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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2023

or

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

For the Transition Period from ____ to _____.

Commission File No. 001-35366

FORTRESS BIOTECH, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware **(State or Other Jurisdiction of Incorporation or Organization)**	**20-5157386** **(I.R.S. Employer Identification 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 registered pursuant to Section 12(b) of the Act:

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	FBIO	Nasdaq Capital Market
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock	FBIOP	Nasdaq Capital Market

Securities registered pursuant to section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate 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 ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The 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 completed second fiscal quarter: $52,871,646.

Class of Stock	Outstanding Shares as of March 27, 2024
Common Stock, $0.001 par value	19,234,526
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock, $0.001 par value	3,427,138

FORTRESS BIOTECH, INC.
ANNUAL REPORT ON FORM 10-K
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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;
- 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 the applicable lending agreements may restrict our operations. Further, the occurrence of any default event under an applicable loan document could adversely affect our business.
- Our research and development ("R&D") programs will require additional capital, which we may be unable to raise as needed and which may impede our R&D programs, commercialization efforts, or planned acquisitions.
- If we raise additional capital by issuing equity, 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. Three of Journey's marketed products, Qbrexza, Amzeeq and Zilxi, as well as DFD-29, a modified release oral minocycline for the treatment of rosacea licensed from Dr. Reddy's Laboratories, currently have patent protection. Three of Journey's marketed products, Accutane, Targadox, and Exelderm, do not have patent protection or otherwise are not eligible for patent protection. With respect to Journey products that are covered by valid claims of issued patents, such patents may be subject to invalidation, which would harm our operating income.
- Continued sales and coverage, including formulary inclusion without the need for a prior authorization or step edit therapy, of our products for commercial sale will depend in part on the availability of reimbursement from third-party payors, 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 guarantor and/or indemnitor of certain obligations of our subsidiaries and partner companies, which could require us to pay substantial amounts based on the actions or omissions of said entities.

Risks Pertaining to Reliance on Third Parties

- We rely heavily on third parties for several aspects of our operations, including manufacturing and developing product candidates, conducting clinical trials, and producing commercial product supply. Such reliance on third parties reduces our ability to control every aspect of the drug development process and may hinder our ability to develop and commercialize our products in a cost-effective and timely manner.

Risks Pertaining to Intellectual Property and Potential Disputes with Licensors Thereof

- If we are unable to obtain and maintain patent protection for our technologies and products, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technologies and products similar or identical to ours, and our ability to successfully commercialize our technologies and products may be impaired.
- We or our licensors may be subject to costly and time-consuming litigation for infringement of third-party intellectual property rights or to enforce our or our licensors' patents.
- Any dispute with our licensors may affect our ability to develop or commercialize our product candidates.

Risks Pertaining to Generic Competition and Paragraph IV Litigation

- Generic drug companies may submit applications seeking approval to market generic versions of our products.
- In connection with these applications, generic drug companies may seek to challenge the validity and enforceability of our patents through litigation and/or with the United States Patent and Trademark Office ("PTO"). Such challenges may subject us to costly and time-consuming litigation and/or PTO proceedings.
- As a result of the loss of any patent protection from such litigation or PTO proceedings, or the "at-risk" launch by a generic competitor of our products, our products could be sold at significantly lower prices, and we could lose a significant portion of product sales in a short period of time, which could adversely affect our business, financial condition, operating results and prospects.

Risks Pertaining to the Commercialization of Product Candidates

- If our 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, 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.

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 ("COH" or "City of Hope"), Fred Hutchinson Cancer Center, St. Jude Children's Research Hospital ("St. Jude"), Dana-Farber Cancer Institute, Nationwide Children's Hospital, Cincinnati Children's Hospital Medical Center, Columbia University, the University of Pennsylvania, Mayo Foundation for Medical Education and Research ("Mayo Clinic"), AstraZeneca plc, and Dr. Reddy's Laboratories, Ltd.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and financial expertise to help the partners achieve their goals. Partner 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 two have consummated strategic partnerships with industry leaders AstraZeneca plc as successor-in-interest to Alexion Pharmaceuticals, Inc. ("AstraZeneca") and Sentynl Therapeutics, Inc. ("Sentynl"), respectively.

Our subsidiary and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates are Avenue Therapeutics, Inc. (Nasdaq: ATXI, "Avenue"), Baergic Bio, Inc. ("Baergic," a subsidiary of Avenue), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. (Nasdaq: CKPT, "Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Journey Medical Corporation (Nasdaq: DERM, "Journey" or "JMC"), Mustang Bio, Inc. (Nasdaq: MBIO, "Mustang"), Oncogenuity, Inc. ("Oncogenuity") and Urica Therapeutics, Inc. ("Urica"). Aevitas Therapeutics, Inc. ("Aevitas") was a consolidated subsidiary company until the sale of its primary asset to 4D Molecular Therapeutics in April 2023.

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.

Product Candidates and Other Intellectual Property

Revenue Portfolio

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

- 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).

Additionally, Journey sells two authorized generic products:

- sulconazole nitrate cream and solution, 1% antifungal agents indicated for the treatment of *tinea cruris* and *tinea corporis* caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, and *Microsporum canis*,* and for the treatment of *tinea versicolor*. *Efficacy for this organism in the organ system was studied in fewer than 10 infections. EXELDERM® Cream is also indicated for the treatment of *tinea pedis* (athlete's foot). Effectiveness of EXELDERM® Solution has not been proven in *tinea pedis*; and
- doxycycline hyclate immediate release 50mg tablets, indicated as adjunctive therapy for severe acne to reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of doxycycline hyclate and other antibacterial drugs.

Late Stage Product Candidates

Cosibelimab (anti-PD-L1 antibody)

Our partner company Checkpoint is currently developing its lead product candidate, cosibelimab, an anti-programmed death-ligand 1 ("anti-PD-L1") monoclonal antibody licensed from the Dana-Farber Cancer Institute, in solid tumor indications. In 2017, Checkpoint commenced a Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers. In January 2022, Checkpoint announced top-line results from a cohort of this study with cosibelimab administered as a fixed dose of 800 mg every two weeks in patients with metastatic cutaneous squamous cell carcinoma ("cSCC"). The cohort met its primary endpoint, with cosibelimab demonstrating a confirmed overall response ("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 RECIST 1.1.

In June 2022, Checkpoint announced interim results from another cohort of this study with cosibelimab 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. Cosibelimab 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. The design of the interim analysis incorporated feedback from the FDA and is intended to potentially support the approval of cosibelimab in this indication.

In July 2023, Checkpoint announced longer-term results for cosibelimab 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 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 U.S. Food and Drug Administration ("FDA") for cosibelimab in January 2023. On December 15, 2023, the FDA issued a Complete Response Letter ("CRL") for the cosibelimab BLA for the treatment of patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or radiation. The CRL only cited findings that arose during a multi-sponsor inspection of our third-party contract manufacturing organization as approvability issues to address in a resubmission. The CRL did not state any concerns about the clinical data package, safety, or labeling. Following resolution of the inspection issues at the third-party contract manufacturing organization raised in the CRL, a resubmission of the BLA is planned in 2024 to support the marketing approval of cosibelimab.

Checkpoint also previously had a collaboration agreement with TG Therapeutics, Inc. ("TGTX") whereby TGTX was granted the rights to develop and commercialize cosibelimab in the field of hematological malignancies, while Checkpoint retained the right to develop and commercialize these assets in solid tumors. Effective September 30, 2023, Checkpoint and TGTX agreed to mutually terminate these collaborations, with full rights reverting back to Checkpoint.

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

Through our partner company Journey, in collaboration with Dr. Reddy's Laboratories, Ltd. ("DRL"), we are developing DFD-29, a modified release oral minocycline being evaluated for the treatment of inflammatory lesions of rosacea.

Under the DRL arrangement, Journey is responsible for the development of DFD-29, which includes conducting two Phase 3 studies to assess the efficacy, safety and tolerability of DFD-29 for the treatment of rosacea and the regulatory submission of a new drug application under Section 505(b)(2) of the FDCA. DRL provides development support including the monitoring of two Phase 3 clinical trials, which were initiated in the first quarter of 2022, and completed enrollment in January 2023. In July 2023, Journey announced positive topline data from our two DFD-29 Phase 3 clinical trials for the treatment of papulopustular rosacea. The Phase 3 clinical trials achieved the co-primary and all secondary endpoints and subjects completed the 16-week treatment and the drug was well-tolerated. DFD-29 demonstrated statistical superiority over both the standard of care, Oracea® capsules, and placebo for Investigator's Global Assessment treatment success and the reduction in the total inflammatory lesion count in both studies. Journey filed a New Drug Application ("NDA") with the FDA for DFD-29 on January 4, 2024, paying a $4.0 million filing fee, and announced on March 18, 2024 that the FDA accepted the NDA and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of November 4, 2024.

CUTX-101 (copper histidinate injection for Menkes disease)

Our partner company 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, however, 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 now 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. The CUTX-101 rolling NDA submission is ongoing and is expected to be completed by Sentynl in 2024.

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 ClinicalTrials.gov using identifier NCT04074512. Information on clinicaltrials.gov does not constitute part of this Annual Report on Form 10-K.

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, we announced that we had received a second CRL. We submitted a formal dispute resolution request ("FDRR") with the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, we 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, we submitted a FDRR with the Office of New Drugs ("OND") of the FDA. On October 21, 2021, we 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 the 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 as soon as possible, subject to having the necessary financing.

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.

In September 2018, Checkpoint announced preliminary interim safety and efficacy data from the ongoing Phase 1 clinical trial. The data were presented in an oral presentation at the International Association for the Study of Lung Cancer ("IASLC") 19th World Conference on Lung Cancer in Toronto. Additional information on the Phase 1 trial can be found on ClinicalTrials.gov using identifier NCT02926768. Information on clinicaltrials.gov does not constitute part of this Annual Report on Form 10-K.

In November 2020, NeuPharma, Inc. commenced a Phase 3 clinical trial in China evaluating olafertinib in treatment-naïve locally advanced or metastatic NSCLC patients whose tumors have EGFR exon 19 deletion mutations.

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-K.

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 $350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive 42.4% of all possible proceeds of the transaction, including approximately $148 million to Fortress, with $31.8 million upon BLA approval.

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") complications in the transplant setting. 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 (ClinicalTrials.gov 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 (ClinicalTrials.gov Identifier: NCT02506933). Triplex is currently the subject of four, grant-funded trials in various clinical settings including: adults 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"). Helocyte secured an exclusive, worldwide license to Triplex from COH in April 2015. Helocyte secured an exclusive, worldwide license to Triplex from COH in April of 2015. Information on clinicaltrials.gov does not constitute part of this Annual Report on Form 10-K.

