journey received approval in November 2024 for Emrosi (also referred to as DFD-29), a 40mg minocycline hydrochloride extended release capsule for oral use indicated to treat inflammatory lesions (papules and pustules) of rosacea in adults. Emrosi is now the lowest approved oral minocycline hydrochloride dose. It was developed using Multiple Unit Pellet System technology, which combines Immediate Release (25%) and Extended Release (75%) Minocycline pellets for uniform drug release. Emrosi has shown superiority to Oracea® and placebo on the co-primary endpoints and all secondary endpoints in two Phase 3 studies, including reduction of total lesion count, as well as reduction in erythema compared to placebo in both studies and was well-tolerated. The results from the Phase 3 studies were published in *JAMA Dermatology* in March 2025.

The NDA was filed under Section 505(b)(2) of the Food Drug and Cosmetic Act ("FDCA") in January 2024 and was approved in November 2024 by the FDA (NDA 219015). Emrosi has Orange Book-listed patents that extend through January of 2039. In March 2025, Journey announced the commercial launch of Emrosi.

## UNLOXCYT (cosibelimab-ipdl)

Our partner company Checkpoint received approval in December 2024 for UNLOXCYT, which is the first and only programmed death-ligand 1 blocking antibody to receive FDA marketing approval for the treatment of adults with metastatic cSCC or locally advanced cSCC who are not candidates for curative surgery or curative radiation.

UNLOXCYT is a fully human monoclonal antibody of IgG1 subtype that directly binds to PD-L1 and blocks the PD-L1 interaction with the programmed death receptor-1 ("PD-1") and B7.1 receptors. The primary mechanism of action is based on the inhibition of the interaction between PD-L1 and its receptors PD-1 and B7.1, which removes the suppressive effects of PD-L1 on anti-tumor CD8+ T-cells to restore the cytotoxic T cell response. Additionally, UNLOXCYT has been shown to induce antibody-dependent cellular cytotoxicity ("ADCC") in vitro.

Checkpoint commenced a Phase 1, multi-center clinical study for cosibelimab-ipdl in October 2017 to evaluate the safety and tolerability of ascending doses in checkpoint therapy-naive patients with selected recurrent or metastatic cancers. Following completion of dose escalation in March 2018, multiple dose expansion cohorts were initiated, including cohorts in locally advanced and metastatic cSCC. The primary endpoint is objective response rate ("ORR"), and secondary endpoints include duration of response, progression-free survival ("PFS"), and overall survival. In January 2022, top-line results were announced from a cohort of this study with cosibelimab-ipdl administered as a fixed dose of 800 mg every two weeks in patients with metastatic cSCC. The cohort met its primary endpoint, with cosibelimab-ipdl demonstrating a confirmed ORR of 47.4% (95% CI: 36.0, 59.1) based on independent central review of 78 patients enrolled in the metastatic cSCC cohort using Response Evaluation Criteria in Solid Tumors version 1.1 ("RECIST 1.1"). In June 2022, interim results were announced from another cohort of this study with cosibelimab-ipdl administered as a fixed dose of 800 mg every two weeks in patients with locally advanced cSCC that are not candidates for curative surgery or radiation in which cosibelimab-ipdl demonstrated a confirmed ORR of 54.8% (95% CI: 36.0, 72.7) based on independent central review of 31 patients enrolled in the cohort. In July 2023, longer-term results were announced for cosibelimab-ipdl from its pivotal studies in locally advanced and metastatic cSCC. These results demonstrated a deepening of response over time, resulting in complete response rates of 26% and 13% in locally advanced and metastatic cSCC, respectively. Additionally, the confirmed ORR in metastatic cSCC increased to 50.0% based on independent central review. Furthermore, responses continue to remain durable over time with the median duration of response not yet reached in either group. Updated safety data across 247 patients enrolled and treated with cosibelimab-ipdl in all cohorts of the ongoing study remain consistent with those previously reported.

Based on these results, Checkpoint submitted a Biologics License Application ("BLA") to the FDA in January 2023. On December 15, 2023, the FDA issued a complete response letter ("CRL") citing only findings that arose during a multi-sponsor inspection of Checkpoint's third-party contract manufacturing organization as approvability issues to address in a resubmission. In July 2024, Checkpoint announced the completion of a resubmission of the BLA to the FDA to potentially address the approvability issues cited in the CRL. In December 2024, Checkpoint announced that the FDA granted approval for UNLOXCYT (cosibelimab-ipdl) for the treatment of adults with metastatic cSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation. The recommended commercial dosage of UNLOXCYT is 1,200 mg administered as an intravenous infusion over 60 minutes every three weeks. In January 2025, Checkpoint

submitted a labeling supplement to the FDA to update the UNLOXCYT label to reflect the longer-term data announced in July 2023.

In March 2025, we announced that Checkpoint entered into an agreement to be acquired by Sun Pharma for \$4.10 per share in cash plus a contingent value right of up to \$0.70 per share upon the achievement of EU approval. 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. We expect the transaction to close in the second quarter of 2025, although there can be no assurance that the transaction closes in a timely manner, or at all. Due to uncertainties as to the timing of the completion of the acquisition, 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, Fortress may not realize the anticipated benefits of the proposed transaction in the time frame expected, or at all.

### Late Stage Product Candidates

## CUTX-101 (copper histidinate injection for Menkes disease)

Our subsidiary Cyprium was previously developing CUTX-101, a copper histidinate injection for the treatment of Menkes disease. Menkes disease is a rare X-linked pediatric disease caused by gene mutations of copper transporter ATP7A, which affects approximately 1 in 34,810 live male births, and potentially as high as 1 in 8,664 live male births, based on a recent genome-based ascertainment study. Menkes disease is characterized by distinctive clinical features, including sparse and depigmented hair ("kinky hair"), failure to thrive, connective tissue disorders and severe neurological symptoms such as seizures and hypotonia. Biochemically, Menkes patients may have low serum copper levels, as well as abnormal levels of catecholamine, but definitive diagnosis is typically made by sequencing of the ATP7A gene. There is no current FDA-approved treatment for Menkes disease. CUTX-101, along with an AAV-ATP7A gene therapy that is being developed by Cyprium, was granted Orphan Drug Designation by the FDA and the European Medicines Agency ("EMA") Committee for Orphan Medicinal Products. CUTX-101 was also granted Rare Pediatric Disease Designation by the FDA for the treatment of Menkes disease, Fast Track Designation for classic Menkes disease in patients who have not demonstrated significant clinical progression, and Breakthrough Therapy Designation.

In August 2020, Cyprium reported positive top-line clinical efficacy results for CUTX-101. The study demonstrated statistically significant improvement in overall survival for Menkes disease subjects who received early treatment ("ET") with CUTX-101, compared to an untreated historical control ("HC") cohort, with a nearly 80% reduction in the risk of death (Hazard Ratio = 0.21, p<0.0001). Median survival for the ET cohort was 14.8 years (177.1 months) compared to 1.3 years (15.9 months) for the untreated HC cohort.

On February 24, 2021, Cyprium entered into a development and asset purchase agreement (the "Sentynl APA") with Sentynl Therapeutics, a U.S.-based specialty pharmaceutical company owned by the Zydus Group. Under the Sentynl APA, Sentynl provided certain development funding for the CUTX-101 program, with Cyprium initially remaining in control of development of such program. Pursuant to a contractual right exercised by Sentynl in October 2023, Cyprium assigned the NDA and certain other assets pertaining to the CUTX-101 program to Sentynl and received \$4.5 million in connection with the closing of such transaction.

Sentynl is obligated 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 as follows: (i) 3% of annual net sales up to \$75 million; (ii) 8.75% of annual net sales between \$75 million and \$100 million; and (iii) 12.5% of annual net sales in excess of \$100 million. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued if the NDA for CUTX-101 is approved.

On January 6, 2025, we announced that the FDA accepted the NDA for CUTX-101 for priority review, and on January 16, 2025, we disclosed the extension of the PDUFA target action date to September 30, 2025.

Cyprium previously enrolled patients into an Intermediate-Size Patient Population Expanded Access Protocol which is now administered by Sentynl Therapeutics. Additional information on the Expanded Access study and requirements can

be found on <u>ClinicalTrials.gov</u> using identifier NCT04074512. Information on clinicaltrials.gov does not constitute part of this Annual Report on Form 10-K.

## Triplex (cytomegalovirus (CMV) vaccine)

Through our subsidiary Helocyte, we are developing Triplex, a universal recombinant Modified Vaccinia Ankara viral vector vaccine engineered to induce a rapid, robust and durable virus-specific T cell response to three immuno-dominant proteins (UL83 (pp65), UL123 (IE1), and UL122 (IE2)) linked to cytomegalovirus ("CMV"). In a Phase 1 study, Triplex was observed to be safe, well-tolerated and highly immunogenic when administered to healthy volunteers at multiple dose levels (<u>ClinicalTrials.gov</u> Identifier: NCT01941056). In a Phase 2 trial, Triplex was observed to be safe, well-tolerated, highly immunogenic and a reduction in CMV events in allogeneic stem cell transplant recipients was observed (<u>ClinicalTrials.gov</u> Identifier: NCT02506933).

As of March 2025, Triplex is currently the subject of multiple, ongoing trials in various clinical settings including: patients undergoing stem cell transplant; adults co-infected with CMV and Anti-Human Immunodeficiency Virus ("HIV"); and in combination with a CAR T cell therapy for adults with non-Hodgkin lymphoma ("NHL") or acute lumphoblastic leukemia ("ALL"). Helocyte has an exclusive, worldwide license to Triplex from COH. Information on clinicaltrials.gov does not constitute part of this Annual Report on Form 10-K.

## Solid organ transplant

In May 2024, Helocyte announced that the first patient was dosed in a multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation. The trial is funded by a grant from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health that could provide over \$20 million in aggregate, non-dilutive funding (ClinicalTrials.gov Identifier: NCT06075745).

## Stem cell transplant

In January 2025, Helocyte announced that the first patient was dosed in a Phase 2 multi-center, placebo-controlled, randomized clinical trial to evaluate Triplex's effectiveness when administered to human leukocyte antigen ("HLA") matched related stem cell donors to reduce CMV events in adults undergoing hematopoietic stem cell transplantation ("HSCT"). The trial is funded by a grant from the National Cancer Institute ("NCI") (ClinicalTrials.gov Identifier: NCT06059391).

Helocyte anticipates that its Phase 2 multicenter, double-blind, randomized, placebo-controlled study measuring the safety and effectiveness of Triplex in reducing CMV complications in patients previously infected with CMV and undergoing donor hematopoietic cell transplant to be completed in the second half of 2025 (ClinicalTrials.gov Identifier: NCT02506933).

Additionally, Helocyte is recruiting for a Phase 1/2 trial to study side effects and dosage for Triplex in treating pediatric patients with positive cytomegalovirus who are undergoing donor stem cell transplant (<u>ClinicalTrials.gov</u> Identifier: NCT03354728).

## HIV

In December 2021, Helocyte announced that a Phase 2 double-blind, randomized, placebo-controlled clinical trial was initiated to evaluate the safety and efficacy of Triplex, a CMV vaccine, in eliciting a CMV-specific immune response and reducing CMV replication in people living with HIV. The trial is being conducted by the AIDS Clinical Trials Group and is funded by the National Institute of Allergy and Infectious Disease, part of the National Institutes of Health (ClinicalTrials.gov Identifier: NCT05099965).

Additionally, a trial has been initiated for a Phase 1 trial to evaluate the feasibility and safety of Triplex in combination with a bispecific CMV-HIV CAR for adults living with HIV-1 on stable ART who have maintained viral suppression. The study is funded by a \$11.3 million grant from the California Institute of Regenerative Medicine (CIRM) in addition to other non-dilutive sources (ClinicalTrials.gov Identifier: NCT06252402).

#### Oncology

Helocyte is currently recruiting for two Phase 1 trials in combination with autologous CMV-specific CD19 CAR T cell therapy for adults with intermediate or high grade B-lineage NHL, and in settings following stem cell transplant in patients with high grade B-cell NHL (ClinicalTrials.gov Identifiers: NCT05801913 and NCT05432635).

Additionally, a trial has been initiated for a Phase 1 trial in combination with an allogeneic anti-CD19-CAR CMV-specific T cell therapy for patients with high-risk ALL after matched related donor hematopoietic stem cell transplant (<u>ClinicalTrials.gov</u> Identifier: NCT06735690).

## CAEL-101 (monoclonal antibody for AL amyloidosis)

Our former subsidiary Caelum, in collaboration with AstraZeneca plc ("AstraZeneca"), is working to develop a novel, first-in-class monoclonal antibody called CAEL-101 for the treatment of amyloid light chain ("AL") amyloidosis. CAEL-101 is designed to improve organ function by reducing or eliminating amyloid deposits in the tissues and organs of patients with AL amyloidosis. The antibody is designed to bind to insoluble light chain amyloid protein, including both kappa and lambda subtypes and received Orphan Drug Designation from the FDA as a therapy for patients with AL amyloidosis, and as a radio-imaging agent in AL amyloidosis. CAEL-101 is currently in two Phase 3 trials for AL amyloidosis and additional information on those trials can be found at ClinicalTrials.gov using identifiers: NCT04512235 and NCT04504825. Information on clinicaltrials.gov does not constitute part of this Annual Report on Form 10-

In October 2021, AstraZeneca acquired Caelum for an upfront payment of approximately \$150 million paid to Caelum shareholders, of which approximately \$56.9 million was paid to Fortress, which was net of the ten percent escrow holdback amount and other miscellaneous transaction expenses. 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 possible potential milestone payments, which together with the upfront payment, would total up to approximately \$182 million.

### Early and Mid-Stage Product Candidates

## Dotinurad (urate transporter (URAT1) inhibitor for gout)

Through our subsidiary Urica Therapeutics, Inc. ("Urica"), we acquired an exclusive license from Fuji Yakuhin Co. Ltd. ("Fuji") to develop a URAT1 inhibitor product candidate in development for the treatment of gout, dotinurad, in North America, Europe, the Middle East and North Africa. 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 rights to 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 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 to be paid by Crystalys, and 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 and in China in December 2024 for the treatment of gout patients with hyperuricemia.

## MB-101 (IL13Ra2 CAR T Cell Program for Glioblastoma)

Mustang is currently developing MB-101 for malignant brain tumors, including glioblastoma ("GBM"). MB-101 is an optimized CAR T product targeting IL13R $\alpha$ 2 on the surface of the malignant cells and incorporates enhancements in CAR T design and T cell engineering to improve antitumor potency and T cell persistence.

GBM is the most common brain and central nervous system ("CNS") cancer, accounting for approximately 52% of malignant primary brain and CNS tumors and approximately 14% of all primary brain and CNS tumors. On average during

the years 2017 through 2021, more than 13,000 new cases of GBM were diagnosed per year in the U.S. While GBM is a rare disease, with only 3.3 cases per 100,000 persons per year in the U.S., it is quite lethal, with a median survival of only 9 months. Standard of care therapy for patients less than 70 years of age consists of maximal surgical resection, radiation, chemotherapy with temozolomide, and alternating electric field therapy. This front-line regimen has remained relatively unchanged for the last 20 years due to the failure of novel therapies to improve survival, and there is no standard of care whatsoever for recurrent GBM.

Immunotherapy approaches targeting brain tumors offer promise over conventional treatments. IL13R $\alpha$ 2 is an attractive target for CAR T therapy, as it has limited expression in normal tissue but is over-expressed on the surface of greater than 50% of GBM tumors. CAR T cells are designed to express membrane-tethered IL-13 receptor ligand mutated at a single site (glutamic acid at position 13 to a tyrosine; E13Y) with high affinity for IL13R $\alpha$ 2 and reduced binding to IL13R $\alpha$ 1 in order to reduce healthy tissue targeting (Kahlon KS *et al. Cancer Research.* 2004;64:9160-9166).

Having optimized MB-101 dose, schedule, route of administration and T cell selection in a completed Phase 1 trial, ongoing COH sponsored studies include:

- MB-101 with or without nivolumab and ipilimumab in treating patients with recurrent or refractory glioblastoma (currently
  enrolling patients; ClinicalTrials.gov Identifier: NCT04003649);
- MB-101 in treating patients with recurrent or refractory glioblastoma with a substantial component of leptomeningeal disease (currently enrolling patients; ClinicalTrials.gov Identifier: NCT04661384); and
- MB-101 in treating children with recurrent or refractory IL13Rα2 positive brain tumors (currently enrolling patients; ClinicalTrials.gov Identifier: NCT04510051) sponsored by COH.

Information on clinicaltrials gov does not constitute part of this Annual Report on Form 10-K.

The final planned MB-101 trial will be in combination with the HSV-1 oncolytic virus (MB-108) in treating patients with recurrent or refractory glioblastoma and anaplastic astrocytoma. The objective of this trial is to turn immunologically "cold" tumors "hot" with MB-108 in order to potentially enhance the efficacy of MB-101, then infuse MB-101 loco-regionally as was done in the Phase 1 single-agent MB-101 trial. The combination of MB-101 and MB-108 is referred to as MB-109.

## MB-108 (HSV-1 Oncolytic Virus C134 for recurrent GBM)

MB-108 is a next-generation oncolytic herpes simplex virus ("oHSV") treatment in development at Mustang that is conditionally replication competent; that is, it is designed to replicate in tumor cells, but not in normal cells, thus killing the tumor cells directly through this process. It was in-licensed from Nationwide Children's Hospital, and the University of Alabama at Birmingham ("UAB") is evaluating the safety of this oncolytic virus in patients with recurrent glioblastoma in an ongoing Phase 1 trial (<u>ClinicalTrials.gov</u> Identifier: NCT03657576). Information on clinicaltrials.gov does not constitute part of this Annual Report on Form 10-K.

The rationale for in-licensing MB-108 was to potentially enhance the efficacy of MB-101 by first turning immunologically "cold" malignant glioma tumors "hot" with MB-108, then infusing MB-101 loco-regionally, as was done in the Phase 1 single-agent MB-101 trial. This combination is to be referred to as MB-109.

## MB-109 (MB-101 (IL13Ra2-targeted CAR T Cell Therapy) + MB-108 (HSV-1 oncolytic virus))

Mustang is developing MB-109, a combination approach of MB-101 and MB-108, as a potential treatment for IL13Rα2+ relapsed or refractory glioblastoma ("GBM") and anaplastic astrocytoma ("AA"). An attractive novel approach to control glioblastoma is adoptive cellular immunotherapy utilizing CAR T cells. CAR T cells can be engineered to recognize very specific antigenically distinct tumor populations and to migrate through the brain parenchyma to kill malignant cells. In addition, oncolytic viruses ("OVs") have been developed to effectively infect and kill cancer cells in the tumor, as well as modify the microenvironment to increase tumor immunogenicity and immune cell trafficking within the tumor. Due to

these properties, OVs have been studied in combination with other treatments to enhance the effectiveness of immunotherapies.

Preliminary anti-tumor activity has been observed in clinical studies administering the OV (MB-108) and CAR T cell therapy (MB-101) as single agents; however, the combination has not yet been explored. To determine if the combination of both therapies will result in a synergistic effect, investigators from COH developed preclinical studies in orthotopic GBM models in nude mice. Dr. Christine Brown from City of Hope presented these preclinical studies at the American Association for Cancer Research 2022 Annual Meeting. It was observed that co-treatment with MB-108 OV and IL13R $\alpha$ 2-directed CAR-T cells gave no adverse events and, more notably, that pretreatment with MB-108 re-shaped the tumor microenvironment by increasing immune cell infiltrates and enhanced the efficacy of subtherapeutic doses of CAR-T cell therapy delivered either intraventricularly or intratumorally. These preclinical studies aimed to provide a deeper understanding of this combination approach to support the potential benefit of a combination study that will evaluate an oHSV (MB-108) and IL13R $\alpha$ 2-directed CAR-T cells (MB-101).

In October 2023, Mustang announced that the FDA had accepted the Investigational New Drug ("IND") application of MB-109 for the treatment of recurrent GBM and high-grade astrocytoma. Mustang is currently planning a Phase 1 clinical study that will investigate increasing doses of intratumorally administered MB-108 followed by dual intratumoral and intraventricular administration of MB-101 to treat recurrent GBM and high-grade astrocytomas that express IL13Rα2 on the surface of tumor cells.

In November 2024, Mustang announced that the FDA granted Orphan Drug Designation to Mustang for MB-108 for the treatment of malignant glioma.

Mustang is currently exploring with COH to conduct an investigator-sponsored single-institution trial under the COH IND to treat patients with IL13R $\alpha$ 2+ recurrent GBM and high-grade astrocytoma with MB-109 that could potentially be initiated in the fourth quarter of 2025.

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

Mustang is currently developing MB-106 in a collaboration with Fred Hutchinson Cancer Center ("Fred Hutch"), a CD20-targeted, 3rd generation autologous CAR T-cell therapy, for patients with relapsed or refractory B-cell non-Hodgkin lymphomas ("NHL"), chronic lymphocytic leukemia ("CLL"), and autoimmune diseases. In the first quarter of 2024, Mustang completed a successful End-of-Phase 1 meeting with the FDA regarding a potential pivotal Phase 2 single-arm clinical trial for the treatment of Waldenstrom macroglobulinemia ("WM"). Per the discussions, the FDA agreed with the proposed overall design of the pivotal trial for WM at the recommended dose of 1 x 10<sup>7</sup> CAR-T cells/kg and requested only minimal modifications to the study protocol. Due to limited resources, and as a result of the reduction in work force conducted in 2024, Mustang does not expect to initiate a pivotal Phase 2 single-arm clinical trial of MB-106 for the treatment of WM trial in 2025.

Also in the first quarter of 2024, Mustang completed enrollment of the indolent lymphoma arm in the multicenter Phase 1 trial. The tenth and final patient enrolled on that arm was a patient with follicular lymphoma (FL) who achieved a complete response following treatment with 1 x 10<sup>7</sup> CAR-T cells/kg. As a result, the overall complete response rate for FL in the Phase 1 portion of this trial was sustained at 100% (N=6), with no occurrence of cytokine release syndrome ("CRS") above grade 1 and no immune effector cell-associated neurotoxicity syndrome ("ICANS") of any grade, despite not using prophylactic tocilizumab or dexamethasone.

In March 2024, Mustang announced plans to collaborate with Fred Hutch for a proof-of-concept Phase 1 investigator-sponsored clinical trial evaluating MB-106 in autoimmune diseases.

Also in March 2024, Mustang was granted the Regenerative Medicine Advanced Therapy ("RMAT") designation by the FDA for the treatment of relapsed or refractory CD20 positive WM and FL, based on potential improvement in response as seen in clinical data to date.

In June 2024, Mustang announced that updated data for MB-106 in the Phase 1/2 Fred Hutch investigator-sponsored trial showed a favorable safety and efficacy profile in 10 patients with WM. There was an ORR of 90% with durable responses

observed, including three complete responses ("CR"), two very good partial responses ("VGPR"), and four partial responses ("PR"). One of the patients who achieved a CR remained in remission for 31 months, with an immunoglobulin M (IgM) level that decreased rapidly to the normal range after treatment with MB-106 and remained normal since. Patients had a median of nine prior lines of therapy, and only one patient started additional anti-WM treatment after being treated with MB-106. From a safety perspective, CRS occurred in nine patients: five patients with grade 1 and four patients with grade 2. One patient experienced grade 1 ICANS. No grade 3 or 4 CRS or grade 2, 3 or 4 ICANS was observed, despite dose escalation.

In May 2024, Mustang informed the clinical sites participating in the Mustang-sponsored Phase 1/2 study in non-Hodgkin lymphoma and chronic lymphocytic leukemia, MB106-CD20-001, that Mustang had decided to close the trial. In June 2024, Mustang similarly informed the clinical sites participating in the Mustang-sponsored Long-term Follow-up Study in Patients Previously Treated with Mustang Bio, Inc. CAR-T Cell Investigational Products, MB100-OBS-001, that Mustang had decided to close that trial. As a result, further clinical development of MB-106 is currently focused solely on autoimmune diseases unless funding and resources become available to restart the program for hematologic malignancies.

Planning for the aforementioned Phase 1 investigator-sponsored clinical trial in autoimmune diseases is in progress, with initiation of the trial planned for 2025.

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

In February 2023, Avenue announced the license of intellectual property rights underlying AJ201 from AnnJi Pharmaceutical Co. Ltd ("AnnJi"). AJ201 is currently being studied in a Phase 1b/2a multicenter, randomized, double-blind clinical trial at six clinical sites across the U.S. for the treatment of spinal and bulbar muscular atrophy ("SBMA"), also known as Kennedy's Disease (ClinicalTrials.gov Identifier: NCT05517603). Enrollment was completed in January 2024. Information on clinicaltrials.gov does not constitute part of this Annual Report on Form 10-K.

SBMA is a rare, inherited, X-linked genetic neuromuscular disease primarily affecting men and AJ201 was designed to modify SBMA through multiple mechanisms including degradation of the abnormal AR protein and by stimulating Nrf1 and Nrf2, which are involved in protecting cells from oxidative stress which can lead to cell death.

AJ201 has been granted Orphan Drug Designation by the FDA for the indications of SBMA, Huntington's Disease, and Spinocerebellar Ataxia.

On March 3, 2025, Avenue received a "notice of intent to terminate" letter from AnnJi, the licensor of AJ201, with respect to the license agreement under which Avenue was granted rights to the product candidate; Avenue believes that the grounds for termination stated in the purported termination notice are without merit and intends to avail itself of the dispute resolution procedures set forth in the AJ201 license agreement.

## IV Tramadol

Our partner company Avenue is developing an intravenous formulation of tramadol ("IV tramadol"), a schedule IV opioid for the treatment of post-operative acute pain. Avenue completed two Phase 3 efficacy studies in 2018 and 2019 and announced that both had met their primary endpoints and all key secondary endpoints. In December 2019, Avenue submitted an NDA for IV tramadol to treat moderate to moderately severe postoperative pain pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA"), and following a CRL received in October 2020, resubmitted the NDA in February 2021. The FDA assigned a PDUFA goal date of April 12, 2021 for the resubmitted NDA for IV Tramadol. On June 14, 2021, Avenue announced that the receipt of a second CRL. Avenue submitted a formal dispute resolution request ("FDRR") with the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, Avenue received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to the FDRR submitted on July 27, 2021. On August 31, 2021, Avenue submitted a FDRR with the Office of New Drugs ("OND") of the FDA. On October 21, 2021, Avenue received a written response from the OND of the FDA stating that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR.

In February 2022, Avenue held an Advisory Committee meeting with the FDA regarding IV tramadol. In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: "Has the Applicant submitted

adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?" The results were 8 yes votes and 14 no votes. In March 2022, Avenue received an Appeal Denied Letter from the Office of New Drugs in response to the formal dispute resolution request. In August 2022, Avenue participated in a Type A Meeting with the FDA Division of Anesthesia, Analgesia, and Addiction Products ("DAAAP") regarding a briefing document submitted that presented a study design Avenue believed would have the potential to address the comments and deficiencies noted in the Letter.

In January 2024, Avenue announced that they reached final agreement with the FDA on the Phase 3 safety study protocol and statistical analysis approach, including the primary endpoint. The final non-inferiority study is designed to assess the risk of opioid-induced respiratory depression related to opioid stacking on IV tramadol compared to IV morphine. The study will randomize approximately 300 post bunionectomy patients to IV tramadol or IV morphine for pain relief administered during a 48-hour post-operative period. Of note, the same surgical model was used in a pivotal Phase 3 Trial. In the Phase 3 safety study to be conducted, patients will have access to IV hydromorphone, a Schedule II opioid, for rescue of breakthrough pain. The primary endpoint is a composite of elements indicative of respiratory depression. Avenue plans to initiate the study in the future, subject to having the necessary financing.

## BAER-101 (GABA<sub>A</sub> \alpha2/3 positive allosteric modulator)

Through Avenue's subsidiary Baergic, we are developing BAER-101, a high affinity, selective modulator of the gamma-aminobutyric acid ("GABA") A, which is a receptor system with differential binding and modulatory properties dependent on the particular GABA A subtype. Baergic intends to explore BAER-101 in a number of CNS disorders where patients are not adequately treated, including epilepsy and acute anxiety disorders.

In August 2023, Avenue reported preclinical data for BAER-101 from an in vivo evaluation in SynapCell's Genetic Absence Epilepsy Rate from Strasbourg ("GAERS") model of absence epilepsy. The GAERS model mimics behavioral, electrophysiological and pharmacological features of human absence seizures and has shown to be an early informative indicator of efficacy in anti-seizure drug development. In the model, BAER-101 demonstrated full suppression of seizure activity with a minimal effective dose of 0.3 mg/kg administered orally. In December 2023, Avenue presented the preclinical in vivo data evaluating BAER-101 using the GAERS model of absence epilepsy at the American Epilepsy Society (AES) 2023 Annual Meeting.

### Olafertinib (also known as CK-101, EGFR inhibitor for EGFR mutation-positive NSCLC)

Checkpoint is currently evaluating a lead small-molecule, targeted anti-cancer agent, olafertinib, as an oral, third-generation, irreversible kinase inhibitor against selective mutations of epidermal growth factor receptors ("EGFR") for the potential treatment of adult patients with metastatic NSCLC, whose tumors have EGFR exon 19 deletion mutations. Checkpoint believes that olafertinib has the potential to be effective in this population as a monotherapy or in combination with other anti-tumor immune response potentiating compounds. Olafertinib has FDA Orphan Drug Designation for the treatment of EGFR mutation-positive NSCLC.

## Preclinical Product Candidates

## AAV-ATP7A Gene Therapy

Through our subsidiary Cyprium, we are developing adeno-associated virus ("AAV")-based gene therapy ("AAV-ATP7A") for the treatment of Menkes disease. Cyprium entered into a license agreement with *Eunice Kennedy Shriver* National Institute of Child Health and Human Development to acquire the global rights to develop and commercialize AAV-ATP7A gene therapy. AAV-ATP7A gene therapy has demonstrated the ability to rescue neurological phenotypes and improve survival when coadministered with copper histidinate injections in a mouse model of Menkes disease and has been granted Orphan Drug Designation by the FDA.

In March 2024, Cyprium announced a \$4.1 million grant from the National Institute of Neurological Disorders and Stroke ("NINDS") of the NIH was awarded to the Research Institute at Nationwide Children's Hospital and Principal Investigator, Stephen G. Kaler, M.D., M.P.H., to fund the completion of preclinical studies, manufacturing, and preparation of an IND application for a first-in-human clinical trial.

## AVTS-001 Gene Therapy

In April 2023, we announced the execution of an asset purchase agreement, pursuant to which 4D Molecular Therapeutics ("4DMT") acquired Aevitas' proprietary rights to its short-form human complement factor H ("sCFH") asset for the treatment of complement-mediated diseases. Under the terms of the agreement, Aevitas is eligible to receive cash payments from 4DMT totaling up to \$140 million in potential late-stage development, regulatory and sales milestones. A range of single-digit royalties on net sales are also payable.

Prior to the agreement with 4DMT, Aevitas licensed the sCFH asset from the University of Pennsylvania and also collaborated with University of Massachusetts Medical to optimize AAV constructs.

### CK-103 (BET Inhibitor)

Checkpoint is currently developing CK-103, a novel, selective and potent small molecule inhibitor of bromodomain and extra-terminal ("BET") bromodomains. Checkpoint plans to develop CK-103 for the treatment of various advanced and metastatic solid tumor cancers, including, but not limited to, those associated with elevated c-Myc expression. Checkpoint entered into an exclusive license agreement with Jubilant Biosys Limited to develop and commercialize novel compounds that inhibit BET bromodomains on a worldwide basis. Checkpoint entered into a Sublicense Agreement with TGTX to develop and commercialize CK-103 in the field of hematological malignancies. Checkpoint retains the right to develop and commercialize CK-103 in solid tumors. Currently, Checkpoint has completed the required CMC, pharmacology and toxicology activities that it believes will support an IND application filing.

## CEVA-D and CEVA-102

Through our subsidiary Cellvation, we are developing CEVA-D, a novel bioreactor device that is designed to enhance the anti-inflammatory potency of bone marrow-derived cells without genetic manipulation, using wall shear stress to suppress tumor necrosis factor-a ("TNF-a") production by activated immune cells. CEVA-102 is the first cell product produced by CEVA-D, and may be applicable for various indications, including the treatment of severe traumatic brain injury.

#### CK-302 (Anti-GITR)

CK-302 is a fully human agonistic monoclonal antibody in development at Checkpoint that is designed to bind and trigger signaling in Glucocorticoid-Induced TNFR-Related ("GITR") expressing cells. Scientific literature indicates GITR is a co-stimulatory molecule of the TNF receptor family and is expressed on activated T cells, B cells, NK and regulatory T cells. Checkpoint believes that an anti-GITR monoclonal antibody has the potential to be effective in one or more oncological indications as a monotherapy or in combination with an anti-PD-L1 antibody as well as other anti-tumor immune response potentiating compounds and targeted therapies.

## CK-303 (Anti-CAIX)

Also in development at Checkpoint is CK-303, a fully human anti-carbonic anhydrase IX ("CAIX") antibody designed to recognize CAIX expressing cells and kill them via antibody-dependent cell-mediated cytotoxicity and complement-dependent cytotoxicity ("CDC"). Scientific literature indicates that CAIX is a well characterized tumor associated antigen with expression almost exclusively limited to the cells of renal cell carcinoma ("RCC"). More than 85% of RCC cases have been demonstrated to express high levels of CAIX expression. There is very limited expression of this antigen on healthy tissue which Checkpoint believes will limit reactivity of this antibody against healthy tissues.

## ONCOlogues (Oligonucleotide Platform)

Our subsidiary Oncogenuity is developing a delivery platform that allows peptic nucleic acids to enter a cell membrane and nucleus, displace the targeted mutant DNA strand, and prevent mutant mRNA transcription. Oncogenuity is seeking to optimize lead candidates targeting genetically driven cancers, including KRAS G12D, and other genetic disorders.

#### **Intellectual Property Generally**

Our goal is to obtain, maintain and enforce patent protection for our product candidates, formulations, processes, methods and any other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisers, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently, and will in the future, rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisers and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

## Competition

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than we do. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in research in direct competition with us. We also may compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors are pursuing the development and/or acquisition of pharmaceuticals, medical devices and over-the-counter ("OTC") products that target the same diseases and conditions that we are targeting in biotechnology, biopharmaceutical, dermatological and other therapeutic areas. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions or decreased volume of sales, or both. Most new products that we introduce must compete with other products already on the market or products that are later developed by competitors. The principal methods of competition for our products include quality, efficacy, market acceptance, price, and marketing and promotional efforts, patient access programs and product insurance coverage reimbursement.

The only pharmaceutical area in which we sell marketed products is dermatology, and the dermatology competitive landscape is highly fragmented, with a large number of mid-size and smaller companies competing in both the prescription sector and the OTC sector. Our competitors are pursuing the development and/or acquisition of pharmaceuticals, medical devices and OTC products that target the same diseases and conditions that we are targeting in dermatology. Competitive factors vary by product line and geographic area in which our products are sold. The principal methods of competition for our products include quality, efficacy, market acceptance, price, and marketing and promotional efforts.

Branded products often must compete with therapeutically similar branded or generic products or with generic equivalents. Such competition frequently increases over time. For example, if competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products could be subject to progressive price reductions and/or decreased volume of sales. To successfully compete for business, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care. Accordingly, we face pressure to continually seek out technological innovations and to market our products effectively.

Our major competitors in dermatology, including Galderma Laboratories, Almirall, Ortho-Dermatologics, Mayne Pharmaceuticals, Sun Pharma, Leo Pharma, and Arcutis Biotherapeutics, among others, vary depending on therapeutic and product category, dosage strength and drug-delivery systems, among other factors.

## **Generic Competition**

Our partner company Journey faces increased competition from manufacturers of generic pharmaceutical products, who may submit applications to FDA seeking to market generic versions of Journey's 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 U.S. Patent and Trademark Office ("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. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required to be utilized before or in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care. Generic products generally face intense competition from other generic equivalents (including authorized generics) and therapeutically similar branded or generic products.

## Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing.

## United States Pharmaceutical Product Development Process

In the United States, the FDA regulates pharmaceutical (drug and biological) products under the Federal Food, Drug and Cosmetic Act, and implementing regulations. Pharmaceutical products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product-development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA compliance and enforcement actions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial compliance or enforcement action could have a material adverse effect on us. The process required by the FDA before a pharmaceutical product may be marketed in the United States generally includes the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to good laboratory practices ("GLPs") or other applicable regulations;
- submission to the FDA of an IND, which must be in effect before human clinical trials may begin in the United States;
- performance of adequate and well-controlled human clinical trials according to the FDA's current good clinical practices ("GCPs"), to establish the safety and efficacy of the proposed pharmaceutical product for its intended use;
- submission to the FDA of an NDA or BLA for a new pharmaceutical product;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the
  pharmaceutical product is produced to assess compliance with the FDA's current Good Manufacturing Practices ("cGMPs"),
  to assure that the facilities, methods and controls are adequate to preserve the pharmaceutical product's identity, strength,
  quality and purity;
- potential FDA audit of the preclinical and clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA.

The regulatory review and approval process is lengthy, expensive and uncertain. The process of seeking required approvals before we can market or sell a product, and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and we cannot guarantee that we will be able to obtain the appropriate marketing authorization for any product candidate

Before testing any compounds with potential therapeutic value in humans, the pharmaceutical product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the pharmaceutical product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA places the IND on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a pharmaceutical product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be certain that submission of an IND will automatically result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that causes such clinical trial to be suspended or terminated.

Clinical trials involve the administration of the pharmaceutical product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by the sponsor. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA if conducted under a U.S. IND. Clinical trials must be conducted in accordance with GCP requirements. Further, each clinical trial must be reviewed and approved by an Institutional Review Board ("IRB") or ethics committee if conducted outside of the United States, at or servicing each institution at which the clinical trial will be conducted. An IRB or ethics committee is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB or ethics committee also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trials and will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our planned clinical trials and will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols and to play a significant role in the subsequent collection and analysis of data from these trials. The failure by any of such third parties to meet expected timelines, adhere to our protocols or meet regulatory standards could adversely impact the subject product development program. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The pharmaceutical product is usually introduced into a small group of healthy human subjects and tested for safety,
  dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or lifethreatening diseases, such as cancer treatments, especially when the product may be too inherently toxic to ethically
  administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The pharmaceutical product is evaluated in a larger, but still limited patient population to identify possible adverse
  effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine
  dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish safety and efficacy, the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, it has been the FDA's position that Congress intended at least two adequate and well-controlled Phase 3 clinical trials for approval of an NDA or BLA or foreign authorities for approval of marketing applications.

Post-approval studies, or Phase 4 clinical trials, may be required after initial receipt of marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA after it has been approved, and is on the market, as an ongoing condition of approval.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or, if used, its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB or ethics committee can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's or ethics committee's requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the pharmaceutical product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the pharmaceutical product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final pharmaceutical product. Additionally, appropriate packaging must be selected, tested and stability studies must be conducted to demonstrate that the pharmaceutical product candidate does not undergo unacceptable deterioration over its shelf life.

## United States Review and Approval Process

The data and results generated from product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the pharmaceutical product, proposed labeling and other required information are submitted to the FDA as part of an NDA or BLA submission before the product can be marketed and sold.

The review and approval process for an NDA or BLA is lengthy and difficult and the FDA may not approve an NDA or BLA if the applicable regulatory criteria are not satisfied or if the data and results in the submission are insufficient to support a finding of safety and efficacy, FDA may also require additional clinical data or other data and information to address deficiencies in an application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Even if a product receives regulatory approval, the approval may be significantly limited with respect to dosages, indications for use, or other label claims related to those disease states, conditions and patient populations for which the product is safe and effective and, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and are subject to periodic unannounced inspections by the FDA for compliance with cGMPs, which impose additional regulatory requirements upon us and our third-party manufacturers. We cannot be certain that we or our suppliers will be able to fully comply with the cGMPs or other FDA regulatory requirements.

## Post-Approval Requirements

Any pharmaceutical products for which we receive FDA approvals are subject to continuing postmarket regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, promoting pharmaceutical products for uses or in patient populations that are not described in the pharmaceutical product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, compliance and enforcement actions initiated by the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. The FDA also may require Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

#### Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, accelerated approval, priority review and breakthrough therapy designation, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. To be eligible for fast track designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life-threatening disease or condition and based on preclinical or preliminary clinical data demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors.

The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. These six- and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, drugs studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint and under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Moreover, a sponsor can request designation of a drug candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval and priority review. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Additionally, under FDORA, a platform technology incorporated within or utilized by a drug or biological product is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a drug approved under an NDA; (2) preliminary evidence submitted by the sponsor of the approved or licensed drug, or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a drug that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original NDA for a drug that uses or incorporates

the platform technology. Designated platform technology status does not ensure that a drug will be developed more quickly or receive FDA approval.

Even if a product candidate or our platform qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, priority review, accelerated approval and breakthrough therapy designation, do not change the standards for approval and may not ultimately expedite the development or approval process.

## Section 505(b)(2) Regulatory Approval Pathway

Section 505(b)(2) was added to the Act by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). Section 505(b)(2) of the FDCA provides an alternate regulatory pathway for approval of a new drug by allowing the FDA to rely on data not developed by the applicant. Specifically, Section 505(b)(2) permits the submission of an NDA where one or more of the investigations relied upon by the applicant for approval was not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and/or the FDA's findings of safety and effectiveness for an approved drug already on the market. Approval or submission of a 505(b)(2) application, like those for abbreviated new drugs, or ANDAs, may be delayed because of patent and/or exclusivity rights that apply to the previously approved drug.

Under the 505(b)(2) regulatory approval pathway, the applicant may reduce some of the burdens of developing a full clinical program by relying on investigations not conducted by the applicant and for which the applicant has not obtained a right of reference, such as prior investigations involving the listed drug. In such cases, some clinical trials may not be required or may be otherwise limited.

A 505(b)(2) application may be submitted for a new chemical entity (NCE), when some part of the data necessary for approval is derived from studies not conducted by or for the applicant and when the applicant has not obtained a right of reference. Such data are typically derived from published studies, rather than FDA's previous findings of safety and effectiveness of a previously approved drug. For changes to a previously approved drug however, an applicant may rely on the FDA's finding of safety and effectiveness of the approved drug, coupled with information needed to support the change from the approved drug, such as new studies conducted by the applicant or published data. When based on an approved drug, the 505(b)(2) drug may be approved for all of the indications permitted for the approved drug, as well as any other indication supported by additional data.

Section 505(b)(2) applications also may be entitled to marketing exclusivity if supported by appropriate data and information. As discussed in more detail below, three-year new data exclusivity may be granted to the 505(b)(2) application if one or more clinical investigations conducted in support of the application, other than bioavailability/bioequivalence studies, were essential to the approval and conducted or sponsored by the applicant. Five years of marketing exclusivity may be granted if the application is for an NCE, and pediatric exclusivity is likewise available.

## Orange Book Listing and Paragraph IV Certification

For NDA submissions, including 505(b)(2) applications, applicants are required to list with the FDA certain patents with claims that cover the applicant's product. Upon approval, each of the patents listed in the application is published in Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Any applicant who subsequently files an ANDA or a 505(b)(2) application that references a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification.

If an applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the holder of the NDA for the approved drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to

notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months from the date of the lawsuit, the applicant's successful defense of the suit, or expiration of the patent.

#### **Orphan Drugs**

Under the Orphan Drug Act, special incentives exist for sponsors to develop products for rare diseases or conditions, which are defined to include those diseases or conditions that affect fewer than 200,000 people in the United States. Requests for orphan drug designation must be submitted before the submission of an NDA or BLA.

If a product that has an orphan drug designation is the first such product to receive FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity for that use. This means that, subsequent to approval, the FDA may not approve any other applications to market the same drug that designated orphan use, except in limited circumstances, for seven years. The FDA may approve a subsequent application from another person if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. If the FDA approves someone else's application for the same drug that has orphan exclusivity, but for a different use, the competing drug could be prescribed by physicians outside its FDA approval for the orphan use, notwithstanding the existence of orphan exclusivity. A grant of an orphan designation is not a guarantee that a product will be approved. If a sponsor receives orphan drug exclusivity upon approval, there can be no assurance that the exclusivity will prevent another person from receiving approval for the same or a similar drug for the same or other uses.

## U.S. Marketing Exclusivity and Patent Term Extensions

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension ("PTE") under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a PTE of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, PTE cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The PTE period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension. In the future, we intend to apply for PTE for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical

studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described below, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the U.S. which, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the active moiety and patent terms. This six month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA issued "Written Request" for such a trial, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

### **Pediatric Information**

Under the Pediatric Research Equity Act ("PREA"), NDAs and BLAs or supplements to NDAs and BLAs must contain data to assess the safety and effectiveness of the treatment for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the treatment is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any product for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act provides BLA holders a six-month extension of any exclusivity-patent or non-patent-for a product if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within a specific time frame.

### **DEA Regulation**

The Controlled Substances Act (CSA) imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls, prescription and order form requirements and restrictions on prescription refills for certain kinds of pharmaceutical products. A principal factor for determining the particular requirements of the CSA applicable to a product, if any, is its actual or potential abuse profile, which is classified into a DEA schedule. A product may be listed as a Schedule I, II, III, IV or V controlled substance, with Schedule I presenting the highest perceived risk of abuse and Schedule V presenting the least.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance and registration is specific to the particular location, activity and controlled substance schedule.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II controlled substances and less stringent requirements for Schedules III, IV, and V. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings.

In addition to federal scheduling, some drugs may be subject to state-controlled substance regulation and thus more extensive requirements than those determined by the DEA and FDA.

#### Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice, the DEA and individual United States Attorney offices within the Department of Justice, and state and local governments.

We will also be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either (1) the referral of an individual to a person for furnishing any item or service for which payment is available under a federal health care program, or (2) the purchase, lease, order or recommendation thereof of any good, facility, service or item for which payment is available under a federal health care program;
- The False Claims Act and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly
  presenting, or causing to be presented, false or fraudulent claims for payment from the federal government or making or using, or
  causing to be made or used, a false record or statement material to a false or fraudulent claim;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program, obtaining money or property of the health care benefit program through false representations or knowingly and willingly falsifying, concealing or covering up a material fact, making false statements or using or making any false or fraudulent document in connection with the delivery of, or payment for, health care benefits or services:
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its
  implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually
  identifiable health information:
- The provision under the Affordable Care Act ("ACA") commonly referred to as the Sunshine Act, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and group purchasing organizations; applicable manufacturers are also required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and
- State law equivalents of each of the above federal laws, such as the Anti-Kickback Statute and False Claims Act, and state laws
  concerning security and privacy of health care information, which may differ in substance and application from state-to-state
  thereby complicating compliance efforts.

The ACA broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. Section 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute.

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

## Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and markets in other countries, sales of any products for which we receive regulatory approval 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 any products for which we obtain regulatory approval to enable us to realize an appropriate return on our investment in research and product development. We are unable to predict the future course of federal or state healthcare legislation and regulations, including the ACA. The ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the payments received for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare programs result in a similar reduction in payments from private payors. We are unable to predict what these changes may look like in the future.

## International Regulation

In addition to regulations in the United States, there are a variety of foreign regulations governing clinical trials, pricing and reimbursement, and commercial sales and distribution of any product candidates. Importantly, the level of evidence of efficacy and safety necessary to apply for marketing authorization for a drug candidate differs from country to country, the approval process also varies from country to country, and the time may be longer or shorter than that required for FDA approval. Typically, if a foreign regulatory authority is satisfied that a company has presented adequate evidence of safety, quality and efficacy, then the regulatory authority will grant a marketing authorization. This foreign regulatory approval process, however, involves risks similar or identical to the risks associated with FDA approval discussed above, and therefore there are no guarantees that any company will be able to obtain the appropriate marketing authorization for any product in any particular country.

### **Employees and Human Capital Management**

As of December 31, 2024, we had 101 full-time employees at Fortress and our subsidiaries and partner companies. None of our employees is represented by a labor union. We have retained a number of expert advisors and consultants who help navigate us through different aspects of our business. We consider our relations with our employees to be good and have not experienced any work stoppages, slowdowns or other serious labor problems that have materially impeded our business operations.

Our human capital management objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our new and existing employees. The principal purpose of our equity incentive plan is to attract, retain, and motivate selected employees, consultants, and directors through the granting of share-based compensation awards and cash-based bonus awards.

## **Available Information**

We and certain of our affiliates file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy and information statements and amendments to reports filed or furnished pursuant to Sections 13(a), 14 and 15(d) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"). The SEC also maintains a website at <a href="http://www.sec.gov">http://www.sec.gov</a> that contains reports, proxy and information statements and other information regarding our Company and other companies that file materials with the SEC electronically. Copies of our and certain of our affiliates' reports on Form 10-K, Forms 10-Q and Forms 8-K may also be obtained, free of charge, electronically through our website at www.fortressbiotech.com. Our website also includes announcements of investor conferences and events, information on our business strategies and results, corporate governance information, and other news and announcements that investors might find useful or interesting. The information contained on our website is not included in, or incorporated by reference into, this Annual Report on Form 10-K.

#### 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 Annual Report on Form 10-K including the consolidated financial statements and the related notes, as well as the risks, uncertainties and other information set forth in the reports and other materials filed or furnished by our 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 inlicensing 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 December 31, 2024, the total amount of debt outstanding, net of the debt discount, was \$58.0 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 \$110.4 million and \$142.3 million for the years ended December 31, 2024 and 2023, respectively. At December 31, 2024, we had an accumulated deficit of approximately \$740.9 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 years ended December 31, 2024 and 2023, 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 Annual Report on Form 10-K. 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. Excelderm 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. There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act.

Changes to and under the Affordable Care Act remain possible but it is unknown what form any such changes or any law proposed to replace or revise the Affordable Care Act would take, and how or whether it may affect our business in the future. 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, could have a material adverse effect on the healthcare industry. We also expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, 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. 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, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

We cannot be sure 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 on our products or any future product candidates may be. In addition, increased Congressional scrutiny of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. We do not know what actions will be taken by the new presidential administration. Such actions may impact the development and commercialization of drug products and could materially harm our business and financial condition.

# 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 thirdparty 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 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

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

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 ("Al") 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 1B. Unresolved Staff Comments

None.

#### Item 1C. Cybersecurity

# Cybersecurity Risk Management and Strategy

We have established certain processes for identifying, evaluating, and managing material risks from cybersecurity threats as a part of our overall technology management strategy. These processes are designed and reassessed on a periodic basis to help protect our technology assets and operations from internal and external security threats. We also engage with third parties, including consultants, to enhance our security processes.

We have previously engaged and currently engage third parties to assess the effectiveness of our cybersecurity and technology management strategy and continue to seek to implement new, and improve existing, processes regularly to adjust for changes in technology, internal or external threats, business strategy, and regulatory requirements. We, and our third parties, have deployed managed detection and response services to monitor our technology infrastructure and information systems for possible threats. Our technology management strategy also includes ongoing security training and education for employees regarding threats, including their role and responsibility in detecting and responding to such threats.

We review the processes of our third party vendors and consider their ability to adhere to relevant industry practices and maintain adequate technology risk programs. In addition, we maintain cyber and cyber-related crime insurance coverage policies as part of our overall risk management strategy, however, our policies may not be sufficient to cover against all potential future claims, if any.

In the last two fiscal years, we have not identified cybersecurity threats that have materially affected, or are reasonably likely to materially affect, our business, results of operations, or financial condition. Although we proactively attempt to prevent all threats, we are unable to eliminate all risk from cybersecurity threats or provide assurance that we have not experienced an undetected cybersecurity incident. For more information about these risks, please see Item 1A. Risk Factors "Our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or third parties' cybersecurity".

# Cybersecurity Governance

While our board of directors is responsible for oversight and risk management in general, our Audit Committee provides oversight of our technology management strategy to ensure that cybersecurity threats and risks are identified, evaluated, and managed. The Audit Committee receives periodic updates from our management team regarding the overall state of our technology management strategy and any relevant risks from cybersecurity threats and cybersecurity incidents.

Our management team is responsible for assessing and managing the material risks from cybersecurity threats and our Chief Financial Officer leads these efforts on behalf of the management team. Our management team members have expertise in information systems, compliance and corporate governance, which we believe are disciplines that are effective in the management of the Company's cybersecurity risk. Our Chief Financial Officer is well-informed on emerging cybersecurity risks and solutions used to mitigate and remediate loss due to cybersecurity incidents and is responsible for our internal cybersecurity programs and oversight of third-party cybersecurity vendors who monitor and execute on the prevention, detection, and mitigation of cybersecurity threats and incidents.

# Item 2. Properties

We, and our subsidiaries and partner companies, primarily lease office space and other facilities as set forth in the table below. The only office space owned by us is our office space in Bay Harbor Islands, FL. We believe that our existing facilities are adequate to support our current requirements and that we will be able to obtain suitable additional facilities on commercially reasonable terms if needed.

Company	Location	Туре	Square Footage
Fortress	Bay Harbor Islands, FL	Office space	1,600
Fortress	New York, NY	Office space	23,000
Fortress	Waltham, MA	Office space	6,100
Journey	Scottsdale, AZ	Office space	3,801
Mustang	Worcester, MA <sup>1</sup>	Manufacturing, lab facility, and office space	27,043
Mustang	Worcester, MA <sup>2</sup>	Office space	11,916

Note 1: Mustang exited the lease of its manufacturing facility in Worcester, Massachusetts in February 2025.

Note 2: Mustang exited the sublease of its additional office space in Worcester, Massachusetts in June 2024.

# Item 3. Legal Proceedings

To our knowledge, there are no material legal proceedings pending against us, other than routine actions and administrative proceedings, and other actions we have deemed not material and not expected to have, individual or in the aggregate, 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, negligence and other matters, and seeking resulting alleged damages.

## Item 4. Mine Safety Disclosures

Not applicable.

## PART II

# Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

# **Market Information for Common Stock**

Our Common Stock is listed for trading on the Nasdaq Capital Market under the symbol "FBIO."

# Market Information for 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock

Our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock is listed for trading on the Nasdaq Capital Market under the symbol "FBIOP."

# **Holders of Record**

As of March 27, 2025, there were approximately 394 holders of record of our Common Stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose

shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

# Dividends

We have never paid cash dividends on our Common Stock and currently intend to retain our future earnings, if any, to fund the development and growth of our business. Dividends on Series A Preferred Stock accrue daily and are cumulative from, and including, the date of original issue and are payable monthly at the rate of 9.375% per annum of its liquidation preference, which is equivalent to \$2.34375 per annum per share. In July 2024, the Fortress Board of Directors paused the payment of dividends on the 9.375% Series A Preferred Stock until further notice.

Unregistered	Sales of	Equity	Securities
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None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 6. Reserved

Reserved.

# Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Statements in the following discussion and throughout this report that are not historical in nature are "forward-looking statements." You can identify forward-looking statements by the use of words such as "expect," "anticipate," "estimate," "may," "will," "should," "intend," "believe," and similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described under Item 1A "Risk Factors." We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. Please see the section of this report titled "Cautionary Note Regarding Forward-Looking Statements" at the beginning of this Form 10-K. As used 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.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes thereto and other financial information appearing elsewhere in this Form 10-K. We undertake no obligation to update any forward-looking statements in the discussion of our financial condition and results of operations to reflect events or circumstances after the date of this report or to reflect actual outcomes.

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 our extensive network of key opinion leaders to identify and evaluate promising products and product candidates for potential acquisition. We have executed arrangements 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 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 AstraZeneca plc as successor-in-interest to Alexion Pharmaceuticals, Inc. ("AstraZeneca") and Sentynl Therapeutics, Inc. ("Sentynl") a wholly owned subsidiary of Zydus Lifesciences Ltd.

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").

#### Recent Events

# Revenue Portfolio

- For the years ended December 31, 2024 and 2023, total net revenue was \$57.7 million and \$84.5 million, respectively, which
  includes net product revenue from Journey's commercial portfolio of \$55.1 million and \$59.7 million, respectively. Total net
  revenue in 2023 included the receipt by Journey of a \$19.0 million upfront payment for the exclusive license of certain rights
  relating to Obrexza in Asia.
- In the fourth quarter of 2024, we announced the respective FDA approvals of Emrosi<sup>TM</sup> (Minocycline Hydrochloride Extended-Release Capsules, 40mg), by Journey; and UNLOXCYT<sup>TM</sup> (cosibelimab-ipdl), for the treatment of adults in metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") in adults who are not candidates for curative surgery or radiation, by Checkpoint.

# Late Stage Product Candidates

# UNLOXCYT<sup>TM</sup> (cosibelimab-ipdl, anti-PD-L1 antibody)

- On December 13, 2024, our partner company, 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.
- In September 2024, Checkpoint presented longer-term data from our pivotal trial of cosibelimab during the European Society for Medical Oncology ("ESMO") Congress 2024. Longer-term results for cosibelimab presented at the ESMO Congress demonstrate a deepening of response over time, with higher objective response and complete response rates than initially observed at the primary analyses.
- In July 2024, Checkpoint announced a collaboration to explore the combined therapeutic potential of cosibelimab with GC Cell's Immuncell-LC, an innovative autologous Cytokine Induced Killer ("CIK") T cell therapy composed of cytotoxic T lymphocytes and natural killer T cells.
- UNLOXCYT was sourced by Fortress and developed at Checkpoint.

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

- In November 2024, Journey announced that the FDA approved Emrosi<sup>TM</sup> (Minocycline Hydrochloride Extended-Release Capsules, 40mg) for the treatment of inflammatory lesions of rosacea in adults. Journey announced the launch of Emrosi in March 2025.
- The approval of Emrosi is supported by positive data from Journey's two Phase 3 clinical trials for the treatment of rosacea. The Phase 3 clinical trials met all co-primary and secondary endpoints, and subjects completed the 16-week treatment with no significant safety issues. Emrosi demonstrated statistically significant superiority over both the current standard-of-care treatment, Oracea® 40mg capsules, and placebo for Investigator's Global Assessment treatment success as well as the reduction in total inflammatory lesion count in both studies. Results from Journey's two Phase 3 clinical trials for Emrosi were published in JAMA Dermatology in March 2025.
- In October 2024, data assessing the dermal and systemic pharmacokinetics ("PK") of oral DFD-29 (versus oral doxycycline 40 mg capsules (Oracea) in healthy subjects were presented at the 44th Fall Clinical Dermatology Conference. DFD-29 40mg showed higher dermal concentration than doxycycline from Day 1 onward at a similar dose, which may translate into a clinically meaningful impact for treating patients with rosacea.
- Emrosi (DFD-29) was developed for the treatment of rosacea at our partner company, Journey, in collaboration with Dr. Reddy's Laboratories Ltd.

#### CUTX-101 (copper histidinate injection 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.

## CAEL-101 (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 studies of CAEL-101 for Mayo Stage IIIa and Mayo Stage IIIb AL amyloidosis. (ClinicalTrials.gov identifiers: NCT04512235 and NCT04504825). (Information on clinicaltrials.gov does not constitute part of this Annual Report on Form 10-K.).
- 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.

# Triplex (cytomegalovirus (CMV) vaccine)

- Triplex, a potential vaccine for 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).
- In May 2024, we announced that the first patient was dosed in a multi-center, placebo-controlled, randomized Phase 2 study of
  Triplex in patients undergoing liver transplantation. The trial is funded by a grant from the National Institutes of Health's National
  Institute of Allergy and Infectious Diseases ("NIH/NIAID") that could provide over \$20 million in non-dilutive funding and will
  be conducted in up to 20 nationally recognized transplant centers in the United States (NCT06075745).
- 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).

- In 2023, Helocyte additionally entered into an option agreement with City of Hope for exclusive worldwide rights to a novel bispecific CMV/HIV CAR T cell therapy (optionally for use in combination with Triplex), which is currently the subject of a Phase 1 trial in adults living with HIV-1 (see NCT06252402).
- Triplex was sourced by Fortress and is currently in development at our subsidiary, Helocyte.

### **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 being acquired by Crystalys in July 2024

### MB-109 (IL13Ra2-targeted CAR T Cells (MB-101) + HSV-1 oncolytic virus (MB-108))

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

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

- In March 2024, Mustang announced an expansion into 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.
- 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.

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

- In May 2024, we announced that the last patient completed dosing in a Phase 1b/2a study, which is evaluating AJ201 in the U.S. for the treatment of spinal and bulbar muscular atrophy, also known as Kennedy's Disease. Kennedy's Disease is a debilitating rare genetic neuromuscular disease primarily affecting men.
- AJ201 was sourced by Fortress and is currently in development at our partner company, Avenue.
- On March 3, 2025, Avenue received a "notice of intent to terminate" letter from AnnJi Pharmaceutical Co. Ltd., the licensor of
  AJ201, with respect to the license agreement under which Avenue was granted rights to the product candidate; Avenue believes
  that the grounds for termination stated in the purported termination notice are without merit and intends to avail itself of the
  dispute resolution procedures set forth in the AJ201 license agreement.

### General Corporate and Other - Fortress

- In March 2025, Fortress and Checkpoint announced the entry into agreement for Checkpoint 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 for Checkpoint's UNLOXCYT product candidate. Fortress also entered into a royalty agreement with Checkpoint and Sun Pharma pursuant to which Fortress is eligible to receive a royalty of 2.5% on worldwide net sales of UNLOXCYT.
- In July 2024, Fortress' Board of Directors paused the payment of dividends on the Company's 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (the "Series A Preferred Stock") until further notice. 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.
- In July 2024, Fortress announced the reduction of total debt outstanding and the entry into a new \$50 million term loan with Oaktree Capital Management with a maturity in 2027. The Company borrowed \$35.0 million under the agreement on the closing date and is able to draw up to an additional \$15.0 million at the lenders' discretion to support future business development activities. In connection with the new term loan, Fortress repaid the prior \$50 million term loan with Oaktree.
- Throughout 2024, Fortress raised total net proceeds of approximately \$21.1 million through equity offerings.

### General Corporate and Other - Public Subsidiaries

- In March 2025, Checkpoint announced that it had 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 at a meeting of Checkpoint's stockholders. We expect the transaction to close in the second quarter of 2025, although there can be no assurance that the transaction closes in a timely manner, or at all. Additionally, due to uncertainties as to the timing of the completion of the acquisition, 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, Fortress may not realize the anticipated benefits of the proposed transaction in the time frame expected, or at all.
- 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.
- In July 2024, Journey entered into an amendment of its existing credit facility with SWK, increasing the amount of the facility from \$20 million to \$25 million.
- In April 2024, Avenue effected a 1-for-75 reverse stock split to achieve compliance with the minimum bid price listing requirement of the Nasdaq Capital Market.

- In April 2024, Mustang's board of directors approved a reduction in its workforce of approximately 81% of its employee base in
  order to reduce costs and preserve capital; the reduction occurred primarily in April 2024 and was substantially complete in the
  second quarter of 2024.
- Throughout 2024, Checkpoint raised total net proceeds of approximately \$32.8 million through equity offerings and the exercise of existing warrants. Subsequently, Checkpoint raised \$36.0 million through the exercise of warrants in March 2025.
- Throughout 2024, Mustang raised total net proceeds of approximately \$11.2 million through equity offerings and the exercise of existing warrants. Subsequently, Mustang raised net proceeds of \$6.9 million in a public offering in February 2025.
- Throughout 2024, Avenue raised total net proceeds of approximately \$9.8 million through equity offerings and the exercise of
  existing warrants.
- Throughout 2024, Journey Medical raised total net proceeds of approximately \$7.9 million through equity offerings.

### **Critical Accounting Policies and Use of Estimates**

Our consolidated financial statements included in this Annual Report on Form 10-K include certain amounts that are based on management's best estimates and judgments. Our 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. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

While our significant accounting policies are described in the Notes to our Consolidated Financial Statements included in "Part II, Item 8, Financial Statements and Supplementary Data" in this Annual Report on Form 10-K, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

### **Revenue Recognition**

Our gross product revenues are subject to a variety of deductions, which generally are estimated and recorded in the same period that the revenues are recognized. Such variable consideration represents chargebacks, coupons, discounts, other sales allowances and sales returns. These deductions represent estimates of the related obligations and, as such, knowledge and judgment are required when estimating the impact of these revenue deductions on gross sales for a reporting period. Historically, adjustments to these estimates to reflect actual results or updated expectations have not been material to our overall business. Coupons, however, can have a significant impact on year-over-year individual product revenue growth trends. If any of our ratios, factors, assessments, experiences, or judgments are not indicative or accurate estimates of our future experience, our results could be materially affected. The potential of our estimates to vary differs by program, product, type of customer and geographic location.

### Fair Value Measurement

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

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

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

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

Certain of the Company's working capital assets and liabilities, including cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and other current liabilities, are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to their liquid or short-term nature. The carrying value of our 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.

### **Issuance of Debt and Equity**

Fortress and its partner companies and subsidiaries issue complex financial instruments which include equity and/or debt features. We analyze each instrument under ASC 480, *Distinguishing Liabilities from Equity*, ASC 815, *Derivatives and Hedging* and, ASC 470, *Debt*, in order to establish whether such instruments include any embedded derivatives.

We accounted for the debt with Oaktree with detachable warrants in accordance with ASC 470, *Debt*. We assessed the classification of the common stock purchase warrants issued in connection with such transactions and determined that such instruments met the criteria for equity classification. The note proceeds were allocated between the 2024 Oaktree Note (as defined below) and the warrants on a relative fair value basis.

We recorded the related issue costs and value ascribed to the warrants as a debt discount of the 2024 Oaktree Note (as defined below). The discount is being amortized utilizing the effective interest method over the term of the Oaktree Note, which is approximately 15.39% at December 31, 2024.

# Accrued Research and Development Expense

We record accruals for estimated costs of research, preclinical, clinical and manufacturing development within accrued expenses which are significant components of research and development expenses. A substantial portion of our ongoing research and development activities is conducted by third-party service providers. We accrue the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion or actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses until the services are rendered.

If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust accrued expenses or prepaid expenses accordingly, which impact research and development expenses. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

### **Recent Accounting Pronouncements**

See Note 2, Summary of Significant Accounting Policies, in the Notes to the Consolidated Financial Statements included in "Part II, Item 8, Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

## **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 (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K, have reduced disclosure obligations regarding executive compensation, and smaller reporting companies are permitted to delay adoption of certain recent accounting pronouncements discussed in Note 2 to our Consolidated Financial Statements located in "Part II, Item 8, Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

## **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 basic ownership of the issued and outstanding common and preferred shares in consolidated Fortress subsidiaries:

	December 31,
Partner Company/Subsidiary	2024
Avenue (OTC: ATXI)	9.2 %
Cellvation	79.6 %
Checkpoint (Nasdaq: CKPT)	8.3 %
Cyprium	73.1 %
Helocyte	83.0 %
Journey (Nasdaq: DERM)	44.5 %
Mustang (Nasdaq: MBIO)	6.3 %
Oncogenuity	73.5 %
Urica	69.6 %

# **Results of Operations**

# Comparison of Years Ended December 31, 2024 and 2023

	Year Ende		Change			
(\$ in thousands)	2024	2023		%		
Revenue						
Product revenue, net	\$ 55,134			(8)%		
Collaboration revenue	1,500	,	( ) /	(71)%		
Revenue – related party	41		03 (62)	(60)%		
Other revenue	1,000			(95)%		
Net revenue	57,675	84,5	(26,838)	(32)%		
Operating expenses						
Cost of goods - (excluding amortization of acquired intangible assets)	20,879	22,89	93 (2,014)	(9)%		
Amortization of acquired intangible assets	3,424	,		(9)%		
Research and development	56,629	101,74	47 (45,118)	(44)%		
Research and development – licenses acquired	252	2 4,32	24 (4,072)	(94)%		
Selling, general and administrative	87,731	90,98	31 (3,250)	(4)%		
Loss recovery	(4,553	3) -	- (4,553)	100 %		
Asset impairment	3,692	2 3,14	13 549	17 %		
Total operating expenses	168,054	226,85	55 (58,801)	(26)%		
Loss from operations	(110,379	(142,34	12) 31,963	(22)%		
Other income (expense)						
Interest income	2,683	3,00	03 (320)	(11)%		
Interest expense and financing fee	(13,527	(15,31)	15) 1,788	(12)%		
Gain (loss) on common stock warrant liabilities	(638	3) 4,42	24 (5,062)	(114)%		
Other income (expense)	1,318	3,40	)3) 4,721	(139)%		
Total other expense	(10,164	(11,29	91) 1,127	(10)%		
Loss before income tax expense	(120,543	(153,63	33,090	(22)%		
Income tax expense	312	2 52	21 (209)	(40)%		
Net loss	(120,855		()	(22)%		
Ivet 1055	(120,03	(134,1	33,299	(22) 70		
Less: net loss attributable to non-controlling interest	74,858	93,51	17 (18,659)	(20)%		
Net loss attributable to Fortress	\$ (45,997	\$ (60,63	<u>\$ 14,640</u>	(24)%		

# Revenue

	Year Ended l	Decemb	er 31,		Change				
(\$ in thousands)	2024 2023				\$	%			
Revenue									
Product revenue, net	\$ 55,134	\$	59,662	\$	(4,528)	(8)%			
Collaboration revenue	1,500		5,229		(3,729)	(71)%			
Revenue – related party	41		103		(62)	(60)%			
Other revenue	1,000		19,519		(18,519)	(95)%			
Net revenue	\$ 57,675		84,513	\$	(26,838)	(32)%			

For the year ended December 31, 2024 we generated \$57.7 million of net revenue, of which \$55.1 million relates to product revenue derived from Journey's branded and generic products, \$1.5 million relates to collaboration revenue from Sentynl for the NDA submission acceptance milestone relating to CUTX-101, and \$1.0 million in other revenue relates to a milestone payment from Cutia related to the approval of Amzeeq in China. For the year ended December 31, 2023, we generated \$84.5 million of net revenue, of which \$59.7 million relates to product revenue derived from Journey's branded and generic products, \$19.5 million relates to Journey's royalties from Maruho, \$5.2 million relates to Cyprium's collaboration revenue with Sentynl and \$0.1 million relates to Checkpoint's prior collaboration agreements with TGTX.

For the year ended December 31, 2024, net product revenues decreased by \$4.5 million, or 8%, to \$55.1 million for the year ended December 31, 2024, from \$59.7 million for the year ended December 31, 2023. The decrease is primarily due to overall higher managed care rebate costs across Journey's product portfolio and lower unit volumes, mainly from Journey's legacy products, Targadox, Ximino and Exelderm, driven specifically by continued generic competition for Targadox. In addition, Amzeeq net product revenues decreased by approximately \$1.2 million, due to both higher managed care rebates and decreased unit sales volumes from 2023. Increases in unit sales volumes for Qbrexza, Accutane and Zilxi were offset by higher rebate costs compared to 2023.

### Cost of goods sold

		Year Ended	Decemb	Change			
(\$ in thousands)		2024		2023	\$	%	
Cost of goods sold – (excluding amortization of acquired							
intangible assets)	\$	20,879	\$	22,893	\$ (2,014)	(9)%	

We had \$20.9 million and \$22.9 million of costs of goods sold in connection with JMC branded and generic product revenue for the years ended December 31, 2024 and 2023, respectively. Cost of goods sold decreased by \$2.0 million, or 9% year-over-year, with the decrease mainly due to lower royalties on lower net sales, and a permanent contractual decrease in royalties owed on Qbrexza from the prior-year period. These decreases were offset, in part, by an increase in product-related cost of goods sold of \$0.5 million as a result of product mix, mainly driven by the higher Accutane net product revenue from 2023.

	 Year Ended l	Decemb	er 31,	 Change			
	Decem	ber 31,		 Chang	e		
(\$ in thousands)	2024		2023	\$	%		
Amortization of acquired intangible assets	\$ 3,424	\$	3,767	\$ (343)	(9)%		

Amortization of acquired intangible assets decreased by \$0.3 million, or 9%, to \$3.4 million for the year ended December 31, 2024, from \$3.8 million for the year ended December 31, 2023 due to the discontinuation of Ximino in the third quarter of 2023.

# 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 licenses and milestones, costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, laboratory costs and other supplies.

For the years ended December 31, 2024 and 2023, R&D expenses were approximately \$56.6 million and \$101.7 million, respectively. The table below provides a summary of research and development by entity, for the years ended December 31, 2024 and 2023:

	Year E Decemb		Change			
(\$ in thousands)	2024		2023	\$	%	
Research & development						
Fortress <sup>1</sup>	\$ (4,443)	\$	3,996	\$ (8,439)	(211)%	
Avenue	6,645		6,131	514	8 %	
Checkpoint	36,152		43,566	(7,414)	(17)%	
JMC	9,857		7,541	2,316	31 %	
Mustang	8,418		40,513	(32,095)	(79)%	
Total research & development expense	\$ 56,629	\$	101,747	\$ (45,118)	(44)%	

Note 1: Includes Fortress and private subsidiaries primarily funded by Fortress: Aevitas (until April 2023), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

The decrease in R&D spending at Mustang of \$33.0 million is primarily attributed to decreased expenses of \$13.9 million for personnel related costs, primarily driven by the reduction in Mustang's workforce, a decrease of \$8.2 million in laboratory supply costs, including vector manufacturing costs due to the termination of the MB-106 clinical trial, a \$6.1 million decrease in program-related expenses due primarily to terminated licenses and the closing the MB-106 clinical trial, a decrease of \$2.9 million in consulting expenses, and a decrease of \$1.8 million in other expenses, including depreciation and rent expense. Checkpoint's reduced R&D expense of \$4.0 million is due to the costs associated with the BLA submission in 2023, including the \$3.2 million PDUFA fee and a milestone payment of \$2.3 million due as a result of the BLA filing, and an \$8.2 million reduction in costs related to commercial manufacturing costs and inventory build, which were expensed prior to approval, to support the potential launch of cosibelimab-ipdl. R&D at Fortress has decreased due to cost reductions at both Cyprium (CUTX-101 development program) and Urica (dotinurad clinical program) as those programs were transitioned to Sentynl and Crystalys, respectively. R&D at Fortress is inclusive of annual PIK dividend income received from the subsidiaries (see Note 16, Related Party Transactions, in the Notes to the Consolidated Financial Statements included in "Part II, Item 8, Financial Statements and Supplementary Data" in this Annual Report on Form 10-K). Journey's increased R&D costs are due to the Emrosi FDA fee of \$4.1 million paid in January 2024 (FDA approval was received in November 2024), and the \$3 million milestone paid to Dr. Reddy's Laboratories, Ltd triggered by the FDA's acceptance of the Emrosi NDA in March 2024, offset by lower clinical trial expenses to develop Emrosi, as the clinical phase of the project has concluded.

Noncash, stock-based compensation expense included in R&D for the years ended December 31, 2024 and 2023, was \$7.1 million and \$3.2 million, respectively.

		Year Ended	Change				
(\$ in thousands)	2024		2023			\$	%
Stock-based compensation - research & development							
Fortress <sup>1</sup>	\$	1,746	\$	1,624	\$	122	7 %
Avenue		269		199		70	35 %
Checkpoint		5,248		1,169		4,079	349 %
JMC		508		112		396	353 %
Mustang		(650)		133		(783)	(589)%
Total stock-based compensation expense - research and development	\$	7,121	\$	3,237	\$	3,884	120 %

Note 1: Includes Fortress and private subsidiaries primarily funded by Fortress: Aevitas (until April 2023), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

The increase in stock-based compensation expense included in R&D for the year ended December 31, 2024 is primarily attributable to performance-based vesting of grants at Checkpoint, triggered by the FDA approval of UNLOXCYT in December 2024.

We expect research and development costs to decrease in 2025.

Research and development - licenses acquired

		Year Ended I	)ecemt	oer 31,	Change			
	(\$ in thousands)	2024		2023	\$	%		
	Research and development – licenses acquired	\$ 252	\$	4,324	\$ (4,072)	(94)%		

The decrease in research and development – licenses acquired of \$4.1 million in 2024 is due primarily to \$4.2 million paid by Avenue to AnnJi for the AJ201 license in 2023. There were no comparable transactions in the year ended December 31, 2024.

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 research and development expenses. For the years ended December 31, 2024 and 2023, selling, general and administrative expenses were \$87.7 million and \$91.0 million, respectively. The table below provides a summary by entity of selling, general and administrative expenses for the years ended December 31, 2024 and 2023, respectively:

		Year Decem	Ended ber 31	Change			
(\$ in thousands)	_	2024 2023		_	\$	%	
Selling, general & administrative							
Fortress <sup>1</sup>	\$	18,691	\$	25,987	\$	(7,296)	(28)%
Avenue		4,638		4,179		459	11 %
Checkpoint		20,063		8,685		11,378	131 %
JMC		40,204		43,910		(3,706)	(8)%
Mustang		4,135		8,220		(4,085)	(50)%
Total selling, general & administrative expense	\$	87,731	\$	90,981	\$	(3,250)	(4)%

Note 1: Includes Fortress and private subsidiaries primarily funded by Fortress: Aevitas (until April 2023), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

For the year ended December 31, 2024, the decrease in selling, general and administrative expenses of \$3.3 million, or 4%, is primarily attributable to decreased expenses at Fortress relating to general operational cost reductions and lower legal expenses incurred by private subsidiaries. The decrease at Mustang is attributable to cost reduction efforts and optimization relating to personnel, consulting, and infrastructure, as well as the \$1.5 million gain on sale of property and equipment recognized in 2023, and the decrease at Journey is related to continued expense management efforts resulting in cost savings of \$8.7 million, offset by an increase of \$3.1 million in non-cash share-based compensation due to new grants, a \$1.7 million increase attributed to the commencement of launch efforts for Emrosi, and the expansion of access and coverage platforms. These decreases were partially offset by an increase in general and administrative expenses at Checkpoint, primarily driven by the increase in stock-based compensation due to performance-based vesting.

Stock-based compensation expense included in selling, general and administrative expenses in the years ended December 31, 2024 and 2023 was \$25.5 million and \$13.8 million, respectively.

		ear Ended	Decen	ıber 31,		ige	
(\$ in thousands)		2024		2023		\$	%
Stock-based compensation - Selling, general and administrative							
Fortress <sup>1</sup>	\$	8,737	\$	8,428	\$	309	4 %
Avenue		967		707		260	37 %
Checkpoint		10,004		1,728		8,276	479 %
JMC		5,590		2,494		3,096	124 %
Mustang		200		435		(235)	(54)%
Total stock-based compensation expense - selling, general and administrative	\$	25,498		13,792	\$	11,706	85 %

Note 1: Includes Fortress and private subsidiaries primarily funded by Fortress: Aevitas (until April 2023), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

The increase in stock-based compensation expense included in selling, general and administrative expense for the year ended December 31, 2024 is primarily attributable to performance-based vesting of grants at Checkpoint, triggered by the FDA approval of UNLOXCYT received in December 2024, and additional expense incurred at Journey related to new employee grants.

We expect selling, general and administrative expenses to remain flat or decrease in 2025.

# Loss Recovery

Journey recorded a loss recovery benefit to income of \$4.6 million in connection with the recovery of funds related to a previously disclosed cybersecurity incident in September 2021. Journey received the \$4.6 million in cash in December 2024.

### Asset Impairment

	Year Ended	Decemb	Change			
(\$ in thousands)	 2024		2023	\$	%	
Asset impairment	\$ 3,692	\$	3,143	\$ 549	17 %	

For the year ended December 31, 2024, Mustang recorded an asset impairment of \$3.7 million, comprised of \$2.2 million impairment loss allocated to leasehold improvements, \$0.4 million impairment related to right-of-use asset, and \$1.0 million related to equipment based on an expected transaction. For the year ended December 31, 2023, Journey recorded a charge of \$3.1 million related to its write-off of Ximino, triggered by the decision to discontinue marketing of the product.

# Other expense

	Year Ended I	Change				
(\$ in thousands)	2024 2023			\$	%	
Other expense						
Interest income	\$ 2,683	\$	3,003	\$ (320)	(11)%	
Interest expense and financing fee	(13,527)		(15,315)	1,788	(12)%	
Gain (loss) on common stock warrant liabilities	(638)		4,424	(5,062)	(114)%	
Other income (expense)	1,318		(3,403)	4,721	(139)%	
Total other expense	\$ (10,164)		(11,291)	\$ 1,127	(10)%	

Total other expense decreased \$1.1 million, or 10%, from expense of \$11.3 million for the year ended December 31, 2023 to expense of \$10.2 million for the year ended December 31, 2024, primarily due to the increase in expense related to the change in fair value of warrant liabilities associated with warrants related to financings at Avenue and Checkpoint of \$5.1 million, partially offset by a decrease of \$1.8 million in interest expense and financing fees due to costs associated with debt payoff at Journey and Mustang incurred in 2023 related to East West Bank and Runway debt, respectively, and a decrease of \$4.7 million in other expense in the year ended December 31, 2024 due primarily to \$4.1 million expense associated with the deconsolidation and dissolution of partner companies incurred in 2023, as compared to \$1.1 million gain on extinguishment of debt recognized at Journey in the year ended December 31, 2024.

### Liquidity and Capital Resources

## Sources of Liquidity

At December 31, 2024, we had an accumulated deficit of \$740.9 million primarily as a result of research and development 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. At December 31, 2024, we had cash and cash equivalents of \$57.3 million of which \$20.9 million relates to Fortress and the private subsidiaries (primarily funded by Fortress), \$6.6 million relates to Checkpoint, \$6.8 million relates to Mustang, \$20.3 million relates to JMC and \$2.6 million relates to Avenue. Restricted cash primarily relates to office leases and totals \$1.6 million.

We will require additional financing to fully develop and prepare regulatory filings and obtain regulatory approvals for our existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for our potential products, and sales and marketing capabilities. We have funded our operations to date primarily through the sale of equity and debt securities. We believe that our current cash and cash equivalents is sufficient to fund operations for at least the next twelve months. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We may seek funds through equity or debt financings, joint venture or similar development collaborations, the sale of partner companies, 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"). For the year ended December 31, 2024, the Company issued and sold approximately 2.0 million shares of common stock at an average price of \$1.98 per share for gross proceeds of \$3.9 million. In connection with these sales, the Company paid aggregate fees of \$0.1 million. As of December 31, 2024, \$43.1 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, our board of directors paused the payment of dividends on our Series A Preferred Stock until further notice. As a result, we are no longer eligible to use Form S-3 and have lost the ability to use the 2024 Shelf.

In September 2024, Fortress closed a registered direct offering of an aggregate of 3,939,394 shares of its common stock at a purchase price of \$1.65 per share. In a concurrent private placement, the Company also agreed to issue to the same investors that participated in the registered direct offering warrants to purchase up to 3,939,394 shares of common stock (the "Private Placement Warrants"). The Private Placement Warrants have an exercise price of \$1.84 per share, are exercisable commencing six months from the date of issuance, and will expire five and one-half years following the date of issuance.

In a separate concurrent private placement, Dr. Rosenwald, our Chairman, President and Chief Executive Officer, purchased 763,359 shares of common stock at a price of \$1.84 per share, which represented the consolidated closing bid price of the Company's common stock on the Nasdaq Capital Market on September 19, 2024, and warrants to purchase up to 763,359 shares of common stock, purchased at a price of \$0.125 per warrant (the "Concurrent Private Placement Warrants"). The Concurrent Private Placement Warrants have an exercise price of \$1.84 per share, are exercisable commencing six months from the date of issuance, and will expire five and one-half years following the date of issue. Net proceeds to Fortress from the September 2024 registered direct offering and the concurrent private placements, after deducting the placement agent's fees and other offering expenses and assuming no exercises of the Private Placement Warrants or the Concurrent Private Placement Warrants, were approximately \$7.3 million. The Company filed a registration statement (No. 333-282384) on Form S-1 to register the resale of the shares of Common Stock issuable upon exercise of the Private Placement Warrants and the Concurrent Private Placement Warrants, which was declared effective by the SEC on October 7, 2024.

In January 2024, Fortress closed a registered direct offering of an aggregate of 3,303,305 shares of its common stock and warrants to purchase up to 3,303,305 shares of its common stock at a combined purchase price of \$3.33 per share of common stock and accompanying warrant priced at-the-market under Nasdaq rules. The warrants have an exercise price of \$3.21 per share, were immediately exercisable, and expire five years following the date of issue. Net proceeds to Fortress, after deducting the placement agent's fees and other offering expenses, were approximately \$10.1 million.

## Journey

In December 2022, Journey filed a shelf registration statement on Form S-3 (File No. 333-269079), which was declared effective in January 2023 (the "Journey 2022 S-3"). This shelf registration statement 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. For the year ended December 31, 2024, Journey issued approximately 1.6 million shares of common stock at an average price of \$5.19 per share for net proceeds of \$7.9 million after deducting aggregate fees of \$0.2 million. At December 31, 2024, 2,586,987 shares remain available for issuance under the Journey 2022 S-3.

## 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 December 31, 2024, approximately \$65.7 million of the securities remain available for sale through the Checkpoint 2023 S-3.

In November 2024, Checkpoint received approximately \$9.2 million upon the exercise of existing Series B warrants to purchase 3,256,269 shares of Checkpoint common stock, which warrants were originally issued and sold in a registered direct offering from May 2023 with an exercise price of \$2.821 per share. The shares of common stock issuable upon the exercise of the warrants were registered under the Checkpoint 2023 S-3.

In July 2024, Checkpoint closed on a registered direct offering (the "Checkpoint July 2024 Registered Direct Offering") for the issuance and sale of an aggregate of 1,230,000 shares of its common stock at a purchase price of \$2.05 per share. In addition, the offering includes 4,623,659 shares of common stock in the form of pre-funded warrants at a price of \$2.0499. In a concurrent private placement, Checkpoint issued and sold common warrants (the "Checkpoint July 2024 Common Stock Warrants") to purchase up to 5,853,659 shares of common stock. The Checkpoint July 2024 Common Stock Warrants have an exercise price of \$2.05 per share, will be exercisable after requisite approval of Checkpoint's stockholders is received, and have a term of exercise of five years from the issuance date. Checkpoint also issued the placement agent warrants to purchase up to 351,220 shares of common stock with an exercise price of \$2.5625 per share. The total net proceeds from the Checkpoint July 2024 Registered Direct Offering, after deducting placement agent's fees and other offering expenses, were approximately \$11.0 million. The shares of common stock and the shares underlying the pre-funded warrants were sold in a registered offering under the Checkpoint 2023 S-3. In August 2024, Checkpoint filed a registration statement on Form S-3 to register the public resale of the shares of Checkpoint common stock issuable upon exercise of each of the Checkpoint July 2024 Common Stock Warrants and the placement agent warrants, which was declared effective August 30, 2024 (File No. 333-281650). All of the pre-funded warrants from the Checkpoint July 2024 Registered Direct Offering have been exercised.

In January 2024, Checkpoint closed on a registered direct offering (the "Checkpoint January 2024 Registered Direct Offering") for the issuance and sale of 1,275,000 shares of its common stock at a purchase price of \$1.805 per share. In addition, the offering includes prefunded warrants to purchase 6,481,233 shares of common stock, which were sold at a price of \$1.8049. In a concurrent private placement, Checkpoint issued and sold common warrants (the "Checkpoint January 2024 Common Warrants") to purchase up to 7,756,233 shares of Checkpoint common stock. The Checkpoint January 2024 Common Warrants are exercisable immediately upon issuance and will expire five years following the issuance date and have an exercise price of \$1.68 per share. Checkpoint also issued the placement agent warrants to purchase up to 465,374 shares of common stock with an exercise price of \$2.2563 per share. Net proceeds to Checkpoint from the Checkpoint January 2024 Registered Direct Offering were \$12.6 million after deducting commissions and other transaction costs. The offer and sale of the shares of common stock and the shares underlying the pre-funded warrants were registered under the Checkpoint 2023 S-3. In March 2024, Checkpoint filed a registration statement on Form S-3 to register the public resale of the shares of Checkpoint common stock issuable upon exercise of each of the Checkpoint January 2024 Common Stock Warrants and the placement agent warrants, which was declared effective April 5, 2024 (File No. 333-278397). All of the pre-funded warrants from the Checkpoint January 2024 Registered Direct Offering have been fully exercised.

#### Mustang

On April 23, 2021, Mustang filed a shelf registration statement on Form S-3 (File No. 333-255476) (the "Mustang 2021 S-3"), which was declared effective on May 24, 2021. Through the Mustang 2021 S-3, Mustang was able to sell up to a total of \$200 million of its securities. In 2024, Mustang sold approximately \$4.4 million of securities under the Mustang 2021 S-3 until Mustang's ability to register new offers and sales of securities under such registration statement expired on May 24, 2024.

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 December 31, 2024, approximately \$34.8 million of the Mustang 2024 S-3 remains available for sales of securities, subject to General Instruction I.B.6. of Form S-3. The ability of Mustang to register new offers and sales of securities under the Mustang 2024 S-3 expires on June 12, 2027.

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 year ended December 31, 2024, Mustang issued approximately 0.1 million shares of common stock at an average price of \$18.78 per share for net proceeds of \$2.5 million under the Mustang ATM, after deducting aggregate fees of approximately \$0.1 million.

In October 2024, Mustang entered into a definitive agreement for the exercise of certain existing warrants to purchase an aggregate of 337,552 shares of its common stock having an exercise price of \$11.85 per share, originally issued in May 2024. The issuance or resale of the shares of common stock issuable upon exercise of the existing warrants are registered pursuant to an effective registration statement filed by Mustang on Form S-1 (File No. 333-278006). The net proceeds to Mustang from the exercise of the existing warrants were approximately \$3.6 million, after deducting placement agent fees and offering expenses payable by Mustang of \$0.4 million.

In consideration for the immediate exercise of the existing warrants for cash, Mustang issued two new series of unregistered warrants to purchase up to an aggregate of 675,104 shares of common stock. The new warrants have an exercise price of \$13.50 per share and became exercisable commencing on the effective date of stockholder approval of the issuance of the shares issuable upon exercise of the new warrants (the "Stockholder Approval"). One of the new series of warrants to purchase 337,552 shares of common stock has a term of five years from the Stockholder Approval, and the other new series of warrants to purchase 337,552 shares of common stock has a term of twelve months from the Stockholder Approval.

In June 2024, Mustang closed on a registered direct offering of 60,500 shares of common stock at \$20.50 per share (or common stock equivalent) priced at-the-market under Nasdaq rules and pre-funded warrants to purchase up to 62,100 shares of common stock, at a price per pre-funded warrant equal to \$20.495, the price per share of common stock, less \$0.005. The pre-funded warrants have an exercise price of \$0.005 per share, became exercisable upon issuance and remain exercisable until exercised in full. In a concurrent private placement, Mustang also agreed to issue and sell unregistered warrants to purchase up to 62,100 shares of its common stock, with an exercise price of \$20.495 per share, exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the warrants and will expire five years from the date of such stockholder approval. Net proceeds were approximately \$2.1 million, after placement agent's fees and other offering expenses. All of the 62,100 pre-funded warrants have since been exercised.