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.

In August 2022, Helocyte announced that Triplex received a grant from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health that could provide over $20 million in non-dilutive funding. This competitive award will fund a multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation. The company believes this data set could ultimately be used to support approval of Triplex in this setting and the trial is expected to commence in 2024.

Early and Mid-Stage Product Candidates

Dotinurad (urate transporter (URAT1) inhibitor for gout)

Through our partner company Urica, in May 2021, we acquired an exclusive license from Fuji Yakuhin Co. Ltd. ("Fuji") to develop dotinurad in North America and Europe (with the exclusive licensed territory later expanded to include the Middle East and North Africa). Dotinurad is a potential best-in-class urate transporter (URAT1) inhibitor for gout and possibly other hyperuricemic indications. Dotinurad (URECE® tablet) was approved in Japan in 2020 as a once-daily oral

therapy for gout and hyperuricemia. Dotinurad was efficacious and well-tolerated in more than 500 Japanese patients treated for up to 58 weeks in Phase 3 clinical trials. The clinical program supporting approval included over 1,000 patients.

In June 2023, Urica announced data from the Phase 1 clinical trial in healthy volunteers showed comparable pharmacokinetic, pharmacodynamic and safety profile between U.S. and Japanese healthy subjects. In the third quarter of 2023, Urica initiated a Phase 1b clinical trial in patients with gout and hyperuricemia in the U.S. to compare U.S. patients' response to dotinurad with data generated in Japan, and to assess drug-drug interactions, if any, with allopurinol. Urica expects to announce data from this trial in the first half of 2024.

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") and chronic lymphocytic leukemia ("CLL").

Under their IND, Fred Hutch is currently conducting a Phase 1/2 clinical study to evaluate the anti-tumor activity and safety of administering CD20-directed third-generation CAR T cells incorporating both 4-1BB and CD28 co-stimulatory signaling domains (MB-106) to patients with relapsed or refractory B-NHL or CLL (ClinicalTrials.gov Identifier: NCT03277729). Secondary endpoints of this study include safety and toxicity, preliminary antitumor activity as measured by overall response rate and complete remission rate, progression-free survival, and overall survival. The study is also assessing CAR T cell persistence and the potential immunogenicity of the cells. Fred Hutch intends to enroll approximately 50 subjects on the study, which is being led by Principal Investigator Mazyar Shadman, M.D., M.P.H., Assistant Member of Fred Hutch's Clinical Research Division.

The Fred Hutch IND was amended in 2019 to incorporate an optimized manufacturing process that had been developed in collaboration with Mustang.

In December 2023, Mustang announced initial data from its ongoing multicenter, open-label, non-randomized Phase 1/2 clinical trial (Clinicaltrials.gov Identifier: NCT05360238) evaluating the safety and efficacy of MB-106 CAR-T cell therapy at the 2023 American Society of Hematology ("ASH") Annual Meeting. Initial data show that all patients responded clinically to treatment with MB-106 (n=9); 100% overall response rate for patients with follicular lymphoma ("FL") and Waldenstrom macroglobulinemia ("WM"). 100% of patients with FL (n=5) had a complete response; 1 very good partial response and 2 partial responses were observed in WM patients (n=3); and the hairy cell leukemia variant ("HCL-v") patient experienced stable disease, with prolonged, ongoing independence from blood transfusions. Complete responses were observed in patients previously treated with CD19-targeted CAR T-cell therapy. MB-106 demonstrated a tolerable safety profile in patients with indolent NHL, with no occurrence of cytokine release syndrome ("CRS") above grade 1 and no immune effector cell-associated neurotoxicity syndrome ("ICANS") of any grade. Outpatient administration was allowed and found to be feasible. Information on clinicaltrials.gov does not constitute part of this Annual Report on Form 10-K.

In June 2023, Mustang announced final results from the FL cohort of the Fred Hutch Phase 1/2 clinical study, and the data showed an ORR of 95% (n=19/20) and complete response rate ("CR") of 80% (n=16/20). Ten patients were in remission for over one year, seven of whom were in remission for over two years. All cytokine release syndrome events were grade1 (n=5/20) or grade 2 (n=1/20) with no grade 3 or higher cytokine release syndrome ("CRS") events. There was no occurrence of immune effector cell-associated neurotoxicity syndrome ("ICANS") of any grade.

MB-101 (IL13Rα2 CAR T Cell Program for Glioblastoma)

Mustang is also currently developing MB-101 for malignant brain tumors, including glioblastoma ("GBM"). MB-101 is an optimized CAR T product targeting IL13Rα2 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 49% of malignant primary brain and CNS tumors, 54% of all gliomas, and 16% of all primary brain and CNS tumors. More than 14,490 new glioblastoma cases were predicted in the U.S. for 2023. Malignant brain tumors are the most common cause of cancer-

related deaths in adolescents and young adults aged 15-39 and the most common cancer occurring among 15-19 year-olds in the U.S. While GBM is a rare disease, it is quite lethal, with five-year survival rates historically under 10%. Standard of care therapy consists of maximal surgical resection, radiation, and chemotherapy with temozolomide, which, while rarely curative, is shown to extend median overall survival from 4.5 to 15 months. GBM remains difficult to treat due to the inherent resistance of the tumor to conventional therapies.

Immunotherapy approaches targeting brain tumors offer promise over conventional treatments. IL13Rα2 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 IL13Rα2 and reduced binding to IL13Rα1 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); and

- MB-101 in treating patients with recurrent or refractory glioblastoma with a substantial component of leptomeningeal disease (currently enrolling patients; ClinicalTrials.gov Identifier: NCT04661384).

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") 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 (ClinicalTrials.gov 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 (IL13Rα2-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 IL13Rα2-directed CAR-T cells gave no adverse events and, more notably, that pre-treatment with MB-108 re-shaped the tumor microenvironment by increasing immune cell infiltrates and enhanced the efficacy of sub-therapeutic 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 IL13Rα2-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.

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. 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, with topline data anticipated in the second quarter of 2024.

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.

MB-117 (Ex vivo Lentiviral Gene Therapy for Newly Diagnosed X-linked Severe Combined Immunodeficiency ("XSCID")) and MB-217 (Ex vivo Lentiviral Gene Therapy for Previously Transplanted XSCID)

In partnership with St. Jude, Mustang's XSCID gene therapy programs are being developed under an exclusive license to intellectual property underpinning potentially curative treatment for XSCID, a rare genetic immune system condition in which affected patients do not live beyond infancy without treatment. St. Jude's first-in-class *ex vivo* lentiviral ("LV") gene therapy has been utilized in two Phase 1/2 clinical trials involving two different autologous cell products produced via transduction of patients' hematopoietic stem cells using a predecessor LV vector. These cell products were designated MB-107 and MB-207, and the respective Phase 1/2 clinical trials were: a multicenter trial of the MB-107 product in newly diagnosed infants sponsored by St. Jude (ClinicalTrials.gov Identifier: NCT01512888; referred to at St. Jude as LVXSCID-ND) and a single-center trial of the MB-207 product in previously transplanted patients sponsored by the National Institutes of Health ("NIH") (ClinicalTrials.gov Identifier: NCT01306019; referred to at the NIH as LVXSCID-OC).

Going forward, this predecessor LV vector will be replaced by a modified LV vector which will be used to produce the MB-117 and MB-217 cell products. In 2024, following availability of the modified LV vector, we expect that St. Jude will initiate its Phase 1 trial to treat newly diagnosed infants with MB-117 and that the NIH will initiate its Phase 1 trial to treat previously transplanted patients with MB-217.

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

Mustang is developing MB-110, a first-in-class *ex vivo* treatment for recombinase-activating gene-1 ("RAG1") Severe combined immunodeficiency ("SCID"), through an exclusive license and in partnership with Leiden University Medical Centre ("LUMC"). SCID due to complete recombinase-activating gene-1 (RAG1) deficiency is a rare, genetic disorder due to null mutations in the RAG1 gene resulting in less than 1% of wild type V(D)J recombination activity. Neonatal patients present with life-threatening, severe, recurrent infections by opportunistic fungal, viral and bacterial micro-organisms, as well as skin rashes, chronic diarrhea, failure to thrive and fever. Immunologic observations include profound T and B cell lymphopenia, low or absent serum immunoglobulins, and normal natural killer cell counts. As is the case with

other types of SCID, RAG1-SCID is fatal in infancy unless immune reconstitution is achieved with hematopoietic stem cell transplantation (HSCT).

MB-110, which includes low-dose conditioning prior to reinfusion of the patients' own gene-modified blood stem cells, is currently being evaluated in a Phase 1/2 multicenter clinical trial in Europe. The ongoing clinical trial has enrolled its first patient, and additional clinical sites are expected to be added in the near future. The RAG1-SCID program has been granted Orphan Drug Designation by the European Medicines Agency.

BAER-101 ($GABA_A$ α2/3 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 the 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.

Preclinical Product Candidates

Mayo Clinic In Vivo CAR T Platform Technology

In August 2021, Mustang announced an exclusive license agreement with the Mayo Clinic for a novel technology to create *in vivo* CAR T cells that may be able to transform the administration of CAR T therapies and has the potential to be used as an off-the-shelf therapy. Preclinical proof-of-concept has been established, and the ongoing development of this technology is continuing in partnership with the Mayo Clinic.

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 trial until completed. We intend to use third-party clinical research organizations ("CROs") to administer and 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 life-threatening 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, 2023, we had 186 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.

Executive Officers of Fortress

The following table sets forth certain information about our executive officers as of December 31, 2023.

Name	Age	Position
Lindsay A. Rosenwald, M.D.	68	Chairman of the Board of Directors, President and Chief Executive Officer
David Jin	34	Chief Financial Officer and Head of Corporate Development
George Avgerinos, Ph.D.	70	Senior Vice President, Biologics Operations
Michael S. Weiss	57	Executive Vice Chairman, Strategic Development

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 (Nasdaq: 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 as Interim Chief Financial Officer and Chief Operating Officer of Avenue. 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.

George Avgerinos, Ph.D. has served as our Senior Vice President, Biologics Operations since June 2013. Dr. Avgerinos joined us from AbbVie, Inc., where he was Vice President, HUMIRA® Manufacturing Sciences and External Partnerships. In his 22-year career at AbbVie, Inc., formerly Abbott Laboratories, formerly BASF Bioresearch Corporation (BASF), Dr. Avgerinos was responsible for many aspects of biologics development and operations. These included the HUMIRA® operations franchise, global biologics process and manufacturing sciences, biologics CMC, manufacturing operations, and third-party manufacturing. During his tenure, Dr. Avgerinos led and participated in the development of numerous clinical candidates which included the launch of HUMIRA®. He supported expansion of the supply chain to over $9.0 billion in annual global sales. Dr. Avgerinos' efforts on HUMIRA® have been recognized with numerous awards, including the prestigious Abbott's Chairman's award in 2011. Dr. Avgerinos received a B.A. in Biophysics from the University of Connecticut and a Ph.D. in Biochemical Engineering from the Massachusetts Institute of Technology. Dr. Avgerinos also provides services for TG Therapeutics, Inc., a related party, pursuant to a shared services agreement.

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 Checkpoint (Nasdaq: CKPT) and Mustang (Nasdaq: MBIO). Mr. Weiss is currently the Executive Chairman of Mustang Bio, Inc. and the Chairman of the Board of Directors of Checkpoint. From March 2015 until February 2019, Mr. Weiss served on the board of Avenue (Nasdaq: ATXI). 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.

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, or the Exchange Act. The SEC also maintains a website at http://www.sec.gov 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 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 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, preventing us from generating revenue from such products' sale. Alternatively, even if a product candidate is approved for marketing, future adverse events could lead to the withdrawal of such product from the market.

Suspensions or delays in the completion of clinical testing could result in increased costs and/or delay or prevent our ability to complete development of that product candidate or generate product revenues.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements and on a timely basis. Further, a clinical trial may be modified, suspended or terminated by us, an IRB, an ethics committee or a data safety monitoring committee overseeing the clinical trial, any clinical trial site with respect to that site, or the FDA or other regulatory authorities, due to a number of factors, including, but not necessarily limited to:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- stopping rules contained in the protocol;
- unforeseen safety or chemistry, manufacturing and control issues, or other determination that the clinical trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trial.

Regulatory requirements and guidance may change, and we may need to amend clinical trial protocols to reflect these changes. Any such change may require us to resubmit clinical trial protocols to IRBs, which may in turn impact a clinical trial's cost, timing, and likelihood of success. If any clinical trial is delayed, suspended, or terminated, our ability to obtain regulatory approval for that product candidate will be delayed, and the commercial prospects, if any, for the product candidate may suffer. In addition, many of these factors may ultimately lead to the denial of regulatory approval of a product candidate.

If our competitors develop treatments for any of our product candidates' target indications and those competitor products are approved more quickly, marketed more successfully or demonstrated to be more effective, the commercial opportunity for our product candidates will be reduced or eliminated.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. Any of these developments may render one or more of our product candidates obsolete or noncompetitive.

Competitors may seek to develop alternative formulations that do not directly infringe on our in-licensed patent rights. The commercial opportunity for one or more of our product candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing capabilities.

As a result of these factors, our competitors may obtain regulatory approval for their products more rapidly than we are able to, or may obtain patent protection or other intellectual property or exclusivity rights that limit our ability to develop or commercialize one or more of our product candidates. Our competitors may also develop drugs that are more effective, safe, useful and/or less costly than ours and may be more successful than us in manufacturing and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We will also face competition from these third parties in establishing clinical trial sites, in patient registration for clinical trials, and in identifying and in-licensing new product candidates.

Negative public opinion and increased regulatory scrutiny of the therapies that underpin many of our product candidates may damage public perception of our product candidates, or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

If any of the technologies underpinning our product candidates, including gene therapy, is claimed to be unsafe, such product candidate may not gain the acceptance of the public or the medical community. The success of our gene therapy platforms in particular depends upon physicians who specialize in treating the diseases targeted by our product candidates prescribing treatments involving our product candidates in lieu of, or in addition to, treatments with which they are already familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Adverse events in our clinical

trials, even if not ultimately attributable to our product candidates, and the resulting publicity, could lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that do obtain approval and/or a decrease in demand for any such product candidates. Concern about environmental spread of our products, whether real or anticipated, may also hinder the commercialization of our products.

The making, use, sale, importation, exportation and distribution of controlled substances are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies.

Controlled substances are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Controlled substances are regulated under the Federal Controlled Substances Act of 1970 ("CSA") and regulations of the DEA. IV tramadol, under development by our partner company Avenue, will be subject to these regulations.

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

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

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

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

The FDA limits regulatory approval for our product candidates to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to the indications for use and related treatment of those specific diseases set forth in the approval for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain

FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may prescribe drugs for uses that are not described in the product's label or that differ from those tested in clinical studies and approved by the regulatory authorities ("off label uses"), our ability to promote the products is limited to those indications that are specifically approved by the FDA. Such off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the practice of medicine or behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies regarding the promotion of off-label use.

If our promotional activities fail to comply with these regulations or guidelines, we may be subject to compliance or enforcement actions, including Warning Letters or Untitled Letters, by, these authorities. In addition, our failure to follow FDA laws, regulations and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, request a recall, institute fines, or could result in disgorgement of money, operating restrictions, corrective advertising, injunctions or criminal prosecution, any of which could harm our business.

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

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

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

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

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

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

At December 31, 2023, the total amount of debt outstanding, net of the debt discount, was $60.9 million. If we default on our obligations, the holders of our debt may declare the outstanding amounts immediately payable together with accrued interest, and/or take possession of any pledged collateral. If an event of default occurs, we may be unable to cure it within the applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment and we may be unable to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. In addition, current or future debt obligations may limit our ability to finance future operations, satisfy capital needs, or to engage in, expand or pursue our business activities. Such restrictions may also prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding debt, which may not be desirable or possible.

On August 27, 2020, we entered into a $60 million senior secured credit agreement (the "Oaktree Agreement" and the debt thereunder, the "Oaktree Note") with Oaktree Fund Administration, LLC and the lenders from time-to-time party thereto (collectively, "Oaktree"). At December 31, 2023 the amount outstanding under the Oaktree Agreement was $50 million. The Oaktree Agreement contains certain affirmative and negative covenants restricting our and certain of our subsidiaries' abilities to take certain actions, especially as pertains indebtedness, liens, investments, affiliate transactions, acquisitions, mergers, dispositions, prepayment of other indebtedness, dividends and other distributions (subject in each case to exceptions). The Oaktree Agreement also contains financial covenants obligating us to maintain a minimum liquidity amount and a minimum amount of revenue, in both cases subject to exceptions. The breach of any such provisions (even, potentially, in an immaterial manner) could result in an event of default under the Oaktree Agreement, the announcement and impact of which could have a negative impact on the trading prices of our securities. The restrictions imposed by such provisions may also inhibit our and certain of our subsidiaries and partner companies' ability to enter into certain transactions or arrangements that management otherwise believes would be in our 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 $142.3 million and $203.6 million for the years ended December 31, 2023 and 2022, respectively. At December 31, 2023, we had an accumulated deficit of approximately $694.9 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, 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, including Journey, is a distinct legal entity and, under certain circumstances, legal and contractual restrictions may limit our ability to obtain cash from our subsidiaries.

Our ability to continue to reduce our indebtedness will depend upon factors including our future operating performance, our ability to access the capital markets to refinance existing debt and prevailing economic conditions and financial, business and other factors, many of which are beyond our control. We can provide no assurance of the amount by which we will reduce our debt, if at all. In addition, servicing our debt will result in a reduction in the amount of our cash flow available for other purposes, including operating costs and capital expenditures that could improve our competitive position and results of operations.

We may need substantial additional funding and may be unable to raise capital when needed, which may force us to delay, curtail or eliminate one or more of our R&D programs, commercialization efforts or planned acquisitions and potentially change our growth strategy.

Our R&D programs will require substantial additional capital for research, preclinical testing and clinical trials, establishing pilot scale and commercial scale manufacturing processes and facilities, and establishing and developing quality control, regulatory, marketing, sales, and administrative capabilities to support these programs. We expect to fund our R&D activities from a combination of cash generated from royalties and milestones from our partners in various past, ongoing, and future collaborations, and through additional equity or debt financings from third parties. These financings could depress the 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, 2023 and 2022, we incurred R&D expenses of approximately $101.7 million and $134.2 million, respectively. We expect to continue to spend significant amounts on our growth strategy. We believe that our current cash and cash equivalents will enable us to continue to fund operations in the normal course of business for at least the next 12 months from the filing of this 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.

Under current SEC regulations, if at the time we file our Annual Report on Form 10-K our public float is less than $75 million, and for so long as our public float remains less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float, which is referred to as the “baby shelf rules.” SEC regulations permit us to use the highest closing sales price of our common stock (or the average of the last bid and last ask prices of our common stock) on any day within 60 days of sales under the registration statement to calculate our public float.

As of the date of this Form 10-K, our public float was less than $75 million. As a result, for sales following the date of this Form 10-K, and until we again have a public float with a value in exceeds of $75 million, if ever, we only have the capacity to sell shares up to one-third of our public float under shelf registration statements in any twelve-month period. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statements will also decrease.

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.

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 and Luxamend, 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. Three of our marketed products, Qbrexza, Amzeeq and Zilxi, as well as one of our product candidates, DFD-29, currently have patent protection. Three of our marketed products, Accutane, Targadox, and Exelderm, do not have patent protection or otherwise are not eligible for patent protection. Accutane currently competes in the Isotretinoin market with five other therapeutically equivalent A/B rated products. Targadox currently competes with one therapeutically equivalent A/B rated generic product. Exelderm may face A/B rated generic competition in the future.

Generic versions are generally significantly less expensive than branded versions, and, where available, may be required to be utilized before or in preference to the branded version by third-party payors, or substituted by pharmacies. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care. Any reduction in sales of our products or the prices we receive for our products as a result of generic competition could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline.

Any disruptions to the capabilities, composition, size or existence of Journey's field sales force may have a significant adverse impact on our existing revenue stream. Further, our ability to effectively market and sell any future products that we may develop and for which we receive marketing authorization, will depend on our ability to establish and maintain sales and marketing capabilities or to enter into agreements with third parties to market, distribute and sell any such products.

Journey's field sales force has been and is expected to continue to be an important contributor to our commercial success. Any disruptions to our relationship with such field sales force or the professional employer organization that employs our field sales force, could materially adversely affect our product sales. Journey currently relies, and may continue to rely, on professional employer organizations and staffing organizations for the employment of its field sales force.