In May 2024, Mustang closed on an equity offering of 23,200 shares of common stock and pre-funded warrants to purchase up to 314,352 shares of common stock (or common stock equivalents in lieu thereof), and three series of 337,552 warrants each for a total of 1,012,656 warrants with a combined equity offering price of \$11.85 per share (or per share common stock equivalent in lieu thereof) and accompanying warrants with an exercise price of \$11.85 per share. The Series A-1 warrants have a five-year term, the Series A-2 warrants have a twenty-four month term, and the Series A-3 warrants have a nine month term. 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 equity offering, after deducting the fees and expenses of the placement agent and other offering expenses payable by Mustang was approximately \$3.2 million. All of the 314,352 pre-funded warrants have since been exercised.

#### 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. As of December 31, 2024, approximately \$3.9 million of the securities were available for sale under the Avenue 2021 S-3, subject to General Instruction I.B.6. of Form S-3.

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 offer and sale of the shares will be made pursuant to a base prospectus forming a part of the Avenue 2021 S-3, and the related prospectus supplement dated May 10, 2024. During the year ended December 31, 2024, Avenue issued 0.6 million shares through the Avenue ATM for net proceeds of \$1.6 million.

On January 5, 2024, Avenue entered into (i) an inducement offer letter agreement (the "January 2023 Investor Inducement Letter") with a certain investor (the "January 2023 Investor") in connection with certain outstanding warrants to purchase up to an aggregate of 25,871 shares of Common Stock, originally issued to the January 2023 Investor on January 31, 2023 (the "January 2023 Warrants") and (ii) an inducement offer letter agreement (the "November 2023 Investor Inducement Letter Agreement" and, together with the January 2023 Investor Inducement Letter, the "January 2024 Warrant Inducement") with certain investors (the "November 2023 Investors" and, together with the January 2023 Investor, the "Holders") in connection with certain outstanding warrants to purchase up to an aggregate of 194,667 shares of Common Stock, originally issued to the November 2023 Investors on November 2, 2023 (the "November 2023 Warrants" and, together with the January 2023 Warrants, the "Existing Warrants"). The January 2023 Warrants had an exercise price of \$116.25 per share, and the November 2023 Warrants had an exercise price of \$22.545 per share.

Pursuant to the January 2024 Warrant Inducement, (i) the January 2023 Investor agreed to exercise its January 2023 Warrants for cash at a reduced exercise price of \$22.545 per share and (ii) the November 2023 Investors agreed to exercise their November 2023 Warrants for cash at the existing exercise price of \$22.545, in each case in consideration for Avenue's agreement to issue in a private placement (x) Series A Warrants to purchase up to 220,538 shares of Avenue Common Stock and (y) Series B Warrants to purchase up to 220,538 shares of Avenue Common Stock. The net proceeds to Avenue from the exercise of the warrants was approximately \$4.5 million, after deducting placement agent fees and estimated offering costs, but without giving effect to the exercise of the Series A Warrants and Series B Warrants issued in the January 2024 Warrant Inducement.

Also in April 2024, Avenue entered into definitive agreements for the immediate exercise of certain of its existing outstanding warrants to purchase an aggregate of 689,680 shares of Avenue's common stock at a reduced exercise price of \$6.20 per share (the "May 2024 Warrant Inducement"). The exercised warrants are comprised of warrants to purchase shares of common stock originally issued by Avenue on October 11, 2022, each having an exercise price of \$116.25 per share, Series A and Series B warrants to purchase shares of common stock originally issued by Avenue on November 2, 2023, each having an exercise price of \$22.545 per share, and warrants to purchase shares of common stock originally issued by Avenue on January 9, 2024, each having an exercise price of \$22.545 per share. Total net proceeds to Avenue were approximately \$3.7 million after deducting placement agent fees and other expenses payable by Avenue.

In consideration for the immediate exercise of the warrants for cash in the May 2024 Warrant Inducement, Avenue issued two new unregistered series of warrants (the "Avenue May 2024 Warrants") to purchase up to a total of 1,379,360 shares of Avenue common stock for a payment of \$0.125 per warrant. The Avenue May 2024 Warrants have an exercise price of \$6.20 per share, and terms of eighteen months for one series and five years for the other series.

Debt

### Oaktree Facility

On July 25, 2024, Fortress entered into a \$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 under which the remaining \$50.0 million balance was repaid in full. 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. 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). The Company is required to make quarterly interest-only payments until the maturity date. 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. The New 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 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, 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 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 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 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 capital raise and minimum stake covenants and financial covenants, including minimum liquidity and minimum net sales, 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, Oaktree 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 the Agent, 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 Agreement.

### **SWK Facility**

On December 27, 2023 (the "SWK Closing Date"), Journey entered into a Credit Agreement with SWK Funding LLC ("SWK"). The Credit Agreement provides for a term loan facility (the "Credit Facility") in the original principal amount of up to \$20.0 million. On the SWK Closing Date, Journey drew \$15 million. On June 26, 2024, Journey drew the remaining \$5.0 million under the Credit Facility. On July 9, 2024, Journey entered into an Amendment to the Credit Agreement with SWK. This amendment increased the original principal amount of the Credit Facility from \$20.0 million to \$25.0 million. The \$5.0 million of additional principal added was contractually required to be drawn upon FDA approval of Emrosi, subject to Journey receiving approval on or before June 30, 2025. Journey received FDA approval for Emrosi on November 4, 2024 and drew on the remaining \$5.0 million on November 25, 2024. Loans under the Credit Facility mature on December 27, 2027, and bear interest at a rate per annum equal to the three-month term Secured Overnight Financing Rate ("SOFR") (subject to a SOFR floor of 5%) plus 7.75%. The interest rate resets quarterly. Interest payments began in February 2024 and are paid quarterly. Beginning in February 2026, the Company 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.

### **Cash Flows**

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

	Year Ended December 31,					
(\$ in thousands)		2024		2023		Change
Total cash (used in)/provided by:						
Operating activities	\$	(80,191)	\$	(128,225)	\$	48,034
Investing activities		(15,000)		(2,103)		(12,897)
Financing activities		70,641		32,739		37,902
Net decrease in cash and cash equivalents and restricted cash	\$	(24,550)	\$	(97,589)	\$	73,039

#### Operating Activities

Net cash used in operating activities decreased by \$48.0 million from the year ended December 31, 2023 to the year ended December 31, 2024. The decrease is primarily attributable to the decrease in net loss of \$33.3 million, the increase of \$15.6 million in stock-based compensation expense, the one-time loss recovery payment of \$4.6 million received by Journey from their previously disclosed September 2021 cybersecurity incident, the net decrease in cash from changes in operating assets and liabilities of \$4.4 million offset by the decrease in loss from deconsolidation and dissolution of subsidiaries of \$4.1 million and a \$2.8 million decrease in research and development – licenses acquired expense due to Avenue's license purchase in 2023.

# Investing Activities

Net cash used by investing activities for the year ended December 31, 2023 of \$2.1 million increased \$12.9 million to \$15.0 million for the year ended December 31, 2024. The change is due to Journey's payment of the \$15 million milestone due to Dr. Reddy in December 2024 triggered by the FDA 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.

### Financing Activities

Net cash provided by financing activities increased \$37.9 million from the year ended December 31, 2023 to the year ended December 31, 2024. The increase is primarily due to proceeds from long term debt of \$33.7 million, the issuance of common stock in public offerings of \$17.4 million and at-the-market offerings, net of \$3.7 million, proceeds from partner company offerings and warrant exercises of \$49.7 million, and proceeds from partner company at-the-market offerings, net of \$12.0 million, partially offset by repayment of debt of \$51 million in the year ended December 31, 2024.

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

	For the Year Ended December 31, 2024											
(\$ in thousands)		Fortress <sup>1</sup>		Avenue		Checkpoint	<u> </u>	JMC		Mustang		Total
Statement of cash flows data:												
Total cash (used in)/provided by:												
Operating activities		\$ (19,527)	)	\$ (9,026	6)	\$ (31,101	)	\$ (9,12	27)	\$ (11,410	) \$	(80,191)
Investing activities		_		_	-	_	-	(15,00	00)	_	-	(15,000)
Financing activities		(231	)	9,837	7	32,777	7	16,99	93	11,265	5	70,641
Net increase (decrease) in cash and cash equivalents and												
restricted cash		\$ (19,758	)	\$ 811	_	\$ 1,676	<u> </u>	\$ (7,13	34)	\$ (145	5) \$	(24,550)
			_		_		_					_
				Fe	or th	ne Year Ende	d De	ecember 31,	202	23		
(\$ in thousands)		Fortress <sup>1</sup>		Avenue	C	heckpoint		JMC		Mustang		Total
Statement of cash flows data:												
Total cash (used in)/provided by:												
Operating activities	\$	(26,947)	\$	(9,451)	\$	(47,590)	\$	5,240	\$	(49,477)	\$	(128,225)
Investing activities		11		(3,000)		_		(5,000)		5,886		(2,103)
Financing activities		15,648		7,526		40,450		(4,804)		(26,081)		32,739
Net decrease in cash and cash equivalents and												
restricted cash	\$	(11,288)	\$	(4,925)	\$	(7,140)	\$	(4,564)	\$	(69,672)	\$	(97,589)

Note 1: Includes Fortress and non-public subsidiaries.

# **Contractual Obligations**

Our short-term and long-term contractual obligations as of December 31, 2024 include:

- Contractual payments related to our long-term debt (see Note 9, Debt and Interest, to our Consolidated Financial Statements included in "Part II, Item 8, Financial Statements and Supplementary Data" in this Annual Report on Form 10-K);
- obligations under our leases (see Note 14, Commitments and Contingencies to our Consolidated Financial Statements); and
- obligations under license agreements (see Note 7, License Agreements to our Consolidated Financial Statements).

Under the license agreements, we are required to make milestone payments upon successful completion and achievement of certain development, regulatory and commercial milestones, the payment obligations of which are contingent upon future events, such as our achievement of specified development, regulatory and commercial milestones, and the amount, timing, and likelihood of such payments are not known. We may also be required to make milestone payments and royalty payments in connection with the sale of products developed under these agreements, if approved and sold.

Additionally, we enter into agreements in the normal course of business with CROs and other vendors for clinical trials and with vendors for preclinical services and products for operating purposes, which are generally terminable by us upon written notice.

### Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

#### Item 8. Financial Statements and Supplementary Data.

The information required by this Item is set forth in the consolidated financial statements and notes thereto beginning at page F-1 of this Annual Report on Form 10-K.

# Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

### Item 9A. Controls and Procedures.

#### **Disclosure Controls and Procedures**

### **Controls and Procedures**

Disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) are designed only to provide reasonable assurance that they will meet their objectives. 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 December 31, 2024, 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.

# **Internal Control over Financial Reporting**

#### Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting refers to the process designed by, or under the supervision of, our principal executive officer and principal financial officer, and effected by our Board of Directors, management and other personnel, 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, and includes those policies and procedures that:

- (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets:
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and
- (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making the assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control - Integrated Framework (2013)*. Based on the results of this assessment, management (including our Chief Executive Officer and our Chief Financial Officer) has concluded that, as of December 31, 2024, our internal control over financial reporting was effective.

## Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### Item 9B. Other Information

During the three months ended December 31, 2024, 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 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

#### PART III

## Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth certain information regarding our executive officers and directors, including their ages as of the date of this Form 10-K.

Name	Age	Position
Lindsay A. Rosenwald, M.D.	69	Chairman of the Board of Directors, President and Chief Executive Officer
David Jin	35	Chief Financial Officer and Head of Corporate Development
Michael S. Weiss	59	Executive Vice Chairman, Strategic Development
Jimmie Harvey, Jr., M.D.	73	Director
Malcolm Hoenlein	81	Director
Dov Klein, CPA	73	Director
J. Jay Lobell	62	Director
Kevin L. Lorenz, J.D.	60	Director
Lucy Lu, M.D.	50	Director

Lindsay A. Rosenwald, M.D. has served as a member of the Company's Board of Directors since October 2009 and as Chairman, President and Chief Executive Officer of the Company since December 2013. Dr. Rosenwald also currently serves as a member of the board of directors of Fortress partner companies Avenue (OTC: ATXI), Checkpoint (Nasdaq: CKPT), Mustang (Nasdaq: MBIO) and Journey (Nasdaq: DERM). Additionally, Dr. Rosenwald serves as a member of the board of directors of each of Fortress' private subsidiaries (and has so served in each case since company inception). From 1991 to 2008, Dr. Rosenwald served as the Chairman of Paramount BioCapital, Inc. Over the past 30 years, Dr. Rosenwald has acted as a biotechnology entrepreneur and has been involved in the founding, recapitalization and sale of numerous public and private biotechnology and life science companies. He received his B.S. in finance from Pennsylvania State University and his M.D. from Temple University School of Medicine.

**David Jin** has served as our Chief Financial Officer since August 2022 and as Head of Corporate Development since May 2020. He also serves on the Board of Directors of Mustang (Nasdaq: MBIO) and as Interim Chief Financial Officer and Chief Operating Officer of Avenue (OTC: ATXI) (both Fortress partner companies). Previously, he was on the investment team in the Private Equity & Real Assets group at Barings, Director of Corporate Development at Sorrento Therapeutics, Vice President of Healthcare Investment Banking at FBR & Co., and was in the management consulting group at IMS Health (now IQVIA). He holds a B.S. in Industrial Engineering & Management Sciences with a double-major in Mathematical Methods in the Social Sciences from Northwestern University.

Michael S. Weiss has served as our Executive Vice Chairman, Strategic Development since February 2014. He currently serves as a member of the board of directors of several of our partner companies, including as Chairman of the Board of Directors of Checkpoint (Nasdaq: CKPT) and Executive Chairman of the Board of Directors of Mustang (Nasdaq: MBIO). Since December 2011, Mr. Weiss has served in multiple capacities at TG Therapeutics, Inc. (Nasdaq: TGTX), a related party, and is currently its Executive Chairman, Chief Executive Officer and President. In 1999, Mr. Weiss founded Access Oncology, which was later acquired by Keryx Biopharmaceuticals (Nasdaq: KERX) in 2004. Following the merger, Mr. Weiss remained as CEO of Keryx. He began his professional career as a lawyer with Cravath, Swaine & Moore LLP. Mr. Weiss earned his B.S. in Finance from The University of Albany and his J.D. from Columbia Law School

Jimmie Harvey, Jr., M.D. has served as a member of the Board of Directors since December 2008. In 1984, Dr. Harvey founded Birmingham Hematology and Oncology Associates, L.L.C. (now Alabama Oncology, L.L.C.), a private medical company located in Birmingham, Alabama. Dr. Harvey served as President of Alabama Oncology, LLC until 2020. Dr. Harvey has experience in clinical trial execution and management and was a principal investigator in two trials, one investigating a novel monoclonal antibody and the other investigating a small molecule used to treat immunologic malignancies. Dr. Harvey holds a B.A. in chemistry from Emory University and received his M.D. from Emory University School of Medicine. Dr. Harvey completed his medical oncology training at the Vincent T. Lombardi Cancer Center at Georgetown University. Based on Dr. Harvey's medical background, including his oncology expertise, the Board of Directors believes that Dr. Harvey has the appropriate set of skills to serve as a member of the Board in light of the Company's business and structure.

Malcolm Hoenlein has served as a member of the Board of Directors since February 2014. From 1986 to 2021, Mr. Hoenlein served as Executive Vice Chairman of the Conference of Presidents of Major American Jewish Organizations, the coordinating body on international and national concerns for 51 national American Jewish organizations and since 2021 continues as Vice Chairman Emeritus. Previously, he served as the founding Executive Director of the Jewish Community Relations Council of Greater New York. Prior to that, he was the founding Executive Director of the New York Conference on Soviet Jewry. A National Defense Fellow at the Near East Center of the University of Pennsylvania, Mr. Hoenlein taught International Relations in the Political Science Department and served as a Middle East specialist at the Foreign Policy Research Institute. In addition, he served on the editorial staff of ORBIS, the Journal of World Affairs. He serves currently as a director of Nanox Imaging Plc. and Bonus BioGroup. He previously served as a director for DarioHealth Corp, WellSense Technology, Delek Oil, Eco-Fusion North America, Inc., Powermat USA, and Bank Leumi USA. Mr. Hoenlein has a B.A. in Political Science from Temple University and an M.A. in International Relations from the University of Pennsylvania, as well as an Hon. LL.D. from Touro College, an Hon. D.H.L. from Yeshiva University, an Hon. D.H.L. from Temple University and an Hon. D.H.L. from Bar Ilan University. Based on Mr. Hoenlein's demonstrated sound business judgment and leadership and management experience, the Board of Directors believes that Mr. Hoenlein has the appropriate set of skills to serve as a member of the Board in light of the Company's business and structure.

Dov Klein, CPA, has served as a member of the Board of Directors since July 2015. From January 2016 through December 31, 2020, Mr. Klein was an audit partner at Marks Paneth LLP, a certified public accounting and consulting firm. Effective January 1, 2021, Mr. Klein is a retired partner of Marks Paneth LLP. Prior to 2016, Mr. Klein was an audit partner at RSSM CPA LLP, a certified public accounting and strategic advisory firm, which he joined in 2001. His practice focused on audits and reviews and compilation of financial statements for clients in various industries. Mr. Klein has also consulted on matters in litigation and conducted financial due diligence in mergers and acquisitions as well as business planning for growing businesses. Mr. Klein has been a certified public accountant since 1978 and is a member of the American Institute of Certified Public Accountants and the New York State Society of Certified Public Accountants. Mr. Klein received his BSc in Accounting from Brooklyn College, The City University of New York.

J. Jay Lobell has served as a member of the Board of Directors since June 2006. Mr. Lobell is President of GMF Capital, LLC which he co-founded in January 2016. Mr. Lobell was also a founder of Beech Street Capital, LLC, a real estate lending company, serving as its Vice Chairman from December 2009 until the company's sale to Capital One Financial Corporation in November 2013. From January 2005 to December 2009, Mr. Lobell served as President and Chief Operating Officer of Paramount Biosciences, LLC, or PBS, a private biotechnology investment and development company. In that capacity, he had substantial responsibility for the assembly and oversight of companies PBS founded and incubated, including the Company. Mr. Lobell currently serves on the board of directors of several private companies, including Sava Senior Care, where he has served since September 2013, Tender Touch Rehabilitation Services, where he has served since October 2014, and Pardes Biosciences, where he has served since January 2021. Mr. Lobell was a partner in the law firm Covington & Burling LLP from October 1996 through January 2005, where he advised companies and individuals as a member of the firm's securities litigation and white collar defense practice group. Mr. Lobell received his B.A. (summa cum laude, Phi Beta Kappa) from The City University of New York and his J.D. from Yale Law School, where he was senior editor of The Yale Law Journal.

Kevin L. Lorenz, J.D., has served as a member of the Board of Directors since August 2019. Mr. Lorenz has over 25 years of experience guiding and implementing investment strategies across public and private companies. Since 2021, Mr. Lorenz has served as a Director at Adventus Capital Partners. Since 2015, Mr. Lorenz has been Chief Investment Officer, Senior Vice President, Treasury & Private Investments at the Katz Group in the family office of Daryl Katz, which has operations in sports and entertainment, real estate, and public and private investments. Mr. Lorenz works directly with the principal of the Katz Group to oversee the design, implementation, and monitoring of the overall investment strategy for public and private passive investments. Prior to joining the Katz Group, Mr. Lorenz was Director, Ultra High Net Worth ("UHNW") Private Client Business at Credit Suisse Securities, LLC from 2009 - 2015, where he was selected to expand Credit Suisses's UHNW private client business into Canada. From 2004 to 2009, Mr. Lorenz was the Director, UHNW Management Group at UBS Financial Services, Inc., where he was a key contributor to the formation and development of the company's first dedicated UBS UHNW office. Earlier in his career, he held positions of increasing responsibility at Merrill Lynch Pierce Fenner & Smith, Inc. and the Office of the Comptroller of the Currency, an independent bureau within the U.S. Department of the Treasury that charters, regulates and supervises all national banks and thrift institutions. Mr. Lorenz holds a J.D. from George Mason University Antonin Scalia Law School, an M.B.A. from Benedictine University and a B.S. in economics from Illinois State University.

Lucy Lu, M.D., has served as a member of the Board of Directors since December 2022. She previously served as the Executive Vice President and Chief Financial Officer of the Company from February 2012 to June 2017 and the President and Chief Executive Officer of Avenue Therapeutics, Inc. (OTC: ATXI) from July 2017 until March 2022. Prior to working in the biotech industry, Dr. Lu had 10 years of experience in healthcare-related equity research and investment banking. Additionally, Dr. Lu has served as a member of the Board of Directors of Veru, Inc. where she is the Chair of the Audit Committee and serves on the Compensation Committee, since 2021, a position she also held from 2016 to 2018, and has served as a member of the Board of Directors of Iventiva S.A. since 2018. From February 2007 through January 2012, Dr. Lu was a senior biotechnology equity analyst with Citigroup Investment Research. From 2004 until joining Citigroup, she was with First Albany Capital, serving as Vice President from April 2004 until becoming a Principal of the firm in February 2006. Dr. Lu holds an M.D. degree from the New York University School of Medicine and an M.B.A. from the Leonard N. Stern School of Business at New York University. Dr. Lu obtained a B.A. from the University of Tennessee's College of Arts and Science.

# Family Relationships

There is no family relationship between and among any of our executive officers or directors.

# **Board Structure and Leadership**

Our Bylaws provide that our Board shall consist of between one and nine directors, and such number of directors within this range may be determined from time to time by resolution of our board of directors or our stockholders. Currently, we have eight directors.

The Board does not have a formal policy regarding the separation of the roles of Chief Executive Officer and Chairman of the Board, as the Board believes that it is in the best interests of the Company to make that determination based on the direction of the Company and the current membership of the Board. The Board has determined that having a director who is also the Chief Executive Officer serve as the Chairman is in the best interest of the Company's stockholders at this time.

During 2024, our Board held ten meetings. During 2024, each director attended at least 88% of the meetings of the Board and the meetings of those committees on which each director served, in each case during the period that such person was a director. Our directors are expected to attend each Annual Meeting of Stockholders.

# **Director Independence**

Fortress adheres to the corporate governance standards adopted by The Nasdaq Stock Market LLC ("Nasdaq"). Nasdaq rules require our Board to make an affirmative determination as to the independence of each director. Consistent with these rules, our Board completed its annual review of director independence on March 27, 2025. During the review, our Board considered relationships and transactions during 2024 and during the past three fiscal years between each director or any member of his or her immediate family, on the one hand, and the Company and our partner companies and affiliates, on the other hand. The purpose of this review was to determine whether any such relationships or transactions were inconsistent with a determination that the director is independent. Based on this review, our Board determined that Dr. Harvey and Messrs. Hoenlein, Klein, Lobell, and Lorenz are independent under the criteria established by Nasdaq and our Board.

### **Board Committees**

The permanent committees established by our Board are the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee, descriptions of which are set forth in more detail below.

#### **Audit Committee**

The Audit Committee currently consists of Messrs. Klein (chair) and Lobell, and Dr. Harvey. During 2024, the Audit Committee held four meetings. The duties and responsibilities of the Audit Committee are set forth in the Charter of the Audit Committee which was recently reviewed by our Audit Committee. Our Audit Committee determined that no revisions needed to be made to the charter at this time. A copy of the Charter of the Audit Committee is available on our website, located at <a href="https://www.fortressbiotech.com">www.fortressbiotech.com</a>, under the <a href="https://www.fortressbiotech.com">Investors – Governance – Governance – Governance – Governance – Bocuments</a> section. Among other matters, the duties and responsibilities of the Audit Committee include reviewing and monitoring our financial statements and internal accounting procedures, the selection of our independent registered public accounting firm. Our Audit Committee has sole discretion over the retention, compensation, evaluation and oversight of our independent registered public accounting firm.

The SEC and Nasdaq have established rules and regulations regarding the composition of audit committees and the qualifications of audit committee members. Our Board of Directors has examined the composition of our Audit Committee and the qualifications of our Audit Committee members in light of the current rules and regulations governing audit committees. Based upon this examination, our Board of Directors has determined that each member of our Audit Committee is independent and is otherwise qualified to be a member of our Audit Committee in accordance with the rules of the SEC and Nasdaq.

Additionally, the SEC requires that at least one member of the Audit Committee have a "heightened" level of financial and accounting sophistication. Such a person is known as the "audit committee financial expert" under the SEC's rules. Our Board has determined that Mr. Klein is an "audit committee financial expert," as the SEC defines that term, and is an independent member of our Board of Directors and our Audit Committee. Please see Mr. Klein's biography in "Item 10. Directors, Executive Officers, and Corporate Governance" for a description of his relevant experience.

#### **Compensation Committee**

The Compensation Committee held one meeting and took action by unanimous consent one time during 2024. The Compensation Committee currently consists of Messrs. Lobell (chair), Klein and Dr. Harvey. The duties and responsibilities of the Compensation Committee are set forth in its charter. A copy of the charter of the Compensation Committee is available on the Company's website, located at www.fortressbiotech.com, under the Investors — Governance — Governance Documents section. As discussed in its charter, among other things, the duties and responsibilities of the Compensation Committee include annually evaluating the performance of the Chief Executive Officer and our other executive officers, determining the overall compensation of the Chief Executive Officer and our other executive compensation programs, including, but not limited to, our incentive and equity-based plans. The Compensation Committee also reviews and discusses with management the compensation disclosures in our proxy statement and reviews and approves the say on pay and frequency proposals to be periodically included in our proxy statement. The Compensation Committee applies discretion in the determination of individual executive compensation packages to ensure compliance with the Company's compensation philosophy. The Chief Executive Officer makes recommendations to the Compensation Committee with respect to the compensation packages for officers other than himself. The Compensation Committee may delegate its authority to grant awards to certain employees, and within specified parameters under the Compensation Committee Charter, to a special committee consisting of one or more directors who may but need not be officers of the Company.

Nasdaq has established rules and regulations regarding the composition of compensation committees and the qualifications of compensation committee members. Our Board of Directors has examined the composition of our Compensation Committee and the qualifications of our Compensation Committee members in light of the current rules and regulations governing compensation committees. Based upon this examination, our Board of Directors has determined that each member of our Compensation Committee is independent and is otherwise qualified to be a member of our Compensation Committee in accordance with such rules.

### **Nominating Committee**

The Nominating and Corporate Governance Committee is currently composed of Messrs. Lobell (chair), Hoenlein and Klein. The functions of the Nominating and Corporate Governance Committee include, among other things:

- making recommendations to the Board of Directors regarding the size and composition of the Board of Directors;
- developing minimum qualifications for director candidates and evaluating such candidates in such a manner as the Nominating and Corporate Governance Committee deems appropriate;
- except where otherwise required, selecting candidates for election to the Board of Directors and to fill any vacancies on the Board of Directors, such selected candidates to then be voted by the Board of Directors;
- establishing procedures for the nomination process;
- establishing and administering periodic assessment procedures relating to the performance of the Board of Directors as a whole and its individual members; and
- making recommendations to the Board of Directors regarding corporate governance matters and practices, including formulating and periodically reviewing corporate governance guidelines to be adopted by the Board of Directors.

The Nominating and Corporate Governance Committee of the Board of Directors is responsible for establishing the qualifications for director candidates. The Committee does not have a formal policy on Board of Directors candidate qualifications. It may consider those factors it deems appropriate in evaluating director nominees made either by the Board of Directors or stockholders, including judgment, skill, strength of character, experience with businesses and organizations comparable in size or scope to the Company, experience and skills relative to other Board of Directors' members, specialized knowledge or experience, and diversity. Depending upon the current needs of the Board of Directors, certain factors may be weighed more or less heavily than others. In considering candidates for the Board of Directors, the directors evaluate the entirety of each candidate's credentials and do not currently have any specific minimum qualifications that must be met. The directors will consider candidates from any reasonable source, including current Board of Directors' members, stockholders, professional search firms or other persons. The directors will not evaluate candidates differently based on who made the recommendation. Our policy describing our director nomination process is included in our Nominating and Corporate Governance Committee Charter, which is available on the Company's website, located at www.fortressbiotech.com, under the Investors — Governance — Governance Documents section. We believe that the current process in place functions effectively to select director nominees who will be valuable members of our Board of Directors. We identify potential nominees to serve as directors through a variety of business contacts, including current executive officers, directors, community leaders and stockholders. We may, to the extent appropriate, retain a professional search firm or other advisors to identify potential nominees.

We will also consider candidates recommended by stockholders for nomination to our Board. A stockholder who wishes to recommend a candidate for nomination to our Board must submit such recommendation to our General Counsel and Corporate Secretary, Sam Berry, at our offices located at 1111 Kane Concourse Suite 301, Bay Harbor Islands, FL 33154. Any recommendation must be received not less than 45 calendar days nor more than 75 calendar days before the anniversary date of the previous year's annual meeting. All stockholder recommendations of candidates for nomination for election to our Board must be in writing and must set forth the following: (i) the candidate's name, age, business address, and other contact information, (ii) the number of shares of common stock beneficially owned by the candidate, (iii) the date or dates such shares were acquired and the investment intent of such acquisition, (iv) a complete description of the candidate's qualifications, experience, background and affiliations, as would be required to be disclosed in the proxy statement pursuant to Schedule 14A under the Exchange Act, (v) a written statement by the candidate in which he or she consents to being named in the proxy statement as a nominee and to serve as director if elected, and (vi) the name and address of the stockholder(s) of record making such a recommendation.

We believe that our Board as a whole should encompass a range of talent, skill, and expertise enabling it to provide sound guidance with respect to our operations and interests. Our independent directors evaluate all director candidates by reviewing their biographical information and qualifications. If the independent directors determine that a candidate is qualified to serve on our Board, such candidate is interviewed by at least one of the independent directors and our Chief Executive Officer. Other members of the Board also have an opportunity to interview qualified candidates. The independent directors then determine, based on the background information and the information obtained in the interviews, whether to recommend to the Board that the candidate be nominated for approval by the stockholders to fill a directorship. With respect to an incumbent director whom the independent directors are considering as a potential nominee for re-election, the independent directors review and consider the incumbent director's service during his or her term, including the number of meetings attended, level of participation, and overall contribution to the Board. The manner in which the independent directors evaluate a potential nominee does not differ based on whether the candidate is recommended by our directors or stockholders.

We consider the following qualifications, among others, when making a determination as to whether a person should be nominated to our Board: the independence of the director nominee; the director nominee's character and integrity; financial literacy; level of education and business experience, including experience relating to biopharmaceutical companies; whether the director nominee has sufficient time to devote to our Board; and the director nominee's commitment to represent the long-term interests of our stockholders. We review candidates in the context of the current composition of the Board and the evolving needs of our business. We believe that each of the current members of our Board (all of whom are director nominees) has the requisite business, biopharmaceutical, financial or managerial experience to serve as a member of the Board, as described above in their biographies under the heading "Our Board of Directors." We also believe that each of the current members of our Board has other key attributes that are important to an effective board, including integrity, high ethical standards, sound judgment, analytical skills, and the commitment to devote significant time and energy to service on the Board and its committees.

#### Code of Business Conduct and Ethics

We have adopted the Code of Business Conduct and Ethics, or the Code, which applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. The Code includes guidelines dealing with the ethical handling of conflicts of interest, compliance with federal and state laws, financial reporting, and our proprietary information. The Code also contains procedures for dealing with and reporting violations of the Code. We have posted our Code of Business Conduct and Ethics under the Investors — Governance — Governance Documents section of the Company's website, located at www.fortressbiotech.com. Any changes to or waivers of the Code of Ethics will be posted at that website.

## Insider Trading Policy Prohibiting Hedging and Speculative Trading

We maintain an insider trading policy ("Insider Trading Policy") that governs the purchase, sale and other dispositions of our securities by the Company, directors, officers and employees. Our Insider Trading Policy is designed to promote compliance with insider trading laws, rules and regulations and any applicable listing standards. Additionally, pursuant to our Insider Trading Policy, our officers, directors, and employees are prohibited from engaging in speculative trading, including hedging transactions or short sale transactions with respect to Company securities.

# **Delinquent Section 16(a) Reports**

Section 16(a) of the Exchange Act requires our directors, executive officers, and beneficial owners of more than ten percent of our common stock to file reports with the SEC indicating their holdings of and transactions in our equity securities, and to provide copies of such reports to us. Based solely on a review of our records, publicly available information, and written representations by the persons required to file such reports, we believe that during the fiscal year ended December 31, 2024, there were no Section 16(a) filings that were untimely.

## Item 11. Executive Compensation

### **Named Executive Officers**

As determined in accordance with SEC rules, our "named executive officers" ("NEOs"), which include all executive officers serving during 2024, are the individuals set forth below:

- Lindsay A. Rosenwald, M.D., our Chairman, President and Chief Executive Officer;
- David Jin, our Chief Financial Officer and Head of Corporate Development; and
- Michael S. Weiss, our Executive Vice Chairman, Strategic Development

The following table sets forth information concerning compensation paid by the Company and its consolidated subsidiaries to our NEOs for their services rendered in all capacities during the years ended December 31, 2024, and 2023.

### **Summary Compensation Table**

Name and principal position(s) Lindsay A. Rosenwald, M.D. Chairman, President and Chief Executive Officer	Year 2024 2023	Salary (\$) \$ 62,665 62,665	Bonus (\$) — \$	Stock Awards <sup>(1)</sup> (\$) 1,153,032 805,920	Option Awards <sup>(1)</sup> (\$) \$ 64,500 104,000	Non-equity Incentive Plan Compensation (\$)	All Other Compensation <sup>(2)</sup> (S) \$ 150,000 150,000	Total (\$) \$ 1,430,197 1,122,585
David Jin Chief Financial Officer and Head of Corporate Development	2024 2023	420,000 400,000	160,000 <sup>(3)</sup>	1,899,900 330,400	582,500	Ξ	14,467 7,333	2,334,367 1,480,233
Michael S. Weiss Executive Vice Chairman, Strategic Development	2024 2023	62,665 62,665	=	1,047,680 779,994	Ξ	Ξ	120,000 120,000	1,230,345 962,659

- (1) Represents the aggregate grant date fair value of equity-based awards granted by the Company and its consolidated subsidiaries, computed in accordance with FASB Accounting Standards Codification Topic 718, Stock Compensation, as modified or supplemented ("FASB ASC Topic 718"), as described in Note 13. In accordance with the terms of the LTIP (as defined below), on January 1, 2025, Dr. Rosenwald and Mr. Weiss were each awarded 454,163 shares of restricted common stock of the Company (or one percent (1%) of the total outstanding shares of the Company) for their performance in 2024. In 2024 Mr. Jin was awarded 1,000,000 Restricted Stock Units of the Company and 65,000 Restricted Stock Units of Avenue for his roles as Interim Chief Operating Officer, Chief Financial Officer and Corporate Secretary of Avenue. Additionally, Dr. Rosenwald received 82,051 restricted shares of Checkpoint common stock, 9,728 restricted shares of Journey common stock, and 30,000 options in respect of Avenue common stock for his role on the Board of Directors of those companies for the year ended December 31, 2024. Mr. Weiss received 82,051 restricted shares of Checkpoint common stock in his capacity as Chairman of the Board of Checkpoint for the year ended 2024.
- (2) All Other Compensation for 2024 for Dr. Rosenwald comprises \$50,000 in cash fees from each of Checkpoint, Mustang, and Journey for his service on the Boards of Directors of those companies for the year ended December 31, 2024. All Other Compensation for 2024 for Mr. Weiss, in each case to an LLC wholly-owned by Mr. Weiss, comprises \$60,000 cash fees received for his service as Chairman of the Board of Checkpoint, and \$60,000 in cash fees received for his service as Chairman of Mustang. All Other Compensation for 2024 for Mr. Jin comprises Company matching 401(k) contributions of \$14,467.
- (3) This amount represents an discretionary bonus awarded by the Compensation Committee to Mr. Jin in January 2025. Although this bonus was not awarded until 2025, it relates to services performed in 2023 and we have therefore restated Mr. Jin's 2023 compensation to include it. Other than the addition of this bonus amount, no other changes have been made to Mr. Jin's previously reported 2023 compensation.

# **Summary of Material Components of Compensation Program**

The Company believes in providing its executive management team a competitive total compensation package featuring a combination of elements. The executive compensation programs are designed to achieve the following objectives:

- reward performance:
- attract, motivate and retain executives of outstanding ability and potential; and
- ensure that executive compensation is rationally related to building stockholder value.

The Board of Directors believes that the Company's executive compensation programs should include short- and long-term components, including cash and equity-based compensation, and should reward consistent performance that meets or exceeds expectations.

### **Base Salaries**

Base salaries for the Company's executives are initially established through arm's-length negotiation at the time the executive is hired, taking into account such executive's qualifications, experience, prior salary, the scope of his or her responsibilities, and competitive market compensation paid by other companies for similar positions within the industry. Base salaries are reviewed annually, typically in connection with the annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, and experience. While other of the Company's executives are paid salaries typical within the industry for persons of their experience and expertise, Dr. Rosenwald and Mr. Weiss have elected to largely forego the payment of salary from the Company.

# **Annual Discretionary Bonuses**

In addition to the payment of base salaries, the Company believes that discretionary bonuses can play an important role in providing appropriate incentives to its executives to achieve the Company's strategic objectives. However, for 2024, no annual bonuses were paid to our executive officers.

### Amended and Restated Long Term Incentive Plan

The Fortress Biotech, Inc. Amended and Restated Long Term Incentive Plan (the "LTIP") is designed to compensate Dr. Rosenwald and Mr. Weiss based on their responsibilities and for their contributions to the successful achievement of certain corporate goals and objectives of the Company. The LTIP awards are intended to enable each executive to share in the successes and risks of the Company. Eligible participants in the LTIP include Dr. Rosenwald, Mr. Weiss, or any limited liability company or limited partnership owned and controlled by Dr. Rosenwald or Mr. Weiss, provided such entity has a bona fide service provider relationship with the Company ("Eligible Entities" and together with Dr. Rosenwald and Mr. Weiss, the "LTIP Participants").

On January 1 of each year, until and including 2025, the LTIP entitles the Company to grant restricted shares of common stock of the Company to each of the LTIP Participants equal to up to one percent (1%) of the total outstanding shares of common stock of the Company, such actual amount to be based upon the achievement of the goals and objectives of each individual as set by the Compensation Committee for the preceding year. In the case of the LTIP Participants, such goals and objectives include, among other things: the Company's inlicensing of new medical technologies of substantial promise; operational and cash management; the Company's issuance of new debt securities; the Company's achievement of developmental, regulatory and clinical milestones in respect of its in-licensed technologies; the recruitment and retention of personnel; share price performance; trading volume of the Company's public securities; and the overall positioning of the Company within its relevant market.

Restricted shares granted under the LTIP vest upon (i) the Company achieving a specified increase in market capitalization since the grant date and (ii) the participant remaining in service with the Company until (or being involuntarily terminated prior to) July 16, 2025. The award would also vest upon a change in control of the Company before July 16, 2025, provided the eligible participant remains in service with the Company until the date of such transaction. If the restricted shares do not vest as described above, 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.

In addition, pursuant to the LTIP, upon the formation of each new subsidiary of the Company, the LTIP Participants are to each receive five percent (5%) of the total outstanding shares of common stock of the subsidiary.

# **Retirement Plans**

We maintain a tax-qualified retirement plan (the "401(k)") plan for eligible employees, including our named executive officers. Eligible employees may make voluntary contributions from their eligible pay and may defer up to 86% of their annual compensation, up to certain limitations imposed by the Internal Revenue Code of 1986, as amended. We match employee contributions in an amount equal to 100% of 4% of the employee's eligible compensation. All such employee contributions and matching contributions are immediately and fully vested.

### **Equity Incentive Compensation**

The Company believes that by providing its executives the opportunity to increase their ownership of Company stock, the interests of its executives will be more closely aligned with the best interests of the Company's stockholders, encouraging long-term performance. The stock awards enable the executive officers to participate in the appreciation of the value of the Company's stock, while personally participating in the risks of business setbacks. The Company grants equity awards to its executives pursuant to the Fortress Biotech, Inc. 2013 Stock Incentive Plan, as has been amended from time to time (the "2013 Plan").

While the Company has awarded stock options to the executive officers as incentives in the past, it more recently has awarded restricted stock or restricted stock units ("RSUs") to its executives. These RSU or restricted stock awards generally vest in installments over a period of several years. Several of the Company's subsidiaries also periodically grant awards of stock options, restricted stock or RSUs to executive officers of the Company in respect of their service as officers or directors of those subsidiaries.

# OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table sets forth certain information regarding outstanding equity awards held by the Company's named executive officers, in securities of the Company and its subsidiaries, as of December 31, 2024.

		Option Award	s		Stock Awards				
Name	Number of Securities Underlying Unexercised Options/ Warrant Exercisable (#)	Options	Option/ Warrant Exercise Price (\$)	Option/ Warrant Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)	Equity Incentive Plan Awards: Number or Unearned Shares (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares (\$)(1)	
Lindsay A.									
Rosenwald, M.D.	1,666 (2)	)	\$ 20.55	10/05/2025	104,295 (3)	\$ 333,744	81,286 (4)	)\$ 164,604	
M.D.	1,000 (-)	889 (5)		6/30/2033	348,838 (6)	706,397	216,465 (7)		
		30,000 (8)		9/23/2034	9,728 (9)	38,036	210,405	430,342	
	_	50,000	2.40	)/23/203 <del>4</del>	239 (10)				
					23,	2,113			
David Jin	125,000	125,000	1.14 (11	6/30/2033	10,000 (12)	39,100	_	_	
	62,500	187,500	1.29 (13)	0 10/10/2033	32,500 (14)	65,000	_	_	
	_	_	_	_	1,000,000 (15)	2,025,000	_	_	
	_	_	_	_	105,000 (16)	,	_	_	
	_	_	_	_	41,250 (17)	83,531	_		
Michael S. Weiss	_	_	_	_	104,295 (3)	333,744	81,286 (4)	) 164,604	
	_	_	_	_	348,838 (6)	706,397	216,465 (7)	438,342	
	_	<del>_</del>	_	_	239 (10)		_	_	
					87,970 (18)	178,139	_	_	

<sup>(1)</sup> Based on the closing stock price on the Nasdaq Capital Market on the last trading day of the most recently completed fiscal year, as applicable, Fortress: \$2.025; Checkpoint: \$3.20, Journey: \$3.91, Mustang: \$8.85 and Avenue: \$2.00.

- (2) Represents vested options in respect of Fortress common stock.
- (3) Represents restricted shares in Checkpoint that vest as follows: 4,761 restricted shares that vest on June 16, 2025; 17,483 restricted shares that vest on June 13, 2026; 32,051 restricted shares that vest on May 14, 2027; and 50,000 shares that vest in three equal installments on the first, second and third anniversaries of the grant date of May 14, 2024.
- (4) Represents restricted shares of the Company that vest if both of the following conditions are met: (a) there is an increase in the market capitalization of the Company of at least \$100,000,000 since January 1, 2023 and before July 16, 2025, and (b) the grantee (or a limited liability company or limited partnership owned by the grantee) either remains in service with the Company through July 16, 2025 or experiences an involuntary separation prior to such date.
- (5) Represents options in respect of Avenue common stock, which vest (or vested) in equal installments on January 1 of each of 2024, 2025 and 2026.
- (6) Represents restricted shares of the Company that vest on July 16, 2025.
- (7) Represents restricted shares of the Company that vest if both of the following conditions are met: (a) there is an increase in the market capitalization of the Company of at least \$100,000,000 since January 1, 2024 and before July 16, 2025, and (b) the grantee (or a limited liability company or limited partnership owned by the grantee) either remains in service with the Company through July 16, 2025 or experiences an involuntary separation prior to such date.
- (8) Represents options in respect of Avenue common stock, which vest in equal installments on January 1 of each of 2025, 2026 and 2027.
- (9) Represents restricted shares in Journey that vest on July 8, 2025.
- (10) Represents restricted shares in Mustang that vest as follows: 95 restricted shares that vest on June 17, 2025 and 144 restricted shares that vest on July 5, 2026.
- (11) Represents options in respect of Avenue common stock, which vest (or vested) in equal installments on August 1 of each of 2023, 2024, 2025 and 2026.
- (12) Represents restricted stock units in Journey which vest in equal installments on July 21 of each of 2025 and 2026.
- (13) Represents options in respect of Urica common stock, which vest (or vested) in equal installments on October 10 of each of 2023, 2024, 2025 and 2026.
- (14) Represents restricted stock units in Avenue that vest in equal installments on September 23 of each of 2025 and 2026.
- (15) Represents deferred restricted stock units of the Company that vest in 16 equal quarterly installments through the period ending December 31, 2028.
- (16) Represents deferred restricted stock units of the Company that vest in 12 equal quarterly installments through the period ending December 31, 2027.
- (17) Represents deferred restricted stock units of the Company that vest in 22 equal monthly installments through the period ending October 31, 2026.
- (18) Represents restricted shares of the Company that vest on December 19, 2027.

## Summary of Employment or Agreements and Arrangements

# **Executive Employment Agreements**

The Company has not entered into employment agreements with Dr. Rosenwald, Mr. Weiss, or Mr. Jin. The forfeiture conditions applicable to restricted shares granted to Dr. Rosenwald, Mr. Weiss or related entities under the LTIP lapses upon the occurrence of a corporate transaction (as defined in the LTIP) if the eligible employee is in service on the date of the corporate transaction, or upon a termination of service other than a voluntary separation.

### **Clawback Policy**

Pursuant to Nasdaq listing requirements, we have adopted a policy providing for the recovery of erroneously awarded incentive-based compensation received by our executive officers or the executive officers of one of our subsidiaries during an applicable recovery period (the "Clawback Policy"). Under the Clawback Policy, in the event that financial results upon which a cash or equity-based incentive award was based becomes the subject of a financial restatement that is required because of material non-compliance with financial reporting requirements, the Compensation Committee will conduct a review of awards covered by the Clawback Policy and recoup any erroneously awarded incentive-based compensation to ensure that the ultimate award reflects the financial results as restated. The Clawback Policy covers any cash or equity-based incentive compensation award that was paid, earned or granted to covered executive officers during the last completed three fiscal years immediately preceding the date on which we are required to prepare the accounting restatement.