The establishment, development, and/or expansion of a field sales force, either by us or certain of our partners or vendors, or the establishment of a contract field sales force to market any products for which we may have or receive marketing approval is expensive and time-consuming and could delay any such product launch or compromise the successful commercialization of such products. If we are unable to establish and maintain sales and marketing capabilities or any other non-technical capabilities necessary to commercialize any products that may be successfully developed, we will need to contract with third parties to market and sell such products. We may not be able to establish or maintain arrangements with third parties on commercially reasonable terms, or at all.

If our products are not included in managed care organizations' formularies or coverage by other organizations, our products' utilization and market shares may be negatively impacted, which could have a material adverse effect on our business and financial condition.

In the United States, continued sales and coverage, including formulary inclusion without the need for a prior authorization or step edit therapy, of our products for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our products to enable us to realize an appropriate return on our investment of our currently marketed products or those which we may acquire or develop in the future.

Managed care organizations and other third-party payors try to negotiate the pricing of medical services and products to control their costs. Managed care organizations and pharmacy benefit managers typically develop formularies to reduce their cost for medications. Formularies are based on the prices and therapeutic benefits of available products. Due to their lower costs, generic products are often favored. The breadth of the products covered by formularies varies considerably from one managed care organization to another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of our products. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic products, this could have a material adverse effect on our business, 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.

Legislative and regulatory changes to the healthcare systems of the United States and certain foreign countries could impact our ability to sell our products profitably. Several federal agencies including FDA, CMS, DEA and HHS, in addition to state and local governments, regulate drug product development and marketing. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products by revising the payment methodology for many products reimbursed by Medicare, resulting in lower rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. In addition, this law provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions

of this law and future laws could decrease the coverage and price that we will receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Therefore, any limitations in reimbursement that results from the MMA may result in reductions in payments from private payors.

Since 2003, there have been several other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "Affordable Care Act" or "ACA," was enacted and made significant changes to the United States' healthcare system. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business.

In the United States there is significant interest in containing healthcare costs and increasing the scrutiny of pharmaceutical pricing practices. Congress has continually explored legislation intended to address the cost of prescription drugs. Notably, the Inflation Reduction Act of 2022 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. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known.

While we cannot predict what additional proposals may ultimately become law, the elements under consideration could significantly change the landscape in which the pharmaceutical market operates.

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

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services, including prescription drugs. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and prescription drugs may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the payment that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidate, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

Risks Pertaining to our Business Strategy, Structure and Organization

We have entered, and will likely in the future enter, into certain collaborations or divestitures which may cause a reduction in our business' size and scope, market share and opportunities in certain markets, or our ability to compete in certain markets and therapeutic categories. We have also entered into several arrangements under which we have agreed to contingent dispositions of subsidiaries, partner companies and/or their assets. The failure to consummate any such transaction may impair the value of such companies and/or assets, and we may not be able to identify or execute alternative arrangements on favorable terms, if at all.

We have entered into and consummated several partnerships and/or contingent sales of our assets and subsidiaries, including an equity investment and contingent acquisition agreement between Caelum and AstraZeneca (the acquisition component of which has consummated) and a development funding and contingent asset purchase between Cyprium and Sentynl (the acquisition component of which has not yet consummated). Each of these arrangements has been time-consuming and has diverted management's attention. As a result of these consummated/contingent sales, as with other similar transactions that we may complete, we may experience a reduction in the size or scope of our business, our market share in particular markets, our opportunities with respect to certain markets, products or therapeutic categories or our ability to compete in certain markets and therapeutic categories.

In addition, in connection with any transaction involving a (contingent or non-contingent) sale of one of our subsidiaries, partner companies or their assets, we may surrender our ability to realize long-term value from such asset or company, in the form of foregone product sales, royalties, milestone payments, sublicensing revenue or otherwise, in exchange for upfront and/or other payments. In the event, for instance, that a product candidate underpinning any such asset or company is granted FDA approval for commercialization following the execution of documentation governing the sale by us of such asset or company, the transferee of such asset or company may realize tremendous value from commercializing such product, which we would have realized for ourselves had we not executed such sale transaction and been able to achieve applicable approvals independently.

Should we seek to enter into collaborations or divestitures with respect to other assets or companies, we may be unable to consummate such arrangements on satisfactory or commercially reasonable terms within our anticipated timelines. In addition, our ability to identify, enter into and/or consummate collaborations and/or divestitures may be limited by competition we face from other companies in pursuing similar transactions in the biotechnology and pharmaceutical industries.

Any collaboration or divestiture we pursue, whether we are able to complete it or not, may be complex, time consuming and expensive, may divert from management's attention, may have a negative impact on our customer relationships, cause us to incur costs associated with maintaining the business of the targeted collaboration or divestiture during the transaction process and also to incur costs of closing and disposing the affected business or transferring the operations of the business to other facilities. In addition, if such transactions are not completed for any reason, the market price of our Common Stock may reflect a market assumption that such transactions will occur, and a failure to complete such transactions could result in a negative perception by the market of us generally and a decline in the market price of our 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 Common Stock may be issued. Depending on the terms of such arrangements, we may be contractually obligated to pay substantial amounts to third parties, or issue a substantially dilutive number of shares of our Common Stock, based on the actions or inactions of our subsidiaries and/or partner companies, regulatory agencies or other third parties.

We act, and are likely to continue acting, as indemnitor of potential losses or liabilities that may be experienced by one or more of our subsidiaries, partner companies and/or their partners or investors. If we become obligated to pay all or a portion of such indemnification amounts, our business and the market value of our Common Stock, 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, recent 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.

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.

We also rely on third-party manufacturers to purchase from third-party suppliers the raw materials and equipment necessary to produce product candidates for anticipated clinical trials. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture those products. We do not have direct control over the process or timing of the acquisition of these raw materials by our third-party manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials since such agreements are entered into by our third-party manufacturers and their qualified suppliers. Any significant delay in the supply of raw material components

related to an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval.

We do not expect to have the resources or capacity to engage in our own commercial manufacturing of our product candidates, if they received marketing approval, and would likely continue to be heavily dependent upon third-party manufacturers. Our dependence on third parties to manufacture and supply clinical trial materials, as well as our planned dependence on third party manufacturers for any products that may be approved, may adversely affect our ability to develop and commercialize products in a timely or cost-effective manner, or at all. In addition to the manufacturing and supply functions they provide, third-party manufacturers also play a key role in our efforts to obtain marketing approval for our product candidates, by interacting with, providing important information to, and hosting inspections by, applicable regulatory authorities. If a given contract development and manufacturing organization upon whom we rely in such a capacity is unwilling or unable to perform these activities on our behalf, the successful development and/or approval of the applicable product candidate could be delayed significantly.

In addition, because of the sometimes-limited number of third parties who specialize in the development, manufacture and/or supply of our clinical and preclinical materials, we are often compelled to accept contractual terms that we deem less than desirable, including without limitation as pertains representations and warranties, supply disruptions/failures, covenants and liability/indemnification. Especially as pertains liability and indemnification provisions, because of the frequent disparities in negotiating leverage, we are often compelled to agree to low caps on counterparty liability and/or indemnification language that could result in outsized liability to us in situations where we have zero or relatively little culpability.

We rely heavily on third parties for the development and manufacturing of products and product candidates.

To date, we have engaged primarily in intellectual property acquisitions, and evaluative and R&D activities; and we have not generated any revenues from product sales (except through Journey). We have incurred significant net losses since our inception. As of December 31, 2023, we had an accumulated deficit of approximately $694.9 million. We may need to rely on third parties for activities critical to the product candidate development process, including but not necessarily limited to:

- identifying and evaluating product candidates;
- negotiating, drafting and entering into licensing and other arrangements with product development partners; and
- continuing to undertake pre-clinical development and designing and executing clinical trials.

We have also not demonstrated the ability to perform the functions necessary for the successful commercialization of any of our development-stage product candidates, should any of them be approved for marketing. If we were to have any such product candidates approved, the successful commercialization of such products would be dependent on us performing or contracting with third parties for performance, of a variety of critical functions, including, but not necessarily limited to:

- advising and participating in regulatory approval processes;
- formulating and manufacturing products for clinical development programs and commercial sale; and
- conducting sales and marketing activities.

Our operations have been limited to acquiring, developing and securing the proprietary rights for, and undertaking pre-clinical development and clinical trials of, product candidates, both at the Fortress level and via our subsidiaries and partner companies. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to develop and commercialize potential product candidates, as well as for you to assess the advisability of investing in our securities.

We rely on third parties to conduct clinical trials. If these third parties do not meet agreed-upon deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful, and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We rely on third-party contract research organizations and site management organizations to conduct most of our preclinical studies and all of our clinical trials for our product candidates. We expect to continue to rely on third parties, such as contract research organizations, site management organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct some of our preclinical studies and all of our clinical trials. These CROs, investigators, and other third parties will and do play a significant role in the conduct of our trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators or other third parties upon which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fails to meet expected deadlines or fails to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of the clinical trial sites terminates for any reason, we may lose follow-up information on patients enrolled in our ongoing clinical trials unless the care of those patients is transferred to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisers or consultants to us from time to time and receive cash and/or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site, or the FDA's willingness to accept such data, may be jeopardized.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities or potential liability. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with 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 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 recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

We also may rely on the regulatory period of market exclusivity for any of our biologic product candidates that are successfully developed and approved for commercialization. Although this period in the United States is generally 12 years from the date of marketing approval (depending on the nature of the specific product), there is a risk that the U.S. Congress could amend laws to significantly shorten this exclusivity period. Once any regulatory period of exclusivity expires, depending on the status of our patent coverage and the nature of the product, we may not be able to prevent others from marketing products that are biosimilar to or interchangeable with our products, which would materially adversely affect our business.

If we or our licensors are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our success also depends on our ability, and the abilities of any of our respective current or future collaborators, to develop, manufacture, market and sell product candidates without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our or our licensors' intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we or our licensors are not aware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the US and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or such licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we and our licensors were the first to file for patent protection of such inventions. In the event that a third party has also filed a US patent application relating to our product candidates or a similar invention, depending upon the priority dates claimed by the competing parties, we may have to participate in interference proceedings declared by the PTO to determine priority of invention in the US. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our licensors' patent rights are highly uncertain.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or any of our licensors, suppliers or collaborators infringe the third party's intellectual property rights, we may have to, among other things:

- obtain additional licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign products or processes to avoid infringement, which may demand substantial funds, time and resources and which may result in inferior or less desirable processes and/or products;

- pay substantial damages, including the possibility of treble damages and attorneys' fees, if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;

- pay substantial royalties, fees and/or grant cross-licenses to our product candidates; and/or

- defend litigation or administrative proceedings which may be costly regardless of outcome, and which could result in a substantial diversion of financial and management resources.