### **Timing of Equity Awards**

While we have no set policy or practice regarding the timing of stock option awards or similar instruments in relation to the disclosure of material nonpublic information, we do not time the release of material information to affect the value of stock options. In general, the timing of stock option awards is dictated by the event or circumstance giving rise to the award and the schedules of the directors responsible for approving the award. In 2024, options were not issued to our named executive officers during the period beginning four business days before and ending one business day after the filing of a Form 10-Q, Form 10-K or Form 8-K that discloses material nonpublic information. If, in the future, a stock option grant is made at a time that material nonpublic information exists, the directors approving the award would be responsible for considering the anticipated effect of that information on our stock price and would take such effect into account when sizing and pricing the award.

## **Director Compensation**

Non-employee directors are compensated pursuant to the Company's Non-Employee Director Compensation Policy and each non-employee director is eligible to receive a board fee of \$30,000 annually, payable in quarterly installments. Audit Committee members are eligible to receive an additional committee fee of \$7,500 annually, payable in quarterly installments, and the chair of the Audit Committee is eligible to receive an additional Audit Committee chair fee of \$55,000 annually, payable in quarterly installments. Compensation Committee, Nominating and Governance Committee, and Strategic Transaction Committee members are each eligible to receive an additional committee fee of \$5,000 annually, payable in quarterly installments, and chairs of each of those committees are eligible to receive a committee chair fee of \$10,000 annually, payable in quarterly installments.

Non-employee directors may also receive stock options, restricted stock, or a restricted stock unit grant for shares of the Company's common stock upon appointment and on an annual basis thereafter. Similarly, Strategic Transaction Committee members may also receive an additional equity award upon appointment to that committee and on an annual basis thereafter.

On January 1, 2024, all non-employee directors received \$10,000 worth of restricted stock and Strategic Transaction Committee members each received an additional \$10,000 worth of restricted stock, with the number of shares determined in each case based on the closing price of our common stock on the last trading day prior to the grant date, and in each case vesting in three equal installments on January 1 of 2025, 2026 and 2027.

Beginning on January 1, 2025, non-employee directors are also eligible to receive, on an annual basis on each January 1, a number of shares of the Company's common stock equal to \$100,000 divided by the closing price of the Company's common stock on the final trading day of the previous calendar year, with such shares vesting in three (3) equal tranches on each of the first three (3) anniversaries of the grant date.

# Non-Qualified Deferred Compensation

On March 12, 2015, the Compensation Committee of the Board approved the Deferred Compensation Plan for Directors (the "Plan") for non-employee directors ("Participants"). The Plan is administered by the Compensation Committee.

Pursuant to the Plan, a Participant can defer all or a portion of such Participant's unearned annual fees, meeting fees and committee fees, including restricted stock and restricted stock units. Deferred cash compensation will be converted into a number of stock units, determined based upon the closing price of the Company's common stock on the date such fees would otherwise have been payable and placed into the Participant's deferred compensation account ("Account"). Deferred restricted stock unit grants will be converted on a share-for-share basis on the date such restricted stock units would otherwise have been payable and placed into the Participant's Account.

On the tenth business day of January of the year following the Participant's separation from service on the Board due to resignation, removal, failure to be re-elected or retirement, the amount of deferred compensation in the Participant's Account will be distributed to the Participant in a lump sum payment of a number of shares of the Company's common stock under the Plan equal to the number of whole stock units in the Account and cash in lieu of any fractional shares. Distributions from the Account may be accelerated in the event of the Participant's death or upon a corporate transaction (as defined in the Plan).

#### **Director Compensation Table**

The following table and related footnotes show the compensation paid to or accrued for the benefit of the Company's non-employee directors in the fiscal year ended December 31, 2024.

Name	or	s Earned Paid in ish <sup>(1)</sup> (\$)	A	Stock Awards <sup>(2)</sup> (\$)	Total (\$)
Jimmie Harvey, Jr., M.D.	\$	47,500	\$	20,065 (3) \$	67,565
Malcolm Hoenlein		35,000		10,032 (3)	45,032
Dov Klein, CPA		100,000		20,065 (4)	120,065
J. Jay Lobell		67,500		20,065	87,565
Kevin L. Lorenz, J.D.		30,000		10,032	40,032
Lucy Lu, M.D.		30,000		10,032 (3)	40,032
Eric K. Rowinsky, M.D		17,500		20,065 (3)	37,565

- (1) Represents director and committee fees earned in 2024.
- (2) Amounts listed represent the aggregate fair value amount computed as of the grant date of each award during 2024 in accordance with FASB ASC Topic 718, as described in Note 13.
- (3) In 2024, Drs. Harvey, Rowinsky, Lu and Mr. Hoenlein elected to defer 100% of the value of their stock awards. This amount was credited to each of their deferred compensation accounts, respectively.
- (4) In 2024, Mr. Klein elected to defer 80% of the value of his stock award. This amount was credited to his deferred compensation account
- (5) In 2024, Dr. Rowinsky earned a prorated portion of his director compensation fees through May 23, 2024, as he did not stand for reelection.

At December 31, 2024, the aggregate number of restricted stock, restricted stock units ("RSUs"), and options issued to each non-employee director that remains unvested was as follows: Dr. Harvey, 13,332 restricted stock awards ("RSAs"); Mr. Hoenlein, 6,666 RSAs, Mr. Klein, 13,332 RSAs; Mr. Lobell, 13,332 RSAs; Mr. Lorenz, 6,666 RSAs, and Dr. Lu, 6,666 RSAs.

# Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

# Securities Authorized for Issuance Under Equity Compensation Plans

Our equity compensation plans consist of the Coronado Biosciences, Inc. 2012 Employee Stock Purchase Plan, the Fortress Biotech, Inc. 2013 Stock Incentive Plan, as amended, and the Fortress Biotech, Inc. Long Term Incentive Plan, all of which were approved by our stockholders. We do not have any equity compensation plans or arrangements that have not been approved by our stockholders.

The following table contains information about our equity compensation plans as of December 31, 2024.

				Number of
	Number of			Securities
	Securities to be			Remaining
	Issued Upon			Available for
	Exercise of		Weighted-	Future Issuance
	Outstanding	A	verage Exercise	Under Equity
	Options,		Price of	Compensation
	Restricted		Outstanding	Plans (Excluding
	Stock Units,		Options,	Securities
	Warrants and	1	Warrants and	Reflected in
Plan Category	Rights (a) (1)		Rights (2)	Column(a)) (3)
Equity compensation plan approved by shareholders	3,718,186	\$	\$ 1.78	9,003,196
Equity compensation plan not approved by shareholders				
Total	3,718,186	\$	1.78	9,003,196

- Includes 558,896 stock options, 176,660 deferred shares of restricted stock, 1,609,964 restricted stock units, and 1,372,666 deferred restricted stock units.
- (2) Restricted Stock Units are not included in calculation of weighted-average exercise price, as they do not have an exercise price.
- (3) Includes 8,003,399 shares available in the Fortress Biotech, Inc. 2013 Stock Incentive Plan and 999,797 shares under the Coronado Biosciences, Inc. 2012 Employee Stock Purchase Plan.

## Stock Ownership of Our Directors, Executive Officers, and 5% Beneficial Owners

The following table shows information, as of March 27, 2025, concerning the beneficial ownership of our common stock by:

- each person we know to be the beneficial owner of more than 5% of our common stock;
- each of our current directors;
- each of our Named Executive Officers ("NEOs"); and
- all current directors and NEOs as a group.

As of March 27, 2025, there were 29,533,840 shares of our common stock outstanding. In order to calculate a specific stockholder's percentage of beneficial ownership, we include in that stockholder's calculation those shares underlying options, warrants, or restricted stock units beneficially owned by that stockholder that are vested or that will vest within 60 days of the Record Date. Shares of restricted stock are deemed to be outstanding. Options, warrants, or restricted stock units held by other stockholders that are not attributed to the named beneficial owner are disregarded in this calculation. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the shares of our common stock. Unless we have indicated otherwise, each person named in the table below has sole voting power and investment power for the shares listed opposite such person's name, except to the extent authority is shared by spouses under community property laws.

	Shares of Common Stock	Shares Under Exercisable Options, Warrants and Restricted Stock	Total Shares Beneficially	Percentage Beneficially
Name of Beneficial Owner	Owned	Units(1)	Owned	Owned
Lindsay A. Rosenwald, M.D. <sup>(2)</sup>	4,111,417	2,332,840	6,444,257	20.2 %
Michael S. Weiss <sup>(3)</sup>	1,801,138	147,058	1,948,196	6.6 %
J. Jay Lobell	165,075	1,666	166,741	* %
David Jin	10,893	164,375	175,268	* %
Jimmie Harvey, Jr., M.D.	3,339	61,660	64,999	* %
Dov Klein, CPA	27,438	47,987	75,425	* %
Malcolm Hoenlein	42,750	29,997	72,747	* %
Kevin L. Lorenz, J.D.	73,687	_	73,687	* %
Lucy Lu, M.D.	5,224	3,333	8,557	* %
All current executive officers (including NEOs) and directors as a group (9 persons)	6,240,961	2,788,916	9,029,877	27.9 %

Less than 1%

### Item 13. Certain Relationships and Related Transactions, and Director Independence

### **Related-Person Transactions**

Since January 1, 2024, the Company has not been a party to any transaction in which the amount involved exceeded or will exceed \$120,000, and in which any of its directors, named executive officers or beneficial owners of more than 5% of the Company's capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than as set forth below and other than compensation, termination, and change-in-control arrangements, all of which are described under — "Item 11. Executive Compensation" above.

The written charter of the Audit Committee authorizes, and the Nasdaq Stock Market listing rules require, the Audit Committee to review and approve related-party transactions. In reviewing related-party transactions, the Audit Committee applies the basic standard that transactions with affiliates should be made on terms no less favorable to the Company than could have been obtained from unaffiliated parties. Therefore, the Audit Committee reviews the benefits of the transactions, terms of the transactions and the terms available from unrelated third parties, as applicable. All transactions other than compensatory arrangements between the Company and its officers, directors, principal stockholders and their affiliates will be approved by the Audit Committee or a majority of the disinterested directors, and will continue to be on terms no less favorable to the Company than could be obtained from unaffiliated third parties.

<sup>(1)</sup> Includes options exercisable and restricted stock units vesting within 60 days of March 27, 2025.

<sup>(2)</sup> Includes 4,050,495 shares held directly by Dr. Rosenwald, 11,398 shares held by Capretti Grandi LLC, and 49,524 shares held by PAB Merger LLC and 1,567,515 shares underlying warrants that are currently exercisable. Dr. Rosenwald has voting and dispositive control over the shares held by Capretti Grandi LLC and PAB Merger LLC. Does not include 96,919 shares of common stock held by trusts established for the benefit of Dr. Rosenwald's family, over which Dr. Rosenwald does not have any voting or dispositive control. Includes 2,332,840 shares underlying warrants that are currently exercisable

<sup>(3)</sup> Includes 147,058 shares underlying warrants that are currently exercisable.

<sup>(4)</sup> Includes 164,375 deferred restricted stock units.

#### Other Related Parties

The Company's Chairman, President and Chief Executive Officer, individually and through certain trusts over which he has voting and dispositive control, beneficially owned approximately 21.5% and 17.2% of the Company's issued and outstanding Common Stock as of December 31, 2024 and 2023, respectively. The Company's Executive Vice Chairman, Strategic Development individually owned approximately 5.4% and 7.5% of the Company's issued and outstanding Common Stock at December 31, 2024 and 2023, respectively.

### **Avenue September 2023 Private Placement**

In September 2023, Avenue entered into an arrangement with Fortress and Dr. Rosenwald, the Company's Chairman, President and Chief Executive Officer and a director on the board of directors of Avenue, pursuant to which Avenue agreed to issue and sell 767,085 shares of Avenue's common stock, par value \$0.0001 per share, for an aggregate purchase price of approximately \$550,000 in a private placement transaction, in compliance with Nasdaq Listing Rule 5365(c).

# Employment Arrangements with Immediate Family Members of Our Executive Officers and Directors

Joshua Rosenwald, son of Dr. Lindsay Rosenwald, our Chairman, President and Chief Executive Officer, was employed by Fortress as a Director of Strategy to work on corporate strategy matters. During the year ended December 31, 2023, Mr. Joshua Rosenwald received total compensation of approximately \$160,000 and left the Company in November 2023 to pursue other opportunities.

### Shared Services Agreement with 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 the Executive Chairman and Interim Chief Executive Officer of TGTX. Under the terms of the agreement, TGTX will reimburse the Company for the salary and benefit costs associated with these employees based upon actual hours worked on TGTX related projects. In connection with the shared services agreement, the Company invoiced TGTX \$0.9 million and \$0.4 million, and received payments of \$0.9 million and \$0.4 million for the years ended December 31, 2024 and 2023, respectively. At December 31, 2024, there was approximately \$36,000 due from TGTX related to this arrangement.

## Desk Share Agreement with TGTX

The desk share agreement between the Company and TGTX (the "Desk Share Agreement"), as amended, requires TGTX to pay 65% of the average annual rent of 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 for the New York, NY office space, for the years ended December 31, 2024 and 2023, the Company paid \$2.9 million and \$2.8 million in rent, respectively, and invoiced TGTX approximately \$1.7 million and \$1.8 million respectively, for its prorated share of the rent base. At December 31, 2023, there were no amounts due from TGTX related to this arrangement.

# **Shared Services Agreement with Journey**

In November 2021, Journey and the Company entered into an arrangement to share the cost of certain legal, finance, regulatory, and research and development employees. The Company's Executive Chairman and Chief Executive Officer is the Executive Chairman of Journey. Under the terms of the arrangement, Journey began reimbursing the Company for the salary and benefit costs associated with these employees based upon actual hours worked on Journey related projects following the completion of their initial public offering in November 2021. In addition, Journey reimburses the Company for various payroll-related costs and selling, general and administrative costs incurred by Fortress for the benefit of Journey. For the years ended December 31, 2024 and 2023, the Company's employees have provided services to Journey totaling approximately \$38,000 and \$0.1 million, respectively. At December 31, 2024, approximately \$0.6 million is due from Journey, primarily related to reimbursable expenses incurred by Fortress on behalf of Journey.

#### Founders Agreement and Management Services Agreement

The Company has entered into founders agreements (the "Founders Agreements") with each of the Fortress partner companies and subsidiaries listed in the table below. Pursuant to each Founders Agreement, in exchange for the time and capital expended in the formation of each partner company/subsidiary and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, Fortress will loan each such partner company/subsidiary an amount representing the up-front fee required to acquire assets. Each Founders Agreement has a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by the Company or upon a Change in Control (as defined in the Founders Agreement) occurs. In connection with each Founders Agreement the Company received a number of either Class A Preferred shares or Class A Common Stock.

The Class A Preferred Stock or Class A Common Stock (such stock, the "Founders Stock") is identical to common stock other than as to voting rights, conversion rights and the Payment-in-Kind ("PIK") Dividend right (as described below). Each share of Founders Stock is entitled to vote the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the shares of outstanding common stock and (B) the whole shares of common stock into which the shares of outstanding Founders Stock are convertible and the denominator of which is the number of shares of outstanding Founders Stock. Thus, the Founders Stock will at all times constitute a voting majority. Each share of Founders Stock is convertible, at the holder's option, into one fully paid and nonassessable share of common stock of such partner company/subsidiary, subject to certain adjustments.

The holders of Founders Stock, as a class, are entitled receive on each effective date or "Trigger Date" (defined as the date that the Company first acquired, whether by license or otherwise, ownership rights to a product) of each agreement (each a "PIK Dividend Payment Date") and on each anniversary date of such date until the date all outstanding Founders Stock is converted into common stock or redeemed (and the purchase price is paid in full), pro rata per share dividends paid in additional fully paid and nonassessable shares of common stock ("PIK Dividends") such that the aggregate number of shares of common stock issued pursuant to such PIK Dividend is equal to two and one-half percent (2.5%) of such partner company or subsidiary's fully-diluted outstanding capitalization on the date that is one (1) business day prior to any PIK Dividend Payment Date. The Company has reached agreements with several of the partner companies and subsidiaries to change the PIK Dividend Interest Payment Date to January 1 of each year - a change that has not and will not result in the issuance of any additional partner company/subsidiary common stock beyond that amount to which the Company would otherwise be entitled absent such change(s). The Company owns 100% of the Founders Stock of each partner company/subsidiary that has a Founders Agreement with the Company.

As additional consideration under the Founders Agreement, each partner company and subsidiary with which the Company has entered into a Founders Agreement will also: (i) pay an equity fee in shares of the common stock of such partner company/subsidiary, payable within five (5) business days of the closing of any equity or debt financing for each partner company/subsidiary or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when the Company no longer has majority voting control in such partner company or subsidiary's voting equity, equal to two and one-half (2.5%) of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to four and one-half percent (4.5%) of such partner company or subsidiary's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a Change in Control, each such partner company/subsidiary will pay a one-time change in control fee equal to five (5x) times the product of (A) net sales for the twelve (12) months immediately preceding the change in control and (B) four and one-half percent (4.5%). In the case of Urica, however, the obligation to pay Fortress royalties under the Founders Agreement survives any such Change in Control.

The following table summarizes, by subsidiary, the effective date of the Founders Agreements and PIK dividend or equity fee payable to the Company in accordance with the terms of the Founders Agreements, exchange agreements (the "Exchange Agreements") and the partner companies'/subsidiaries' certificates of incorporation.

		a % of fully diluted outstanding	Class of Stock
Partner Company/Subsidiary	Effective Date 1	capitalization	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 <sup>3</sup>	2.5 %	Common Stock
Urica	November 7, 2017 <sup>3</sup>	2.5 %	Common Stock

PIK Dividend as

- (1) Represents the effective date of each subsidiary's Founders Agreement. Each PIK dividend and equity fee is payable on the annual anniversary of the effective date of the original Founders Agreement or has since been amended to January 1 of each calendar year.
- (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. Under the support agreement signed by the Company in connection with Checkpoint's pending merger with Sun Pharma, the Company 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 under the Founders Agreement.
- (3) Represents the Trigger Date, the date that the Fortress partner company first acquires, whether by license or otherwise, ownership rights in a product.

# **Equity Fees and PIK Dividends**

The following table summarizes, by subsidiary, the value of the PIK dividend or equity fee recorded by the Company in accordance with the terms of the Founders Agreements, Exchange Agreements and the partner companies'/subsidiaries' certificates of incorporation for the years ended December 31, 2024 and 2023 (\$ in thousands):

	PIK Dividend	Year Ended December 31,		
Partner company	Date	 2024		2023
Avenue	January 1	410		444
Cellvation	October 31	10		10
Checkpoint	January 1	8,633		4,370
Cyprium	January 1	291		304
Helocyte	January 1	39		120
Mustang	January 1	940		591
Oncogenuity	May 8	9		9
Urica	November 25	514		502
Fortress		(10,846)		(6,350)
Total		\$ _	\$	

#### **Management Services Agreements**

The Company has entered into Management Services Agreements (the "MSAs") with certain of its partner companies and subsidiaries. Pursuant to each MSA, the Company's management and personnel provide advisory, consulting and strategic services to each partner company/subsidiary that has entered into an MSA with Fortress for a period of five years (with such term automatically extending for additional five-year periods unless terminated by Fortress or the applicable partner company/subsidiary at least 90 days prior to any such initial or additional term). Such services may include, without limitation, (i) advice and assistance concerning any and all aspects of each such company's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of each such company with accountants, attorneys, financial advisors and other professionals. Each such partner company/subsidiary is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, such companies are not obligated to take or act upon any advice rendered from Fortress, and Fortress shall not be liable to any such partner company/subsidiary for its actions or inactions based upon Fortress' advice. Fortress and its affiliates, including all members of Fortress' Board of Directors, have been contractually exempted from fiduciary duties to each such partner company/subsidiary relating to corporate opportunities.

The following table summarizes, by partner company/subsidiary, the effective date of the MSA and the annual consulting fee payable by the partner company/subsidiary to Fortress in quarterly installments (\$ in thousands):

		Year Ended Decer	nber 31,
Partner Company/Subsidiary	Effective Date	2024	2023
Avenue <sup>1</sup>	February 17, 2015	250	500
Cellvation	October 31, 2016	500	500
Checkpoint	March 17, 2015	500	500
Cyprium	March 13, 2017	500	500
Helocyte	March 20, 2015	500	500
Mustang	March 13, 2015	500	500
Oncogenuity	February 10, 2017	500	500
Urica	November 7, 2017	500	500
Fortress		(3,750)	(4,000)
Consolidated (Income)/Expense	\$	<u> </u>	_

(1) On November 13, 2024, the Company entered into a Subscription and Forgiveness Agreement with Avenue, whereby the Company agreed to convert 50% of a total of \$0.5 million owed by Avenue under the MSA into newly issued common stock of Avenue and forgive the remaining 50% of the accrued balance. Therefore, Avenue issued a total of 122,850 shares to the Company based on the closing price of \$2.035 on the day prior to the execution of the agreement.

# 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.

# Item 14. Principal Accounting Fees and Services

During the year ended December 31, 2024, KPMG LLP audited the consolidated financial statements of the Registrant and its subsidiaries.

#### **Audit Fees**

For the fiscal year ended December 31, 2024 we were billed approximately \$3,785,420 by KPMG in fees for the professional services rendered in connection with the audits of our annual financial statements included in our Annual Report on Form 10-K for the 2024 fiscal year, the review of our financial statements included in our Quarterly Reports on Form 10-Q for 2024, and other services provided in connection with registration statements. In 2024, included in these fees for KPMG is \$2,756,520 related to stand-alone audits and filings of certain of the Company's partner companies and subsidiaries.

For the fiscal year ended December 31, 2023 we were billed approximately \$3,292,500 by KPMG in fees for the professional services rendered in connection with the audits of our annual financial statements included in our Annual Report on Form 10-K for the 2023 fiscal year, the review of our financial statements included in our Quarterly Reports on Form 10-Q for 2023, and other services provided in connection with registration statements. In 2023, included in these fees for KPMG is \$2,405,500 related to stand-alone audits and filings of certain of the Company's partner companies and subsidiaries.

## **Audit-Related Fees**

During the fiscal years ended December 31, 2024 and 2023, we incurred no costs from KPMG for audit-related services reasonably related to the performance of the audits and reviews for the respective fiscal years.

#### Tax Fees

During the fiscal years ended December 31, 2024 and 2023 we were billed approximately \$55,229 and \$65,916, respectively, from KPMG for fees for professional services rendered for tax compliance, tax advice, and tax planning services for certain of the Company's partner companies.

## All Other Fees

During the fiscal years ended December 31, 2024 and 2023 we incurred no costs from KPMG for other accounting fees not related directly to the audit for the respective fiscal years. During the fiscal year ended December 31, 2024, certain of the Company's partner companies and subsidiaries incurred \$25,000 from BDO for other accounting fees not directly related to the audit for the respective fiscal year.

#### **Pre-Approval of Services**

Our Audit Committee has established a policy setting forth the procedures under which services provided by our independent registered public accounting firm will be pre-approved by our Audit Committee. The potential services that might be provided by our independent registered public accounting firm fall into two categories:

- Services that are permitted, including the audit of our annual financial statements, the review of our quarterly financial statements, comfort letters, related attestations, benefit plan audits and similar audit reports, financial and other due diligence on acquisitions, and federal, state, and non-US tax services;
- Services that may be permitted, subject to individual pre-approval, including compliance and internal-control reviews, indirect tax services such as transfer pricing and customs and duties, and forensic auditing; and
- Services that our independent registered public accounting firm may not provide include such services as bookkeeping, certain human resources services, internal audit outsourcing, and investment or investment banking advice.

All proposed engagements of our independent registered public accounting firm, whether for audit services or permissible non-audit services, are pre-approved by the Audit Committee. We jointly prepare a schedule with our independent registered public accounting firm that outlines services which we reasonably expect we will need from our independent

registered public accounting firm and categorize them according to the classifications described above. Each service identified is reviewed and approved or rejected by the Audit Committee.

# PART IV

# Item 15. Exhibits and Financial Statement Schedules.

# (a) Financial Statements.

The following financial statements are filed as part of this report:

Report of Independent Registered Public Accounting Firm (KPMG LLP, New York, NY; PCAOB No.: 185)	F-2
Consolidated Balance Sheets	F-4
Consolidated Statements of Operations	F-5
Consolidated Statements of Changes in Stockholders' Equity	F-6
Consolidated Statements of Cash Flows	F-8
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# (b) Exhibits.

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 to 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 to Amended and Restated Certificate of Incorporation, as amended, of Fortress Biotech, Inc. dated October 1, 2013 (incorporated by reference to Exhibit 3.8 of the Registrant's Annual Report on Form 10-K (file No. 001-35366) filed with the SEC on March 14, 2014).
<u>3.4</u>	Third Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended, 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 the SEC on April 27, 2015).
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated June 18, 2020 (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on June 19, 2020).
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated June 23, 2021 (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on June 23, 2021).
3.7	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated July 8, 2022, (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on July 11, 2022).
3.8	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated October 9, 2023 (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on October 10, 2023).
<u>3.9</u>	Fourth Amended and Restated Bylaws of the Registrant (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 25, 2024.
<u>4.1</u>	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Form 10 (file No. 000-54463) filed with the SEC on July 15, 2011).
4.2	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).
4.3	Certificate of Amendment to the Certificate of Designations of 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).
<u>4.4</u>	Description of Securities of Fortress Biotech, Inc.*
<u>4.5</u>	Form of Amended and Restated Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on June 16, 2023).
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Exhibit Number	Exhibit Title
<u>4.6</u>	Form of Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on November 14, 2023).
<u>4.7</u>	Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on January 3, 2024).
4.8	Form of Warrant issued to certain affiliates of Oaktree Fund Administration, LLC on July 25, 2024 (incorporated by reference to Exhibit 4.8 of the Registrant's Registration Statement on Form S-1 (Reg. No. 33-282384) filed with the SEC on September 27, 2024).
<u>4.9</u>	Form of PIPE Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on September 23, 2024).
<u>10.1</u>	Amended and Restated Consulting Agreement, entered into as of January 1, 2019, by and between the Registrant and Eric Rowinsky (incorporated by reference to Exhibit 10.3 of the Registrant's Annual Report on Form 10-K (file No. 001-35366) filed with the SEC on March 18, 2019).#
10.2	Form of Indemnification Agreement by and between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.25 of the Registrant's Form 10 (file No. 000-54463) filed with the SEC on August 24, 2011).#
10.3	Restricted Stock Issuance Agreement, dated as of February 20, 2014, by and between the Registrant and Michael S. Weiss (incorporated by reference to Exhibit 10.55 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on February 26, 2014).#
10.4	Restricted Stock Issuance Agreement, dated as of December 19, 2013, by and between the Registrant and Michael S. Weiss (incorporated by reference to Exhibit 10.57 of the Registrant's Annual Report on Form 10-K (file No. 001-35366) filed with the SEC on March 14, 2014). #
10.5	Restricted Stock Issuance Agreement, dated as of December 19, 2013, by and between the Registrant and Lindsay A.  Rosenwald, M.D. (incorporated by reference to Exhibit 10.58 of the Registrant's Annual Report on Form 10-K (file No. 001-35366) filed with the SEC on March 14, 2014).
<u>10.6</u>	Coronado Biosciences, Inc. Deferred Compensation Plan for Directors, dated March 12, 2015 (incorporated by reference to Exhibit 10.67 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on March 18, 2015),#
<u>10.7</u>	Coronado Biosciences, Inc. 2012 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.38 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on June 12, 2017).#
<u>10.8</u>	Amendment to Coronado Biosciences, Inc. 2012 Employee Stock Purchase Plan (incorporated by reference to Exhibit A of the Registrant's Schedule 14A (file No. 001-35366) filed with the SEC on April 30, 2018).#
10.9	Amendment to the Coronado Biosciences, Inc. 2012 Employee Stock Purchase Plan (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 June 23, 2023).#
<u>10.10</u>	Amendment to the Coronado Biosciences, Inc. 2012 Employee Stock Purchase Plan (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 May 29, 2024).#

Exhibit Number	Exhibit Title
10.11	Fortress Biotech, Inc. Amended and Restated Long-Term Incentive Plan (incorporated by reference to Exhibit 10.39 of the
	Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on June 12, 2017).#
10.12	Amendment to the Fortress Biotech, Inc. Amended and Restated Long Term Incentive Plan (incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on May 29, 2024).#
10.13	Fortress Biotech, Inc. 2013 Stock Incentive Plan, as amended (incorporated by reference to Appendix A of the Registrant's Schedule 14-A (file No. 001-35366) filed with the SEC on June 4, 2015).#
<u>10.14</u>	Form of Stock Incentive Plan Award Agreement (Fortress Biotech, Inc. 2013 Stock Incentive Plan) (incorporated by reference to Exhibit 10.60 of the Registrant's Form S-8 (file No. 333-194588) filed with the SEC on March 14, 2014).#
10.15	Amendment to the Fortress Biotech, Inc. 2013 Stock Incentive Plan (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 June 19, 2020).#
<u>10.16</u>	Amendment to the Fortress Biotech, Inc. 2013 Stock Incentive Plan (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 June 27, 2022).#
<u>10.17</u>	Amendment to the Fortress Biotech, Inc. 2013 Stock Incentive Plan (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 June 23, 2023).#
10.18	Amendment to the Fortress Biotech, Inc. 2013 Stock Incentive Plan (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 May 29, 2024).#
10.19	Restricted Stock Unit Award Agreement between Fortress Biotech, Inc. and David Jin effective October 26, 2022 (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 October 28, 2022).#
10.20	Indemnification Agreement between Fortress Biotech, Inc. and Lucy Lu, M.D. dated as of December 14, 2022 (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 December 19, 2022).#
10.21	At Market Issuance Sales Agreement between the Company and Cantor Fitzgerald & Co., Oppenheimer & Co. Inc., H.C. Wainwright & Co., LLC, B. Riley FBR, Inc., and Dawson James Securities, Inc., dated May 29, 2020 (incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on May 29, 2020).
10.22	Form of Securities Purchase Agreement, dated September 19, 2024, by and among the Company and the purchasers party thereto (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 September 23, 2024).
10.23	Placement Agent Agreement entered into by and between the Company and the Placement Agent, dated September 19, 2024 (incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on September 23, 2024).

Exhibit Number	Exhibit Title
10.24	Credit Agreement entered into by and among Fortress Biotech, Inc., the lenders from time to time party thereto, and
	Oaktree Fund Administration, LLC on July 25, 2024 (incorporated by reference to Exhibit 10.34 to the Registrant's Registration Statement on Form S-1 (Reg. No. 33-282384) filed with the SEC on September 27, 2024).
	Registration Statement on Point 3-1 (Reg. INC. 53-282304) fried with the SEC on September 27, 2024).
<u>10.25</u>	Asset Purchase Agreement, dated as of July 15, 2024, between Urica Therapeutics, Inc. and Crystalys Therapeutics, Inc.
	(incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (file No. 001-35366) filed
	with the SEC on November 14, 2024).***
<u>10.26</u>	Royalty Agreement, dated as of July 15, 2024, between Urica Therapeutics, Inc. and Crystalys Therapeutics, Inc.
	(incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q (file No. 001-35366) filed
	with the SEC on November 14, 2024).***
19.1	Fortress Biotech, Inc. and Subsidiaries Insider Trading Policy.*
<u>21.1</u>	Subsidiaries of the Registrant.*
23.1	Consent Independent Registered Accounting Firm (KPMG LLP, Short Hills, NJ). *
	<u></u>
<u>31.1</u>	Certification of Chairman, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of
	<u>2002.*</u>
31.2	Certification of the of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
	· · · · · · · · · · · · · · · · · · ·
<u>32.1</u>	Certification of 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.**
	to Section 900 of the Sardanes-Oxiey Act of 2002.
<u>32.2</u>	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.**
97.1	Clawback Policy of Fortress Biotech, Inc. (incorporated by reference to Exhibit 97.1 of the Registrant's Annual Report on
<u> </u>	Form 10-K (file No. 001-35366) filed with the Sec on March 28, 2024).
101 P/G	A U. Albay A
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).*

<sup>#</sup> Management contract or compensatory plan.

<sup>\*</sup> Filed herewith.

<sup>\*\*</sup>Furnished herewith.

\*\*\*Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K.

# Item 16. Form 10-K Summary

None.

# FORTRESS BIOTECH, INC. AND SUBSIDIARIES CONSOLIDATED FINANCIAL STATEMENTS

# Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm (KPMG LLP, New York, NY; PCAOB No.: 185)	F-2
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## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors Fortress Biotech, Inc.:

# 1 Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Fortress Biotech, Inc. and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

## Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

## Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which it relates.

Sufficiency of audit evidence over the classification of warrants issued

As discussed in Notes 2, 9 and 13 to the consolidated financial statements, the Company issued warrants in 2024 in connection with certain equity offerings, private placements, and the New Oaktree Agreement (the 2024 warrants). These warrants were equity-classified and recorded as a component of additional paid-in capital at the time of issuance. As of December 31, 2024, the Company has \$763.6 million of additional paid-in capital.

We identified the evaluation of the sufficiency of audit evidence over the classification of the 2024 warrants as a critical audit matter. Evaluating the sufficiency of audit evidence obtained required especially subjective auditor judgement because of the volume of the 2024 warrants issued by the Company and certain of its partner companies. This included determining the 2024 warrants on which procedures were performed and the supervision and review of those procedures.

The following are the primary procedures we performed to address this critical audit matter. We applied auditor judgment to determine the nature and extent of procedures to be performed over the classification of the 2024 warrants, including the determination of the 2024 warrants issued by the Company and certain of its partner companies on which procedures were to be performed. For a selection of the 2024 warrants, we evaluated the terms and conditions of the warrant agreements and assessed the appropriateness of management's interpretation and application of the relevant accounting literature. We assessed the sufficiency of audit evidence obtained related to the classification of the 2024 warrants by assessing the results of procedures performed, including the appropriateness of the nature and extent of such evidence.

/s/ KPMG LLP

We have served as the Company's auditor since 2021.

New York, New York March 31, 2025

# FORTRESS BIOTECH, INC. AND SUBSIDIARIES

# **Consolidated Balance Sheets**

(\$ in thousands except for share and per share amounts)

		nber 31, 024	December 31, 2023		
ASSETS					
Current assets					
Cash and cash equivalents	\$	57,263	\$	80,927	
Accounts receivable, net		10,231		15,222	
Inventory		14,431		10,206	
Other receivables - related party		171		167	
Prepaid expenses and other current assets		7,110		10,500	
Assets held for sale		1,165		_	
Total current assets		90,371		117,022	
Property, plant and equipment, net		3,260		6,505	
Operating lease right-of-use asset, net		13,861		16,990	
Restricted cash		1,552		2,438	
Intangible assets, net		31,863		20,287	
Other assets		3,316		4,284	
Total assets	S	144,223	\$	167,526	
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)					
Current liabilities					
Accounts payable and accrued expenses	\$	65,501	S	73,562	
Income taxes payable		932	_	843	
Common stock warrant liabilities		214		886	
Operating lease liabilities, short-term		2.623		2.523	
Partner company convertible preferred shares, short-term, net		2,023		3,931	
Partner company installment payments - licenses, short-term		625		3,000	
Other current liabilities		1,504		163	
Total current liabilities		71,399		84,908	
rotal current naomices		71,377		04,700	
Notes payable, long-term, net		57,962		60,856	
Operating lease liabilities, long-term		14,750		18,282	
Other long-term liabilities		1,756		1,893	
Total liabilities		145,867		165,939	
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 December 31, 2024 and December 31, 2023, respectively, liquidation value of \$25.00 per share		3		3	
Common stock, \$0.001 par value, 200,000,000 shares authorized, 27,908,839 and 15,093,053 shares issued		3		,	
and outstanding as of December 31, 2024 and December 31, 2023, respectively		28		15	
Additional paid-in-capital Accumulated deficit		763,573 (740,867)		717,396 (694,870)	
Total stockholders' equity attributed to the Company		22.737	_	22.544	
1 /		,		,-	
Non-controlling interests  Total steakholders' aguity (deficit)		(24,381)		(20,957)	
Total stockholders' equity (deficit)  Total liabilities and stockholders' equity (deficit)	S	(1,644) <b>144,223</b>	S	1,587 <b>167,526</b>	
and stockholders equity (deficit)	9	177,223	9	107,320	

# FORTRESS BIOTECH, INC. AND SUBSIDIARIES

# Consolidated Statements of Operations (\$ in thousands except for share and per share amounts)

		Year Ended Dec	ember 31,	
		2024		2023
Revenue				
Product revenue, net	\$	55,134	\$	59,662
Collaboration revenue		1,500		5,229
Revenue - related party		41		103
Other revenue		1,000		19,519
Net revenue		57,675		84,513
Operating expenses				
Cost of goods - (excluding amortization of acquired intangible assets)		20,879		22,893
Amortization of acquired intangible assets		3,424		3,767
Research and development		56,629		101,747
Research and development - licenses acquired		252		4,324
Selling, general and administrative		87,731		90,981
Loss recovery		(4,553)		70,701
Asset impairment		3,692		3,143
Total operating expenses		168,054		226,855
Loss from operations		(110,379)		
Loss from operations		(110,379)		(142,342)
Other income (expense)				
Interest income		2,683		3,003
Interest expense and financing fee		(13,527)		(15,315)
Gain (loss) on common stock warrant liabilities		(638)		4,424
Other income (expense)		1,318		(3,403)
Total other income (expense)		(10,164)		(11,291)
Loss before income tax expense		(120,543)		(153,633)
Income tax expense		312		521
Net loss		(120,855)		(154,154)
		(120,000)	_	(10 1,10 1)
Net loss attributable to non-controlling interests		74,858		93,517
Net loss attributable to Fortress		(45,997)	\$	(60,637)
Descend A divided desland and and 1/				
Preferred A dividends declared and paid and/or cumulated, and Fortress' share		(0.902)		(8,032)
of subsidiary deemed dividends	Φ.	(9,893)	Ф	( ) /
Net loss attributable to common stockholders	\$	(55,890)	\$	(68,669)
Net loss per common share attributable to common stockholders - basic and				
diluted	\$	(2.69)	\$	(8.47)
Weighted average common shares outstanding - basic and diluted		20,784,334		8,110,906
		,,		-,,-

# FORTRESS BIOTECH, INC. AND SUBSIDIARIES Consolidated Statements of Changes in Stockholders' Equity

(\$ in thousands except for share and per share amounts)

# For the Year Ended December 31, 2024

	Series A Pre	ferred Stock	Comm	on Stock	Common Shares		Additional Paid-In	Accum	ulated	Non-Controll	ina	Total kholders'
(\$ in thousands except for share amounts)		Shares		Shares Amount			Capital	Def		Interests	5	quity
Balance at December 31, 2023	3,427,138	\$ 3	15,093,053	\$ 15	<u>s</u> –	- \$	717,396	\$ (69	94,870)	\$ (20,9	57)	\$ 1,587
Stock-based compensation expense	_	_	_	_	-	_	32,619		_		_	32,619
Issuance of common stock related to equity plans	_	_	582,323	1	-	_	(1)		_		_	_
Issuance of common stock under ESPP	_	_	69,482	_	-	_	99		_		_	99
Issuance of stock for equity offerings, net	_	_	8,006,058	8	_	_	17,396		_		_	17,404
Warrant issued in conjunction with debt							1,104					1,104
Issuance of common stock for at-the-market offering, net	_	_	1,957,331	2	_	_	3,732		_		_	3,734
Common shares issued for dividend on partner company's convertible preferred shares			64,747				114					114
Common shares issued for exchange of partner company's		_	04,747		_	_	114					114
convertible preferred shares	_	_	2,028,345	2	-	_	3,406		_		_	3,408
Warrants issued in conjunction with exchange of partner company's convertible preferred shares							341					341
Preferred A dividends declared and paid							(4,016)					(4,016)
Partner companies' offerings, net		_	_		_		28,852		_			28,852
Partner companies' at-the-market offering, net	_	_			_	_	12,037					12,037
Issuance of common stock under partner company's ESPP	_		_	_	_		257					257
Partner company's dividends declared and paid	_	_	_		_	_	(694)					(694)
Exercise of warrants for cash			107,500	_		_	181					181
Exercise of partner company options and warrants for cash,			107,500		_		101					101
net	_	_	_	_	_	_	22,184		_		_	22,184
Non-controlling interest in subsidiaries	_	_	_	_	_	_	(71,434)		_	71,4	34	
Net loss attributable to non-controlling interest	_	_	_	_	-	_			_	(74,8		(74,858)
Net loss attributable to common stockholders								(4	45,997)			(45,997)
Balance at December 31, 2024	3,427,138	\$ 3	27,908,839	s 28	\$ -	_ s	763,573	\$ (74	40,867)	\$ (24,3	81)	\$ (1,644)

# FORTRESS BIOTECH, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity (\$ in thousands except for share and per share amounts)

# For the Year Ended December 31, 2023

	Series A Pre	ferred Stoo	:k	Comm	on Stock		Common Shares	Additional Paid-In	Accumulated	Non-Controlling		Fotal kholders'
(\$ in thousands except for share amounts)	Sh	ares		Shares	Amount	1	Issuable	Capital	Deficit	Interests	E	quity
Balance at December 31, 2022	3,427,138	\$	3	7,366,283	\$ 7	\$		\$ 675,944	\$ (634,233)	\$ 8,304	\$	50,025
Stock-based compensation expense	_		_	_	_		_	17,029	_	_		17,029
Issuance of common stock related to equity plans	_		_	224,690	_		_	_	_	_		_
Issuance of stock for public offerings, net	_		_	6,994,526	7		_	22,078	_	_		22,085
Issuance of common stock for at-the-market offering, net	_		_	224,003	_		_	2,041	_	_		2,041
Warrant charge in conjunction with Oaktree debt								272				272
Common shares issued for dividend on partner company's												
convertible preferred shares	_		_	58,551	_		_	266	_	_		266
Payment of Series A perpetual preferred stock dividends	_		_	_	_		_	(8,032)	_	_		(8,032)
Exercise of warrants for cash	_		_	225,000	1		_	382	_	_		383
Partner companies' proceeds from stock and warrants, net	_		_		_		_	59,956	_	_		59,956
Partner companies' at-the-market offering, net	_		_	_	_		_	4,620	_	_		4,620
Partner company's exercise of options for cash	_		_	_	_		_	121	_	_		121
Issuance of common stock under partner company's ESPP	_		_	_	_		_	178	_	_		178
Partner company's dividends declared and paid	_		_	_	_		_	(736)	_	_		(736)
Partner company's redemption of preferred shares	_		_	_	_		_	(400)	_	_		(400)
Issuance of partner company's common shares for research								` ′				
and development expenses	_		_	_	_		_	1,240	_	_		1,240
Deconsolidation/dissolution of partner companies	_		_	_	_		_	_	_	6,693		6,693
Non-controlling interest in subsidiaries	_		_	_	_		_	(57,563)	_	57,563		_
Net loss attributable to non-controlling interest	_		_	_	_		_	_	_	(93,517)		(93,517)
Net loss attributable to common stockholders									(60,637)			(60,637)
Balance at December 31, 2023	3,427,138	\$	3	15,093,053	\$ 15	\$		\$ 717,396	\$ (694,870)	\$ (20,957)	\$	1,587

# FORTRESS BIOTECH, INC. AND SUBSIDIARIES Consolidated Statements of Cash Flows (\$\sin \text{thousands})

	Year Ended December 31, 2024 2023			
Cash Flows from Operating Activities:				
Net loss	\$	(120,855)	\$	(154,154)
Reconciliation of net loss to net cash used in operating activities:				
Depreciation expense		1,040		2,230
Loss on disposal of property and equipment		29		(1,466)
Bad debt expense		516		435
Amortization of debt discount		2,054		3,032
Accretion of partner company convertible preferred shares		(737)		757
Non-cash interest		_		353
Loss on extinguishment of debt		2,457		2,796
Amortization of acquired intangible assets		3,424		3,767
Reduction in the carrying amount of operating lease right-of-use assets		2,846		2,078
Stock-based compensation expense		32,619		17,029
Issuance of partner company's common shares for research and development expenses		_		1,240
Common shares issued for dividend on partner company's convertible preferred shares		114		266
Change in fair value of partner companies' warrant liabilities		487		(4,424)
Research and development - licenses acquired, expense		250		3,085
Loss from deconsolidation/dissolution of subsidiaries		_		4,127
Asset impairment loss		3,692		3,143
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and				
liabilities:				
Accounts receivable		4,475		12,551
Inventory		(4,225)		3,953
Other receivables - related party		(4)		(29)
Prepaid expenses and other current assets		(624)		(848)
Other assets		968		(808)
Accounts payable and accrued expenses		(6,390)		(24,382)
Income taxes payable		89		121
Lease liabilities		(3,620)		(2,291)
Other long-term liabilities		1,204		(786)
Net cash used in operating activities		(80,191)		(128,225)
Cash Flows from Investing Activities:				
Acquired intangible assets		(15,000)		(5,000)
Purchase of property and equipment				(63)
Proceeds from sale of property and equipment		_		6,000
Other		_		(5)
Purchase of research and development licenses		_		(3,035)
Net cash used in investing activities		(15,000)		(2,103)
	-	· · ·		