We may be involved in lawsuits to protect or enforce our patents or the patents of licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our or our licensors' patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging invalidity of our or our licensors' patents or that we infringe their patents; or provoke those parties to petition the PTO to institute *inter partes* review against the asserted patents, which may lead to a finding that all or some of the claims of the patent are invalid. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensor's is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found to be unenforceable, or interpreted narrowly and could likewise put pending patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

We in-license from third parties 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 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, if approved.

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; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our businesses. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our businesses.

As we continue to execute our growth strategy, we may be subject to further government regulation which could adversely affect our financial results, including without limitation the Investment Company Act of 1940.

If we engage in business combinations and other transactions that result in holding minority or non-control investment interests in a number of entities, we may become subject to regulation under the Investment Company Act of 1940, as amended (the "Investment Company Act"). If we do become subject to the Investment Company Act, we would be required to register as an investment company and could be expected to incur significant registration and compliance costs in the future.

General and Other Risks

Our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or third parties' cybersecurity.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information, including, but not limited to, information related to our intellectual property and proprietary business information, personal information, and other confidential information. It is critical that we maintain such confidential information in a manner that preserves its confidentiality, availability and integrity. Furthermore, we have outsourced elements of our operations to third party vendors, who each have access to our confidential information, which increases our disclosure risk.

We are in the process of implementing our internal security and business continuity measures and developing our information technology infrastructure. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, third-party software, data center facilities, lab equipment, and connection to the internet, face the risk of breakdown or other damage or interruption from service interruptions, system malfunctions, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware and other malicious code, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), each of which could compromise our system infrastructure or lead to the loss, destruction, alteration, disclosure, or dissemination of, or damage or unauthorized access to, our data or data that is processed or maintained on our behalf, or other assets.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, and could result in financial, legal, business, and reputational harm to us. For example, in 2021, our partner company Journey was the victim of a cybersecurity incident that affected its accounts payable function and led to approximately $9.5 million in wire transfers being misdirected to fraudulent accounts. The details of the incident and its origin were investigated with the assistance of third-party cybersecurity experts working at the direction of legal counsel. The matter was reported to the Federal Bureau of Investigation and does not appear to have compromised any personally identifiable information or protected health information. The federal government has been able to seize a significant amount of cryptocurrency assets associated with the breach. Once the cryptocurrency has been converted back into U.S. dollars, Journey expects to receive a notification letter to initiate the return of the cash. This process could take as long as six months or more to complete. Fortress and Journey may incur additional expenses and losses as a result of this cybersecurity incident, including those related to investigation fees and remediation costs.

In addition, the loss or corruption of, or other damage to, clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our drug candidates or any future drug candidates and to conduct clinical trials, and similar events relating to their systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Sophisticated cyber attackers (including foreign adversaries engaged in industrial espionage) are skilled at adapting to existing security technology and developing new methods of gaining access to organizations' sensitive business data, which could result in the loss of proprietary information, including trade secrets. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies.

Any security breach or other event leading to the loss or damage to, or unauthorized access, use, alteration, disclosure, or dissemination of, personal information, including personal information regarding clinical trial subjects, contractors, directors, or employees, our intellectual property, proprietary business information, or other confidential or proprietary

information, could directly harm our reputation, enable competitors to compete with us more effectively, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, or otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Each of the foregoing could result in significant legal and financial exposure and reputational damage that could adversely affect our business. Notifications and follow-up actions related to a security incident could impact our reputation or cause us to incur substantial costs, including legal and remediation costs, in connection with these measures and otherwise in connection with any actual or suspected security breach. We expect to incur significant costs in an effort to detect and prevent security incidents and otherwise implement our internal security and business continuity measures, and actual, potential, or anticipated attacks may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants. We may face increased costs and find it necessary or appropriate to expend substantial resources in the event of an actual or perceived security breach.

The costs related to significant security breaches or disruptions could be material, and our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Furthermore, if the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

We may not be able to hire or retain key officers or employees needed to implement our business strategy and develop products and businesses.

Our success depends on the continued contributions of our executive officers, financial, scientific, and technical personnel and consultants, and on our ability to attract additional personnel as we continue to implement growth strategies and acquire and invest in companies with varied businesses. During our operating history, many essential responsibilities have been assigned to a relatively small number of individuals. However, as we continue to implement our growth strategy, the demands on our key employees will expand, and we will need to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel, or our inability to attract additional personnel to fill critical positions, could adversely affect our business.

We currently depend heavily upon the efforts and abilities of our management team and the management teams of our partners. The loss or unavailability of the services of any of these individuals could have a material adverse effect on our business, prospects, financial condition and results. In addition, we have not obtained, do not own, and are not the beneficiary of key-person life insurance for any of our key personnel. We only maintain a limited amount of directors' and officers' liability insurance coverage. There can be no assurance that this coverage will be sufficient to cover the costs of the events that may occur, in which case, there could be a substantial impact on our ability to continue operations.

Our employees, consultants, or third-party partners may engage in misconduct or other improper activities, including but not necessarily limited to noncompliance with regulatory standards and requirements or internal procedures, policies or agreements to which such employees, consultants and partners are subject, any of which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, consultants, or third-party partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with cGMPs, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, comply with internal procedures, policies or agreements to which such employees, consultants or partners are subject, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Employee, consultant, or third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation, as well as civil and criminal liability. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other civil and/or criminal sanctions.

We receive a large amount of proprietary information from potential or existing licensors of intellectual property and potential acquisition target companies, all pursuant to confidentiality agreements. The confidentiality and proprietary invention assignment agreements that we have in place with each of our employees and consultants prohibit the unauthorized disclosure of such information, but such employees or consultants may nonetheless disclose such information through negligence or willful misconduct. Any such unauthorized disclosures could subject us to monetary damages and/or injunctive or equitable relief. The notes, analyses and memoranda that we have generated based on such information are also valuable to our businesses, and the unauthorized disclosure or misappropriation of such materials by our employees and consultants could significantly harm our strategic initiatives – especially if such disclosures are made to our competitor companies.

We may be subject to claims that our employees and/or consultants have wrongfully used or disclosed to us alleged trade secrets of their former employers or other clients.

As is common in the biopharmaceutical industry, we rely on employees and consultants to assist in the development of product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biopharmaceutical companies, including our competitors or potential competitors. We may become subject to claims related to whether these individuals have inadvertently or otherwise used, disclosed or misappropriated trade secrets or other proprietary information of their former employers or their former or current clients. Litigation may be necessary to defend against these claims. Even if we are successful in defending these claims, litigation could result in substantial costs and be a distraction to management and/or the employees or consultants that are implicated.

The market price of our securities may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

The stock prices of our securities may experience substantial volatility as a result of a number of factors, including, but not necessarily limited to:

- announcements we make regarding our current product candidates, acquisition of potential new product candidates and companies and/or in-licensing through multiple partners/affiliates;
- sales or potential sales of substantial amounts of our Common Stock;
- issuance of debt or other securities;
- our delay or failure in initiating or completing pre-clinical or clinical trials or unsatisfactory results of any of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors and/or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;

- governmental regulation and legislation;
- unstable regional political and economic conditions;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market prices of our securities, regardless of our actual operating performance.

Sales or other issuances of a substantial number of shares of our Common Stock, or the perception that such sales or issuances may occur, may adversely impact the price of our Common Stock.

Almost all of our outstanding shares of our Common Stock, inclusive of outstanding equity awards, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), or an effective registration statement. In addition, pursuant to our current shelf registration statements on Form S-3, from time to time we may issue and sell shares of our Common Stock or Series A Preferred Stock having an aggregate offering price of up to $100.1 million as of December 31, 2023. 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. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We have never paid and currently do not intend to pay cash dividends in the near future, except for the dividend we pay on our Series A Preferred Stock. As a result, capital appreciation, if any, will be the sole source of gain for our Common Stockholders.

We have never paid cash dividends on our Common Stock, or made stock dividends, except for the dividend we pay on shares of our Series A Preferred Stock, and we currently intend to retain future earnings, if any, to fund the development and growth of our businesses, and retain our stock positions. In addition, the terms of existing and future debt agreements may preclude us from paying cash or stock dividends. Equally, each of our subsidiaries and partner companies is governed by its own board of directors with individual governance and decision-making regimes and mandates to oversee such entities in accordance with their respective fiduciary duties. As a result, we alone cannot determine the acts that could maximize value to you of such 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.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business or the business of our partners.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, ability to accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

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

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

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.

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. 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 management team is informed of and monitors 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	Type	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	3,681
Mustang	Worcester, MA	Manufacturing, lab facility, and office space	27,043
Mustang	Worcester, MA	Office space	11,916

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, 2024, there were approximately 432 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.

Unregistered Sales of Equity Securities

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 "Special Cautionary Notice 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, St. Jude Children's Research Hospital ("St. Jude"), Dana-Farber Cancer Institute, Nationwide Children's Hospital, Cincinnati Children's Hospital Medical Center, Columbia University, the University of Pennsylvania, Mayo Foundation for Medical Education and Research ("Mayo Clinic"), AstraZeneca plc and Dr. Reddy's Laboratories, Ltd.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and financial expertise to help the partners achieve their goals. Partner 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 two 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 Avenue Therapeutics, Inc. (Nasdaq: ATXI, "Avenue"), Baergic Bio, Inc. ("Baergic", a subsidiary of Avenue), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. (Nasdaq: CKPT, "Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Journey Medical Corporation (Nasdaq: DERM, "Journey" or "JMC"), Mustang Bio, Inc. (Nasdaq: MBIO, "Mustang"), Oncogenuity, Inc. ("Oncogenuity") and Urica Therapeutics, Inc. ("Urica"). Aevitas Therapeutics, Inc. ("Aevitas") was a consolidated subsidiary company until the sale of its primary asset to 4D Molecular Therapeutics in April 2023.