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

Cash Flows from Financing Activities:         2024         2023           Payment of Series A perpetual preferred stock dividends         \$ (4,016)         \$ (8,032)           Proceeds from issuance of common stock for equity offerings, net         17,404         22,078           Proceeds from issuance of common stock under ESPP         101         —           Exercise of warrants for cash         181         382           Proceeds from partner companies' ESPP         257         178           Partner company's dividends declared and paid         (694)         (736)           Partner company's redemption of preferred shares         —         (400)           Proceeds from partner companies' equity offerings and warrant exercises, net         49,669         51,637           Proceeds from exercise of partner companies' at-the-market offering, net         12,037         4,620           Proceeds from exercise of partner company's options, net         207         121           Repayment of Oaktree Note and debt issuance costs         (51,000)         —           Repayment of partner company installment payments - licenses         (1,250)         (1,000)           Proceeds from partner company convertible preferred shares         —         854           Stock and warrants issued for exchange of partner company preferred shares         —         (210)
Proceeds from issuance of common stock for equity offerings, net         17,404         22,078           Proceeds from issuance of common stock for at-the-market offering, net         3,734         2,041           Proceeds from issuance of common stock under ESPP         101         —           Exercise of warrants for cash         181         382           Proceeds from partner companies' ESPP         257         178           Partner company's dividends declared and paid         (694)         (736)           Partner company's redemption of preferred shares         —         (400)           Proceeds from partner companies' equity offerings and warrant exercises, net         49,669         51,637           Proceeds from partner companies' at-the-market offering, net         12,037         4,620           Proceeds from exercise of partner company's options, net         207         121           Repayment of Oaktree Note and debt issuance costs         (51,000)         —           Repayment of partner company installment payments - licenses         (1,250)         (1,000)           Proceeds from partner company convertible preferred shares         —         854           Stock and warrants issued for exchange of partner company preferred shares         —         (210)           Proceeds from long-term debt, net         33,720         —           <
Proceeds from issuance of common stock for at-the-market offering, net         3,734         2,041           Proceeds from issuance of common stock under ESPP         101         —           Exercise of warrants for cash         181         382           Proceeds from partner companies' ESPP         257         178           Partner company's dividends declared and paid         (694)         (736)           Partner company's redemption of preferred shares         —         (400)           Proceeds from partner companies' equity offerings and warrant exercises, net         49,669         51,637           Proceeds from partner companies' at-the-market offering, net         12,037         4,620           Proceeds from exercise of partner company's options, net         207         121           Repayment of Oaktree Note and debt issuance costs         (51,000)         —           Repayment of partner company installment payments - licenses         (1,250)         (1,000)           Proceeds from partner company convertible preferred shares         —         854           Stock and warrants issued for exchange of partner company preferred shares         —         (210)           Proceeds from long-term debt, net         33,720         —           Proceeds from partner company's long-term debt, net         9,950         14,529           Repayment o
Proceeds from issuance of common stock under ESPP101—Exercise of warrants for cash181382Proceeds from partner companies' ESPP257178Partner company's dividends declared and paid(694)(736)Partner company's redemption of preferred shares—(400)Proceeds from partner companies' equity offerings and warrant exercises, net49,66951,637Proceeds from partner companies' at-the-market offering, net12,0374,620Proceeds from exercise of partner company's options, net207121Repayment of Oaktree Note and debt issuance costs(51,000)—Repayment of partner company installment payments - licenses(1,250)(1,000)Proceeds from partner company convertible preferred shares—854Stock and warrants issued for exchange of partner company preferred shares—4210Proceeds from long-term debt, net33,720—Proceeds from partner company's long-term debt, net9,95014,529Repayment of partner companies' long-term debt—(50,375)
Exercise of warrants for cash         181         382           Proceeds from partner companies' ESPP         257         178           Partner company's dividends declared and paid         (694)         (736)           Partner company's redemption of preferred shares         —         (400)           Proceeds from partner companies' equity offerings and warrant exercises, net         49,669         51,637           Proceeds from partner companies' at-the-market offering, net         12,037         4,620           Proceeds from exercise of partner company's options, net         207         121           Repayment of Oaktree Note and debt issuance costs         (51,000)         —           Repayment of partner company installment payments - licenses         (1,250)         (1,000)           Proceeds from partner company convertible preferred shares         —         854           Stock and warrants issued for exchange of partner company preferred shares         341         —           Payment of debt issuance costs associated with partner company convertible preferred shares         —         (210)           Proceeds from long-term debt, net         33,720         —           Proceeds from partner company's long-term debt, net         9,950         14,529           Repayment of partner companies' long-term debt         —         (50,375)
Proceeds from partner companies' ESPP257178Partner company's dividends declared and paid(694)(736)Partner company's redemption of preferred shares—(400)Proceeds from partner companies' equity offerings and warrant exercises, net49,66951,637Proceeds from partner companies' at-the-market offering, net12,0374,620Proceeds from exercise of partner company's options, net207121Repayment of Oaktree Note and debt issuance costs(51,000)—Repayment of partner company installment payments - licenses(1,250)(1,000)Proceeds from partner company convertible preferred shares—854Stock and warrants issued for exchange of partner company preferred shares341—Payment of debt issuance costs associated with partner company convertible preferred shares—(210)Proceeds from long-term debt, net33,720—Proceeds from partner company's long-term debt, net9,95014,529Repayment of partner companies' long-term debt—(50,375)
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Proceeds from exercise of partner company's options, net207121Repayment of Oaktree Note and debt issuance costs(51,000)—Repayment of partner company installment payments - licenses(1,250)(1,000)Proceeds from partner company convertible preferred shares—854Stock and warrants issued for exchange of partner company preferred shares341—Payment of debt issuance costs associated with partner company convertible preferred shares—(210)Proceeds from long-term debt, net33,720—Proceeds from partner company's long-term debt, net9,95014,529Repayment of partner companies' long-term debt—(50,375)
Repayment of Oaktree Note and debt issuance costs(51,000)—Repayment of partner company installment payments - licenses(1,250)(1,000)Proceeds from partner company convertible preferred shares—854Stock and warrants issued for exchange of partner company preferred shares341—Payment of debt issuance costs associated with partner company convertible preferred shares—(210)Proceeds from long-term debt, net33,720—Proceeds from partner company's long-term debt, net9,95014,529Repayment of partner companies' long-term debt—(50,375)
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Stock and warrants issued for exchange of partner company preferred shares341—Payment of debt issuance costs associated with partner company convertible preferred shares—(210)Proceeds from long-term debt, net33,720—Proceeds from partner company's long-term debt, net9,95014,529Repayment of partner companies' long-term debt—(50,375)
Payment of debt issuance costs associated with partner company convertible preferred shares  Proceeds from long-term debt, net  Proceeds from partner company's long-term debt, net  Repayment of partner companies' long-term debt  (50,375)
Proceeds from long-term debt, net 33,720 — Proceeds from partner company's long-term debt, net 9,950 14,529 Repayment of partner companies' long-term debt — (50,375)
Proceeds from partner company's long-term debt, net 9,950 14,529 Repayment of partner companies' long-term debt – (50,375)
Repayment of partner companies' long-term debt — (50,375)
Proceeds from partner company's line of credit — 28,000
Repayment of partner company's line of credit (30,948)
Net cash (used in) provided by financing activities 70,641 32,739
Net increase (decrease) in cash and cash equivalents and restricted cash (24,550) (97,589)
Cash and cash equivalents and restricted cash at beginning of period 83,365 180,954
Cash and cash equivalents and restricted cash at end of period \$\\\ 58,815 \\\ 83,365
Supplemental disclosure of cash flow information:
Cash paid for interest         \$ 7,159         \$ 7,945
Cash paid (refunded) for income taxes \$ 120 \$ (55)
Supplemental disclosure of non-cash financing and investing activities:
Exchange of partner company convertible preferred shares for common shares \$ 3,408 \$ —
Fair value of assets received by partner company in repurchase transaction \$ 2,209 —
Fair value of supplies received by partner company expensed to research and development \$ 2,509 —
Partner company accounts received by partner company expensed to research and development \$ 2,500 —
Partner company accounts payable write-off related to repurchase transaction \$ 3,644 —
Partner company's deferred purchase consideration \$ (1,295) —
Unpaid partner company's offering cost \$ - \$ 263
Partner company derivative warrant liability associated with partner company convertible preferred shares \$ - \$ 33
Warrants issued in conjunction with debt  \$ 1,104 \$
Unpaid debt offering cost \$ 118 \$ —
Unpaid research and development licenses acquired \$ 250 \$ 50
Lease Liabilities arising from obtaining right-of-use assets \$ 188 \$ 923

# FORTRESS BIOTECH, INC. AND SUBSIDIARIES Notes to the 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 such arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center, Fred Hutchinson Cancer Center, 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 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 agreement as described in Note 9. Current cash and cash equivalents of \$20.9 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 the Company's Annual Report on 10-K. 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 20, grants or other arrangements to develop and prepare regulatory filings and obtain regulatory approvals for the existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for the potential products, sales and marketing capabilities. If such funding is not available or not available on terms acceptable to the Company, the Company's current development plans and plans for expansion of its general and administrative infrastructure may be curtailed. Fortress also has the ability, subject to

limitations imposed by Rule 144 of the Securities Act of 1933 and other applicable laws and regulations, to raise money from the sale of common stock of the public companies in which it has ownership positions.

#### 2. Summary of Significant Accounting Policies

# Basis of Presentation and Principles of Consolidation

The Company's consolidated financial statements have been prepared in conformity with 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.

## Reclassification

Certain prior period amounts have been reclassified to conform to the current period classification. The Company has historically included amortization of acquired intangible assets within cost of goods sold on the consolidated statement of operations. For the years ended December 31, 2024 and 2023, "Costs of goods sold – product revenue" as presented in the consolidated statement of operations was disaggregated into "Costs of goods sold – (excluding amortization of acquired intangible assets)" and "Amortization of acquired intangible assets". This presentation has been conformed for all previous periods presented and has no impact on previously reported financial results.

## Use of Estimates

The preparation of the Company's 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 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.

# Revenue Recognition

The Company records and recognizes revenue in a manner that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company's revenues primarily result from contracts with customers, which are generally short-term and have a single performance obligation – the delivery of product. The Company's performance obligation to deliver products is satisfied at the point in time that the goods are received by the customer, which is when the customer obtains title to and has the risks and rewards of ownership of the products. The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both.

Many of the Company's products sold are subject to a variety of deductions. Revenues are recorded net of provisions for variable consideration, including coupons, chargebacks, wholesaler fees, specialty pharmacy discounts, managed care rebates, product returns, and other deductions customary to the pharmaceutical industry. Accruals for these provisions are presented in the consolidated financial statements as reductions to gross sales in determining net sales and as a contra asset within accounts receivable, net (if settled via credit) and other current liabilities (if paid in cash). Amounts recorded for revenue deductions can result from a series of judgements about future events and uncertainties and can rely on estimates

and assumptions. The following section briefly describes the nature of the Company's provisions for variable consideration and how such provisions are estimated:

Coupons — The Company offers coupons on products for qualified commercially-insured parties with prescription drug co-payments. Such product sales flow through both traditional wholesaler and specialty pharmacy channels. Coupons are processed and redeemed at the time of prescription fulfilment by the pharmacy. The majority of the coupon reserve accrual at the end of the period reflects expected redemptions for product in the distribution channel. The expected accrual reserve requires us to estimate the distribution channel inventory at period end, the expected redemption rates, and the cost per coupon claim that the Company expects to receive. The estimate of product remaining in the distribution channel is comprised of estimated inventory at the wholesaler as well as an estimate at the specialty pharmacies, which the Company estimates based upon historical ordering patterns. The estimated redemption rate is based on historical redemptions as a percentage of units sold. The cost per coupon is based on the coupon rate.

Chargebacks and Government Chargebacks — The Company sells a portion of its products indirectly through wholesaler distributors to contracted indirect customers and qualified government healthcare providers. The Company enters into specific agreements with or provides discounts to these indirect customers and entities to establish pricing for the Company's products, and in turn, the indirect customers and entities independently purchase these products. The Company's provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to the indirect customers and estimated wholesaler inventory levels as well as historical chargeback rates. The Company continually monitors its reserve for chargebacks and adjusts the reserve accordingly when expected chargebacks differ from actual experience.

Wholesaler fees — The Company provides allowances to its wholesale customers for sales order management, data, and distribution services. The Company also pays administrative and other fees to certain wholesale customers consistent with pharmaceutical industry practices. The Company records a provision for these fees based on contracted rates. Assumptions used to establish the provision include contract sales volumes and average contract pricing. The Company regularly reviews the information related to these estimates and adjusts the provision accordingly.

Specialty Pharmacy Discounts — The Company has in place contractual arrangements with specialty pharmacies and provides for contractually agreed upon discounts. These discounts are recorded at the time of sale based on the customer's contracted rate and recorded as a reduction of revenue.

Managed Care Rebates — The Company is subject to rebates in connection with its agreements with certain contracted commercial payers. The Company estimates its managed care rebates based on the Company's estimated payer mix and the applicable contractual rebate rate. The Company's accrual for managed care rebates is based on an estimate of future claims that the Company expects to receive, which considers an estimate for inventory in the distribution channel. The accrual is recognized at the time of sale, resulting in a reduction of gross product revenue.

Product Returns — Consistent with industry practice, the Company offers customers a right to return any unused product. The customer's right of return commences six months prior to product expiration date and ends one year after product expiration date. Products returned for expiration are reimbursed at current wholesale acquisition cost or indirect contract price. The Company estimates the amount of its product sales that may be returned by the Company's customers and accrues this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company estimates products returns as a percentage of sales to its customers.

## Collaboration Revenue

The Company's collaboration revenue includes service revenue, license fees and future contingent milestone-based payments. Collaboration revenue is recognized for contracted R&D services performed for its customers over time. The Company measures its progress using an input method based on the effort expended or costs incurred toward the satisfaction of the Company's performance obligation. The Company estimates the amount of effort to be expended, including the time it will take to complete the activities, or the costs that may be incurred in a given period, relative to the estimated total effort or costs to satisfy the performance obligation. This results in a percentage that is multiplied by the transaction price to determine the amount of revenue the Company recognizes each period subject to the constraint on

variable consideration. This approach requires the use of estimates and judgement. If the Company's estimates or judgements change over the course of the collaboration, they may affect the timing and amount of revenue that is recognized in the current and future periods.

#### Fair Value Measurement

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

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

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

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

Certain of the Company's working capital assets and liabilities, including cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and other current liabilities, are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to their liquid or short-term nature. The carrying value of our 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.

## 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 18 for segment information.

# Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents at December 31, 2024 and 2023, consisted of cash and certificates of deposit in institutions in the United States. The Company maintains its cash and cash equivalent balances with high-quality financial institutions and, consequently, the Company believes that such funds are currently adequately protected against credit risk. At times, portions of the Company's cash and cash equivalents may be uninsured or in deposit accounts that exceed

Federal Deposit Insurance Corporation ("FDIC") limits, though the Company customarily invests a significant portion of its cash in Insured Cash Sweep ("ICS") accounts to maximize FDIC insurance coverage across its holdings. As of December 31, 2024, the Company had not experienced losses on these accounts, and management believes the Company is not exposed to significant risk on such accounts. The Company's cash equivalents and investments may comprise money market funds that are invested in U.S. Treasury obligations, corporate debt securities, U.S. Treasury obligations and government agency securities.

# Property and Equipment

Computer equipment, furniture and fixtures and machinery and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful life of each asset. Leasehold improvements are amortized over the shorter of the estimated useful lives or the term of the respective leases.

# Assets Held for Sale

Assets held for sale represent assets that have met the criteria of "held for sale" accounting, as specified by Accounting Standards Codification ("ASC") 360, "Long-lived Assets." As of December 31, 2024, there were \$1.2 million of lab and cell processing equipment, furniture and fixtures and computer equipment that are recorded as assets held for sale. The effect of suspending depreciation on the assets held for sale is immaterial to the results of operations. The assets held for sale are part of Mustang's repurchase of assets from uBriGene (Boston) Biosciences, Inc. ("uBriGene") (see Note 3).

## Intangible Assets

The Company's finite-lived intangible assets consist of intangible assets acquired by Journey. Intangible assets are reported at cost, less accumulated amortization and impairments. Intangible assets with finite lives are amortized over their estimated useful lives, which represents the estimated life of the product. Amortization is calculated primarily using the straight-line method.

During the ordinary course of business, the Company has entered into certain licenses and asset purchase agreements. Potential milestone payments for achieving sales targets or regulatory development milestones are recorded when it is probable of achievement. Upon a milestone being achieved, the milestone payment will be capitalized and amortized over the remaining useful life for approved products and expensed for milestones prior to FDA approval. Royalty payments for approved products are recorded as cost of goods sold as sales are recognized.

## Impairment of Long-Lived Assets

The Company reviews long-lived assets, including intangible assets with finite useful lives, for impairment at least annually or whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable (a "triggering event"). Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the long-lived asset in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. During the year ended December 31, 2024, Mustang recorded an asset impairment charge of \$3.7 million (see Note 5). During the year ended December 31, 2023, Journey recorded an asset impairment charge of \$3.1 million (see Note 8).

# Restricted Cash

The Company records cash held in trust or pledged to secure certain debt obligations as restricted cash. As of December 31, 2024 and 2023, the Company had \$1.6 million and \$2.4 million, respectively, 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 consolidated balance sheets to the consolidated statements of cash flows as of the dates presented:

	 December 31,			
	 2024		2023	
Cash and cash equivalents	\$ 57,263	\$	80,927	
Restricted cash	 1,552		2,438	
Total cash and cash equivalents and restricted cash	\$ 58,815	\$	83,365	

## Inventories

The Company's inventory consists of raw materials, work-in-process and finished goods supporting Journey's sales of dermatology products. Inventories are recorded at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. The Company periodically reviews the composition of inventory in order to identify excess, obsolete, slow-moving or otherwise non-saleable items taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand. If non-saleable items are observed and there are no alternate uses for the inventory, the Company records a write-down to net realizable value in the period that the decline in value is first recognized. The Company's inventory reserves were \$0.5 million and \$0.3 million at December 31, 2024 and 2023, respectively.

## Accounts Receivable, Net

The Company's accounts receivable consists of amounts due from customers to Journey related to dermatological product sales and have payment terms. For certain customers, the accounts receivable for the customer are net of prompt payment or specialty pharmacy discounts. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company reserves against accounts receivable for estimated losses that may arise from a customer's inability to pay, and any amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The Company has historically not experienced significant credit losses. The allowance for doubtful accounts was \$0.6 million and \$0.5 million at December 31, 2024 and 2023, respectively.

# Research and Development

Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved.

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

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 commercial feasibility and has no alternative future use. Such licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and has no alternative future use. Accordingly, the total purchase price for the licenses acquired is reflected in research and development – licenses acquired in the Company's Consolidated Statements of Operations.

#### Accrued Research and Development Expense

The Company records accruals for estimated costs of research, preclinical, clinical and manufacturing development within accrued expenses which are significant components of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers. Costs incurred under agreements with these third parties are accrued based on estimates of actual work completed in accordance with the respective agreements. Estimated costs are determined through discussions with internal personnel and external service providers as to the progress, or stage of completion or actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses until the services are rendered.

If the actual timing of the performance of services or the level of effort varies from the estimate, accrued expenses or prepaid expenses are adjusted accordingly, which impact research and development expenses. Estimates are not expected to be materially different from amounts actually incurred, understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

# Contingencies

The Company records accruals for contingencies and legal proceedings expected to be incurred in connection with a loss contingency when it is probable that a liability has been incurred and the amount can be reasonably estimated.

If a loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, the nature of the contingent liability, together with an estimate of the range of possible loss if determinable and material, would be disclosed.

#### Warrants

The Company and its subsidiaries have issued freestanding warrants to purchase shares of common stock in connection with financing activities (see Note 13) and accounts for them in accordance with applicable accounting guidance as either liabilities or as equity instruments depending on the specific terms of the warrant agreements. Warrants classified as liabilities are remeasured each period they are outstanding. Any resulting gain or loss related to the change in the fair value of the warrant liability is recognized in change in fair value of warrant liabilities (see Note 6), a component of other income (loss), in the consolidated statements of operations.

#### Leases

The Company accounts for its leases under ASC 842, *Leases*. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the consolidated balance sheet as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line rent expense over the lease term. For finance leases, interest on the lease liability and the amortization of the right-of-use asset results in front-loaded expense over the lease term. Variable lease expenses are recorded when incurred.

In calculating the right-of-use asset and lease liability, the Company elects to combine lease and non-lease components.

## Issuance of Debt and Equity

Fortress and its partner companies and subsidiaries issue complex financial instruments which include equity and/or debt features. We analyze each instrument under ASC 480, *Distinguishing Liabilities from Equity*, ASC 815, *Derivatives and Hedging* and, ASC 470, *Debt*, in order to establish whether such instruments should be classified as debt or equity in the financial statements, and whether they include any embedded derivatives.

We accounted for the debt with Oaktree with detachable warrants in accordance with ASC 470, *Debt*, and assessed the classification of the common stock purchase warrants issued in connection with such transactions and determined that such instruments met the criteria for equity classification. The note proceeds were allocated between the Oaktree note and the warrants on a relative fair value basis.

The Company recorded the related issue costs and value ascribed to the warrants as a debt discount of the 2024 Oaktree Note (see Note 9). The discount is being amortized utilizing the effective interest method over the term of the 2024 Oaktree Note, which is approximately 15.39% at December 31, 2024.

## Stock-Based Compensation

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards and forfeitures, which are recorded upon occurrence. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

#### Income Taxes

The Company accounts for income taxes under ASC 740, *Income Taxes* ("ASC 740"). ASC 740 requires the recognition of deferred tax assets and liabilities for both the expected impact of differences between the financial statement and tax basis of assets and liabilities and for the expected future tax benefit to be derived from tax loss and tax credit carry forwards. ASC 740 additionally requires a valuation allowance to be established when it is more likely than not that all or a portion of deferred tax assets will not be realized.

ASC 740 also clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim period, disclosure and transition. Based on the Company's evaluation, as of December 31, 2024 and December 31, 2023, the Company has recorded a liability related to an uncertain tax position of \$0.9 million and \$0.8 million, respectively. The 2021 through 2023 tax years are the only periods subject to examination upon filing of appropriate tax returns. The Company believes that its income tax positions and deductions would be sustained on audit and does not anticipate any adjustments that would result in a material change to its financial position.

The Company's policy for recording interest and penalties associated with audits is to record such expense as a component of income tax expense. As of December 31, 2024 and December 31, 2023, the Company accrued interest related to uncertain tax positions of \$0.2 million and \$0.1 million, respectively. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

# 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 Dividend declared and paid and/or cumulated, and Fortress' share of 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 incurred in all periods.

# Non-Controlling Interests

The Company records net loss attributable to non-controlling interests in its consolidated statements of operations and presents non-controlling interests as a component of stockholders' equity on its consolidated balance sheets. All intercompany income and/or expense items are eliminated entirely in consolidation prior to the allocation of net gain/loss

attributable to non-controlling interest, which is based on a quarterly calculation of ownership interests for each relevant subsidiary.

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

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

## Comprehensive Loss

The Company's comprehensive loss is equal to its net loss for all periods presented.

# Recent Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures
The amendments in ASU 2023-07 improve reportable segment disclosure requirements through enhanced disclosures about significant
segment expenses. The amendments introduce a new requirement to disclose significant segment expenses regularly provided to the chief
operating decision maker ("CODM"), extend certain annual disclosures to interim periods, clarify that single reportable segment entities
must apply ASC 280 in its entirety, permit more than one measure of segment profit or loss to be reported under certain conditions, and
require disclosure of the title and position of the CODM. This guidance is effective for fiscal years, beginning after December 15, 2023,
and interim periods within fiscal years beginning after December 15, 2024. The Company adopted this new standard for its consolidated
financial statements for the year ended December 31, 2024. The Company's adoption of this guidance resulted in increased disclosures in
the notes to the financial statements.

In December 2023, the FASB issued ASU 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 of the new standard on its consolidated 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 Agreements

## Mustang

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

On May 18, 2023, Mustang entered into an Asset Purchase Agreement (the "Original Asset Purchase Agreement") with uBriGene, pursuant to which Mustang agreed to sell its leasehold interest in its cell processing facility located in Worcester,

Massachusetts (the "Facility"), and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility to uBriGene (the "Transaction"). Mustang and uBriGene subsequently entered into Amendment No. 1 to the Original Asset Purchase Agreement, dated as of June 29, 2023 ("Amendment No. 1"), and Amendment No. 2 to the Original Asset Purchase Agreement, dated as of July 28, 2023 ("Amendment No. 2," and together with the Original Asset Purchase Agreement and Amendment No. 1, the "Prior Asset Purchase Agreement").

On July 28, 2023, pursuant to the Prior Asset Purchase Agreement, Mustang completed the sale of all of its assets that primarily relate to the manufacturing and production of cell and gene therapies at the Facility (such operations, the "Transferred Operations" and such assets, the "Transferred Assets") to uBriGene for upfront consideration of \$6 million cash (the "Base Amount"). The Transferred Assets included all of Mustang's assets, except for Mustang's lease and related leasehold improvements of the Facility and contracts that are primarily used in the Transferred Operations. Mustang recorded a gain of \$1.4 million in connection with the sale of the Transferred Assets and recorded approximately \$0.3 million of the base consideration as deferred income, that was to be recognized upon the transfer of the lease.

In connection with the Prior Asset Purchase Agreement, Mustang and uBriGene submitted a voluntary joint notice to the U.S. Committee on Foreign Investment in the United States ("CFIUS"). Following CFIUS's review and subsequent investigation of the transactions related to the Prior Asset Purchase Agreement, on May 13, 2024, Mustang, together with uBriGene and CFIUS, executed a National Security Agreement (the "NSA"), pursuant to which Mustang and uBriGene agreed to abandon the transactions related to the Prior Asset Purchase Agreement and the agreements entered into in connection therewith. The NSA obligated uBriGene and Mustang to terminate agreements between the two parties, including the Manufacturing Services Agreement, Quality Services Agreement, and Subcontracting CDMO Agreement. In addition, uBriGene must sell, or otherwise dispose of, the equipment assets purchased within 180 days after the execution of the NSA.

# June 2024 Repurchase of Assets

On June 27, 2024 (the "Effective Date"), Mustang entered into an Asset Purchase Agreement (the "Repurchase Agreement") with uBriGene, pursuant to which Mustang agreed, subject to the terms and conditions set forth therein, to repurchase the Transferred Assets, primarily lab equipment and supplies (collectively, the "Repurchased Assets"). Pursuant to the terms of the Repurchase Agreement, Mustang and uBriGene also terminated existing manufacturing and services agreements.

As consideration for the Repurchase Agreement, Mustang has agreed to pay to uBriGene a total purchase price (the "Purchase Price") of \$1.4 million, consisting of (i) an upfront payment of \$0.1 million due within five (5) business days of the Effective Date and a (ii) subsequent amount of \$1.3 million due on the date that is twelve (12) months after the closing date (the "Deferred Amount"). In the event that as of the original (or any extended) date on which the Deferred Amount is payable, Mustang has, as of the date of the public reporting of its then-most recent quarterly audited or unaudited financial statements, net assets below \$20 million, then Mustang may, upon written notice to uBriGene, elect to delay its payment obligation of the Deferred Amount by an additional six (6) months, with no limit on the number of such extensions available to Mustang. Notwithstanding the foregoing, if Mustang has not paid the Deferred Amount in full as of the date that is twelve (12) months after closing of the Repurchase Agreement, any amounts that remain outstanding will accrue interest at a rate of 5% per annum beginning on the date that is twelve (12) months after closing and until the Deferred Amount is paid in full. Additionally, in connection with the termination of the agreements described above under the Repurchase Agreement, Mustang agreed to forgive a net receivable from uBriGene of approximately \$3.3 million, comprised of outstanding receivables of \$6.9 million and payables of \$3.6 million, resulting in total purchase consideration in the Repurchase Transactions of approximately \$4.7 million. The upfront payment of \$0.1 million was paid in July 2024, and as of December 31, 2024, the \$1.3 million Deferred Amount was recorded in Accrued Expenses - Other (see Note 10).

Mustang allocated the total purchase consideration of \$4.7 million to the Repurchased Assets on a relative fair value basis. Mustang used a third-party to perform a valuation of the repurchased equipment, which resulted in a fair value less costs to sell of approximately \$2.2 million. The remaining purchase consideration of \$2.5 million was allocated to the supplies repurchased. The supplies repurchased with no alternative future use were recognized as research and development expense in an amount of \$2.2 million. Repurchased supplies with an alternative future use of \$0.3 million were also recognized in research and development expense, as Mustang does not have plans to resume operations in the facility, and

it intends to dispose of the supplies in a single transaction with the equipment. Mustang concluded that the disposal group, which includes the repurchased equipment assets and associated supplies with an aggregate value of approximately \$2.2 million, met the criteria to be classified as held for sale at the date of acquisition. As of December 31, 2024, the disposal group continues to be held for sale at an approximate value of \$1.2 million (see Note 5).

## Cyprium

## Agreement with Sentynl

On February 24, 2021, Cyprium entered into a development and asset purchase agreement (the "Sentynl APA") with Sentynl, a U.S.-based specialty pharmaceutical company owned by the Zydus Group. Under the Sentynl APA, Sentynl provided \$8.0 million of upfront development funding for Cyprium's CUTX-101 program, with Cyprium remaining in control of development of such program; upon approval of the NDA for CUTX-101 by the FDA, Cyprium would be obligated to assign the NDA and certain other assets pertaining to the CUTX-101 program to Sentynl, after which point Sentynl would commercialize the drug and owe Cyprium royalties and regulatory and sales milestones.

The Sentynl APA contained an alternative "Approval Deadline Transfer" mechanism pursuant to which, in the event that CUTX-101 NDA approval had not been obtained by September 30, 2023, then Sentynl could elect, during the subsequent 45-day period, to assume control over development of CUTX-101 by effecting a Closing under the Sentynl APA. Cyprium received notice of Sentynl's election to effect the Approval Deadline Transfer during such 45-day period, and the Closing of such transfer occurred in December 2023. The Approval Deadline Transfer obligated Sentynl to pay Cyprium \$4.5 million in connection with the Closing, which was received by Cyprium in December 2023 and recorded as collaboration revenue by Fortress in its consolidated statements of operations for the year ended December 31, 2023. There were no further obligations required by Cyprium in regards to the \$4.5 million.

Following such Closing, Sentynl is obligated 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 as follows: (i) 3% of annual net sales up to \$75 million; (ii) 8.75% of annual net sales between \$75 million and \$100 million; and (iii) 12.5% of annual net sales in excess of \$100 million. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.

With respect to the \$8.0 million upfront payment from Sentynl received in 2021, the Company recognized revenue over the period in which the development activities occurred using an input method based upon the costs incurred to date in relation to the total estimated costs to complete the development activities. As of the date of the Approval Deadline Transfer, the revenue related to the upfront payment has been fully recognized. For the year ended December 31, 2023, the Company recognized revenue from this arrangement of \$0.7 million.

In December 2024, the NDA for CUTX-101 was accepted by the FDA. The NDA, which has been granted Priority Review, has an assigned Prescription Drug User Fee Act ("PDUFA") target action date of September 30, 2025. Cyprium received a milestone payment of \$1.5 million from Sentynl that was due upon NDA acceptance, which was recorded as collaboration revenue by Fortress in its Consolidated Statements of Operations for the year ended December 31, 2024.

# Urica Therapeutics, Inc. ("Urica")

# Agreement with Crystalys Therapeutics, Inc ("Crystalys")

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, 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 (see Note 7) 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 it raises \$150 million in equity securities.

The Transaction Documents also grant Urica a secured three percent (3%) royalty on future net sales of dotinurad to be paid by Crystalys, as well as the right to receive \$0.6 million cash reimbursement for certain clinical and development costs incurred by Urica related to dotinurad. 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; in the event that Crystalys has not consummated a qualified financing of at least \$120 million before January 8, 2026. Urica recorded a liability for the \$0.6 million received, which will be accreted up to the repurchase price over the term of the repurchase option, and will not recognize an asset for its ownership interest received in Crystalys until the expiration of the repurchase option. Accordingly, for the year ended December 31, 2024, Urica recorded accretion of \$0.7 million of the repurchase option price, booked to interest expense in the condensed consolidated statement of operations.

## Aevitas

# Agreement with 4DMT

On April 21, 2023, Aevitas entered into an Asset Purchase Agreement (the "4DMT APA") with 4DMT under which 4DMT acquired Aevitas' proprietary rights to its short-form human complement factor H ("sCFH") asset for the treatment of complement-mediated diseases. Under the terms of the 4DMT APA, 4DMT will make cash payments totaling up to \$140 million if certain late-stage development, regulatory and sales milestones are met with respect to sCFH. A range of single-digit royalties on net sales are also payable. The aforementioned payments are payable solely to Aevitas, and 4DMT will be responsible for license payment obligations to the licensor of sCFH, University of Pennsylvania. 4DMT is not a related party to the Company and has assumed all ongoing and future development costs. The fair value of the interest in Aevitas retained by the Company of \$2.6 million was based on the risk-adjusted present value of the aforementioned potential cash payments (see Note 6).

In connection with the 4DMT APA, the preferred shares of Aevitas held by the Company converted to Aevitas common shares, at which point the Company no longer maintained voting control of Aevitas. As a result, the Company deconsolidated its holdings in Aevitas. In connection with this transaction, the Company recorded a loss on deconsolidation of Aevitas of \$3.4 million during the year ended December 31, 2023 in other expense in the Consolidated Statement of Operations.

#### Avenue

# Agreements with InvaGen

In November 2018, Avenue entered into a Stock Purchase and Merger Agreement (the "Avenue SPMA") with InvaGen Pharmaceuticals Inc. In November 2021, Avenue delivered InvaGen notice of termination of the Avenue SPMA and, in July 2022, Avenue entered into a Share Repurchase Agreement (the "Avenue SRA") with InvaGen which closed in October 2022. In connection with the closing of the Avenue SRA, Avenue repurchased all the common shares of Avenue held by InvaGen, and all of the rights retained by InvaGen pursuant to the Stockholders Agreement entered into by and among Avenue, InvaGen and Fortress on November 12, 2018, were terminated. Under the Avenue SRA, Avenue agreed to pay InvaGen seven and a half percent (7.5%) of the proceeds from future financings, up to \$4 million. In connection with funds raised in 2024 and 2023 (see Note 13), Avenue made payments totaling \$0.7 million and \$0.5 million, respectively, to InvaGen.

## 4. Inventory

Inventory consisted of the following:

(\$ in thousands)	Dec	December 31, 2024		December 31, 2023	
Raw materials	\$	3,196	\$	4,640	
Work-in-process		367		884	
Finished goods		11,381		4,987	
Inventory reserve		(513)		(305)	
Total inventories	\$	14,431	\$	10,206	

## 5. Property and Equipment

Fortress' property and equipment consisted of the following:

(\$ in thousands)	Useful Life (Years)	De	ecember 31, 2024	De	cember 31, 2023
Computer equipment	3	\$	595	\$	595
Furniture and fixtures	5		1,017		1,017
Leasehold improvements	15		13,175		13,175
Buildings	40		581		581
Construction in progress	N/A		_		29
Total property and equipment			15,368		15,397
Impairment - Leasehold Improvements			(2,176)		_
Less: Accumulated depreciation			(9,932)		(8,892)
Property and equipment, net		\$	3,260	\$	6,505

Fortress' depreciation expense for the years ended December 31, 2024 and 2023 was \$1.0 million and \$2.2 million, respectively, and was recorded in research and development, and selling, general and administrative expense in the Consolidated Statements of Operations.

# Impairment of Long-Lived Assets

During the year ended December 31, 2024, Mustang concluded it had a triggering event requiring assessment of impairment for certain leasehold improvements and the related right-of-use asset. Mustang assessed the carrying value of the asset group consisting of the leasehold improvements and right-of-use asset in accordance with ASC 360, given the significant changes to Mustang's operations, operating cash and the repurchase of equipment. The assessment of the recoverability of the asset group concluded that there was impairment on the carrying value of the asset group of approximately \$2.6 million, which was allocated on a pro rata basis using the relative carrying amounts of the assets. Approximately \$2.2 million of the impairment loss was allocated to leasehold improvements, with the remaining \$0.4 million allocated to the right-of-use asset. At December 31, 2024, Mustang assessed the remaining improvements, right-of-use asset, and property, plant and equipment held for sale for impairment and concluded that the property, plant and equipment held for sale were impaired, based primarily on offers received from third parties. As such, Mustang recorded an additional impairment charge of \$1.0 million for the property, plant and equipment held for sale. See Note 8 for asset impairment of \$3.1 million recognized in the year ended December 31, 2023.

# 6. Fair Value Measurements

# Fair Value of Aevitas

The Company valued its retained investment in Aevitas, which is accounted for as an equity method investment for which the Company elected the fair value option, and estimated the fair value to be \$2.6 million based on a per share value of \$0.328. The following inputs were utilized to derive the value: risk free rate of return of 3.7%, volatility of 80% and a discount for lack of marketability of 39.7%.

# Common Stock Warrant Liabilities

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity*. For warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter

(\$ in thousands)	Warrants liabilities
Balance at December 31, 2022	\$ 13,869
Avenue common stock warrants	2,235
Urica placement agent warrants	33
Change in fair value of common stock warrants - Avenue	(4,258)
Change in fair value of common stock warrants - Checkpoint	(7,924)
Change in fair value of placement agent warrants - Urica	52
Exercise of common stock warrants - Checkpoint	 (3,121)
Balance at December 31, 2023	886
Change in fair value of common stock warrants - Avenue	(170)
Change in fair value of common stock warrants - Checkpoint	73
Change in fair value of placement agent warrants - Urica	(24)
Exercise of common stock warrants - Avenue	(400)
Exchange of common stock warrants - Urica	(151)
Balance at December 31, 2024	\$ 214

## Checkpoint

On December 16, 2022, Checkpoint closed on an offering for the sale of shares of its common stock and pre-funded warrants (the "Checkpoint December 2022 Registered Direct Offering"). The common stock and the pre-funded warrants were sold together with December 2022 Common Stock Warrants. Checkpoint also issued the placement agent warrants to purchase up to 104,046 shares of common stock with an exercise price of \$5.406 per share (the "December 2022 Placement Agent Warrants"). Checkpoint deemed the December 2022 Common Stock Warrants and 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 Common Warrants and December 2022 Placement Agent Warrants were recorded at the time of closing at a fair value, determined by using the Black-Scholes Model

In October 2023, Checkpoint entered into the October 2023 Inducement with a holder of certain of its existing warrants to exercise for cash an aggregate of 6,325,354 shares of Checkpoint's common stock at a reduced exercise price of \$1.76 per share. Included in the exercise were the entirety of the December 2022 Common Stock Warrants. Checkpoint revalued the December 2022 Common Stock Warrants on October 4, 2023, resulting in a fair value of \$3.1 million. Checkpoint also revalued the December 2022 Common Stock Warrants and December 2022 Placement Agent Warrants at each reporting period in 2023, and the decrease in the fair value of the common stock warrant liability throughout the year resulted in an offsetting gain on common stock warrant liabilities in the Statements of Operations. Since the December 2022 Placement Agent Warrants issued in the December 2022 Registered Direct Offering were not included in the October 2023 Inducement and have not been exercised, they will continue to be revalued at each reporting period for as long as

they remain outstanding. Checkpoint revalued the warrants at December 31, 2024 and 2023, resulting in a fair value of approximately \$0.2 million and \$0.1 million, respectively.

	Checkpoint
	Warrant
(\$ in thousands)	 Liability
Common Stock Warrant liabilities at December 31, 2022	\$ 11,170
Change in fair value of common stock warrant liabilities	(7,924)
Exercise of common stock warrants	(3,121)
Common Stock Warrant liabilities at December 31, 2023	125
Change in fair value of common stock warrant liabilities	73
Common Stock Warrant liabilities at December 31, 2024	\$ 198

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

	Decer	nber 31,	Dec	ember 31,
Checkpoint Warrants	2	024		2023
Exercise price	\$	5.41	\$	5.41
Volatility		111.1 %		96.4 %
Expected life in years		3.0		4.0
Risk-free rate		4.3 %		3.8 %

#### Avenue

Avenue issued freestanding warrants to purchase shares of its common stock in connection with financing activities in October 2022 (the "October 2022 Warrants") and January 2023 (the "January 2023 Warrants", collectively the "Avenue Warrants"). The Avenue 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 (see Note 13) 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 Offering in January 2023. The Black-Scholes model was used to value the October 2022 Warrants and January 2023 Warrants as of December 31, 2024 and 2023.

For the years ended December 31, 2024 and 2023, the decrease in the fair value of the Avenue Warrants resulted in a decrease in common stock warrant liabilities of \$0.2 million and \$4.3 million, respectively, with an offsetting gain recorded in the Statements of Operations.

	Avenue
	Warrant
(\$ in thousands)	 Liability
Avenue common stock warrant liabilities at December 31, 2022	\$ 2,609
Issuance of common warrants	2,235
Change in fair value of common stock warrant liabilities	 (4,258)
Avenue common stock warrant liabilities at December 31, 2023	586
Exercise of Avenue common warrants	(400)
Change in fair value of common stock warrant liabilities	 (170)
Avenue common stock warrant liabilities at December 31, 2024	\$ 16

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:

	December 31, 2024	December 31 2023
Stock price	\$ 2.00	\$ 12.00
Risk-free interest rate	4.27 %	3.84 - 4.23 %
Expected dividend yield	_	_
Expected term in years	2.8	2.1 - 3.8
Expected volatility	155 %	148 - 175 %

#### Urica

Urica's outstanding contingently issuable placement agent warrants were exchanged at the time of the exchange of the Urica 8% Cumulative Convertible Class B Preferred Stock on June 27, 2024 (see Note 9) for 202,834 warrants to purchase Fortress common stock at an exercise price of \$1.68. The Fortress common stock warrants have a five-year life, expiring on June 27, 2029. The Company determined the placement agent warrants met the criteria for equity classification. At December 31, 2024 and 2023, the value of Urica's contingent payment warrant was nil and \$0.2 million, respectively, and was recorded on the consolidated balance sheet.

	December 31, 2023
Risk-free interest rate	3.93 %
Expected dividend yield	_
Expected term in years	0.5
Expected volatility	153.6 %

## 7. 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 commercial 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 commercial feasibility and have no alternate use. The purchase prices of the licenses acquired is classified as research and development-licenses acquired in the consolidated statements of operations and for the years ended December 31, 2024 and 2023, expense recognized was \$0.3 million and \$4.3 million, respectively.

# Journey

Emrosi (also known as DFD-29)

In June 2021, Journey entered a license, collaboration, and assignment agreement (the "Emrosi Agreement") to obtain global rights for the development and commercialization of Emrosi<sup>TM</sup> (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 including Brazil, Russia, India and China. Pursuant to the terms and conditions of the Emrosi Agreement, Journey paid \$10.0 million. In addition, Journey paid two developmental milestones in 2024. In April 2024 Journey paid a \$3.0 milestone to DRL, based on FDA acceptance of the NDA application for Emrosi, and in December of 2024 Journey paid 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 (see Note 8). Pursuant to the Emrosi Agreement, Journey may be required to pay additional contingent regulatory, commercial, and corporate-based milestone payments, 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.

#### Obrexza

In March 2021, Journey executed an Asset Purchase Agreement (the "Qbrexza APA") with Dermira, Inc., a subsidiary of Eli Lilly and Company ("Dermira"). Pursuant to the terms of the Qbrexza APA, Journey acquired the rights to Qbexza® (glycopyrronium), a prescription cloth towelette to treat primary axillary hyperhidrosis in patients nine years of age or older from Dermira, Inc., Journey paid the upfront fee of \$12.5 million to Dermira. In addition, Journey is obligated to pay Dermira up to \$144 million in the aggregate upon the achievement of certain sales milestones. The royalty structure for the agreement is tiered with royalties for the first two years ranging approximately 40% to 30%. Thereafter for a period of eight years royalties are approximately 12% to 19%. Royalty amounts are subject to certain reductions in the event there is loss of exclusivity.

On August 31, 2023, Journey entered into a license agreement (the "New License Agreement") with Maruho, whereby Journey agreed to grant an exclusive license to Maruho to develop and commercialize Qbrexza® for the treatment of primary axillary hyperhidrosis, in South Korea, Taiwan, Hong Kong, Macau, Thailand, Indonesia, Malaysia, Philippines, Singapore, Vietnam, Brunei, Cambodia, Myanmar and Laos (the "Territory"). Under the terms of the New License Agreement, in exchange for the exclusive rights to Qbrexza in the Territory and the amendment to the royalty payments associated with the Japanese license, Maruho paid \$19.0 million to Journey as a non-refundable upfront payment. Prior to the date of the New License Agreement, Journey and Maruho were party to an existing exclusive amended and restated license agreement (the "First A&R License Agreement"), under which Maruho acquired exclusive license rights to Qbrexza® in Japan. In connection with Journey's entry into the New License Agreement, Journey and Maruho also entered into the Second Amended and Restated Exclusive License Agreement (the "Second A&R License Agreement"), which supersedes the First A&R License Agreement. The Second A&R License Agreement contains modifications that remove Maruho's obligation to pay Journey royalties on its net sales of Rapifort® (the Japanese equivalent of Qbrexza®) in Japan for sales occurring after October 1, 2023 and removes Maruho's obligation to pay \$10 million to Journey in the event that Maruho achieves net sales of at least \(\frac{1}{2}\)4 billion (yen) of Rapifort® during a single fiscal year. All other remaining potential milestone payment obligations, which aggregate to \$45 million, remain in full force and effect. Journey recognized \(\frac{1}{2}\)10,0 million as other revenue in the consolidated statements of operations during the year ended December 31, 2023.