Recent Events

Revenue Portfolio

- For the years ended December 31, 2023 and 2022, total net revenue was $84.5 million and $75.7 million, respectively, which includes net product revenue from Journey's commercial portfolio of $59.7 million and $71.0 million, respectively.
- In August 2023, Journey entered into an exclusive license agreement with Maruho Co., Ltd. ("Maruho"), a Japanese company specializing in dermatology and also Journey's exclusive licensing partner that developed and is commercializing Qbrexza (Rapifort®) in Japan. Under the terms of the agreement, Journey Medical received a $19 million upfront payment and granted Maruho an exclusive license to develop and commercialize Qbrexza® (Rapifort) for the treatment of hyperhidrosis in additional territories in Asia (the "Territory"). Maruho is responsible for all development and commercialization costs for the program throughout the Territory.

Late Stage Product Candidates

Cosibelimab (anti-PD-L1 antibody)

- Our partner company, Checkpoint, submitted a Biologics License Application ("BLA") to the U.S. Food and Drug administration ("FDA") for cosibelimab, its investigational anti-PD-L1 antibody, as a treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") who are not candidates for curative surgery or radiation, in January 2023. In December 2023, the FDA issued a complete response letter ("CRL") for the cosibelimab BLA. The CRL only cited findings that arose during a multi-sponsor inspection of Checkpoint's third-party contract manufacturing organization as approvability issues to address in a resubmission. The CRL did not state any concerns about the clinical data package, safety, or labeling for the approvability of cosibelimab. We believe we can address the feedback in a resubmission to enable marketing approval in 2024.
- In October 2023, Checkpoint announced the publication of results from the multicenter, multiregional, pivotal trial evaluating cosibelimab in patients with metastatic cSCC in the *Journal for ImmunoTherapy of Cancer (JITC)*, the peer-reviewed, online journal of the Society of Immunotherapy of Cancer. The paper, entitled, "Efficacy and Safety of Cosibelimab, an Anti–PD-L1 Antibody, in Metastatic Cutaneous Squamous Cell Carcinoma" (doi:10.1136/jitc-2023-007637), describes safety and efficacy results from 78 patients with metastatic cSCC enrolled at clinical sites in eight countries.
- In July 2023, Checkpoint announced new, longer-term data for cosibelimab from its pivotal studies in locally advanced and metastatic cSCC. These results demonstrate a deepening of response over time, resulting in substantially higher complete response rates than previously reported (55% objective response rate; 23% complete response rate in locally advanced cSCC and 50% objective response rate; 13% complete response rate in metastatic cSCC). Furthermore, responses continue to remain durable over time.
- In June 2023, Checkpoint announced that new pharmacokinetic modeling data on cosibelimab supporting the extension to an every-three-week dosing regimen were presented at the Population Approach Group Europe 2023 annual meeting. The results support the comparability of cosibelimab 800 mg every-two-week and 1200 mg every-three-week dosing regimens.
- A resubmission of the cosibelimab BLA is expected in 2024.
- Cosibelimab was sourced by Fortress and is currently in development at Checkpoint.

CUTX-101 (copper histidinate injection for Menkes disease)

- In December 2023, our subsidiary, Cyprium completed the asset transfer of CUTX-101 to Sentynl. Sentynl is obligated under the agreement to use commercially reasonable efforts to develop and commercialize CUTX-101, including the funding of the same. Additionally, Cyprium remains eligible to receive up to $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 the New Drug Application (" NDA") approval for CUTX-101.

- The CUTX-101 rolling NDA submission is ongoing and is expected to be completed by Sentynl in 2024.
- CUTX-101 was sourced by Fortress and was developed by Cyprium until the asset transfer in December 2023.

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

- In January 2024, Journey submitted an NDA to the FDA seeking approval for DFD-29 (minocycline hydrochloride modified release capsules, 40 mg) for the treatment of inflammatory lesions and erythema of rosacea in adults. If approved, DFD-29 has the potential to become the only oral, systemic therapy to address both inflammatory lesions and erythema (redness) from rosacea. Journey announced on March 18, 2024 that the FDA accepted the NDA and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of November 4, 2024.
- In October 2023, Journey announced data from a comparative bioavailability study of DFD-29 demonstrating systemic exposure of DFD-29 was significantly lower than that of Solodyn® (minocycline hydrochloride extended-release tablets, 105mg) and that DFD-29 was safe and well tolerated throughout the study.
- In July 2023, Journey announced positive topline data from the two DFD-29 Phase 3 clinical trials (MVOR-1 & MVOR-2) for the treatment of rosacea and achievement of co-primary and all secondary endpoints and subjects completed the 16-week treatment with no significant safety issues. DFD-29 demonstrated statistical superiority compared to Oracea® and placebo for Investigator's Global Assessment ("IGA") treatment success and the reduction in total inflammatory lesion count in both studies. In November 2023, Journey also announced data for the secondary endpoint relating erythema assessment, in which DFD-29 showed significantly superior reduction in Clinicians Erythema Assessment ("CEA") compared to placebo in both trials. In January 2024, Journey also announced results from the Phase 3 studies (MVOR-1 & MVOR-2) for DFD-29 on a secondary endpoint related to erythema (redness) assessment. DFD-29 showed significantly superior reduction in CEA compared to placebo in both MVOR-1 and MVOR-2 clinical trials.
- In June 2023, Journey announced positive topline data from the Phase 1 clinical trial assessing the impact of DFD-29 on the microbial flora of healthy adults and also evaluated the safety and tolerability of DFD-29. The study achieved all primary objectives and no significant safety issues were noted during the study. The results indicate that DFD-29 can be safely used for up to 16 weeks with no significant risk of microbiota suppression or development of resistance.

CAEL-101 (monoclonal antibody for AL amyloidosis)

- CAEL-101 was sourced by Fortress in 2017 and was developed by Caelum until it was acquired by AstraZeneca on October 5, 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 $350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive 42.4% of all proceeds of the transaction, including approximately $148 million to Fortress, with $31.8 million upon BLA approval.
- There are two ongoing Phase 3 studies of CAEL-101 for AL amyloidosis. (ClinicalTrials.gov identifiers: NCT04512235 and NCT04504825).
- CAEL-101 (anselamimab) was sourced by Fortress and was developed by Caelum (founded by Fortress) until its acquisition by AstraZeneca in October 2021.

IV Tramadol

- In January 2024, Avenue reached a final agreement with the FDA on the Phase 3 safety study protocol for IV tramadol and statistical analysis approach, including the primary endpoint which will be a composite of elements indicative of opioid-induced respiratory depression.
- The final non-inferiority safety 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. Patients will have access to IV hydromorphone, a Schedule II opioid, for rescue of breakthrough pain.

- IV tramadol was sourced by Fortress and is currently in development at our partner company, Avenue.

Triplex (cytomegalovirus (CMV) vaccine)

- In October 2023, we announced an exclusive option agreement with COH for patent rights to use Triplex, a cytomegalovirus vaccine, in combination with cytomegalovirus ("CMV")-specific, Anti-Human Immunodeficiency Virus ("HIV") Chimeric Antigen Receptor ("CAR") (collectively, CMV/HIV-CAR) T Cells for the treatment of adults living with HIV. Additionally, the California Institute for Regenerative Medicine ("CIRM") recently awarded an $11.3 million grant to COH to fund a Phase 1 clinical trial involving the CMV/HIV-CAR T cells. In preclinical studies, administration of the dual-action CAR T cells followed by administration of a CMV vaccine successfully eradicated HIV, including from latent reservoirs.
- In June 2023, we announced that the National Cancer Institute awarded a $3.2 million grant to COH for clinical studies of Triplex, a CMV vaccine being developed by Helocyte and COH. This award will fund two planned multicenter, placebo-controlled, randomized Phase 2 studies to evaluate the potential safety and immunological response of Triplex and its ability to enhance CMV-specific T cell immunity in stem cell donors to reduce the risk of CMV events in recipients of allogeneic hematopoietic cell transplant.
- Triplex is also the subject of a grant from the National Institute of Allergy and Infectious Diseases that could provide over $20 million in non-dilutive funding for a 420-patient multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation. The trial is expected to begin enrollment this year and we believe this data set could ultimately be used to support approval of Triplex in this setting.
- Triplex is currently the subject of multiple ongoing clinical trials, including: a Phase 1/2 trial for CMV control in pediatric recipients of HCT (ClinicalTrials.gov identifier: NCT03354728); a Phase 2 trial for reduction in viral load of Human Immunodeficiency Virus ("HIV") in adults co-infected with HIV and CMV (ClinicalTrials.gov identifier: NCT05099965); and a Phase 1 trial of Triplex in combination with a bi-specific CMV/CD-19 Chimeric Antigen Receptor T Cell for the treatment of Non-Hodgkin Lymphoma (ClinicalTrials.gov identifier: NCT05432635). Triplex is also the subject of several planned studies, including: a Phase 2 evaluation for CMV control in recipients of liver transplant (ClinicalTrials.gov identifier: NCT06075745); a Phase 2 trial for CMV control in recipients of kidney transplant; and a Phase 2 trial for CMV control in recipients of stem cell transplant in which the stem cell donor is vaccinated with Triplex (ClinicalTrials.gov identifier: NCT06059391).
- The Phase 2 clinical trial of Triplex for adults co-infected with HIV and CMV is now fully enrolled with topline data anticipated in 2024. The study aims to show that vaccination with Triplex can potentially reduce the in intensity of highly active antiretroviral therapy ("HAART") which is used in up to 1.7 million treated HIV patients.
- Triplex was sourced by Fortress and is currently in development at our subsidiary, Helocyte.

Early Stage Product Candidates

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

- In December 2023, Mustang announced initial data from its ongoing multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 CAR-T cell therapy at the 2023 American Society of Hematology ("ASH") Annual Meeting. Initial data show that all patients responded clinically to treatment with MB-106 (n=9); 100% overall response rate for patients with follicular lymphoma ("FL") and Waldenstrom macroglobulinemia ("WM"). 100% of patients with FL (n=5) had a complete response; 1 very good partial response and 2 partial responses were observed in WM patients (n=3); and the hairy cell leukemia variant ("HCL-v") patient experienced stable disease, with prolonged, ongoing independence from blood transfusions. Complete responses were observed in patients previously treated with CD19-targeted CAR T-cell therapy. MB-106 was well tolerated in patients with indolent NHL, with no occurrence of cytokine release syndrome ("CRS") above grade 1 and no immune effector cell-associated neurotoxicity syndrome ("ICANS") of any grade. Outpatient administration was allowed and found to be feasible.
- Mustang intends to treat the first patient in a non-randomized registrational multicenter trial in relapsed or refractory WM in the second half of 2024.
- MB-106 was sourced by Fortress and is currently in development at our partner company, Mustang.