#### Accutane

In July 2020, Journey entered into an exclusive license and supply agreement for Accutane (the "Accutane Agreement") with DRL. Pursuant to the Accutane Agreement, Journey paid \$5.0 million. Three additional milestone payments totaling \$17.0 million are contingent upon the achievement of certain net sales milestones. Journey is required to pay royalties in an amount equal to a low-double digit percentage of net sales. The term of the Accutane Agreement is ten years and renewable upon mutual agreement. Each party may terminate the Accutane Agreement for an uncured material breach by the other party or for certain bankruptcy or insolvency related events. Journey may also terminate the Accutane Agreement without cause upon 180 days written notice to DRL.

# Vyne

In January 2022, Journey entered into an Asset Purchase Agreement (the "Vyne APA") with Vyne Therapeutics, Inc. ("Vyne") to acquire Vyne's Molecule Stabilizing Technology<sup>TM</sup> franchise (the "Acquisition") for an upfront payment of \$20.0 million and an additional \$5.0 million payment on the one-year anniversary of the closing of the Acquisition. The Vyne APA also provides for contingent net sales milestone payments: in the first calendar year in which annual sales reach each of \$100 million, \$200 million, \$300 million, \$400 million and \$500 million, Journey will be required to make a one-time payment of \$10 million, \$20 million, \$30 million, \$40 million and \$50 million, respectively, in that year only, per product, totaling up to \$450 million. In addition, Journey will pay Vyne 10% of any upfront payment received by Journey from a licensee or sublicensee of the products in any territory outside of the United States, subject to exceptions for certain jurisdictions as detailed in the Vyne APA. There are no subsequent milestone payments or royalties beyond the aforementioned payments. The Acquisition included two FDA-approved products (Amzeeq® and Zilxi®), and a development-stage dermatology program (FCD105), along with the Molecule Stabilizing Technology proprietary platform.

Part of the Vyne APA was Journey's assumption of a license agreement with Cutia Therapeutics (HK) Limited, a Hong Kong biopharmaceutical company with experience in developing pharmaceutical products in the greater China region (the "Cutia Agreement"). Pursuant to the Cutia Agreement, Cutia was granted an exclusive license to obtain regulatory approval of and commercialize Amzeeq (topical 4% minocycline foam) and Zilxi (topical 1.5% minocycline foam) in mainland China, Taiwan, Hong Kong and Macau. Journey has agreed to supply the finished Licensed Products to Cutia for clinical and commercial use at an agreed price. On November 11, 2024, Cutia received marketing approval for topical 4% minocycline foam from the National Medical Products Administration (the "NMPA") of the People's Republic of China (the "PRC"). The approval triggered a \$1.0 million milestone payment to Journey. The \$1.0 million milestone payment was recorded as a component of other revenue in the Company's Consolidated Statements of Operations for the year ended December 31, 2024.

# Ximino

In July 2019, Journey entered into an asset purchase agreement for Ximino® (the "Ximino APA") with Sun Pharmaceutical Industries, Inc. ("Sun"). Pursuant to the Ximino APA, total consideration was \$9.4 million, with an upfront payment of \$2.4 million paid in 2019. Pursuant to the terms of the Ximino APA, the remaining \$7.0 million was due on the second anniversary and for the next four anniversaries of the Ximino APA thereafter. No additional licensing or milestone payments were required. Journey commenced sales of this product in August 2019, and discontinued selling Ximino in September 2023. In August 2024, Journey executed a settlement agreement with Sun for amounts owed under the Ximino APA (see Note 9).

#### 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 agreed to pay \$3.0 million, which was paid in the year ended December 31, 2023.

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

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

In connection with the signing of the AnnJi License Agreement, Avenue issued 11,089 shares of its common stock to AnnJi ("First Tranche Shares") and recognized expense of \$0.9 million; and issued 3,688 shares of common stock ("Second Tranche Shares") and recognized expense of \$0.3 million paid on September 26, 2023 upon enrollment of the eighth patient in the ongoing Phase 1b/2a SBMA clinical trial. Avenue and AnnJi entered into a Subscription Agreement, dated as of February 28, 2023, that provided for the issuance of First Tranche Shares which were issued March 30, 2023. In the event that the common stock of Avenue ceases to be traded on a national securities exchange, AnnJi has the right to

sell the common stock of Avenue back to Avenue at a price of \$2.10 per share, subject to the terms of the AnnJi License Agreement.

On March 3, 2025, Avenue received a "notice of intent to terminate" letter from AnnJi with respect to the AnnJi License Agreement; Avenue believes that the grounds for termination stated in the purported termination notice are without merit and intends to avail itself of the dispute resolution procedures set forth in the AnnJi License Agreement.

# Urica

In May 2021, Urica entered into an exclusive license agreement with Fuji to develop dotinurad in North America, Europe, and the UK. Dotinurad is approved for the treatment of gout and hyperuricemia in Japan. Urica paid a \$3.0 million milestone payment in December 2021 upon IND submission of dotinurad. In December 2022 Urica expanded its exclusive license agreement with Fuji for the development of dotinurad to include the Middle East and North Africa ("MENA") and Turkey territories. The amendment to the exclusive license agreement included a one-time license amendment payment of \$0.3 million. In July 2024, Urica sold the rights to dotinurad to Crystalys (see Note 3).

# Partner Companies and Subsidiaries

The Company's partner companies and subsidiaries have also entered into other various license agreements with research institutions and medical centers. These license agreements include upfront payments which were expensed and various development milestone payments due upon achievement of various milestones which in the aggregate are approximately \$191.3 million, of which \$65.0 million relates to Mustang agreements. The license agreements also have sales-based milestone payments that total approximately \$268.4 million. The agreements also include royalty payments on any future sales.

# 8. Intangible Assets

The Company's finite-lived intangible assets consist of intangible assets acquired by Journey. The table below provides a summary of intangible assets as of December 31, 2024 and 2023, respectively:

(\$ in thousands)	Estimated Useful Lives (Years)	D	ecember 31, 2024	December 31, 2023
Intangible assets – product licenses	3 to 15	\$	52,925	\$ 37,925
Accumulated amortization			(17,919)	(14,495)
Accumulated Impairment loss			(3,143)	(3,143)
Net intangible assets		\$	31,863	\$ 20,287

The Company's amortization expense for the years ended December 31, 2024 and 2023 was approximately \$3.4 million and \$3.8 million, respectively. Amortization expense is recorded as a component of cost of goods sold in the Company's consolidated statements of operations.

In the fourth quarter of 2024, the FDA approved Journey's Emrosi for the treatment of inflammatory lesions of rosacea in adults. The approval triggered a \$15.0 million milestone payment to DRL, which Journey capitalized as an acquired intangible asset. During the year ended December 31, 2023, Journey experienced lower net product revenues and gross profit levels for its Ximino products. Based on these results, Journey revised the financial outlook and plans for its Ximino products. Journey assessed the revised forecast for Ximino and determined that this constituted a triggering event and the results of the analysis indicated the carrying amount was not expected to be recovered. Journey recorded an intangible asset impairment charge of \$3.1 million during the year ended December 31, 2023. This non-cash charge was recorded to operating expenses on the Consolidated Statements of Operations.

The future amortization of these intangible assets is as follows:

(\$ in thousands)	Total Amortization
December 31, 2025	\$ \$ 4,257
December 31, 2026	3,471
December 31, 2027	2,775
December 31, 2028	2,595
December 31, 2029	2,595
Thereafter	12,228
Sub-total	\$ 27,921
Asset not yet placed in service	3,942
Total	\$ 31,863

### 9. Debt and Interest

# Debt

Total debt consists of the following:

(\$ in thousands)	Dec	ember 31, 2024	De	ecember 31, 2023	Interest rate at December 31, 2024	Maturity
2024 Oaktree Note	\$	35,350	\$		12.2 %	July - 2027
2020 Oaktree Note		_		50,000	11.0 %	August - 2025
SWK Term Loan		25,000		15,000	14.8 %	December - 2027
Less: Discount on notes payable		(2,388)		(4,144)		
Total notes payable	\$	57,962	\$	60,856		

As of December 31, 2024, 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 a \$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) in 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). At December 31, 2024, the interest rate applicable to the 2024 Oaktree Note was 12.23%. 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 warrants 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 for the year ended December 31, 2024.

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 capital, 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 capital raise and minimum stake covenants and financial covenants, including minimum liquidity and minimum net sales, 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 the Agent, 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"), later reduced to \$1.65 per share in connection with the financing consummated by the Company in September 2024 (see note 13). 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. In connection with the financing consummated by the Company in September 2024, the Warrants had their exercise price reduced to \$1.65 per share. The Warrants are exercisable from July 25, 2024 and 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 covenants under the New Oaktree Agreement as of December 31, 2024.

#### 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 comply with the Prior Oaktree Agreement covenants would result in an event of default, subject to certain cure rights of the Company.

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 with SWK Funding LLC ("SWK"). The Credit Agreement provides for a term loan facility (the "Credit Facility") in the original principal amount of up to \$20.0 million. On the SWK Closing Date, Journey drew \$15 million. On June 26, 2024, Journey drew the remaining \$5.0 million under the Credit Facility. On July 9, 2024, Journey entered into the Amendment to the Credit Agreement with SWK. The Amendment increased the original principal amount of the Credit Facility from \$20.0 million to \$25.0 million. The \$5.0 million of additional principal added in the 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 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) 2% of the Term Loans prepaid plus the amount of interest that would have been due through the first anniversary of the SWK Closing Date if the Term Loans are prepaid prior to the first anniversary of the SWK Closing Date, (ii) 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 (iii) 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 December 31, 2024 was 14.8%.

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 December 31, 2024, Journey was in compliance with the financial covenants under the SWK Credit Facility.

East West Bank Line of Credit and Long-Term Debt ("EWB Term Loan")

Journey was previously party to a Loan and Security Agreement, dated March 31, 2021 (as amended, the "EWB Facility"), with East West Bank ("EWB"), under which EWB made a \$20.0 million term loan and a \$10 million revolving line of credit available to Journey. In January 2022 and August 2022, Journey borrowed \$15 million and \$5 million, respectively, against the term loan. During 2023, Journey voluntarily repaid the entire \$20 million outstanding term loan principal balance under the EWB Facility. The repayment satisfied all of Journey's outstanding debt obligations under the EWB Facility. Journey has no further obligations to EWB.

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

On April 11, 2023, the long-term debt facility with Runway Growth Finance Corp. (the "Mustang Term Loan" or the "Runway Note"), was terminated upon receipt by Runway of a payoff amount of \$30.4 million from Mustang comprising of principal, interest and the applicable final payment amount. A loss on extinguishment of \$2.8 million was recorded to interest expense in the Consolidated Statement of Operations for the year ended December 31, 2023.

IDB Letters of Credit

The Company has letters of credit ("LOC") with one of its commercial banks, IDB Bank ("IDB"), of approximately \$1.6 million and \$2.4 million as of December 31, 2024 and 2023, respectively, securing rent deposits for lease facilities and an undertaking posted by Cyprium relating to an injunctive proceeding. The Company's LOC's are secured by cash, which is included in restricted cash on the Company's Consolidated Balance Sheet. Interest paid on the letters of credit is 2% per annum.

Urica 8% Cumulative Convertible Class B Preferred Offering

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

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

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

Harley Capital LLC ("Harley") was the primary placement agent for the Urica Offering and received a 10% cash fee on gross proceeds raised, plus either warrants to purchase 10% of the Urica common stock into which the Urica Preferred Stock converts (in the event of a sale of Urica or a qualified financing) or 10% of the Company common stock for which the Urica Preferred Stock is exchanged (in the event neither a sale of Urica nor a qualified financing occurs), in addition to reimbursement of legal and other expenses (see Note 6).

Dividends on the Urica Preferred Stock were payable monthly by Fortress in shares of Fortress Common Stock based upon a 7.5% discount to the average trading price over the 10-day period preceding the dividend payment date. Dividends were recorded as interest expense. For the years ended December 31, 2024 and 2023, the Company recorded expense of \$0.1 million and \$0.3 million, respectively, associated with the Urica dividends paid on the outstanding Urica Preferred Stock.

The shares mandatorily converted into Urica common stock upon either: (i) a qualified financing pursuant to which Urica raises at least \$20 million in aggregate gross proceeds; or (ii) a sale of Urica. Additionally, in the event that neither such a qualified financing nor a sale of Urica had occurred prior to June 27, 2024, then each holder of Urica Preferred Stock was eligible to receive, at Fortress' election, one of: (x) a cash payment equal to the product of the Subscription Price and the number of shares of Urica Preferred Stock held by such holder; (y) a number of shares of Fortress common stock equal to the Fortress Share Exchange Amount; or (z) a combination of the foregoing. On June 27, 2024, as neither a qualified financing nor a sale of Urica occurred, Fortress elected to exchange the outstanding shares of Urica Preferred Stock, which was recorded as a liability, into 2,028,345 shares of Fortress common stock.

# Ximino Settlement

In August 2024, Journey executed a settlement agreement (the "Settlement Agreement") to settle the \$3.0 million of license installment payments Journey owed to Sun associated with the Ximino APA. Pursuant to the Settlement Agreement, Journey agreed to settle the total outstanding obligation owed to Sun for a total of \$1.9 million, payable in three installments: 1) \$0.6 million upon execution of the Settlement Agreement, 2) \$0.6 million on December 1, 2024, and 3) \$0.6 million on January 15, 2025. Journey accounted for the settlement of the license installment payment as a \$1.1 million gain on extinguishment of debt in the Condensed Consolidated Statements of Operations for the year ended December 31, 2024.

# Interest Expense

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

	Year Ended December 31,						
	2024			2023			
(\$ in thousands)	Interest	Fees	Total	Interest	Fees	Total	
2024 Oaktree Note	1,954	323	2,277	_	_	_	
2020 Oaktree Note <sup>1</sup>	6,803	1,219	8,022	5,561	2,073	7,634	
Partner company convertible preferred shares	(290)	90	(200)	1,023	503	1,526	
Partner company installment payments - licenses <sup>2</sup>	_	_	_	353	_	353	
Partner company notes payable <sup>3</sup>	2,385	307	2,692	4,856	492	5,348	
Partner company contingent call option accretion <sup>4</sup>	716	_	716	_	_	_	
Other	20	_	20	122	332	454	
Total Interest Expense and Financing Fee	\$ 11,588	\$ 1,939	\$ 13,527	\$ 11,915	\$ 3,400	\$ 15,315	

- Note 1: Includes loss on extinguishment of debt of \$3.6 million related to the payoff of the 2020 Oaktree Note on July 25, 2024
- Note 2: Imputed interest expense related to Ximino, Accutane, Anti-itch product license and VYNE product licenses (see Note 8) for the year ended December 31, 2023.
- Note 3: Includes loss on extinguishment of debt of \$2.8 million recorded by Mustang related to payoff of the Runway Note on April 11, 2023

Note 4: Relates to Urica's optional repurchase obligation to Crystalys (see Note 3).

# 10. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

(\$ in thousands)	Dec	cember 31, 2024	De	cember 31, 2023
Accounts payable	\$	31,636	\$	34,810
Accrued expenses:				
Professional fees		3,147		1,681
Salaries, bonus and related benefits		6,596		8,531
Research and development		8,509		11,644
Accrued royalties payable		1,374		2,015
Accrued coupon and rebates		6,200		9,987
Return reserve		3,124		4,077
Other <sup>1</sup>		4,915		817
Total accounts payable and accrued expenses	\$	65,501	\$	73,562

Note 1: Other includes approximately \$1.3 million of accrued consideration for the Mustang Repurchase Agreement with uBriGene, see Note 3.

# 11. Non-Controlling Interests

On April 21, 2023, Aevitas ceased to be a controlled Fortress entity and as such is no longer consolidated (see Note 3). Tamid was dissolved in the year ended December 31, 2023 due to inactivity.

The Company's ownership interest in its consolidated subsidiaries in 2024 was similar to 2023, except for Avenue, which increased from 4% to 9.2% due to the acquisition of additional common shares (see Note 16); Journey, which decreased from 50% to 44.5% due to dilution from the issuance of equity securities (see Note 13) and Mustang, which decreased from 19% to 6.3% due to dilution from the issuance of equity securities (see Note 13).

# 12. Net Loss per Common Share

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

The Series A Preferred dividends included in the net loss per share calculation include dividends paid as well as dividends cumulated (but undeclared) (see Note 13). For the years ended December 31, 2024 and 2023, the effect on the net loss per share calculation from Series A Preferred dividends was \$8.0 million and \$8.0 million, respectively, and deemed dividends were \$1.9 million and \$0.7 million, respectively.

The following shares of potentially dilutive securities, weighted during the years ended December 31, 2024 and 2023 have been excluded from the computations of diluted weighted average shares outstanding as the effect of including such securities would be anti-dilutive:

	Decembe	er 31,
	2024	2023
Warrants to purchase Common Stock	14,406,201	873,065
Options to purchase Common Stock	558,896	32,601
Unvested Restricted Stock and deferred Restricted Stock	1,900,630	1,514,208
Unvested Restricted Stock units and deferred Restricted Stock units	2,513,830	372,817
Total	19,379,557	2,792,691

# 13. Stockholders' Equity

# Common Stock

Fortress' Certificate of Incorporation, as amended, authorizes the Company to issue 200,000,000 shares of \$0.001 par value Common Stock of which 27,908,839 and 15,093,053 shares of Common Stock were outstanding as of December 31, 2024 and 2023, respectively.

The terms, rights, preference and privileges of the Common Stock are as follows:

### Voting Rights

Each holder of Common Stock is entitled to one vote per share of Common Stock held on all matters submitted to a vote of the stockholders, including the election of directors. The Company's certificate of incorporation and bylaws do not provide for cumulative voting rights.

# Dividends

Subject to preferences that may be applicable to any then outstanding Preferred Stock, the holders of the Company's outstanding shares of Common Stock are entitled to receive dividends, if any, as may be declared from time to time by the Company's Board of Directors out of legally available funds.

# Liquidation

In the event of the Company's liquidation, dissolution or winding up, holders of Common Stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of the Company's debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of Preferred Stock.

# Rights and Preference

Holders of the Company's Common Stock have no preemptive, conversion or subscription rights, and there is no redemption or sinking fund provisions applicable to the Common Stock. The rights, preferences and privileges of the holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of the Company's Preferred Stock that are or may be issued.

# Series A Cumulative Redeemable Perpetual Preferred Stock

On October 26, 2017, the Company designated 5,000,000 shares of \$0.001 par value preferred stock as Series A Cumulative Redeemable Perpetual Preferred Stock (the "Series A Preferred Stock"). As of December 31, 2024 and 2023, 3,427,138 shares of Series A Preferred Stock were issued and outstanding.

The terms, rights, preference and privileges of the Series A Preferred Stock are as follows:

# Voting Rights

Except as may be otherwise required by law, the voting rights of the holders of the Series A Preferred Stock are limited to the affirmative vote or consent of the holders of at least two-thirds of the votes entitled to be cast by the holders of the Series A Preferred Stock outstanding at the time in connection with the: (1) authorization or creation, or increase in the authorized or issued amount of, any class or series of capital stock ranking senior to the Series A Preferred Stock with respect to payment of dividends or the distribution of assets upon liquidation, dissolution or winding up or reclassification of any of the Company's authorized capital stock into such shares, or creation, authorization or issuance of any obligation or security convertible into or evidencing the right to purchase any such shares; or (2) amendment, alteration, repeal or replacement of the Company's certificate of incorporation, including by way of a merger, consolidation or otherwise in which the Company may or may not be the surviving entity, so as to materially and adversely affect and deprive holders of Series A Preferred Stock of any right, preference, privilege or voting power of the Series A Preferred Stock.

#### Dividends

Dividends on Series A Preferred Stock accrue daily and will be cumulative from, and including, the date of original issue and shall be payable monthly at the rate of 9.375% per annum of its liquidation preference, which is equivalent to \$2.34375 per annum per share. The first dividend on Series A Preferred Stock sold in the offering was payable on December 31, 2017 (in the amount of \$0.299479 per share) to the holders of record of the Series A Preferred Stock at the close of business on December 15, 2017 and thereafter for each subsequent quarter in the amount of \$0.5839375 per share.

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 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. The Company recorded approximately \$4.0 million and \$8.0 million of dividends in Additional Paid in Capital on the Consolidated Balance Sheets as of December 31, 2024 and 2023, respectively. At December 31, 2024, the Company had total undeclared dividends of approximately \$4.0 million, which represents the cumulated (but undeclared) dividends due to Series A Preferred shareholders on December 31, 2024. 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).

# No Maturity Date or Mandatory Redemption

The Series A Preferred Stock has no maturity date, and the Company is not required to redeem the Series A Preferred Stock. Accordingly, the Series A Preferred Stock will remain outstanding indefinitely unless the Company decides to redeem it pursuant to its optional redemption right or its special optional redemption right in connection with a Change of Control (as defined below), or under the circumstances set forth below under "Limited Conversion Rights Upon a Change of Control" and elect to convert such Series A Preferred Stock. The Company is not required to set aside funds to redeem the Series A Preferred Stock.

# Optional Redemption

The Series A Preferred Stock may be redeemed in whole or in part (at the Company's option) any time on or after December 15, 2022, upon not less than 30 days nor more than 60 days' written notice by mail prior to the date fixed for redemption thereof, for cash at a redemption price equal to \$25.00 per share, plus any accumulated and unpaid dividends to, but not including, the redemption date. During the year ended December 31, 2024, no Series A Preferred Stock shares were redeemed.

# Special Optional Redemption

Upon the occurrence a Change of Control (as defined below), the Company may redeem the shares of Series A Preferred Stock, at its option, in whole or in part, within one hundred twenty (120) days of any such Change of Control, for cash at \$25.00 per share, plus accumulated and unpaid dividends (whether or not declared) to, but excluding, the redemption date. If, prior to the Change of Control conversion date, the Company has provided notice of its election to redeem some or all of the shares of Series A Preferred Stock (whether pursuant to the Company's optional redemption right described above under "Optional Redemption" or this special optional redemption right), the holders of shares of Series A Preferred Stock will not have the Change of Control conversion right with respect to the shares of Series A Preferred Stock called for redemption. If the Company elects to redeem any shares of the Series A Preferred Stock as described in this paragraph, the Company may use any available cash to pay the redemption price.

A "Change of Control" is deemed to occur when, after the original issuance of the Series A Preferred Stock, the following have occurred and are continuing:

- the acquisition by any person, including any syndicate or group deemed to be a "person" under Section 13(d)(3) of the Exchange Act of beneficial ownership, directly or indirectly, through a purchase, merger or other acquisition transaction or series of purchases, mergers or other acquisition transactions of the Company's stock entitling that person to exercise more than 50% of the total voting power of all the Company's stock entitled to vote generally in the election of the Company's directors (except that such person will be deemed to have beneficial ownership of all securities that such person has the right to acquire, whether such right is currently exercisable or is exercisable only upon the occurrence of a subsequent condition); and
- following the closing of any transaction referred to in the bullet point above, neither the Company nor the acquiring or surviving entity has a class of common equity securities (or American Depositary Receipts representing such securities) listed on the NYSE, the NYSE American LLC or the Nasdaq Stock Market, or listed or quoted on an exchange or quotation system that is a successor to the NYSE, the NYSE American LLC or the Nasdaq Stock Market.

# Conversion, Exchange and Preemptive Rights

Except as described below under "Limited Conversion Rights upon a Change of Control," the Series A Preferred Stock is not subject to preemptive rights or convertible into or exchangeable for any other securities or property at the option of the holder.

Limited Conversion Rights upon a Change of Control

Upon the occurrence of a Change of Control, each holder of shares of Series A Preferred Stock will have the right (unless, prior to the Change of Control Conversion Date, the Company has provided or provides irrevocable notice of its election to redeem the Series A Preferred Stock as described above under "Optional Redemption," or "Special Optional Redemption") to convert some or all of the shares of Series A Preferred Stock held by such holder on the Change of Control Conversion Date, into the Common Stock Conversion Consideration, which is equal to the lesser of:

- the quotient obtained by dividing (i) the sum of the \$25.00 liquidation preference per share of Series A Preferred Stock plus the amount of any accumulated and unpaid dividends (whether or not declared) to, but not including, the Change of Control Conversion Date (unless the Change of Control Conversion Date is after a record date for a Series A Preferred Stock dividend payment and prior to the corresponding Dividend Payment Date, in which case no additional amount for such accumulated and unpaid dividend will be included in this sum) by (ii) the Common Stock Price (such quotient, the "Conversion Rate");
- 13.05483 shares of common stock, subject to certain adjustments.

In the case of a Change of Control pursuant to which the Company's common stock will be converted into cash, securities or other property or assets, a holder of Series A Preferred Stock will receive upon conversion of such Series A Preferred Stock the kind and amount of Alternative Form Consideration which such holder would have owned or been entitled to receive upon the Change of Control had such holder held a number of shares of the Company's common stock equal to the Common Stock Conversion Consideration immediately prior to the effective time of the Change of Control.

Notwithstanding the foregoing, the holders of shares of Series A Preferred Stock will not have the Change of Control Conversion Right if the acquiror has shares listed or quoted on the NYSE, the NYSE American LLC or Nasdaq Stock Market or listed or quoted on an exchange or quotation system that is a successor to the NYSE, the NYSE American LLC or Nasdaq Stock Market, and the Series A Preferred Stock becomes convertible into or exchangeable for such acquiror's listed shares upon a subsequent Change of Control of the acquiror.

# Liquidation Preference

In the event the Company liquidates, dissolves or is wound up, holders of the Series A Preferred Stock will have the right to receive \$25.00 per share, plus any accumulated and unpaid dividends to, but not including, the date of payment, before any payment is made to the holders of the Company's common stock.

# Ranking

The Series A Preferred Stock will rank, with respect to rights to the payment of dividends and the distribution of assets upon the Company's liquidation, dissolution or winding up, (1) senior to all classes or series of the Company's common stock and to all other equity securities issued by the Company other than equity securities referred to in clauses (2) and (3); (2) on a par with all equity securities issued by the Company with terms specifically providing that those equity securities rank on a par with the Series A Preferred Stock with respect to rights to the payment of dividends and the distribution of assets upon the Company's liquidation, dissolution or winding up; (3) junior to all equity securities issued by the Company with terms specifically providing that those equity securities rank senior to the Series A Preferred Stock with respect to rights to the payment of dividends and the distribution of assets upon the Company liquidation, dissolution or winding up; and (4) junior to all of the Company's existing and future indebtedness.

# **Stock-Based Compensation**

As of December 31, 2024, the Company had three equity compensation plans: the Fortress Biotech, Inc. 2013 Stock Incentive Plan, as amended, the Coronado Biosciences, Inc. 2012 Employee Stock Purchase Plan (the "ESPP") (collectively, the "Plans") and the Fortress Biotech, Inc. Long Term Incentive Plan (the "LTIP"). In the years ended December 31, 2024 and 2023, the Company's Board of Directors and stockholders approved increases of 11.0 million and 0.5 million shares, respectively, to the Plans, bringing the aggregate total of authorized shares available under the Plans to 13.1 million shares. A total of 4.1 million shares have been granted under the Plans, net of cancellations, and 9.0 million shares remained available for issuance as of December 31, 2024.

Certain partner companies have their own equity compensation plan under which shares are granted to eligible employees, directors and consultants in the form of restricted stock, stock options, and other types of grants of stock of the respective partner company's common stock. The table below provides a summary of those plans as of December 31, 2024:

Stock Plan	Shares Authorized	Shares available at December 31, 2024
Avenue Therapeutics, Inc. 2015 Stock Plan	5,070,223	4,575,701
Cellvation Inc. 2016 Incentive Plan	2,000,000	300,000
Checkpoint Therapeutics, Inc. Amended and Restated 2015		
Incentive Plan	18,000,000	8,010,406
Cyprium Therapeutics, Inc. 2017 Stock Plan	2,000,000	675,000
DiaVax Biosciences, Inc. 2015 Incentive Plan	2,000,000	341,667
Journey Medical Corporation 2015 Stock Plan	10,642,857	2,806,824
Mustang Bio, Inc. 2016 Incentive Plan	14,666	6,946
FBIO Acquisition Corp. VII 2017 Incentive Plan	2,000,000	1,200,000
FBIO Acquisition Corp. VIII 2017 Incentive Plan	4,000,000	198,638
	Avenue Therapeutics, Inc. 2015 Stock Plan Cellvation Inc. 2016 Incentive Plan Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan Cyprium Therapeutics, Inc. 2017 Stock Plan DiaVax Biosciences, Inc. 2015 Incentive Plan Journey Medical Corporation 2015 Stock Plan Mustang Bio, Inc. 2016 Incentive Plan FBIO Acquisition Corp. VII 2017 Incentive Plan	Stock Plan         Authorized           Avenue Therapeutics, Inc. 2015 Stock Plan         5,070,223           Cellvation Inc. 2016 Incentive Plan         2,000,000           Checkpoint Therapeutics, Inc. Amended and Restated 2015         18,000,000           Cyprium Therapeutics, Inc. 2017 Stock Plan         2,000,000           DiaVax Biosciences, Inc. 2015 Incentive Plan         2,000,000           Journey Medical Corporation 2015 Stock Plan         10,642,857           Mustang Bio, Inc. 2016 Incentive Plan         14,666           FBIO Acquisition Corp. VII 2017 Incentive Plan         2,000,000

The purpose of the Company's and its subsidiaries' and partner companies' equity compensation plans is to provide for equity awards as part of an overall compensation package of performance-based rewards to attract and retain qualified personnel. Such awards include, without limitation, options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. Vesting of awards may be based upon the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions.

Incentive and non-statutory stock options are granted pursuant to option agreements adopted by the plan administrator. Options generally have 10-year contractual terms.

The Company and its subsidiaries and partner companies estimate the fair value of stock option grants using a Black-Scholes option pricing model. In applying this model, the following assumptions are used:

- Risk-Free Interest Rate: The risk-free interest rate is based on the yields of United States Treasury securities with maturities similar to the expected term of the options for each option group.
- Volatility: The trading history of common stock is used to determine the expected stock price volatility.
- Expected Term: Due to the limited exercise history of the Company's and its subsidiaries' and partner companies' stock
  options, the expected term was determined based on the Simplified Method under SAB 107 and the expected term for nonemployees is the remaining contractual life for both options and warrants.
- Expected Dividend Rate: Neither the Company, nor its subsidiaries and partner companies, have paid and none anticipate
  paying any cash dividends in the near future on their common stock.

The fair value of each option award was estimated on the grant date using the Black-Scholes option-pricing model and expensed under the straight-line method.

The following table summarizes the stock-based compensation expense from stock option, employee stock purchase programs, restricted stock and restricted stock unit awards for the years ended December 31, 2024 and 2023:

	Year Ended December 31, 2024 2023						
(\$ in thousands)	<u></u>	2023					
Fortress:							
Employee and non-employee awards	\$	9,026	\$	8,369			
Executive awards		1,047		1,576			
Partner Companies:							
Avenue		1,236		907			
Checkpoint		15,252		2,897			
Mustang		(450)		567			
Journey		6,098		2,606			
Other		410		107			
Total stock-based compensation expense	\$	32,619	\$	17,029			

For the years ended 2024 and 2023, \$7.1 million and \$3.2 million was included in research and development expenses, and \$25.5 million and \$13.8 million was included in selling, general and administrative expenses, respectively.

# Options

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

	Number of shares	Veighted average exercise price	 Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Options vested and expected to vest at				
December 31, 2023	18,896	\$ 20.55	\$ _	1.76
Granted	540,000	1.68	186,300	6.20
Options vested and expected to vest at	·			
December 31, 2024	558,896	\$ 2.32	\$ 186,300	6.02
Options vested and exercisable at	·			
December 31, 2024	18,896	\$ 20.55	\$ 	1.01

During the years ended December 31, 2024 and 2023, there were no exercises of Fortress stock options.

The Company used the Black-Scholes option pricing model for determining the estimated fair value of stock-based compensation related to stock options. The table below summarizes the assumptions used:

	Year Ended
	December 31, 2024
Risk-free interest rate	4.3 %
Expected dividend yield	_
Expected term in years	7.0
Expected volatility	90.1 %

As of December 31, 2024, Fortress had \$0.4 million of unrecognized stock-based compensation expense related to Fortress stock options, which is expected to be recognized over a weighted-average period of 3.2 years.

As of December 31, 2024, on a consolidated basis, the Company had \$1.0 million of unrecognized stock-based compensation expense related to stock options of Fortress and subsidiaries, which is expected to be recognized over a weighted-average period of 2.1 years.

# Restricted Stock

Consolidated stock-based compensation expense from restricted stock awards and restricted stock units for the years ended December 31, 2024 and 2023 was \$30.9 million and \$16.0 million, respectively. Restricted stock awards and restricted stock unit awards are expensed under the straight-line method over the vesting period. Expense for awards with performance-based vesting criteria are measured and recorded if and when it becomes probable that the milestone will be achieved.

During 2024, the Company granted 0.5 million restricted shares of its Common Stock to executives and directors of the Company and 2.1 million restricted stock units to employees and non-employees of the Company. The fair value of the restricted stock awards issued during 2024 of \$1.4 million and the fair value of the restricted stock unit awards issued during 2024 of \$3.5 million were valued on the grant date using the Company's stock price as of the grant date. The 2024 restricted stock awards and restricted stock unit awards vest upon both the passage of time as well as meeting certain performance criteria.

During 2023, the Company granted 0.2 million restricted shares of its Common Stock to executives and directors of the Company and 0.2 million restricted stock units to employees and non-employees of the Company. The fair value of the restricted stock awards issued during 2023 of \$1.7 million and the fair value of the restricted stock unit awards issued during 2023 of \$0.6 million were valued on the grant date using the Company's stock price as of the grant date. The 2023 restricted stock awards and restricted stock unit awards vest upon both the passage of time as well as meeting certain performance criteria.

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

		avera	eighted age grant
	Number of shares		orice
Unvested balance at December 31, 2023	2,066,810	\$	28.05
Restricted stock granted	468,357		3.01
Restricted stock vested	(17,303)		34.65
Restricted stock units granted	2,054,000		1.72
Restricted stock units forfeited	(19,485)		14.56
Restricted stock units vested	(137,655)		37.88
Unvested balance at December 31, 2024	4,414,724	\$	12.87

The total fair value of restricted stock units and awards that vested during the years ended December 31, 2024 and 2023 was \$5.8 million and \$9.6 million, respectively. As of December 31, 2024, Fortress had unrecognized stock-based compensation expense related to all unvested Fortress restricted stock and Fortress restricted stock unit awards of \$4.2 million and \$4.8 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 0.8 years and 3.4 years, respectively. As of December 31, 2024, on a consolidated basis, the Company had unrecognized stock-based compensation expense related to all unvested restricted stock and restricted stock unit awards of Fortress and subsidiaries of \$9.5 million and \$10.4 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 1.3 years and 2.5 years, respectively. These amounts does not include restricted stock units which are performance-based and vest upon achievement of certain corporate milestones. Stock-based compensation for these awards will be measured and recorded if and when it is probable that the milestone will be achieved.

# Deferred Compensation Plan

On March 12, 2015, the Company's Compensation Committee approved the Deferred Compensation Plan allowing all non-employee directors the opportunity to defer all or a portion of their fees or compensation, including restricted stock and restricted stock units. During the years ended December 31, 2024 and 2023, certain non-employee directors elected to defer an aggregate of approximately 25,000 and 27,000 restricted stock awards, respectively, under this plan.

# Employee Stock Purchase Plan

Eligible employees can purchase the Company's Common Stock at the end of a predetermined offering period at 85% of the lower of the fair market value at the beginning or end of the offering period. The ESPP is compensatory and results in stock-based compensation expense.

As of December 31, 2024, 0.1 million shares have been purchased and 1.0 million shares are available for future sale under the Company's ESPP. The Company recognized share-based compensation expense of approximately \$0.1 million and \$0.1 million for the years ended December 31, 2024 and 2023, respectively.

# Warrants

The following table summarizes Fortress warrant activities, excluding activities related to 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, 2023	5,787,288	\$ 1.88	\$ 7,794,450	4.91		
Issued	8,729,746	2.35	1,131,912	4.83		
Exercised	(107,500)	1.67	_	_		
Canceled	(3,333)	32.40	_	_		
Outstanding as of December 31, 2024	14,406,201	\$ 2.15	\$ 2,933,774	4.46		
Exercisable as of December 31, 2024	14,406,201	\$ 2.15	\$ 2,933,774	4.46		

In connection with the 2024 Oaktree Note (see Note 9), the Company issued warrants to Oaktree and certain of its affiliates to purchase up to approximately 0.5 million shares of Common Stock at a purchase price of \$2.0735 per share (the "2024 Oaktree Warrants"). Oaktree is entitled to a reduction in exercise price if, at any time prior to the expiration of the 2024 Oaktree Warrants, the Company issues equity, warrants or convertible notes (collectively known as "Security Instruments") at a price that is less than 95% of the market price of the Company's Common Stock on the trading day prior to the issuance of the Security Instruments. As a result of the September 2024 registered direct offering (see Note 13), the exercise price on the 2024 Oaktree warrants was lowered to \$1.65 per share, and approximately \$20,000 was recorded to interest expense.

The Company evaluated the accounting treatment of the 2024 Oaktree Warrants and determined that the 2024 Oaktree warrants should be classified in stockholders' equity. As such, the Company used a Black-Scholes model to value the Oaktree Warrants. Utilizing the following inputs: term of 7 years, volatility of 90.52%, risk-free rate of return of 4.18% yielding a value of \$1.1 million and was recorded as a component of Stockholders' Equity in the Company's Condensed Consolidated Balance Sheet.

In connection with the 2020 Oaktree Note (see Note 9), in August 2020 the Company had issued warrants to Oaktree and certain of its affiliates to purchase up to approximately 0.1 million shares of Common Stock at an exercise price of \$8.14 per share (the "Oaktree Warrants"). The Oaktree Warrants expire on August 27, 2030 and may be net exercised at the holder's election. Oaktree is entitled to additional warrants if at any time prior to the expiration of the Oaktree Warrants the Company issues equity, warrants or convertible notes (collectively known as "Security Instruments") at a price that is less than 95% of the market price of the Company's Common Stock on the trading day prior to the issuance of the Security Instruments. As a result of the September 2024 registered direct offering (see Note 13), the Company issued an additional 14,450 warrants to Oaktree and adjusted the exercise price of the Oaktree Warrants to \$7.2392, and recorded the resulting expense of \$27,000 to interest expense.

The Company filed registration statement No. 333-282384 on Form S-1 to register the resale of the shares of Common Stock issuable upon exercise of the 2024 Oaktree Warrants and the additional Oaktree Warrants, which was declared effective by the SEC on October 7, 2024.

Amended and Restated Long-Term Incentive Program ("LTIP")

On July 15, 2015, the stockholders approved the LTIP for the Company's Chairman, President and Chief Executive Officer, Dr. Rosenwald, and Executive Vice Chairman, Strategic Development, Mr. Weiss. 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 compensate LTIP participants based on their responsibilities and for their contributions to the successful achievement of certain corporate goals and objectives of the Company.

On January 1, 2024 and 2023, the Compensation Committee granted 216,465 and 81,286 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 \$0.7 million for the 2024 grant and \$0.8 million for the 2023 grant. For the year ended December 31, 2024 and 2023, the Company recorded stock compensation expense related to LTIP grants of approximately \$6.7 million and \$5.8 million, respectively, on the 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 December 31, 2024, \$43.1 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.

# Common Stock At the Market Offering

For the year ended December 31, 2024, the Company issued approximately 2.0 million shares of common stock at an average price of \$1.98 per share for net proceeds of \$3.8 million after deducting aggregate fees of \$0.1 million. For the year ended December 31, 2023, the Company issued approximately 0.2 million shares of common stock at an average price of \$9.61 per share for net proceeds of \$2.2 million after deducting aggregate fees of \$0.1 million.

# **Equity Offerings and Private Placements**

In September 2024, Fortress closed a registered direct offering of an aggregate of 3,939,394 shares of its common stock at a purchase price of \$1.65 per share. In a concurrent private placement, the Company also agreed to issue to the same investors that participated in the registered direct offering warrants to purchase up to 3,939,394 shares of common stock (the "Private Placement Warrants"). The Private Placement Warrants have an exercise price of \$1.84 per share, are exercisable commencing six months from the date of issuance, and will expire five and one-half years following the date of issuance.

In a separate concurrent private placement, Dr. Rosenwald, the Company's Chairman, President and Chief Executive Officer, purchased 763,359 shares of common stock at a price of \$1.84 per share, which represented the consolidated closing bid price of the Company's common stock on the Nasdaq Capital Market on September 19, 2024, and warrants to purchase up to 763,359 shares of common stock, purchased at a price of \$0.125 per warrant (the "Concurrent Private Placement Warrants"). The Concurrent Private Placement Warrants have an exercise price of \$1.84 per share, are exercisable commencing six months from the date of issuance, and will expire five and one-half years following the date of issue. Net proceeds to Fortress from the September 2024 registered direct offering and the concurrent private placements, after deducting the placement agent's fees and other offering expenses and assuming no exercises of the Private Placement Warrants or the Concurrent Private Placement Warrants, were approximately \$7.3 million.

The Company filed a registration statement (No. 333-282384) on Form S-1 to register the resale of the shares of Common Stock issuable upon exercise of the Private Placement Warrants and the Concurrent Private Placement Warrants, which was declared effective by the SEC on October 7, 2024.

In connection with the financing consummated by the Company in September 2024, the 5,885,000 warrants issued in the November 2023 equity offering (the "November 2023 Warrants") had their exercise price reduced to \$1.65 per share. The November 2023 Warrants contained a one-time exercise price adjustment provision that reduced the exercise price upon the next equity financing at a price lower than the exercise price at issuance which was \$1.70 per share.

In January 2024, Fortress closed a registered direct offering of an aggregate of 3,303,305 shares of its common stock and warrants to purchase up to 3,303,305 shares of its common stock at a combined purchase price of \$3.33 per share of common stock and accompanying warrant priced at-the-market under Nasdaq rules. The warrants have an exercise price of \$3.21 per share, were immediately exercisable, and expire five years following the date of issue. Net proceeds to Fortress, after deducting the placement agent's fees and other offering expenses, were approximately \$10.1 million.

# Journey 2022 Shelf Registration Statement and At the Market Offering (the "Journey ATM")

On December 30, 2022, Journey filed a shelf registration statement on Form S-3 (File No. 333-269079), which was declared effective by the SEC on January 26, 2023 (the Journey 2022 S-3"). 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 has entered into the Sales Agreement with B. Riley, relating to shares of the Journey's common stock. In accordance with the terms of the 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 through or to B. Riley acting as Journey's agent or principal.

For the year ended December 31, 2024, Journey issued approximately 1.6 million shares of common stock at an average price of \$5.19 per share for net proceeds of \$7.9 million under the Journey ATM after deducting aggregate fees of \$0.2 million. At December 31, 2024, 2,586,987 shares remain available for issuance under the Journey 2022 S-3.

# Checkpoint 2023 Shelf Registration Statements

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 December 31, 2024, approximately \$65.7 million of the securities remain available for sale through the Checkpoint 2023 S-3.

# **Checkpoint Registered Direct Offerings**

In November 2024, Checkpoint received approximately \$9.2 million upon the exercise of existing Series B warrants to purchase 3,256,269 shares of Checkpoint common stock, which warrants were originally issued and sold in a registered direct offering from May 2023 with an exercise price of \$2.821 per share. The shares of common stock issuable upon the exercise of the warrants were registered under the Checkpoint 2023 S-3.

In July 2024, Checkpoint closed on a registered direct offering (the "Checkpoint July 2024 Registered Direct Offering") for the issuance and sale of an aggregate of 1,230,000 shares of its common stock at a purchase price of \$2.05 per share. In addition, the offering includes 4,623,659 shares of common stock in the form of pre-funded warrants at a price of \$2.0499. In a concurrent private placement, Checkpoint issued and sold common warrants (the "Checkpoint July 2024 Common Stock Warrants") to purchase up to 5,853,659 shares of common stock. The Checkpoint July 2024 Common Stock Warrants have an exercise price of \$2.05 per share, will be exercisable after requisite approval of Checkpoint's stockholders is received, and have a term of exercise of five years from the issuance date. Checkpoint also issued the placement agent warrants to purchase up to 351,220 shares of common stock with an exercise price of \$2.5625 per share. The total net proceeds from the Checkpoint July 2024 Registered Direct Offering, after deducting placement agent's fees and other offering expenses, were approximately \$11.0 million. The shares of common stock and the shares underlying the pre-funded warrants were sold in a registered offering under the Checkpoint 2023 S-3. In August 2024, Checkpoint filed a registration statement on Form S-3 to register the public rsale of the shares of Checkpoint common stock issuable upon exercise of each of the Checkpoint July 2024 Common Stock Warrants and the placement agent warrants, which was declared effective August 30, 2024 (File No. 333-281650). All of the pre-funded warrants from the Checkpoint July 2024 Registered Direct Offering have been fully exercised.