Dotinurad (urate transporter (URAT1) inhibitor for gout)

- In the third quarter of 2023, Urica initiated a Phase 1b clinical trial in patients with gout and hyperuricemia in the U.S. to compare U.S. patients' response to dotinurad with data generated in Japan, and to assess drug-drug interactions, if any, with allopurinol. Urica expects to announce data from this trial in the first half of 2024.
- In June 2023, Urica announced data from the Phase 1 clinical trial in healthy volunteers showed comparable pharmacokinetic, pharmacodynamic and safety profile between U.S. and Japanese healthy subjects.
- Dotinurad (URECE® tablet) was approved in Japan in 2020 as a once-daily oral therapy for gout and hyperuricemia. Dotinurad was efficacious and well-tolerated in more than 500 Japanese patients treated for up to 58 weeks in Phase 3 clinical trials. The clinical program supporting approval included over 1,000 patients.
- Dotinurad was sourced by Fortress and is currently in development at our subsidiary, Urica.

MB-101 (IL13Rα2-targeted CAR-T cell therapy)

- The Phase 1 clinical trial sponsored by COH for MB-101 (ClinicalTrials.gov Identifier: NCT02208362) has completed the treatment phase, and patients continue to be assessed for long-term safety.
- In March 2024, Mustang announced that Phase 1 clinical data (ClinicalTrials.gov Identifier: NCT02208362) were published in *Nature Medicine*. The data showed stable disease or better was achieved in 50% (n=29/58) of heavily pretreated patients for at least two months, with two partial responses (PR), one complete response (CR), and a second CR after additional CAR-T cycles under compassionate use. Patients with recurrent GBM treated in the final cohort with dual intratumoral/intraventricular delivery and an optimized manufacturing process had a median overall survival of 10.2 months compared to the expected survival rate of six months in patients with recurrent GBM. The median overall survival for all patients was eight months.
- Three additional MB-101 studies are ongoing or planned: 1) MB-101 with or without nivolumab and ipilimumab in treating patients with recurrent or refractory glioblastoma (currently enrolling; ClinicalTrials.gov Identifier: NCT04003649) sponsored by COH; 2) MB-101 in treating patients with recurrent or refractory glioblastoma with a substantial component of leptomeningeal disease (currently enrolling; ClinicalTrials.gov Identifier: NCT04661384) sponsored by COH; and 3) MB-101 in combination with the herpes simplex virus type 1 oncolytic virus (MB-108) in treating patients with recurrent or refractory glioblastoma or high-grade astrocytoma.
- MB-101 was sourced by Fortress and is currently in development at Mustang.

MB-109 (MB-101 + MB-108 (HSV-1 oncolytic virus))

- In October 2023, Mustang announced that the FDA has accepted its IND application to initiate a Phase 1 open label, multicenter clinical trial to assess the safety, tolerability and efficacy of MB-109, a novel combination of MB-101 and MB-108 (herpes simplex virus 1 oncolytic virus), for the treatment of IL13Rα2+ recurrent glioblastoma ("rGBM") and high-grade astrocytoma.
- MB-108 was sourced by Fortress and is currently in development at Mustang.

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

- In July 2022, Mustang announced that the first patient successfully received LV-RAG1 *ex vivo* lentiviral gene therapy to treat recombinase-activating gene-1 ("RAG1") severe combined immunodeficiency ("RAG1-SCID") in an ongoing Phase 1/2 clinical trial taking place in Europe.
- Leiden University Medical Centre is continuing to treat patients and expects to expand the trial to other centers in 2023.
- LV-RAG1 is exclusively licensed by Mustang for the development of MB-110, a first-in-class *ex vivo* lentiviral gene therapy for the treatment of RAG1-SCID.
- MB-110 was sourced by Fortress and is currently in development at Mustang.

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

- In January 2024, Avenue announced that all patients have been enrolled in Avenue's Phase 1b/2a study, which is evaluating AJ201 in the U.S. for the treatment of spinal and bulbar muscular atrophy ("SBMA"), also known as Kennedy's Disease. Topline data for the Phase 1b/2a clinical trial of AJ201 in SBMA are expected in the second quarter of 2024.
- In March 2023, Avenue entered into an exclusive license agreement with AnnJi Pharmaceutical Co., Ltd. for intellectual property related to AJ201. SBMA is a debilitating rare genetic neuromuscular disease primarily affecting men.
- AJ201 was sourced by Fortress and is currently in development at Avenue.

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

- 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. The preclinical data demonstrated that BAER-101 significantly suppressed seizures in a translational animal model of absence epilepsy. In an *in vivo* evaluation using the SynapCell's Genetic Absence Epilepsy Rat from Strasbourg ("GAERS") model, BAER-101 fully suppressed seizure activity with a minimal effective dose of 0.3 mg/kg, PO.
- BAER-101 was sourced by Fortress and is currently in development at Baergic, a majority-owned subsidiary of Avenue.

General Corporate and Other

- In October 2023, Fortress effected a 1-for-15 reverse stock split of its issued and outstanding common stock (the "Reverse Stock Split") which brought the Company into compliance with Nasdaq's $1.00 per share minimum bid price requirement for continued listing.
- In May 2023, Mustang entered into an Asset Purchase Agreement with uBriGene (Boston) Biosciences, Inc. ("uBriGene"), pursuant to which Mustang agreed to sell its leasehold interests in its cell processing facility and associated assets relating to the manufacturing and production of cell and gene therapies. On July 28, 2023, Mustang completed the sale of all of its assets relating to its operations primarily relating to the manufacturing and production of cell and gene therapies. The aforementioned transaction is currently under review by the U.S. Committee on Foreign Investment in the United States ("CFIUS"), with the current review period set to conclude no later than March 28, 2024, although if CFIUS does not conclude on its review by March 28, 2024, the proceeding will transition to a second 45-day phase as CFIUS further investigates the transaction. There can be no assurance that CFIUS will ultimately provide clearance with respect to the transaction, or what mitigating measures may be required in order to obtain such clearance. Depending on the nature and severity of the national security risks identified, CFIUS may, among other mitigation measures, require suspension of the Transaction, require uBriGene to divest the Facility and/or other assets relating thereto, forfeit contracts that CFIUS deems to be sensitive, or require appointment of special compliance personnel or a proxy board consisting of U.S. persons. If CFIUS determines to require mitigating measures with respect to the Transaction, then uBriGene must comply with such measures although the Closing Date has already occurred.
- In April 2023, Aevitas entered into an asset purchase agreement for 4D Molecular Therapeutics ("4DMT") to acquire 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, 4DMT will make cash payments to Aevitas totaling up to approximately $140 million in potential late-stage development, regulatory and sales milestones. A range of single-digit royalties on net sales are also payable. In connection with the 4DMT APA, the Class A 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.

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 product returns, coupons, rebates, allowances and distribution fees paid by Journey to certain wholesalers, inventory realization, 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 IV, Item 15, Exhibits and Financial Statement Schedules" 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 our financial instruments 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, such as accounts payable, accrued expenses and other current liabilities.

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 Oaktree Note with detachable warrants in accordance with ASC 470, *Debt*. We assessed the classification of the common stock purchase warrants issued in connection with such transaction 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.

We recorded the related issue costs and value ascribed to the warrants as a debt discount of the Oaktree Note. The discount is being amortized utilizing the effective interest method over the term of the Oaktree Note, which is approximately 16.13% at December 31, 2023.

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 IV, Item 15, Exhibits and Financial Statement Schedules” 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 IV, Item 15, Exhibits and Financial Statement Schedules" 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:

Partner Company/Subsidiary	December 31, 2023
Avenue[1]	4 %
Cellvation	79 %
Checkpoint[1]	9 %
Cyprium	74 %
Helocyte	83 %
Journey[1]	50 %
Mustang[1]	19 %
Oncogenuity	73 %
Urica	68 %

Note 1: Denotes entities that are publicly-traded.

Results of Operations

Comparison of Years Ended December 31, 2023 and 2022

($ in thousands)	Year Ended December 31, 2023	2022
Revenue		
Product revenue, net	$ 59,662	$ 70,995
Collaboration revenue	5,229	1,882
Revenue – related party	103	192
Other revenue	19,519	2,674
Net revenue	84,513	75,743
Operating expenses		
Cost of goods sold – product revenue	26,660	30,775
Research and development	101,747	134,199
Research and development – licenses acquired	4,324	677
Selling, general and administrative	94,124	113,656
Total operating expenses	226,855	279,307
Loss from operations	(142,342)	(203,564)
Other income (expense)		
Interest income	3,003	1,398
Interest expense and financing fee	(15,315)	(13,642)
Change in fair value of warrant liabilities	4,424	1,129
Other income (expense)	(3,403)	1,215
Total other expense	(11,291)	(9,900)
Loss before income tax expense	(153,633)	(213,464)
Income tax expense	521	449
Net loss	**(154,154)**	**(213,913)**
Less: net loss attributable to non-controlling interest	93,517	127,338
Net loss attributable to Fortress	**$ (60,637)**	**$ (86,575)**

Revenue

($ in thousands)	Year Ended December 31, 2023	2022	Change $	Change %
Revenue				
Product revenue, net	$ 59,662	$ 70,995	$ (11,333)	(16)%
Collaboration revenue	5,229	1,882	3,347	178 %
Revenue – related party	103	192	(89)	(46)%
Other revenue	19,519	2,674	16,845	630 %
Net revenue	**$ 84,513**	**75,743**	**$ 8,770**	**12 %**

For the year ended December 31, 2023 we generated $84.5 million of net revenue, of which $59.7 million relates to the sale of Journey branded and generic products, $19.5 million of other revenue relates to Journey's $19 million milestone payment and royalties of $0.5 million from Maruho Co., Ltd. ("Maruho") related to the manufacturing and marketing approval and sales of Rapifort® Wipes 2.5% in Japan, $5.2 million relates to Cyprium's collaboration revenue with Sentynl, and $0.1 million of revenue relates to Checkpoint's collaborative agreements with TGTX, a related party. For the year ended December 31, 2022, we generated $75.7 million of net revenue, of which $71.0 million relates to the sale of Journey branded and generic products, $2.7 million relates to Journey's royalties from Maruho, $1.9 million relates to Cyprium's collaboration revenue with Sentynl and $0.2 million relates to Checkpoint's collaborative agreements with TGTX.

For the year ended December 31, 2023, the net increase in revenue of $8.8 million or 12% is due to Journey's $19.0 million non-refundable upfront payment from Maruho, offset by a decrease of $11.3 million or 16% of product revenue due to lower unit volumes, due to continued generic competition for Targadox and the discontinuation of Ximino in the third quarter of 2023. Collaboration revenue related to Cyprium's agreement with Sentynl increased $3.3 million due to the receipt of $4.5 million associated with Sentynl's assumption of control of the CUTX-101 development program, as well as recognition of $0.7 million of deferred revenue.