In January 2024, Checkpoint closed on a registered direct offering (the "Checkpoint January 2024 Registered Direct Offering") for the issuance and sale of 1,275,000 shares of its common stock at a purchase price of \$1.805 per share. In addition, the offering includes prefunded warrants to purchase 6,481,233 shares of common stock, which were sold at a price of \$1.8049. In a concurrent private placement, Checkpoint issued and sold common warrants (the "Checkpoint January 2024 Common Warrants") to purchase up to 7,756,233 shares of Checkpoint common stock. The Checkpoint January 2024 Common Warrants are exercisable immediately upon issuance and will expire five years following the issuance date and have an exercise price of \$1.68 per share. Checkpoint also issued the placement agent warrants to purchase up to 465,374 shares of common stock with an exercise price of \$2.2563 per share. Net proceeds to Checkpoint from the Checkpoint January 2024 Registered Direct Offering were \$12.6 million after deducting commissions and other transaction costs. The offer and sale of the shares of common stock and the shares underlying the pre-funded warrants were registered for sale under the Checkpoint 2023 S-3. In March 2024, Checkpoint filed a registration statement on Form S-3 to register the public resale of the shares of Checkpoint common stock issuable upon exercise of each of the Checkpoint January 2024 Common Stock Warrants and the placement agent warrants, which was declared effective April 5, 2024 (File No. 333-278397). All of the pre-funded warrants from the Checkpoint January 2024 Registered Direct Offering have been fully exercised.

# Mustang 2021 Shelf Registration Statement and At-the-Market Offering

On April 23, 2021, Mustang filed a shelf registration statement on Form S-3 (File No. 333-255476) (the "Mustang 2021 S-3"), which was declared effective on May 24, 2021. Through the Mustang 2021 S-3, Mustang was able to sell up to a

total of \$200 million of its securities. In 2024, Mustang sold approximately \$4.4 million of securities under the Mustang 2021 S-3 until Mustang's ability to register new offers and sales of securities under such registration statement expired on May 24, 2024.

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 December 31, 2024, approximately \$34.8 million of the Mustang 2024 S-3 remains available for sales of securities, subject to General Instruction I.B.6. of Form S-3. The ability of Mustang to register new offers and sales of securities under the Mustang 2024 S-3 expires on June 12, 2027.

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 year ended December 31, 2024, Mustang issued approximately 0.1 million shares of common stock at an average price of \$18.78 per share for net proceeds of \$2.5 million under the Mustang ATM, after deducting aggregate fees of approximately \$0.1 million.

During the year ended December 31, 2023, Mustang issued approximately 1,000 shares (adjusted for reverse split) of common stock at an average price of \$158.07 per share for net proceeds of \$0.2 million under the Mustang ATM.

# Mustang Registered Direct and Equity Offerings, Warrant Inducement and Private Placement

In October 2024, Mustang entered into a definitive agreement for the exercise of certain existing warrants to purchase an aggregate of 337,552 shares of its common stock having an exercise price of \$11.85 per share, originally issued in May 2024. The issuance or resale of the shares of common stock issuable upon exercise of the existing warrants are registered pursuant to an effective registration statement filed by Mustang on Form S-1 (File No. 333-278006). The net proceeds to Mustang from the exercise of the existing warrants were approximately \$3.6 million, prior to deducting placement agent fees and offering expenses payable by Mustang of \$0.4 million.

In consideration for the immediate exercise of the existing warrants for cash, Mustang issued two new series of unregistered warrants to purchase up to an aggregate of 675,104 shares of common stock. The new warrants have an exercise price of \$13.50 per share and will be exercisable commencing on the effective date of stockholder approval of the issuance of the shares issuable upon exercise of the new warrants (the "Stockholder Approval"). One of the new series of warrants to purchase 337,552 shares of common stock has a term of five years from the Stockholder Approval, and the other new series of warrants to purchase 337,552 shares of common stock has a term of twelve months from the Stockholder Approval.

In June 2024, Mustang closed on a registered direct offering of 60,500 shares of common stock at \$20.50 per share (or common stock equivalent) priced at-the-market under Nasdaq rules and pre-funded warrants to purchase up to 62,100 shares of common stock, at a price per pre-funded warrant equal to \$20.495, the price per share of common stock, less \$0.005. The pre-funded warrants have an exercise price of \$0.005 per share, became exercisable upon issuance and remain exercisable until exercised in full. In a concurrent private placement, Mustang also agreed to issue and sell unregistered warrants to purchase up to 62,100 shares of its common stock, with an exercise price of \$20.495 per share, exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the warrants and will expire five years from the date of stockholder approval. Net proceeds were approximately \$2.1 million, after placement agent's fees and other offering expenses. All of the 62,100 pre-funded warrants have since been exercised.

In May 2024, Mustang closed on an equity offering of 23,200 shares of common stock and pre-funded warrants to purchase up to 314,352 shares of common stock (or common stock equivalents in lieu thereof), and three series of 337,552 warrants each for a total of 1,012,656 warrants with a combined equity offering price of \$11.85 per share (or per share common stock equivalent in lieu thereof) and accompanying warrants with an exercise price of \$11.85 per share. The Series A-1 warrants have a five-year term, the Series A-2 warrants have a twenty-four month term, and the Series A-3 warrants have a nine month term. 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 equity offering, after deducting the fees and expenses of the placement agent and other offering expenses payable by Mustang was approximately \$3.2 million. All of the 314,352 pre-funded warrants have since been exercised.

Pursuant to the terms of the Second Amended and Restated Founders Agreement, Mustang owes to Fortress 2.5% of the aggregate number of shares of Mustang common stock issued in the offerings noted above. Accordingly, Mustang issued 23,450 common shares to Fortress for the year ended December 31, 2024.

### Avenue 2021 Shelf Registration Statement and At-the-Market Offering

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. As of December 31, 2024, approximately \$2.2 million of the securities were available for sale under the Avenue 2021 S-3, subject to General Instruction I.B.6. of Form S-3.

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 offer and sale of the shares will be made pursuant to a base prospectus forming a part of the Avenue 2021 S-3, and the related prospectus supplement dated May 10, 2024. During the year ended December 31, 2024, Avenue issued 0.6 million shares through the Avenue ATM for net proceeds of \$1.6 million.

# Avenue 2024 Warrant Exercises and Private Placement

On January 5, 2024, Avenue entered into (i) an inducement offer letter agreement (the "January 2023 Investor Inducement Letter") with a certain investor (the "January 2023 Investor") in connection with certain outstanding warrants to purchase up to an aggregate of 25,871 shares of Common Stock, originally issued to the January 2023 Investor on January 31, 2023 (the "January 2023 Warrants") and (ii) an inducement offer letter agreement (the "November 2023 Investor Inducement Letter Agreement" and, together with the January 2023 Investor Inducement Letter, the "January 2024 Warrant Inducement") with certain investors (the "November 2023 Investors" and, together with the January 2023 Investor, the "Holders") in connection with certain outstanding warrants to purchase up to an aggregate of 194,667 shares of Common Stock, originally issued to the November 2023 Investors on November 2, 2023 (the "November 2023 Warrants" and, together with the January 2023 Warrants, the "Existing Warrants"). The January 2023 Warrants had an exercise price of \$116.25 per share, and the November 2023 Warrants had an exercise price of \$22.545 per share.

Pursuant to the January 2024 Warrant Inducement, (i) the January 2023 Investor agreed to exercise its January 2023 Warrants for cash at a reduced exercise price of \$22.545 per share and (ii) the November 2023 Investors agreed to exercise their November 2023 Warrants for cash at the existing exercise price of \$22.545, in each case in consideration for Avenue's agreement to issue in a private placement (x) Series A Warrants to purchase up to 220,538 shares of Avenue Common Stock and (y) Series B Warrants to purchase up to 220,538 shares of Avenue Common Stock. The net proceeds to Avenue from the exercise of the warrants was approximately \$4.5 million, after deducting placement agent fees and estimated offering costs, but without giving effect to the exercise of the Series A Warrants and Series B Warrants issued in the January 2024 Warrant Inducement.

The fair value of the Series A Warrants and Series B Warrants was allocated between the January 2023 Warrants and the November 2023 Warrants on a weighted basis, with approximately \$0.6 million allocated to the January 2023 Warrants and recorded to loss on common stock warrant liabilities in the condensed consolidated statement of operations, and the approximately \$4.3 million allocated to the November 2023 Warrants deemed to be a dividend.

Also in April 2024, Avenue entered into definitive agreements for the immediate exercise of certain of its existing outstanding warrants to purchase an aggregate of 689,680 shares of Avenue's common stock at a reduced exercise price of \$6.20 per share (the "May 2024 Warrant Inducement"). The exercised warrants are comprised of warrants to purchase shares of common stock originally issued by Avenue on October 11, 2022, each having an exercise price of \$116.25 per share, Series A and Series B warrants to purchase shares of common stock originally issued by Avenue on November 2, 2023, each having an exercise price of \$22.545 per share, and warrants to purchase shares of common stock originally issued by Avenue on January 9, 2024, each having an exercise price of \$22.545 per share. Total net proceeds to Avenue were approximately \$3.7 million after deducting placement agent fees and other expenses payable by Avenue.

In consideration for the immediate exercise of the warrants for cash in the May 2024 Warrant Inducement, Avenue issued two new unregistered series of warrants (the "Avenue May 2024 Warrants") to purchase up to a total of 1,379,360 shares

of Avenue common stock for a payment of \$0.125 per warrant. The Avenue May 2024 Warrants have an exercise price of \$6.20 per share, and terms of eighteen months for one series and five years for the other series. The fair value of the Avenue May 2024 Warrants of approximately \$4.5 million is deemed to be a dividend.

Pursuant to the Founders Agreement, Avenue issued to Fortress 2.5% of the aggregate number of shares of Avenue common stock issued in the offerings noted above. Accordingly, Avenue issued 43,772 shares to Fortress for the year ended December 31, 2024.

# 14. Commitments and Contingencies

# Leases

The Company's lease portfolio includes leases for our corporate headquarters, office spaces, and a cell manufacturing facility. Most of the Company's lease liabilities result from the lease of its New York City, NY office, which expires in 2031 and Mustang's Worcester, MA cell processing facility lease, which expires in 2026 (see Note 20). Such leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Certain of the Company's leases include renewal options and escalation clauses; renewal options have not been included in the calculation of the lease liabilities and right of use assets as the Company is not reasonably certain to exercise the options. The Company does not act as a lessor or have any leases classified as financing leases.

For the year ended December 31, 2024, Mustang identified triggering events that required an impairment of the asset group consisting of its right-of-use asset and associated leasehold improvements, and the impairment loss was allocated to leasehold improvements and the right-of-use assets based on the relative arrying amounts of the assets (see Note 5), with \$0.4 million of the impairment allocated to the right-of-use asset group. At December 31, 2024, the Company had operating lease liabilities of \$17.4 million and right of use assets of \$13.9 million, which are included in the Company's Consolidated Balance Sheet.

The Company recognizes rent expense on a straight-line basis over the non-cancellable lease term. Rent expense for the years ended December 31, 2024 and 2023 was \$1.5 million and \$1.9 million, respectively. The components of lease cost are as follows:

		Year Ended I	December 31	,
(\$ in thousands)	2	2024		2023
Operating lease cost	\$	2,758	\$	3,236
Shared lease costs		(2,100)		(2,086)
Variable lease cost		865		761
Total lease expense	\$	1,523	\$	1,911

The following tables summarize quantitative information about the Company's operating leases:

	Year Ended December 31,					
(\$ in thousands)	2024	2023				
Operating cash flows from operating leases	\$ (3,647)	\$	(3,549)			
Right-of-use assets exchanged for new operating lease liabilities	\$ 188	\$	923			
Weighted-average remaining lease term – operating leases (years)	3.8		4.2			
Weighted-average discount rate – operating leases	6.3 %	)	6.5 %			

(S in thousands)	Future Lease Liability
Year Ended December 31, 2025	3,533
Year Ended December 31, 2026	3,272
Year Ended December 31, 2027	2,923
Year Ended December 31, 2028	2,967
Other	8,125
Total operating lease liabilities	20,820
Less: present value discount	(3,447)
Net operating lease liabilities, short-term and long-term	\$ 17,373

# License Agreements

The Company has undertaken to make contingent development and commercial milestone payments to the licensors of its portfolio of drug products and candidates. In addition, the Company shall pay royalties to such licensors based on a percentage of net sales of each drug candidate following regulatory marketing approval. For additional information on future milestone payments and royalties, (see Note 7).

#### Indemnification

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

# **Legal Proceedings**

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

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

Caelum Biosciences, Inc. ("Caelum"), a former subsidiary of Fortress that was sold to AstraZeneca's Alexion Pharmaceuticals, Inc. subsidiary ("Alexion") in October 2021, was the defendant in a lawsuit brought by The University of Tennessee Research Foundation ("UTRF") captioned as *University of Tennessee Research Foundation v. Caelum Biosciences, Inc.*, No. 19-cv-00508, which was formerly pending in the United States District Court for the Eastern District of Tennessee (the "UTRF Litigation"). UTRF brought claims against Caelum, for, *inter alia*, trade secret misappropriation. UTRF primarily alleged that Caelum unauthorizedly used non-patent trade secrets owned by UTRF in the development of Caelum's 11-1F4 monoclonal antibody, known as CAEL-101. Under the agreement pursuant to which Alexion acquired Caelum (as amended, the "DOSPA"), Fortress had certain indemnification obligations of Caelum pertaining to the UTRF litigation and maintained a consent right over any potential settlements of the UTRF litigation by Caelum.

On September 16, 2024, Caelum and UTRF entered into a stipulation with the court pursuant to which UTRF's claims were dismissed without prejudice; on October 16, 2024, Caelum and UTRF entered into a definitive settlement agreement (the "UTRF-Caelum Settlement Agreement") pursuant to which UTRF's claims were dismissed with prejudice and Caelum agreed to make an upfront payment and additional potential milestone-based payments to UTRF. Fortress and the other sellers under the DOSPA are explicit releasees and third party beneficiaries under the UTRF-Caelum Settlement Agreement. In connection with the execution of the UTRF-Caelum Settlement Agreement, Caelum, Alexion and Fortress

entered into an amendment to the DOSPA (the "DOSPA Amendment"), which, *inter alia*: (1) terminated any continuing indemnification by Fortress and the other sellers under the DOSPA in respect of the UTRF Litigation; (2) reduced the amounts of the potential future earn-out payments potentially owing to the sellers under the DOSPA (including Fortress) from an aggregate amount up to \$350 million to an aggregate amount up to \$295 million; (3) released to Caelum all amounts remaining in an escrow fund that had been established at the time of the Alexion acquisition to backstop potential indemnifiable damages, including those incurring under the UTRF Litigation (with 100% of such released amount constituting reimbursement for legal fees and other expenses incurred by Caelum in defending the UTRF Litigation); and (4) memorialized Fortress' consent for Caelum to settle the UTRF Litigation. Neither the UTRF-Caelum Settlement Agreement nor the DOSPA Amendment implicates any out-of-pocket payment by Fortress or any other seller under the DOSPA. Fortress remains eligible to receive approximately \$19 million upon regulatory approval of CAEL-101 and approximately \$125 million in the aggregate across all remaining regulatory and sales milestones.

# Journey Loss Recovery

In September 2021, Journey was the victim of a business email compromise cybersecurity incident, that affected its accounts payable function and led to approximately \$9.5 million in wire transfers being misdirected to fraudulent accounts. Journey recorded the loss as a separate component of operating expenses in its 2021 consolidated financial statements. The FBI was able to trace and seize a portion of the fraudulently transferred cryptocurrency. Subsequently, pursuant to a stipulation and order signed by Journey on September 19, 2024, the United Stated District Court Southern District of New York through the United States Marshalls recovered funds of approximately \$4.6 million on December 4, 2024. The proceeds from the recovery were recorded and classified within Journey's Consolidated Statements of Operations as a separate component of operating expenses, consistent with the initial recognition of the loss in 2021.

# 15. Employee Benefit Plan

On January 1, 2008, the Company adopted a defined contribution 401(k) plan which allows employees to contribute up to a percentage of their compensation, subject to IRS limitations and provides for a discretionary Company match up to a maximum of 4% of employee compensation. For the years ended December 31, 2024 and 2023, the Company paid a matching contribution of \$0.8 million and \$1.1 million, respectively.

# 16. Related Party Transactions

Founders Agreement and Management Services Agreement

The Company has entered into Founders Agreements with each of the Fortress partner companies and subsidiaries listed in the table below. Pursuant to each Founders Agreement, in exchange for the time and capital expended in the formation of each partner company/subsidiary and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, Fortress will loan each such partner company/subsidiary an amount representing the up-front fee required to acquire assets. Each Founders Agreement has a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by the Company or upon a Change in Control (as defined in the Founders Agreement) occurs. In connection with each Founders Agreement the Company received a number of either Class A Preferred shares or Class A Common Stock – see Note 20).

The Class A Preferred Stock or Class A Common Stock (such stock, the "Founders Stock") is identical to common stock other than as to voting rights, conversion rights and the Payment-in-Kind ("PIK") Dividend right (as described below). Each share of Founders Stock is entitled to vote the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the shares of outstanding common stock and (B) the whole shares of common stock into which the shares of outstanding Founders Stock are convertible and the denominator of which is the number of shares of outstanding Founders Stock. Thus, the Founders Stock will at all times constitute a voting majority. Each share of Founders Stock is convertible, at the holder's option, into one fully paid and nonassessable share of common stock of such partner company/subsidiary, subject to certain adjustments.

The holders of Founders Stock, as a class, are entitled receive on each effective date or "Trigger Date" (defined as the date that the Company first acquired, whether by license or otherwise, ownership rights to a product) of each agreement (each

a "PIK Dividend Payment Date") and on each anniversary date of such date until the date all outstanding Founders Stock is converted into common stock or redeemed (and the purchase price is paid in full), pro rata per share dividends paid in additional fully paid and nonassessable shares of common stock ("PIK Dividends") such that the aggregate number of shares of common stock issued pursuant to such PIK Dividend is equal to two and one-half percent (2.5%) of such partner company or subsidiary's fully-diluted outstanding capitalization on the date that is one (1) business day prior to any PIK Dividend Payment Date. The Company has reached agreements with several of the partner companies and subsidiaries to change the PIK Dividend Interest Payment Date to January 1 of each year - a change that has not and will not result in the issuance of any additional partner company/subsidiary common stock beyond that amount to which the Company would otherwise be entitled absent such change(s). The Company owns 100% of the Founders Stock of each partner company/subsidiary that has a Founders Agreement with the Company.

As additional consideration under the Founders Agreement, each partner company and subsidiary with which the Company has entered into a Founders Agreement will also: (i) pay an equity fee in shares of the common stock of such partner company/subsidiary, payable within five (5) business days of the closing of any equity or debt financing for each partner company/subsidiary or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when the Company no longer has majority voting control in such partner company or subsidiary's voting equity, equal to two and one-half (2.5%) of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to four and one-half percent (4.5%) of such partner company or subsidiary's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a Change in Control, each such partner company/subsidiary will pay a one-time change in control fee equal to five (5x) times the product of (A) net sales for the twelve (12) months immediately preceding the change in control and (B) four and one-half percent (4.5%). In the case of Urica, however, the obligation to pay Fortress royalties under the Founders Agreement survives any such Change in Control.

The following table summarizes, by subsidiary, the PIK dividends, annual equity fees, and equity fees recorded by the Company in accordance with the terms of the Founders Agreements, Exchange Agreements and the partner companies'/subsidiaries' certificates of incorporation for the years ended December 31, 2024 and 2023 (\$ in thousands):

	PIK Dividend	Year Ended	December 31,
Partner company	Date	2024	2023
Avenue	January 1	410	444
Cellvation	October 31	10	10
Checkpoint	January 1	8,633	4,370
Cyprium	January 1	291	304
Helocyte	January 1	39	120
Mustang	January 1	940	591
Oncogenuity	May 8	9	9
Urica	November 25	514	502
Fortress		(10,846)	(6,350)
Total		\$ —	\$ —

#### Management Services Agreements

The Company has entered into Management Services Agreements (the "MSAs") with certain of its partner companies and subsidiaries. Pursuant to each MSA, the Company's management and personnel provide advisory, consulting and strategic services to each such partner company/subsidiary for an initial period of five (5) years (with such initial terms automatically renewing for successive five-year periods unless terminated by the Company or the partner company/subsidiary on at least 90 days' notice prior to the expiration of any such five-year period). Such services may include, without limitation, (i) advice and assistance concerning any and all aspects of each such company's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of each such company with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). Each such partner company/subsidiary is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, such companies are not obligated to take or act upon any advice rendered from Fortress, and Fortress shall not be liable to any such partner company/subsidiary for its actions or inactions based upon Fortress' advice. Fortress and its affiliates, including all members of Fortress' Board of Directors, have been contractually exempted from fiduciary duties to each such partner company/subsidiary relating to corporate opportunities.

The following table summarizes, by partner company/subsidiary, the effective date of the MSA and the annual consulting fee payable by the partner company/subsidiary to Fortress in quarterly installments (\$ in thousands):

		Year Ended December 31,						
Partner Company/Subsidiary	Effective Date	2024	2023					
Avenue <sup>1</sup>	February 17, 2015	250	500					
Cellvation	October 31, 2016	500	500					
Checkpoint	March 17, 2015	500	500					
Cyprium	March 13, 2017	500	500					
Helocyte	March 20, 2015	500	500					
Mustang	March 13, 2015	500	500					
Oncogenuity	February 10, 2017	500	500					
Urica	November 7, 2017	500	500					
Fortress		(3,750)	(4,000)					
Consolidated (Income)/Expense	<u>\$</u>		<u> </u>					

Note 1: Avenue's MSA fee for 2024 was subject to a Subscription and Forgiveness Agreement signed in November 2024.

Fees and Stock Issuances 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 TGTX

In July 2015, TGTX and the Company entered into an arrangement to share the cost of certain research and development employees. The Company's Executive Vice Chairman, Strategic Development, is Executive Chairman and Interim Chief Executive Officer of TGTX. Under the terms of the Agreement, TGTX will reimburse the Company for the salary and benefit costs associated with these employees based upon actual hours worked on TGTX related projects. In connection with the shared services agreement, for the years ended December 31, 2024 and 2023, the Company invoiced TGTX \$0.9 million and \$0.4 million, respectively. At December 31, 2024, there was approximately \$36,000 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 years ended December 31, 2024 and 2023, the Company had paid \$2.9 million and \$2.8 million in rent, respectively, and invoiced TGTX approximately \$1.7 million and \$1.8 million respectively, for their prorated share of the rent base. At December 31, 2024, there were no amounts due from TGTX related to this arrangement.

# Avenue Subscription and Forgiveness Agreement

On November 13, 2024, the Company entered into a Subscription and Forgiveness Agreement with Avenue, whereby the Company agreed to convert 50% of a total of \$0.5 million owed by Avenue under the MSA into newly issued common stock of Avenue and forgive the remaining 50% of the accrued balance. Therefore, Avenue issued a total of 122,850 shares to the Company based on the closing price of \$2.035 on the day prior to the execution of the agreement.

# Avenue September 2023 Private Placement

In September 2023, Avenue entered into an arrangement with Fortress and Dr. Lindsay A. Rosenwald (Dr. Rosenwald and Fortress, together, the "Avenue Private Placement Investors"), pursuant to which Avenue agreed to issue and sell 10,227 shares of Avenue common stock for an aggregate purchase price of approximately \$550,000 in a private placement transaction. The Avenue common shares were purchased at a price per share of \$53.775, by the Avenue Private Placement Investors, which was the "consolidated closing bid price" of the Avenue common stock on Nasdaq as of September 7, 2023, in compliance with Nasdaq Listing Rule 5365(c). The net proceeds to Avenue from the private placement were approximately \$550,000.

# 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 years ended December 31, 2024 and 2023, Checkpoint recognized approximately \$153,000 and \$110,000 in expenses related to the advisory agreement, including approximately \$93,000 and \$50,000 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 years ended December 31, 2024 and 2023, Mustang recognized approximately \$60,000 and \$110,000 in expenses related to the advisory agreement, respectively, including \$50,000 in expenses related to annual equity incentive grants in 2023.

# Checkpoint Collaborative Agreements with TGTX

Checkpoint previously entered into various agreements with TGTX to develop and commercialize certain assets in connection with its licenses, including a collaboration agreement for some of the Dana Farber licensed antibodies, and a sublicense agreement for the Jubilant family of patents. Effective September 30, 2023, Checkpoint and TGTX agreed to mutually terminate both the collaboration agreement and the sublicense agreement.

# Shared Services Agreement with Journey

In November 2021, Journey and the Company entered into an arrangement to share the cost of certain legal, finance, regulatory, and research and development employees. The Company's Executive Chairman and Chief Executive Officer is the Executive Chairman of Journey. Under the terms of the arrangement, Journey reimburses the Company for the salary and benefit costs associated with these employees based upon actual hours worked on Journey-related projects. 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 year ended December 31, 2024 and 2023, the Company's employees have provided services to Journey totaling approximately \$38,000 and \$0.1 million, respectively. At December 31, 2024, approximately \$0.6 million is due from Journey, primarily related 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 shares of its 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock ("Cyprium PPS"); as of December 31, 2024, there are 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 the record date are entitled to receive a monthly cash dividend of \$0.19531 per share which yields an annual dividend of \$2.34375 per share. The Cyprium PPS will automatically be redeemed upon the first (and only the first) bona fide, arm's-length sale of a Priority Review Voucher (a "PRV Sale") issued by the FDA in connection with the approval of CUTX-101, a product candidate previously developed by Cyprium. Upon the PRV Sale, each share of Cyprium PPS will be automatically redeemed in exchange for a payment equal to twice 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.

# 17. Income Taxes

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

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The components of the income tax provision are as follows:

	Year En	led Dece	mber 31,
(\$ in thousands)	2024		2023
Current			
Federal	\$	3 \$	33
State	14	10	254
Deferred			
Federal	13	6	194
State	3	33	39
Total	\$ 31	2 \$	521

For the years ended December 31, 2024 and 2023, income tax expense was \$0.3 million and \$0.5 million, respectively, resulting in an effective income tax rate of -0.2% and -0.3%. The income tax expense in 2024 is primarily due to uncovered deferred tax liabilities with respect to investments in subsidiaries, state income taxes and interest accrued related to a prior years' uncertain tax position.

The Company has incurred net operating losses since inception. The Company has not reflected any benefit of such net operating loss carryforwards ("NOL") in the accompanying consolidated financial statements and has established a valuation allowance of \$378.0 million against its net deferred tax assets. Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

The significant components of the Company's deferred taxes consist of the following:

		As of Dece	embei	
(\$ in thousands)		2024	_	2023
Deferred tax assets:				
Net operating loss carryforwards	\$	232,740	\$	211,329
Amortization of license fees		29,421		33,996
Amortization of in-process R&D		242		315
Stock compensation		12,773		13,184
Lease liability		4,763		6,477
Accruals and reserves		3,676		3,897
Tax credits		40,623		37,894
Startup costs		30		40
Unrealized gain/loss on investments		48		55
Section 174 R&D expenditure capitalization		53,510		59,238
State taxes		(70)		33
Business interest limitation		4,154		2,880
Reserve on Sales Return, Discount and Bad Debt		2,714		4,556
Total deferred tax assets		384,624		373,895
Less: valuation allowance		(377,965)		(366,375)
Net deferred tax assets	\$	6,659	\$	7,520
Deferred tax liabilities:				
Section 483 imputed interest	\$	_	\$	(25)
Debt issuance costs	Ψ	(42)	Ψ	(297)
Right of use asset		(3,800)		(5,289)
Basis in subsidiary		(3,219)		(2,142)
Total deferred tax liabilities, net	•		\$	
Total deferred tax flaorities, fiet	\$	(402)	Þ	(233)

A reconciliation of the statutory tax rates and the effective tax rates is as follows:

	For the Year Ended I 2024	December 31, 2023
Percentage of pre-tax income:		
U.S. federal statutory income tax rate	21.0 %	21.0 %
State taxes, net of federal benefit	4.2 %	10.6 %
Credits	1.8 %	3.1
Non-deductible items	(0.5)%	(0.9)%
Provision to return	(3.7)%	(0.7)%
Stock based compensation shortfall	(0.4)%	(2.0)%
Change in state rate	(8.2)%	4.1 %
Change in valuation allowance	(9.6)%	(31.5)%
Change in subsidiary basis	(1.0)%	(1.0)%
Deconsolidation/dissolution of subsidiaries	— %	(2.4)%
Adjustment for warrants	(0.1)%	0.9 %
Section 162(m) compensation disallowance	(3.5)%	(1.2)%
Other	(0.2)%	(0.3)%
Effective income tax rate	(0.2)%	(0.3)%

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

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of all positive and negative evidence, it is more likely than not that some portion, or all, of the deferred tax assets will not be realized. Realization of the deferred tax assets is substantially dependent on the Company's ability to generate sufficient taxable income within certain future periods. Management has considered the Company's history of cumulative tax and book losses incurred since inception, and the other positive and negative evidence, and has concluded that it is more likely than not that the Company will not realize the benefits of the net deferred tax assets as of December 31, 2024 and 2023. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2024 and 2023. The valuation allowance increased by a net \$11.6 million during the current year.

The Company has incurred net operating losses ("NOLs") since inception. At December 31, 2024, the Company had federal NOLs of \$802.4 million, which will begin to expire in the year 2032, state NOLs of \$1,027.7 million, which will begin to expire in 2026, and federal income tax credits of \$36.6 million and state income tax credits of \$5.1 million, which will begin to expire in 2028. Approximately \$606.9 million of the federal NOLs and \$17.3 million of the state NOLs can be carried forward indefinitely. Under the provisions of Section 382 of the Internal Revenue Code, a corporation that undergoes an "ownership change", as defined therein, is subject to limitations on its use of pre-change NOLs and income tax credits carryforwards to offset future tax liabilities. It appears the Company underwent previous ownership changes potentially limiting its use of tax attributes. The Company has recorded a full valuation allowance on all of its deferred tax assets, as it believes that it is more likely than not that the deferred tax assets will not be realized regardless of whether an "ownership change" has occurred.

In accordance with the provisions related to accounting for uncertainty in income taxes, the Company recognizes the benefit of tax position if the position is "more likely than not" to prevail upon examination by the relevant tax authority. The table below sets forth a reconciliation of the beginning and ending amount of unrecognized tax benefits:

For the year ended December 31, 2024, the company has \$3.2 million of unrecognized tax benefits. If the \$3.2 million of unrecognized tax benefits is recognized, approximately \$0.7 million would affect the effective tax rate. It is reasonably possible that the amount of the unrecognized benefit with respect to certain of the Company's recognized tax positions

will significantly increase or decrease within the next 12 months. At this time, the estimate of the range of the reasonably possible outcomes cannot be made.

The Company classifies interest and penalties related to uncertain tax positions as income tax expense. The Company has accrued for \$0.2 million and approximately \$0.1 million of such interest as of December 31, 2024 and 2023, respectively. No penalties have been accrued for. The NOLs from tax years 2010 through 2023 remain open to examination (and adjustment) by the Internal Revenue Service and state taxing authorities. In addition, federal tax years ending December 31, 2021, 2022 and 2023 are open for assessment of federal taxes. The expiration of the statute of limitations related to the various state income and franchise tax returns varies by state.

# 18. Segment Information

The Company's reportable segments for operating income (loss) for the years ending December 31, 2024 and 2023 consist of the following:

Year Ended December 31, 2024		Journey		Avenue		Checkpoint		Mustang		Fortress <sup>1</sup>		onsolidated
Product revenue, net	\$	55,134	\$		\$		\$		\$		\$	55,134
Collaboration revenue		_		_		_		_		1,500		1,500
Revenue - related party		_		_		41		_		· —		41
Other revenue		1,000		_		_		_		_		1,000
Net revenue		56,134				41				1,500		57,675
Cost of goods - (excluding amortization of												
acquired intangible assets)		20,879		_		_		_		_		20,879
Amortization of acquired intangible assets		3,424		_		_		_		_		3,424
Research and development		9,857		6,645		36,152		8,418		(4,443)		56,629
Research and development - licenses acquired				´ —		´ —				252		252
Selling, general and administrative		40,204		4,638		20,063		4,135		18,691		87,731
Loss recovery		(4,553)		´ —		´ —				´ —		(4,553)
Asset impairment				_		_		3,692		_		3,692
Total operating expenses	_	69.811	_	11.283	-	56.215	_	16.245	-	14.500	_	168,054
Loss from operations	_	(13,677)	_	(11,283)	_	(56,174)	_	(16,245)		(13,000)	_	(110,379)
						`						
Interest Income		757		176		11		184		1,555		2,683
Interest expense and financing fee		(2,700)				_		(5)		(10,822)		(13,527)
(Gain) loss on common stock warrant liabilities		1,125		(589)		(73)		_		(1,101)		(638)
Other income (expense)	_	(116)	_		_	(4)	_	314	_	1,124	_	1,318
Total other income (expense)		(934)	_	(413)	_	(66)		493		(9,244)		(10,164)
Loss before income tax expense		(14,611)		(11,696)		(56,240)		(15,752)		(22,244)		(120,543)
Income tax expense benefit		61		_		_		_		251		312
Segment net loss	\$	(14,672)	\$	(11,696)	\$	(56,240)	\$	(15,752)	\$	(22,495)	\$	(120,855)
Net loss attributable to NCI												74,858
Net loss attributable to Fortress											\$	(45,997)
Net loss attributable to Fortiess											Φ	(43,771)
T												
Intersegment activity <sup>2</sup> :	e.		e.	220	Φ	7.620	0	0.61	6	(0.020)	e.	
Research and development	\$ \$	_	\$ \$	329 331	\$ \$	7,638	\$ \$	861 579	\$ \$	(8,828)	\$ \$	_
Selling, general and administrative	3	_	\$	331	\$	1,495	3	5/9	3	(2,405)	\$	_
Other Significant Items:												
Depreciation expense	\$	_	\$	_	\$	_	\$	671	\$	369	\$	1,040
Additions to intangible assets	\$	15,000	\$	_	\$	_	\$	_	\$	_	\$	15,000
Segment Assets	\$	80,241	\$	2,672	\$	7,471	\$	9,308	\$	44,531	\$	144,223
Stock-based compensation - research &												
development	\$	508	\$	269	\$	5,248	\$	(650)	\$	1,746	\$	7,121
Stock-based compensation - Selling, general												
and administrative	\$	5,590	\$	967	\$	10,004	\$	200	\$	8,737	\$	25,498

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

Note 2: Intersegment activity consists of PIK Dividends and MSA and equity fees paid by the subsidiaries to Fortress, see Note 16.

Year Ended December 31, 2023	J	ourney		Avenue		Checkpoint	Mustang	F	ortress <sup>1</sup>	C	onsolidated
Product revenue, net	\$	59,662	\$	_	\$		_	\$	_	\$	59,662
Collaboration revenue		_	•	_		`	_		5,229		5,229
Revenue - related party		_		_		103	_				103
Other revenue		19,519		_		_	_		_		19,519
Net revenue		79,181		_		103			5,229	_	84,513
Cost of goods - (excluding amortization of acquired intangible assets)		22,893		_		_	_		_		22,893
Amortization of acquired intangible assets		3,767		_		_	_		_		3,767
Research and development		7,541		6,131		43,566	40,513		3,996		101,747
Research and development - licenses acquired				4,230		+5,500 —	527		(433)		4,324
Selling, general and administrative		43,910		4,179		8,685	8,220		25,987		90,981
Asset impairment		3,143		T,177			0,220		23,707		3,143
Total operating expenses		81,254		14,540		52,251	49,260	-	29,550		226,855
Loss from operations	_	(2,073)	-	(14,540)		(52,148)	(49,260)	_	(24,321)	_	(142,342)
Loss from operations		(2,073)		(14,340)		(32,148)	(49,200)		(24,321)		(142,342)
Interest Income		322		126		84	850		1,621		3,003
Interest expense and financing fee		(1,698)		(332)		——————————————————————————————————————	(4,109)		(9,176)		(15,315)
Gain (loss) on common stock warrant liabilities		(1,070)		4,258		217	(1,10)		(51)		4,424
Other (Income) expense		(183)		- 1,230			917		(4,137)		(3,403)
Total other (Income) expense	_	(1,559)	-	4,052		301	(2,342)	-	(11,743)	_	(11,291)
Loss before income tax expense		(3,632)		(10,488)		(51,847)	(51,602)		(36,064)		(153,633)
2033 before medine tax expense		(3,032)		(10,400)		(31,047)	(31,002)		(30,004)		(133,033)
Income tax (expense) benefit		221		_		_	_		300		521
Segment net loss	\$	(3,853)	\$	(10,488)	\$	(51,847)\$	(51,602)	\$	(36,364)	\$	(154,154)
		,							,		
Net loss attributable to NCI											93,517
Net loss attributable to Fortress										\$	(60,637)
Intersegment Activity <sup>2</sup> :											
Research and development	\$	_	\$	521			250		(4,190)		
Research and development - licenses acquired	\$	_	\$	_					(477)		_
Selling, general and administrative	\$		\$	422	\$	1,452 \$	364	\$	(2,239)	\$	_
Other Significant Items											
Other Significant Items:	\$		\$	_	¢	- \$	1,860	<b>C</b>	370	¢	2,230
Depreciation expense Segment assets	\$	76,849	\$	1,850					65,707		167,526
Stock-based compensation - research &	Ф	/0,849	Ф	1,830	Þ	3,3/8\$	17,742	Ф	03,707	Ф	107,320
development	\$	110	\$	199	\$	1,169 \$	132	¢	1,624	¢	3,234
Stock-based compensation - Selling, general and	Φ	110	Φ	139	Ф	1,109 \$	132	Ф	1,024	Ф	3,234
administrative	\$	2,496	\$	707	\$	1,728 \$	436	\$	8,428	\$	13,795

Note 1: Includes Fortress and private subsidiaries primarily funded by Fortress: Aevitas (until April 2023), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica; and intercompany eliminations.

Note 2: Intersegment activity consists of PIK Dividends and MSA and equity fees paid by the subsidiaries to Fortress, see Note 16.

# 19. Revenues from Contracts and Significant Customers

# Disaggregation of Total Revenues

All of Journey's product revenues are recorded in the U.S. During 2023, Journey received a one-time upfront license payment totaling \$19.0 million from Maruho Ltd., its exclusive licensing partner in Japan ("Maruho"), under the license agreement Journey entered into with Maruho, dated August 31, 2023 (the "New License Agreement") in which it granted Maruho exclusive rights to Qbrexza in Korea and other Asian countries. The Company's collaboration revenue is from Cyprium's agreement with Sentynl (see Note 3). The Company's revenue - related party is from Checkpoint's collaborations with TGTX (see Note 16).

The table below summarizes the Company's revenue for the years ended December 31, 2024 and 2023:

		Year Ended December 31,									
(\$ in thousands)		2024	2023								
Qbrexza	\$	25,114	\$	25,410							
Accutane		19,407		20,168							
Amzeeq		5,009		6,201							
Zilxi		1,643		1,962							
Other / legacy product revenue		3,961		5,921							
Collaboration revenue		1,500		5,229							
Revenue – related party		41		103							
Other revenue		1,000		19,519							
Total net revenue	\$	57,675	\$	84,513							

Other revenue for the year ended December 31, 2024, reflects a \$1.0 million milestone payment from Cutia triggered by the marketing approval Cutia received in the fourth quarter of 2024 for topical 4% minocycline foam in China (see Note 7). Other revenue for the year ended December 31, 2023, includes \$0.5 million of royalties on sales of Rapifort in Japan from our licensing partner Maruho, from Maruho, and also reflects a net \$19.0 million payment from Maruho under the New License Agreement (see Note 7).

# Significant Customers

For the years ended December 31, 2024 and 2023, none of Journey's Dermatology Products customers individually accounted for more than 10.0% of its total gross product revenue.

For the year ended December 31, 2024, one of Journey's Dermatology Products customers accounted for more than 10% of its total accounts receivable balance at 10.3%. For the year ended December 31, 2023, one of Journey's Dermatology Products customers accounted for more than 10% of its total accounts receivable balance at 13.0%.

# 20. Subsequent Events

# Checkpoint Merger Agreement

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.

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 outstanding the 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) if 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 (but after the date of the Merger Agreement) 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.

# 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:

- \$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 (i) cosibelimab in 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.

# 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 to 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 9, 2025, Fortress beneficially owned an aggregate of approximately 11.2% of the outstanding Shares (consisting of 6,222,249 shares of common stock and 700,000 shares of Class A common stock) 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.

# 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.

# 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.

# March 2025 Warrant Exercise - Checkpoint

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.

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#### February 2025 Public Offering - Mustang

In February 2025, Mustang closed on an equity offering of 2,657,807 shares of common stock (or common stock equivalent in lieu thereof) and Series C-1 warrants to purchase up to 2,657,807 shares of common stock and Series C-2 warrants to purchase up to 2,657,807 shares of common stock at a combined public offering price of \$3.01 per share (or per common stock equivalent in lieu thereof). The warrants have an exercise price of \$3.01 per share and will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the warrants. 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 equity offering, after deducting the fees and expenses of the placement agent and other offering expenses payable by Mustang were \$6.9 million.

### Lease Amendment - Mustang

In February 2025, Mustang concurrently exited the lease of its manufacturing facility in Worcester, Massachusetts, relocating their 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.

# **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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.

# Fortress Biotech, Inc.

March 31, 2025

By: /s/ Lindsay A. Rosenwald, M.D.

Lindsay A. Rosenwald, M.D.

Chairman, President and Chief Executive Officer

(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Lindsay A. Rosenwald, M.D. Lindsay A. Rosenwald, M.D.	Chairman of the Board of Directors, President and Chief Executive Officer ( <i>Principal Executive Officer</i> )	March 31, 2025
/s/ David Jin David Jin	Chief Financial Officer  (Principal Financial Officer and Principal Accounting Officer)	March 31, 2025
/s/ Michael S. Weiss Michael S. Weiss	Executive Vice Chairman, Strategic Development and Director	March 31, 2025
/s/ Jimmie Harvey, Jr., M.D. Jimmie Harvey, Jr., M.D.	Director	March 31, 2025
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director	March 31, 2025
/s/ Dov Klein Dov Klein	Director	March 31, 2025
/s/ J. Jay Lobell J. Jay Lobell	Director	March 31, 2025
/s/ Kevin L. Lorenz, J.D. Kevin Lorenz	Director	March 31, 2025
/s/ Lucy Lu, M.D. Lucy Lu, M.D.	Director	March 31, 2025

# **DESCRIPTION OF SECURITIES**

Fortress Biotech, Inc. ("we," "our," "the Company," or "us) has two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, with \$0.0001 par value ("Common Stock"), and our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock. The following descriptions of our Common Stock, preferred stock and warrants are summaries and are qualified in their entirety by reference to our Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), our Third Amended and Restated Bylaws (the "Bylaws") and our outstanding warrants. We encourage you to read the Certificate of Incorporation, Bylaws, and warrants, as well as the applicable provisions of the General Corporation Law of the State of Delaware, as amended (the "DGCL"), for more information.

# DESCRIPTION OF CAPITAL STOCK

The following summary of the terms of our common stock may not be complete and is subject to, and qualified in its entirety by reference to, the terms and provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. You should refer to, and read this summary together with, our amended and restated certificate of incorporation and restated bylaws to review all of the terms of our common stock that may be important to you.

# Common Stock

The Company's certificate of incorporation, as amended, authorizes the Company to issue up to 200,000,000 shares of \$0.001 par value common stock ("Common Stock"). Our Common Stock is traded on The Nasdaq Capital Market under the symbol "FBIO."

The terms, rights, preference and privileges of the Common Stock are as follows:

Voting Rights

Each holder of Common Stock is entitled to one vote per share of Common Stock held on all matters submitted to a vote of the stockholders, including the election of directors. The Company's certificate of incorporation and bylaws do not provide for cumulative voting rights.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, the holders of the Company's outstanding shares of Common Stock are entitled to receive dividends, if any, as may be declared from time to time by the Company's Board of Directors out of legally available funds.

Liquidation

In the event of the Company's liquidation, dissolution or winding up, holders of Common Stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of the Company's debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preference

Holders of the Company's Common Stock have no preemptive, conversion or subscription rights, and there is no redemption or sinking fund provisions applicable to our Common Stock. The rights, preferences and privileges of the holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of the Company's preferred stock that are or may be issued.

Fully Paid and Nonassessable

All of the Company's outstanding shares of Common Stock are fully paid and nonassessable.

#### Preferred Stock

Under the terms of our Certificate of Incorporation, our board of directors is authorized to issue up to 15,000,000 shares of preferred stock, par value \$0.001 per share. Our board of directors may issue shares of preferred stock in one or more series without stockholder approval, and has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. We may amend from time to time our Certificate of Incorporation to increase the number of authorized shares of preferred stock. Any such amendment would require the approval of the holders of a majority of the voting power of the shares entitled to vote thereon. As of the date of the filing of the Company's Annual Report on Form 10-K to which Description of Securities is attached as an exhibit, we have 15,000,000 shares of preferred shares authorized, which includes the 5,000,000 shares of our Series A Cumulative Redeemable Perpetual Preferred Stock (the "Series A Preferred Stock"). As of the date of the filing of the Company's Annual Report on Form 10-K to which Description of Securities is attached as an exhibit, 3,427,138 shares of our Series A Preferred Stock are issued and outstanding. No other classes of preferred stock have been designated or issued at this time.

It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of the holders of Common Stock until the board of directors determines the specific rights of the holders of preferred stock. However, possible effects of the issuance of preferred stock include restricting dividends on Common Stock, diluting the voting power of Common Stock, impairing the liquidation rights of Common Stock, and making it more difficult for a third party to acquire us, which could have the effect of discouraging a third party from acquiring, or deterring a third party from paying a premium to acquire, a majority of our outstanding voting stock.

The particular terms of any new series of preferred stock being offered by us will set forth in a certificate of designations relating to that series of preferred stock. Those terms may include:

- the title and liquidation preference per share of the preferred stock and the number of shares offered;
- the purchase price of the preferred stock;
- the dividend rate (or method of calculation);
- the dates on which dividends will be paid and the date from which dividends will begin to accumulate;
- any redemption or sinking fund provisions of the preferred stock;
- any listing of the preferred stock on any securities exchange or market;
- any conversion provisions of the preferred stock;
- the voting rights, if any, of the preferred stock; and
- any additional dividend, liquidation, redemption, sinking fund and other rights, preferences, privileges, limitations and restrictions of the preferred stock.

The preferred stock will, when issued, be fully paid and non-assessable.

#### Series A Preferred Stock

On October 26, 2017, the Company designated 5,000,000 shares of preferred stock as the Series A Preferred Stock. Our Series A Preferred Stock is traded on The Nasdaq Capital Market under the symbol "FBIOP."

The terms, rights, preference and privileges of the Series A Preferred Stock are as follows:

#### Voting Rights

Except as may be otherwise required by law, the voting rights of the holders of the Series A Preferred Stock are limited to the affirmative vote or consent of the holders of at least two-thirds of the votes entitled to be cast by the holders of the Series A Preferred Stock outstanding at the time in connection with the: (1) authorization or creation, or increase in the authorized or issued amount of, any class or series of capital stock ranking senior to the Series A Preferred Stock with respect to payment of dividends or the distribution of assets upon liquidation, dissolution or winding up or reclassification of any of the Company's authorized capital stock into such shares, or creation, authorization or issuance of any obligation or security convertible into or evidencing the right to purchase any such shares; or (2) amendment, alteration, repeal or replacement of the Company's certificate of incorporation, including by way of a merger, consolidation or otherwise in which the Company may or may not be the surviving entity, so as to materially and adversely affect and deprive holders of Series A Preferred Stock of any right, preference, privilege or voting power of the Series A Preferred Stock.

#### Dividends

Dividends on Series A Preferred Stock accrue daily and will be cumulative from, and including, the date of original issue and shall be payable monthly, at the rate of 9.375% per annum of its liquidation preference, which is equivalent to \$2.34375 per annum per share. The first dividend on Series A Preferred Stock was payable on December 31, 2017 (in the amount of \$0.299479 per share) to the holders of record of the Series A Preferred Stock at the close of business on December 15, 2017.

# No Maturity Date or Mandatory Redemption

The Series A Preferred Stock has no maturity date, and the Company is not required to redeem the Series A Preferred Stock. Accordingly, the Series A Preferred Stock will remain outstanding indefinitely unless the Company decides to redeem it pursuant to its optional redemption right or its special optional redemption right in connection with a Change of Control (as defined below), or under the circumstances set forth below under "Limited Conversion Rights Upon a Change of Control" and elect to convert such Series A Preferred Stock. The Company is not required to set aside funds to redeem the Series A Preferred Stock.

# Optional Redemption

The Series A Preferred Stock may be redeemed in whole or in part (at the Company's option) any time on or after December 15, 2022, upon not less than 30 days nor more than 60 days' written notice by mail prior to the date fixed for redemption thereof, for cash at a redemption price equal to \$25.00 per share, plus any accumulated and unpaid dividends to, but not including, the redemption date.

#### Special Optional Redemption

Upon the occurrence a Change of Control (as defined below), the Company may redeem the shares of Series A Preferred Stock, at its option, in whole or in part, within one hundred twenty (120) days of any such Change of Control, for cash at \$25.00 per share, plus accumulated and unpaid dividends (whether or not declared) to, but excluding, the redemption date. If, prior to the Change of Control conversion date (the "Change of Control Conversion Date"), the Company has provided notice of its election to redeem some or all of the shares of Series A Preferred Stock (whether pursuant to the Company's optional redemption right described above under "Optional Redemption" or this special optional redemption right), the holders of shares of Series A Preferred Stock will not have the Change of Control conversion right with respect to the shares of Series A Preferred Stock called for redemption. If the Company elects to redeem any shares of the Series A Preferred Stock as described in this paragraph, the Company may use any available cash to pay the redemption price.

A "Change of Control" is deemed to occur when, after the original issuance of the Series A Preferred Stock, the following have occurred and are continuing:

the acquisition by any person, including any syndicate or group deemed to be a "person" under Section 13(d)(3) of the Exchange Act of beneficial ownership, directly or indirectly, through a purchase, merger or other acquisition transaction or series of purchases, mergers or other acquisition transactions of the Company's stock entitling that person to exercise more than 50% of the total voting power of all the Company's stock entitled to vote generally in the election of the Company's directors (except that such person will be deemed to have beneficial ownership of all securities that such person has the right to acquire, whether such right is currently exercisable or is exercisable only upon the occurrence of a subsequent condition); and

following the closing of any transaction referred to in the bullet point above, neither the Company nor the acquiring or surviving entity has a class of common equity securities (or American Depositary Receipts representing such securities) listed on the NYSE, the NYSE American LLC or the Nasdaq Stock Market, or listed or quoted on an exchange or quotation system that is a successor to the NYSE, the NYSE American LLC or the Nasdaq Stock Market.

Conversion, Exchange and Preemptive Rights

Except as described below under "Limited Conversion Rights upon a Change of Control," the Series A Preferred Stock is not subject to preemptive rights or convertible into or exchangeable for any other securities or property at the option of the holder.

Limited Conversion Rights upon a Change of Control

Upon the occurrence of a Change of Control, each holder of shares of Series A Preferred Stock will have the right (unless, prior to the Change of Control Conversion Date, the Company has provided or provides irrevocable notice of its election to redeem the Series A Preferred Stock as described above under "Optional Redemption," or "Special Optional Redemption") to convert some or all of the shares of Series A Preferred Stock held by such holder on the Change of Control Conversion Date, into the Common Stock Conversion Consideration, which is equal to the lesser of:

the quotient obtained by dividing (i) the sum of the \$25.00 liquidation preference per share of Series A Preferred Stock plus the amount of any accumulated and unpaid dividends (whether or not declared) to, but not including, the Change of Control Conversion Date (unless the Change of

- Control Conversion Date is after a record date for a Series A Preferred Stock dividend payment and prior to the corresponding Dividend Payment Date, in which case no additional amount for such accumulated and unpaid dividend will be included in this sum) by (ii) the price of Common Stock at the Change of Control Conversion Date, as determined in accordance with the certificate of designations for the Series A Preferred Stock; and
- 13.05483 shares of Common Stock, subject to certain adjustments.

In the case of a Change of Control pursuant to which the Company's common stock will be converted into cash, securities or other property or assets, a holder of Series A Preferred Stock will receive upon conversion of such Series A Preferred Stock the kind and amount of any alternative form of consideration which such holder would have owned or been entitled to receive upon the Change of Control had such holder held a number of shares of the Company's common stock equal to the Common Stock Conversion Consideration immediately prior to the effective time of the Change of Control.

Notwithstanding the foregoing, the holders of shares of Series A Preferred Stock will not have the right to convert upon a Change of Control if the acquiror has shares listed or quoted on the NYSE, the NYSE American LLC or Nasdaq Stock Market or listed or quoted on an exchange or quotation system that is a successor to the NYSE, the NYSE American LLC or Nasdaq Stock Market, and the Series A Preferred Stock becomes convertible into or exchangeable for such acquiror's listed shares upon a subsequent Change of Control of the acquiror.

Liquidation Preference

In the event the Company liquidates, dissolves or is wound up, holders of the Series A Preferred Stock will have the right to receive \$25.00 per share, plus any accumulated and unpaid dividends to, but not including, the date of payment, before any payment is made to the holders of the Company's Common Stock.

Ranking

The Series A Preferred Stock will rank, with respect to rights to the payment of dividends and the distribution of assets upon the Company's liquidation, dissolution or winding up, (1) senior to all classes or series of the Company's Common Stock and to all other equity securities issued by the Company other than equity securities referred to in clauses (2) and (3); (2) on a par with all equity securities issued by the Company with terms specifically providing that those equity securities rank on a par with the Series A Preferred Stock with respect to rights to the payment of dividends and the distribution of assets upon the Company's liquidation, dissolution or winding up; (3) junior to all equity securities issued by the Company with terms specifically providing that those equity securities rank senior to the Series A Preferred Stock with respect to rights to the payment of dividends and the distribution of assets upon the Company liquidation, dissolution or winding up; and (4) junior to all of the Company's existing and future indebtedness.

### **Transfer Agent**

VStock Transfer, LLC serves as the transfer agent and registrar for all of our Common Stock and Series A Preferred Stock.

#### DESCRIPTION OF WARRANTS

# 2020 Oaktree Warrants

As of December 31, 2024, there were 131,087 warrants to purchase our Common Stock (the "2020 Oaktree Warrants") that were issued on August 27, 2020, pursuant to a senior secured credit agreement with Oaktree Fund Administration, LLC ("Oaktree"), as the administrative agent, and the lenders from time-to-time party thereto (the "2020 Credit Agreement"). The 2020 Oaktree Warrants allow for Oaktree and certain of its affiliates to purchase up to 131,087 shares of our Common Stock.

The following is a summary of certain terms and provisions of the 2020 Oaktree Warrants.

# Exercisability

The 2020 Oaktree Warrants became exercisable immediately upon issuance for a period of ten (10) years. The 2020 Oaktree Warrants are exercisable, at the option of each holder, in whole, or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our Common Stock purchased upon such exercise. Each 2020 Oaktree Warrant is exercisable for one share of our Common Stock (subject to adjustment, as discussed below). The holders of the 2020 Oaktree Warrants do not have the right to exercise any portion of the 2020 Oaktree Warrant if the holder would beneficially own in excess of 9.99% of the shares of our Common Stock outstanding immediately after giving effect to such exercise.

#### Exercise Price

The exercise price of the Common Stock purchasable upon exercise of the 2020 Oaktree Warrants was originally \$48.00 per share. On June 13, 2023, the Company lowered the exercise price of the 2020 Oaktree Warrants to \$8.136 per share. Pursuant to the anti-dilution adjustment mechanism of the 2020 Oaktree Warrants, the exercise price decreased to \$7.2392 per share as a result of the September 2024 registered direct offering which closed on September 23, 2024. The exercise price and the number of shares of Common Stock issuable upon exercise of the 2020 Oaktree Warrants is subject to appropriate adjustment in relation to certain events, such as recapitalizations, stock dividends, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock.

# Rights as Stockholder

Except as otherwise provided in the 2020 Oaktree Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holders of the 2020 Oaktree Warrants do not have the rights or privileges of holders of our Common Stock, including any voting rights, until they exercise their 2020 Oaktree Warrants.

#### Fractional Shares

No fractional shares of Common Stock will be issued upon the exercise of the 2020 Oaktree Warrants. Rather, the Company shall, round up the number of shares of Common Stock to be issued to the nearest whole number.

# Transferability

Subject to applicable laws, the 2020 Oaktree Warrants may be offered for sale, sold, transferred or assigned without our consent.

# Governing Law

The 2020 Oaktree Warrants are governed by New York law.

# **Consulting Warrants**

As of December 31, 2024, there were 3,332 warrants to purchase our Common Stock (the "Consulting Warrants") that were issued on April 14, 2020, to a consultant pursuant to a Common Stock Warrant agreement. The Consulting Warrants allow for the Consultant to purchase up to 3,332 shares of our Common Stock subject to vesting.

The following is a summary of certain terms and provisions of the Consulting Warrants.

# Exercisability

The Consulting Warrants became exercisable immediately upon issuance for a period of seven (7) years. The Consulting Warrants are exercisable, at the option of the holder, in whole, or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our Common Stock purchased upon such exercise. Each Consulting Warrant is exercisable for one share of our Common Stock (subject to adjustment, as discussed below). The Consulting Warrants also have a cashless exercise feature. The holder's right to purchase shares of Common Stock are subject to the following vesting schedule:

- (i) 1,666 of the shares exercisable will vest when the average of the Company's Common Stock trading prices, as reported on the Nasdaq Capital Market ("Nasdaq"), at any time during three (3) years following the issuance date, meets or exceeds \$37.50 for ten (10) consecutive trading days;
- (ii) 1,666 of the shares exercisable will vest when the average of the Company's Common Stock trading prices, as reported on Nasdaq, at any time during three (3) years following the issuance date, meets or exceeds \$60.00 for ten (10) consecutive trading days;
- (iii) 1,666 of the shares exercisable will vest when the average of the Company's Common Stock trading prices, as reported on Nasdaq, at any time during three (3) years following the issuance date, meets or exceeds \$90.00 for ten (10) consecutive trading days; and
- (iv) 1,666 of the shares exercisable will vest when the average of the Company's Common Stock trading prices, as reported on Nasdaq, at any time during three (3) years following the issuance date, meets or exceeds \$150.00 for ten (10) consecutive trading days;

#### Exercise Price

The exercise price of the Common Stock purchasable upon exercise of the Consulting Warrants is \$32.40 per share. The exercise price and the number of shares of Common Stock issuable upon exercise of the Consulting Warrants is subject to appropriate adjustment in relation to certain events, such as recapitalizations, stock dividends, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock.

#### Rights as Stockholder

Except as otherwise provided in the Consulting Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of the Consulting Warrants do not have the rights or privileges of holders of our Common Stock, including any voting rights, dividend rights, until he exercises the Consulting Warrants.

#### Fractional Shares

No fractional shares of Common Stock will be issued upon the exercise of the Consulting Warrants. Rather, the Company shall, round the number of shares of Common Stock to be issued to the nearest whole number.

#### Transferability

Subject to applicable laws, the Consulting Warrants may be offered for sale, sold, transferred or assigned without our consent.

#### Governing Law

The Consulting Warrants are governed by New York law.

# November 2023 Warrants

As of December 31, 2024, there were 5,642,500 outstanding warrants to purchase our Common Stock that were originally issued on November 14, 2023 (the "November 2023 Warrants"). The November 2023 Warrants allow for the holders or their registered assigns to purchase up to 5,642,500 shares of our Common Stock. The following is a summary of certain terms and provisions of the November 2023 Warrants.

# Exercisability

The November 2023 Warrants became exercisable immediately and may be exercised at any time up to the date that is five (5) years after their original issuance (the "Expiration Date"). The November 2023 Warrants are exercisable, at the option of each holder,

in whole, or in part, by delivering to us a duly executed exercise notice and, at any time a registration statement registering the offer and sale of Common Stock underlying the November 2023 Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. If a registration statement registering the offer and sale of the shares of Common Stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may elect to exercise the November 2023 Warrants through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the November 2023 Warrants. No fractional shares of Common Stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

#### Exercise Limitation

A holder of the November 2023 Warrants does not have the right to exercise any portion of the November 2023 Warrants if the holder (together with its affiliates and certain related parties) would beneficially own in excess of 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the November 2023 Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from holder to us.

#### Exercise Price

The exercise price per whole share of Common Stock purchasable upon exercise of the November 2023 Warrants is \$1.70. If, prior to the Expiration Date, the Company sells, enters into an agreement to sell, or grants any option to purchase, or sells or grants any right to reprice, or otherwise disposes of any Common Stock or equivalents of Common Stock (or announces any offer, sale, grant or any option to purchase or other dispositions, provided such transaction occurs), at an effective price per share less than the exercise price then in effect (such lower price, the "Base Share Price" and such issuance collectively, a "Dilutive Issuance"), then simultaneously with the consummation of such first Dilutive Issuance, the exercise price shall be reduced and only reduced to equal the Base Share Price. There may only be one such adjustment, if any, to the exercise price while the November 2023 Warrants are outstanding. Notwithstanding the foregoing, no adjustments will be made in respect of an Exempt Issuance (as defined in the November 2023 Warrants). If the Company enters into a Variable Rate Transaction (as defined in the November 2023 Warrants), the Company will be deemed to have issued Common Stock or equivalents of Common Stock at the lowest possible price, conversion price or exercise price at which such securities may be issued, converted or exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock or other property to our stockholders.

# Transferability

Subject to applicable laws, the November 2023 Warrants may be offered for sale, sold, transferred or assigned without our consent.

# Exchange Listing

The November 2023 Warrants are not listed on any securities exchange or nationally recognized trading system.

# Certificated Warrants

The November 2023 Warrants were issued in certificated form.

# Fundamental Transactions

In the event of a fundamental transaction, as described in the November 2023 Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, or any person or group, becoming the beneficial owner of 50% of the voting power represented by our outstanding capital stock, the holders of the November 2023 Warrants will be entitled to receive upon exercise of the November 2023 Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. As an alternative, in the event of a fundamental transaction, the holder, at its option, exercisable at any time concurrently with, or within 30 days after, the consummation of the fundamental transaction (or, if later, the date of the public announcement of the applicable fundamental

transaction), may cause the Company to purchase the unexercised portion of the November 2023 Warrants from the holder by paying to the holder an amount in cash equal to the Black Scholes Value (as defined in the November 2023 Warrants) of the remaining unexercised portion of the November 2023 Warrants on the date of the consummation of such fundamental transaction.

# Rights as Stockholder

Except as otherwise provided in the November 2023 Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of the November 2023 Warrants does not have the rights or privileges of holders of our Common Stock, including any voting rights, until they exercise their November 2023 Warrants.

#### Governing Law

The November 2023 Warrants are governed by New York law.

# January 2024 Warrants

As of December 31, 2024, there were 3,303,305 outstanding warrants to purchase our Common Stock that were originally issued on January 3, 2024 (the "January 2024 Warrants"). The January 2024 Warrants allow for the holders or their registered assigns to purchase up to 3,303,305 shares of our Common Stock. The following is a summary of certain terms and provisions of the January 2024 Warrants.

#### Exercisability

The January 2024 Warrants became exercisable immediately and may be exercised at any time up to the date that is five (5) years after their original issuance. The January 2024 Warrants are exercisable, at the option of each holder, in whole, or in part, by delivering to us a duly executed exercise notice and, at any time a registration statement registering the offer and sale of Common Stock underlying the January 2024 Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. If a registration statement registering the offer and sale of the shares of Common Stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may elect to exercise the January 2024 Warrants through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the January 2024 Warrants. No fractional shares of Common Stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

#### Exercise Limitation

A holder of the January 2024 Warrants does not have the right to exercise any portion of the January 2024 Warrants if the holder (together with its affiliates and certain related parties) would beneficially own in excess of 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the January 2024 Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from holder to us.

#### Exercise Price

The exercise price per whole share of Common Stock purchasable upon exercise of the January 2024 Warrants is \$3.21. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

# Transferability

Subject to applicable laws, the January 2024 Warrants may be offered for sale, sold, transferred or assigned without our consent.

# Exchange Listing

The January 2024 Warrants are not listed on any securities exchange or nationally recognized trading system.

#### Certificated Warrants

The January 2024 Warrants were issued in certificated form.

#### Fundamental Transactions

In the event of a fundamental transaction, as described in the January 2024 Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, or any person or group, becoming the beneficial owner of 50% of the voting power represented by our outstanding capital stock, the holders of the January 2024 Warrants will be entitled to receive upon exercise of the January 2024 Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. As an alternative, in the event of a fundamental transaction, the holder, at its option, exercisable at any time concurrently with, or within 30 days after, the consummation of the fundamental transaction (or, if later, the date of the public announcement of the applicable fundamental transaction), may cause the Company to purchase the unexercised portion of the January 2024 Warrants from the holder by paying to the holder an amount in cash equal to the Black Scholes Value (as defined in the January 2024 Warrants) of the remaining unexercised portion of the January 2024 Warrants on the date of the consummation of such fundamental transaction.

# Rights as Stockholder

Except as otherwise provided in the January 2024 Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of the January 2024 Warrants does not have the rights or privileges of holders of our Common Stock, including any voting rights, until they exercise their January 2024 Warrants.

# Governing Law

The January 2024 Warrants are governed by New York law.

#### 2024 Oaktree Warrants

As of December 31, 2024, there were 506,390 warrants to purchase our Common Stock (the "2024 Oaktree Warrants") that were issued on July 25, 2024, pursuant to a senior secured credit agreement with Oaktree, as the administrative agent, and the lenders from time-to-time party thereto (the "2024 Credit Agreement"). The 2024 Credit Agreement replaced the 2020 Credit Agreement. The 2024 Oaktree Warrants allow for Oaktree and certain of its affiliates to purchase up to 506,390 shares of our Common Stock.

The following is a summary of certain terms and provisions of the 2024 Oaktree Warrants.

# Exercisability

The 2024 Oaktree Warrants became exercisable immediately upon issuance for a period of seven (7) years and may be net exercised for no cash payment at the holder's election. The 2024 Oaktree Warrants are exercisable, at the option of each holder, in whole, or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our Common Stock purchased upon such exercise. A holder of the 2024 Oaktree Warrants will not have the right to exercise any portion of the 2024 Oaktree Warrants if the holder (together with its affiliates and certain related parties) would beneficially own in excess of 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the 2024 Oaktree Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from the holder to us.

# Exercise Price

The exercise price per whole share of Common Stock purchasable upon exercise of the 2024 Oaktree Warrants is equal to \$1.65 (the "Base Share Price"). The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. The exercise price of the 2024 Oaktree Warrants will also be adjusted if, while the 2024 Oaktree 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 Base Share Price. In such case, the exercise price of the 2024 Oaktree Warrants will be reduced to equal the Base Share Price.

#### Transferability

Subject to applicable laws, the 2024 Oaktree Warrants may be offered for sale, sold, transferred or assigned without our consent.

### Exchange Listing

The 2024 Oaktree Warrants are not listed on any securities exchange or nationally recognized trading system.

#### Fundamental Transactions

In the event of a fundamental transaction, as described in the 2024 Oaktree Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding Common Stock, the holders of the 2024 Oaktree Warrants will be entitled to receive upon exercise of the 2024 Oaktree Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the 2024 Oaktree Warrants immediately prior to such fundamental transaction.

# Rights as a Stockholder

Except as otherwise provided in the 2024 Oaktree Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of a 2024 Oaktree Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the 2024 Oaktree Warrant.

# Governing Law

The 2024 Oaktree Warrants are governed by New York law.

#### **Harley Warrants**

As of December 31, 2024, there were 112,834 warrants to purchase our Common Stock (the "Harley Warrants") that were issued pursuant to the terms of that certain letter agreement dated December 8, 2022 by and among Harley Capital, LLC ("Harley"), Urica Therapeutics, Inc. ("Urica"), a controlled subsidiary of the Company, and the Company (the "Harley Letter Agreement"). Under the Harley Letter Agreement, Urica engaged Harley as placement agent in connection with the private placement of Urica's 8% Cumulative Convertible Class B Preferred Stock (the "Urica Preferred Stock"). As partial consideration for acting as placement agent, Urica granted Harley a warrant to purchase Urica securities and we agreed to issue replacement warrants to the holders following the previously disclosed exchange of the Urica Preferred Stock for shares of Company Common Stock. Pursuant to the Harley Letter Agreement, we issued such Harley Warrants granting Harley and certain of its affiliates to purchase up to 112,834 shares of our Common Stock for which the Urica Preferred Stock was exchanged.

The following is a summary of certain terms and provisions of the Harley Warrants.

# Exercisability

The Harley Warrants became exercisable immediately upon issuance and will expire on June 27, 2030. A holder will not have the right to exercise any portion of the Harley Warrants if the holder (together with its affiliates and certain related parties) would beneficially own in excess of 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Harley Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from the holder to us.

# Exercise Price

The exercise price per whole share of Common Stock purchasable upon exercise of the Harley Warrants is equal to \$1.68. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock

combinations, reclassifications or similar events affecting our Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability

Subject to applicable laws, the Harley Warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing

The Harley Warrants are not listed on any securities exchange or nationally recognized trading system.

Fundamental Transactions

In the event of a fundamental transaction, as described in the Harley Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding Common Stock, the holders of the Harley Warrants will be entitled to receive upon exercise of the Harley Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Harley Warrants immediately prior to such fundamental transaction.

Rights as a Stockholder

Except as otherwise provided in the Harley Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of a Harley Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the Harley Warrant.

Governing Law

The Harley Warrants are governed by New York law.

# PIPE Warrants

As of December 31, 2024, there were 4,702,753 warrants to purchase our Common Stock (the "PIPE Warrants") that were issued on September 23, 2024, pursuant to certain purchase agreements, by and among the Company and the purchasers thereto. The PIPE Warrants allow for the holders or their registered assigns to purchase up to 4,702,753 shares of our Common Stock.

The following is a summary of certain terms and provisions of the PIPE Warrants.

Exercisability

The PIPE Warrants will become exercisable on March 23, 2025 and will expire five and one-half years from the date of their issuance and may be net exercised for no cash payment at the holder's election. A holder will not have the right to exercise any portion of the PIPE Warrants if the holder (together with its affiliates and certain related parties) would beneficially own in excess of 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the PIPE Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from the holder to us.

Exercise Price

The exercise price per whole share of Common Stock purchasable upon exercise of the PIPE Warrants is equal to \$1.84. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability

Subject to applicable laws, the PIPE Warrants may be offered for sale, sold, transferred or assigned without our consent.

#### Exchange Listing

The PIPE Warrants are not listed on any securities exchange or nationally recognized trading system.

#### Fundamental Transactions

In the event of a fundamental transaction, as described in the PIPE Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding Common Stock, the holders of the PIPE Warrants will be entitled to receive upon exercise of the PIPE Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the PIPE Warrants immediately prior to such fundamental transaction. As an alternative, in the event of a fundamental transaction, the holder, at its option, exercisable at any time concurrently with, or within 30 days after, the consummation of the fundamental transaction (or, if later, the date of the public announcement of the applicable fundamental transaction), may cause the Company to purchase the unexercised portion of the PIPE Warrants from the holder by paying to the holder an amount in cash equal to the Black Scholes Value (as defined in the PIPE Warrants) of the remaining unexercised portion of the PIPE Warrants on the date of the consummation of such fundamental transaction.

# Rights as a Stockholder

Except as otherwise provided in the PIPE Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of a PIPE Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the PIPE Warrant.

# Governing Law

The PIPE Warrants are governed by New York law.

# FORTRESS BIOTECH, INC. AND SUBSIDIARIES

# INSIDER TRADING POLICY

January 22, 2024

# PERSONS COVERED

This Insider Trading Policy applies to Fortress Biotech, Inc. ("Fortress") and each of its publicly traded and private subsidiaries in which Fortress has a 50% or greater ownership interest or otherwise has a minority economic interest but majority voting interest. Fortress and each such subsidiary are referenced herein individually as a "Company" and collectively the "Companies."

The term "Insiders" includes: (a) all directors, officers, and employees of the Companies, together with their Family Members (as defined below); and (b) any person who receives Inside Information (as defined below) regarding the Companies, for so long as such Inside Information is material and not publicly known. The term "Family Members" includes (1) any family member who resides with an Insider, (2) any other person who lives in the Insider's household, and (3) any other person who does not live in an Insider's household but whose transactions in a Company's securities are directed by, or subject to the influence or control of, such Insider, or who is otherwise financially dependent on the Insider. Directors, officers, and employees are responsible for informing their Family Members about this Insider Trading Policy.

A director, officer, or employee of a Company must pre-clear trading in, or transfer of, any securities of the Companies for himself or herself and any Family Member in accordance with the procedures in <u>Exhibit A</u>. The pre-clearance requirement applies to all accounts of such persons, including any legal entity that he or she controls (e.g., as general partner of a partnership account, trustee of a trust account, and executor or administrator of an estate account).

Certain consultants to a Company may receive Inside Information and may be subject to trading pre-clearance requirements on a case-by-case basis.

# **PURPOSE**

The purpose of this Insider Trading Policy is to describe the Companies' pre-trading clearance procedures and the circumstances under which trading in, and causing the trading of, the stock of a Company or another publicly-traded company with which a Company has business dealings (each, a "*Third Party*") by an Insider will result in civil liability and criminal penalties, as well as disciplinary action by the Company.

During the course of your employment or service with a Company, you may receive material information about one or more of the Companies or a Third Party that is not publicly available, *i.e.*, not disclosed to the public in a press release or filing with the United States Securities and Exchange Commission ("*Inside Information*"). The fact that information has been disclosed to a few members of the public does not make it public for insider trading purposes. To be "public" the information must have been disseminated in a manner designed to reach investors generally, and the investors must be given the opportunity to absorb the information. Because of your access to this type of information, you may be in a position to profit financially by buying or

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selling or in some other way dealing in one or more of a Company's or a Third Party's stock while in possession of Inside Information, or to disclose (or "tip") such information to a third party who does so (known as a "*Tippee*").

This policy and applicable law prohibit any Insider from trading on or otherwise using Inside Information to gain a personal benefit or to disclose such information to someone else who might do so. There is no *de minimis* exception to this rule. Using Inside Information to gain a personal benefit and tipping are as illegal with respect to a few shares of stock as they are with respect to a large number of shares. You can be held liable both for your own transactions and for transactions by a Tippee, or even a third party who receives Inside Information from a Tippee. Furthermore, it is important that the *appearance* as well as the act of insider trading in stock be avoided.

From time to time, securities regulators have requested that the Companies disclose the names of Insiders of the Companies who may possess Inside Information. The purpose of these requests is to determine whether any insider trading has occurred among our Insiders or their "tippees." The Companies have complied with all such requests in the past and will continue to do so in the future. It is our intention to cooperate with securities regulators in uncovering any insider trading.

# **GENERAL POLICY**

# No Trading or Causing Trading While in Possession of Inside Information

- a) No Insider may purchase or sell any Company security while in possession of Inside Information about the Company.
- b) No Insider who knows of any Inside Information about a Company may communicate that information to any other person, including family and friends.
- c) In addition, no Insider may purchase or sell any security of any other company while in possession of Inside Information about that company that was obtained in the course of his or her involvement with the Companies. Furthermore, no Insider who knows of any such Inside Information may communicate that information to any other person, including family and friends.
- d) For compliance purposes, you should never trade, tip, or recommend securities (or otherwise cause the purchase or sale of securities) while in possession of information that could be viewed as Inside Information, unless you first comply with the pre-trade clearance procedures in <u>Exhibit A</u>.
- e) All transactions in a Company's stock, including purchases, sales, transfers, and the like, by an Insider, must be pre-cleared in accordance with the procedures in <u>Exhibit A</u>.

# **EXCEPTIONS**

Please note that, generally, transactions directly with a Company, *i.e.*, option exercises, the exercise of a tax withholding right pursuant to which a person elects to have a Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock or restricted stock unit or purchases under a Company's employee stock purchase plan, will not have insider trading implications. However, the subsequent sale or other disposition of such stock *is* fully subject to these restrictions. In addition, purchases or sales pursuant to a written plan that meets the requirements of Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (a "10b5-1 Plan"), may be made without restriction provided that it complies with the provisions regarding 10b5-1 Plans set forth below. Finally, automatic sales of shares of the Company's common stock through a Company-contracted service provider or broker to cover any taxes due as a result of the vesting of restricted stock or restricted stock units, where the amount of shares sold is based on the Insider's taxable income, the market price of the common stock on the date that the restricted stock or restricted stock or restricted stock units vest (the "Vesting Date") and the market price on the date of the sale, which date will be as soon as possible after the Vesting Date.

# INSIDE INFORMATION

As a practical matter, it is sometimes difficult to determine whether you possess Inside Information. The key to determining whether nonpublic information you possess about a public company is Inside Information is whether dissemination of the information would be likely to affect the market price of the company's stock or would be information that a reasonable investor would want to know before making an investment decision. Certainly, if the information makes *you* want to trade, it would probably have the same effect on others. Both positive and negative information can be material. If you possess Inside Information about a Company, you must refrain from trading in that Company's stock, advising anyone else to do so or communicating the information to anyone else until you know that the information has been disseminated to the public. These restrictions also apply with respect to Fortress stock if the Company is a Fortress subsidiary. "Trading" includes engaging in short sales, transactions in put or call options, hedging transactions, and other inherently speculative transactions.

Additionally, you may not discuss material, nonpublic information about a Company with anyone outside the Company. This prohibition covers spouses, family members, friends, business associates, or persons with whom we are doing business (except to the extent that such persons are covered by a non-disclosure agreement and the discussion is necessary to accomplish a business purpose of a Company). You may not participate in "chat room" or other electronic discussion groups on the Internet concerning activities of a Company or other companies with which the Companies do business, even if you do so anonymously. You may never recommend to another person that he or she buy or sell a Company stock.

Although this is by no means an exhaustive list, information about the following items may be considered to be Inside Information until it is publicly disseminated:

a) regulatory developments, including developments with the United States Food and Drug Administration and Drug Enforcement Administration;

- b) clinical developments;
- c) financial results or forecasts;
- d) major new products or processes;
- e) establishment of, or developments in, strategic partnerships, joint ventures, or similar collaborations;
- f) communications with government agencies;
- g) strategic plans;
- potential mergers, acquisitions, tender offers, or the sale of assets of a Company or a subsidiary thereof;
- i) significant write-offs;
- j) potential acquisitions of additional product candidates or technology;
- k) notice of issuance of patents or the acquisition of other material intellectual property rights;
- significant changes or developments in the biopharmaceutical industry or technological innovations;
- m) new major contracts, orders, suppliers, customers, or finance sources, or the loss thereof;
- n) significant changes or developments in supplies;
- o) significant pricing changes;
- events regarding a Company's securities (e.g., defaults on senior securities, call of securities for redemption, repurchase plans, stock splits, public or private equity/debt offerings, or changes in a Company's dividend policies or amounts);
- q) significant changes in control or senior management;
- r) significant changes in compensation policies;
- s) bankruptcies or receiverships;
- t) actual or threatened major litigation, or a major development in or the resolution of such litigation; and
- u) change in auditors or a notification that a Company can no longer rely on an auditor's report.

# PROHIBITION OF SPECULATIVE TRADING

No Insider may engage in short sales, transactions in put or call options, hedging transactions, or other inherently speculative transactions with respect to a Company's stock at any time.

Directors and officers of a Company must also comply with the reporting obligations and limitations on short-swing transactions set forth in Section 16 of the Securities Exchange Act of 1934, as amended. Directors and officers may not purchase and sell a Company's securities within a six-month period whether or not they had knowledge of any Inside Information during those times. Neither the receipt of an option under a Company's equity plans, nor the exercise of that option, will be deemed a purchase under Section 16; however, the sale of any such shares is a sale under Section 16. Moreover, no officer or director may ever make a short sale of a Company's stock.

# PRE-CLEARANCE PROCEDURES

A director, officer, or employee of a Company must pre-clear trading in, or transfer of, any securities of the Companies for himself or herself and any Family Member in accordance with the procedures in Exhibit A. The pre-clearance requirement applies to all accounts of such persons, including any legal entity that he or she controls (e.g., as general partner of a partnership account, trustee of a trust account, and executor or administrator of an estate account).

# BLACKOUT PERIODS

- a) *Quarterly Blackout Periods*. Pre-clearance requests will not be approved during the period beginning at the close of the market on the third trading day prior to the date a Company's financial results are publicly disclosed and ending at the close of market on the second trading day following the date such Company's financial results are publicly disclosed. During these periods, Insiders generally possess or are presumed to possess Inside Information about the Company's financial results.
- b) *Exception*. These trading restrictions do not apply to transactions under a 10b5-1 Plan, provided that such 10b5-1 Plan:
  - *i.* Is submitted to and approved by the Insider Trading Compliance Officer after you execute the certification attached to this Insider Trading Policy;
  - *ii.* Is entered into in good faith by the Insider at a time when the Insider is not in possession of material non-public information about the Company (or Fortress if it is a subsidiary); and
  - iii. Gives a third party discretionary authority to execute such purchases and sales, outside the control of the Insider, so long as such third party does not possess any material non-public information about the Company (or Fortress if it is a subsidiary); or explicitly specifies the security or securities to be purchased or sold, the number of shares, the prices and/or dates of transactions, or other formula(s) describing such transactions.

After a 10b5-1 Plan is approved by the Insider Trading Compliance Officer, any revision to it must be reviewed and approved by the Insider Trading Compliance Officer (or in his or her absence, the Chief Executive Officer of the Company) at least one month in advance of any trade under the revised 10b5-1 Plan.

# TRADING WINDOW

From time to time, one or more of the Companies may announce via email that Insiders are permitted to trade in one or more Company's securities during a particular period of time (the "*Trading Window*"). The Company is not obligated to open a Trading Window and may do so infrequently or not at all. If a Trading Window is announced, the Company may in some instances close the Trading Window early if there is new Inside Information. Insiders are still required to submit pre-clearance requests during a Trading Window.

# MARGIN ACCOUNTS AND COLLATERAL

Holding stock of a Company in margin accounts is strongly discouraged. These accounts authorize brokers to sell stock to cover amounts owed to them. A forced sale could occur at a time when the individual has knowledge of Inside Information about a Company. A similar result can occur when Company stock is pledged as collateral for a loan.

#### APPLICATION

a) *Legal Penalties*. Anyone who effects transactions in a Company's or a Third Party's stock (or provides information to enable others to do so) while in possession of Inside Information in violation of this policy can be subject to civil and criminal sanctions, including imprisonment, fines, and civil penalties, and be subject to discipline or adverse employment action.

In addition, a person who tips others may also be liable for transactions by the Tippees to whom he or she has disclosed material non-public information. Tippers can be subject to the same penalties and sanctions as Tippees, and the United States Securities and Exchange Commission (the "SEC") has imposed large penalties even when the tipper did not profit financially from the transaction.

The SEC can also seek substantial penalties from any person who, at the time of an insider trading violation, "directly or indirectly controlled the person who committed such violation," which would apply to the Companies and/or management and supervisory personnel. These control persons may be held liable for up to the greater of \$1 million or three times the amount of the profits gained or losses avoided. Even for violations that result in a small or no profit, the SEC can seek a minimum of \$1 million from a company and/or management and supervisory personnel as control persons.

b) Company-imposed Penalties. Directors, officers, and employees who violate this Insider Trading Policy (or whose Family Members violate this Insider Trading Policy) may be subject to disciplinary action by a Company, including dismissal for cause. Any exceptions to the Insider Trading Policy, if permitted, may only be granted in writing by the Insider Trading Compliance Officer of the relevant Company (or, in his or her absence, the Chief Executive Officer of the Company) and must be provided before any activity contrary to the above requirements takes

place. This Insider Trading Policy will continue to apply to your transactions in a Company's or a Third Party's stock even after your employment or service with the Company has terminated. If you are in possession of material nonpublic information when your employment or service terminates, you may not trade in the Company's stock (or Fortress's stock if the Company is a subsidiary) until the information has become public or is no longer material.

An Insider who has questions about these matters should speak with his or her own attorney or to the Company's Insider Trading Compliance Officer.

Any Insider who knows of or suspects a violation of this Insider Trading Policy should report the violation immediately to the Company's Insider Trading Compliance Officer, Chief Executive Officer, or Compensation Committee of the Board of Directors. Each Company will comply with all requests from the SEC, any securities exchange on which the Company's securities are listed, and other agencies for information related to insider trading investigations.

# **EXHIBIT A**

# FORTRESS BIOTECH, INC. AND SUBSIDIARIES

# PRE-CLEARANCE AND COMPLIANCE PROCEDURES

To ensure compliance with the Companies' Insider Trading Policy and to help prevent in advance any inadvertent violations of the federal securities laws, and to avoid even the appearance of trading on inside information, we are implementing the following pre-clearance and compliance procedures. Terms not otherwise defined herein have the meanings ascribed to them in the Companies' Insider Trading Policy.

Insider Trading Policy or otherwise designated by a Company Board of Directors may not engage in any transaction involving any of the Companies' securities (including market or private purchases or sales, option exercises, pledges, gifts, contributions to a trust, or any other transfers) without first obtaining pre-clearance of the transaction from the Company's Insider Trading Compliance Officer (or in his or her absence, the Chief Executive Officer of the Company). A request for pre-clearance must be submitted via email as set forth below to the Company's Insider Trading Compliance Officer (or in his or her absence, the Chief Executive Officer of the Company) at least two days in advance of the proposed transaction. You must state in the email that you do not possess, material non-public information. The Company's Insider Trading Compliance Officer (or in his or her absence, the Chief Executive Officer of the Company) will then determine whether the transaction may proceed and, if so, provide a response via email and assist in complying with the new reporting requirements.

# Fortress Employees, Officers & Directors

• Requests by Fortress employees, officers and directors to trade in the securities of Fortress or any of the Companies: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at \*\*\* and David Jin at \*\*\*)

# Avenue Employees, Officers & Directors

- Requests by employees, officers or directors of Avenue Therapeutics, Inc. ("Avenue") to trade in the securities of Avenue: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at \*\*\* and David Jin at \*\*\*)
- Requests by employees, officers or directors of Avenue to trade in the securities of Fortress or any other affiliate: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at \*\*\* and \*\*\*)

# Checkpoint Employees, Officers & Directors

• Requests by employees, officers or directors of Checkpoint Therapeutics, Inc. ("*Checkpoint*") to trade in the securities of Checkpoint: Checkpoint's principal

financial officer (as of the date first above written Garrett Grav at \*\*\*)

• Requests by employees, officers or directors of Checkpoint to trade in the securities of Fortress or any other affiliate: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at \*\*\* and David Jin at \*\*\*)

# Journey Employees, Officers & Directors

- Requests by employees, officers or directors of Journey Medical Corporation ("*Journey*") to trade in the securities of Journey: Journey's chief legal officer and principal financial officer (as of the date first above written, Ramsey Alloush at \*\*\* and Joseph Benesch at \*\*\*)
- Requests by employees, officers or directors of Journey to trade in the securities of Fortress or any other affiliate: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at \*\*\* and David Jin at \*\*\*)

# Mustang Employees, Officers & Directors

- Requests by employees, officers or directors of Mustang Bio, Inc. ("Mustang") to trade in the securities of Mustang: Mustang's chief legal officer and principal financial officer (as of the date first above written, for purposes of this Insider Trading Policy, Samuel Berry at \*\*\* and David Jin at \*\*\*)
- Requests by employees, officers or directors of Mustang to trade in the securities of Fortress or any other affiliate: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at \*\*\* and David Jin at \*\*\*)

Any Insider who wishes to implement a new trading plan under SEC Rule 10b5-1 must first pre-clear the plan with the Insider Trading Compliance Officer for each Company whose securities are included in the plan. Transactions effected pursuant to a pre-cleared trading plan will not require further pre-clearance at the time of the transaction if the plan specifies the dates, prices, and amounts of the contemplated trades, or establishes a formula for determining the dates, prices, and amounts. Those transactions, however, must be reported immediately to the Insider Trading Compliance Officer.

2. <u>Broker-Assisted Cashless Exercises of Options</u>. The Sarbanes-Oxley Act makes it illegal for issuers to extend or maintain credit or arrange for the extension of credit in the form of a personal loan to any officer or director. In most broker-assisted cashless exercises, there is typically a delay of a few days from the time of exercise to the date the issuer receives the exercise price. Some attorneys have speculated that these arrangements could be deemed an impermissible extension of credit arranged by issuers for their insiders. Consequently, unless and until this issue gets resolved to our satisfaction, we require receipt of cash simultaneous with any issuance of shares pursuant to the exercise of an option by an insider. We believe that most brokers can do

cashless exercises for you this way.

Any person who has a question about these procedures or their application to any proposed transaction may obtain additional guidance from the Insider Trading Compliance Officer.

# **Certifications and Attestations**

All directors, officers, and employees subject to the procedures set forth in this Insider Trading Policy must certify their understanding of and intent to comply with it, as it may be amended and updated from time to time. Please return the enclosed certification immediately (unless you have previously submitted an executed certification).

You also may be required to periodically attest in writing to your compliance with this Insider Trading Policy and its pre-clearance procedures.

# ${\bf FORTRESS\ BIOTECH, INC.}$

# INSIDER TRADING POLICY

# CERTIFICATION

To Fortress Biotech, Inc. and its Subsidiaries

Insider Trading Policy. I hereby agree to comply with during my employment or other service relationship understand that this policy constitutes a material term	ead a copy of the Fortress Biotech, Inc. and Subsidiaries the specific requirements of the policy in all respects with Fortress Biotech, Inc. and/or its subsidiaries. It of my employment or other service relationship with my failure to comply in all respects with the policy is a
(Signature)	-
(Name)	-
(Date)	<u>-</u>

# SUBSIDIARIES OF FORTRESS BIOTECH, INC.

Subsidiaries of Fortress Biotech, Inc. at December 31, 2024, with jurisdiction of incorporation or formation:

- Aevitas Therapeutics, Inc. (Delaware)
- Avenue Therapeutics, Inc. (Delaware)
- Cellvation, Inc. (Delaware)
- Checkpoint Therapeutics, Inc. (Delaware)
- Cyprium Therapeutics, Inc. (Delaware)
- Helocyte, Inc. (Delaware)
- Journey Medical Corporation (Delaware) Mustang Bio, Inc. (Delaware)
- Oncogenuity, Inc. (Delaware)
- Urica Therapeutics, Inc. (Delaware)

# Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-280342, 333-249983, 333-255185, 333-258145, 333-269687, and 333-279516) on Form S-3 (Nos. 333-184616, 333-194588, 333-206645, 333-221485, 333-233195, 333-249985, 333-267977, 333-274781, 333-274782, 333-279878 and 333-279881) on Form S-8 and (No. 333-282384) on Form S-1 of our report dated March 31, 2025, with respect to the consolidated financial statements of Fortress Biotech, Inc. and subsidiaries.

/s/ KPMG LLP

New York, New York March 31, 2025

# 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 Annual Report on Form 10-K for the year ended December 31, 2024 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 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: March 31, 2025 By: /s/ Lindsay A. Rosenwald, M.D.

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

# CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

- I, David Jin, certify that:
- (1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2024 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 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: March 31, 2025 By: /s/ David Jin

David Jin Chief Financial Officer (Principal Financial Officer)

# 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 Annual Report on Form 10-K of Fortress Biotech, Inc. (the "Company") for the period ended December 31, 2024, 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: March 31, 2025 By: /s/ Lindsay A. Rosenwald, M.D.

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

# 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 Annual Report on Form 10-K of Fortress Biotech, Inc. (the "Company") for the period ended December 31, 2024, 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: March 31, 2025 By: /s/ David Jin

David Jin Chief Financial Officer (Principal Financial Officer)