Cost of goods sold

($ in thousands)	Year Ended December 31, 2023	2022	Change $	Change %
Cost of goods sold – product revenue	$ 26,660	$ 30,775	$ (4,115)	(13)%

We had $26.7 million and $30.8 million of costs of goods sold in connection with the sale of JMC branded and generic products for the years ended December 31, 2023 and 2022, respectively. Cost of goods sold decreased by $4.1 million, or 13% year-over-year, with the decrease mainly due to lower-than-prior-year product royalties driven by lower sales of products from period-to-period, and a permanent contractual decrease in the Qbrexza royalty percentage from the prior-year period.

Research and development expenses

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for 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, 2023 and 2022, research and development expenses were approximately $101.7 million and $134.2 million, respectively. The table below provides a summary of research and development by entity, for the years ended December 31, 2023 and 2022:

($ in thousands)	Year Ended December 31, 2023	2022	Change $	Change %
Research & development				
Fortress	$ 2,172	$ 2,360	$ (188)	(8)%
Subsidiaries/Partner Companies:				
Avenue	5,426	2,381	3,045	128 %
Checkpoint	40,147	47,940	(7,793)	(16)%
JMC	7,540	10,943	(3,403)	(31)%
Mustang	38,830	62,030	(23,200)	(37)%
Other[1]	7,632	8,545	(913)	(11)%
Total research & development expense	**$ 101,747**	**$ 134,199**	**$ (32,452)**	**(24)%**

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

The decrease in research and development spending at Mustang is due to a review of its portfolio of product candidates to determine the future strategy of its programs and the proper allocation of resources, which led to the discontinuation of development of MB-102 (CD123), MB-103 (HER2), MB-104 (CS1) and MB-105 (PSCA) programs, comprising a portion of Mustang's portfolio of CAR T therapies being developed in partnership with COH, in addition to costs offset by reimbursements received from uBriGene through a subcontracting agreement. Journey's decreased research and development costs are due to lower clinical trial expenses to develop DFD-29, as the project winds down and eventually concludes. Potential FDA approval for DFD-29 is expected in the second half of 2024.

Checkpoint's decrease in research and development spending of $7.8 million is attributable to a $6.6 million decrease in manufacturing costs and a $5.6 million decrease in clinical costs, offset by an increase in regulatory costs of $0.8 million, due to the PDUFA fee to the FDA for the BLA filing for cosibelimab, and $2.3 million in license fees due upon the FDA filing acceptance of the BLA. Avenue's increase in research and development in 2023 is primarily attributable to clinical costs related to the Phase 1b/2a of AJ201 for the treatment of SBMA, also known as Kennedy's disease. The decrease in "Other" is attributable to a decrease of $1.3 million in costs incurred by Cyprium for the CUTX-101 development program as it was assumed by Sentynl, a decrease of $0.4 million for Aevitas development since the deconsolidation of that subsidiary due to the transaction with 4DMT, offset by an increase of $1.7 million of costs incurred by Urica for the dotinurad clinical program.

Noncash, stock-based compensation expense included in research and development for the years ended December 31, 2023 and 2022, was $3.2 million and $4.4 million, respectively.

($ in thousands)	Year Ended December 31, 2023	2022	Change $	Change %
Stock-based compensation - research & development				
Fortress	$ 1,624	$ 1,592	$ 32	2 %
Partner Companies:				
Avenue	199	297	(98)	(33)%
Checkpoint	1,169	888	281	32 %
JMC	112	73	39	54 %
Mustang	133	1,583	(1,450)	(92)%
Other[1]	0	10	(10)	(100)%
Total stock-based compensation expense - research and development	$ 3,237	4,443	$ (1,206)	(27)%

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

We expect research and development costs to remain flat or decrease modestly in 2024.

Research and development – licenses acquired

($ in thousands)	Year Ended December 31, 2023	2022	Change $	Change %
Research and development – licenses acquired	$ 4,324	$ 677	$ 3,647	539 %

The increase in research and development – licenses acquired of $3.6 million in 2023 is due primarily to $4.2 million paid for Avenue's license from AnnJi for AJ201.

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, 2023 and 2022, selling, general and administrative expenses were $94.1 million and $113.7 million, respectively. The table below provides a summary by entity of selling, general and administrative expenses for the years ended December 31, 2023 and 2022, respectively:

($ in thousands)	Year Ended December 31, 2023	2022	Change $	Change %
Selling, general & administrative				
Fortress	$ 21,468	$ 26,919	$ (5,451)	(20)%
Subsidiaries/Partner Companies:				
Avenue	3,676	5,013	(1,338)	(27)%
Checkpoint	7,232	7,782	(550)	(7)%
JMC[1]	47,053	59,503	(12,449)	(21)%
Mustang	9,289	10,740	(1,451)	(14)%
Other[2]	5,406	3,699	1,707	46 %
Total selling, general & administrative expense	**$ 94,124**	**$ 113,656**	**$ (19,532)**	**(17)%**

Note 1: Includes an asset impairment charge of $3.1 million in the year ended December 31, 2023 for the Ximino product line.
Note 2: Includes the following subsidiaries: Aevitas (until April 2023), Baergic (until November 2022), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

For the year ended December 31, 2023, the decrease in selling, general and administrative expenses of $19.0 million or 17% is primarily attributable to decreased expenses at Journey related to their expense reduction efforts in sales and marketing, as JMC began a cost reduction initiative designed to improve operational efficiencies, optimize expenses and reduce overall costs to better align costs to their revenue-generating capabilities. JMC's cost reductions were offset slightly by a loss on impairment of intangible assets of $3.1 million related to the impairment of Ximino as a result of lower net product revenues and gross profit levels. JMC discontinued Ximino in September 2023. The decrease in selling, general and administrative costs at Fortress and Mustang is attributable to cost reduction efforts and optimization relating to personnel, consulting, and infrastructure.

Stock based compensation expense included in selling, general and administrative expenses in the years ended December 31, 2023 and 2022 was $13.8 million and $18.5 million, respectively.

($ in thousands)	Year Ended December 31, 2023	2022	Change $	Change %
Stock-based compensation - Selling, general and administrative				
Fortress	$ 8,320	$ 11,060	$ (2,740)	(25)%
Partner Companies:				
Avenue	707	352	355	101 %
Checkpoint	1,728	2,036	(308)	(15)%
JMC	2,494	4,352	(1,858)	(42)%
Mustang	435	700	(265)	(38)%
Other[1]	108	44	64	145 %
Total stock-based compensation expense - selling, general and administrative	$ 13,792	18,544	$ (4,752)	(26)%

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

We expect selling, general and administrative expenses to remain flat or decrease modestly in 2024.

Other expense

($ in thousands)	December 31, 2023	2022	Change $	Change %
Other income (expense)				
Interest income	$ 3,003	$ 1,398	$ 1,605	115 %
Interest expense and financing fee	(15,315)	(13,642)	(1,673)	12 %
Change in fair value of warrant liabilities	4,424	1,129	3,295	292 %
Other income (expense)	(3,403)	1,215	(4,618)	(380)%
Total other expense	$ (11,291)	(9,900)	$ (1,391)	14 %

Total other income (expense) increased $1.4 million, or (14)%, from expense of $9.9 million for the year ended December 31, 2022 to expense of $4.7 million for the year ended December 31, 2023, primarily due to the increase in change in fair value of warrant liabilities associated with warrants related to financings at Avenue and Checkpoint of $9.9 million, and an increase in interest income of $1.6 million, offset by an increase of $1.7 million in interest expense and financing fees due to costs associated with debt payoff at Journey and Mustang, and an increase of $4.6 million in other expense in the year ended December 31, 2023 due primarily to $4.1 million associated with the deconsolidation and dissolution of partner companies.

Liquidity and Capital Resources

Sources of Liquidity

At December 31, 2023, we had an accumulated deficit of $694.9 million primarily as a result of research and development expenses, purchases of in-process research and development and selling, general and administrative expenses.

We 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

We fund our operations through cash on hand, the sale of debt, third-party financings, and the sale of partner companies. At December 31, 2023, we had cash and cash equivalents of $80.9 million of which $40.6 million relates to Fortress and the private partner companies, primarily funded by Fortress, $4.9 million relates to Checkpoint, $6.2 million relates to Mustang, $27.4 million relates to JMC and $1.8 million relates to Avenue. Restricted cash related to an undertaking posted by Cyprium to secure potential damages in an injunctive proceeding and our office leases is $2.4 million.

In July 2021, the Company filed a shelf registration statement (File No. 333-255185) on Form S-3, which was declared effective on July 30, 2021 (the "2021 Shelf"). 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 gross proceeds of $2.2 million. In connection with these sales, the Company paid aggregate fees of $0.1 million. Approximately $100.1 million of securities remain available for sale under the 2021 Shelf as of December 31, 2023. The amount of securities we are able to sell pursuant to the registration statement on Form S-3 may be limited to an aggregate of one-third of our public float. See "Item 1A. Risk Factors– 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."

In February 2023, the Company completed a registered direct offering of common stock priced At-the-Market under Nasdaq rules pursuant to which it issued and sold 1.1 million shares of its common stock at a purchase price of $12.53 per share (as adjusted for the Reverse Stock Split) and secured approximately $13.3 million in net proceeds after deducting estimated offering expenses. This included a concurrent private placement with investors in the registered direct offering for the pro rata rights to acquire securities exercisable into common stock in certain future operating subsidiaries that consummate a specified corporate development transaction within the next five years.

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

Subsequent to 2023, in January 2024, Fortress closed on a registered direct offering for the issuance and sale 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, are immediately exercisable, and will 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 $10.2 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, 2023, Journey issued approximately 0.7 million shares of common stock at an average price of $6.189 per share for gross proceeds of $4.6 million under the Journey ATM. In connection with these sales, Journey paid aggregate fees of $0.1 million. At December 31, 2023, 4,151,297 shares remain available for issuance under the Journey 2022 S-3.

Checkpoint

In March 2023, Checkpoint filed a shelf registration statement (File No. 333-270843) on Form S-3 (the "Checkpoint 2023 S-3"), which was declared effective May 5, 2023. Under the Checkpoint 2023 S-3, Checkpoint may sell up to a total of $150 million of its securities. As of December 31, 2023, approximately $91.7 million of the securities remains available for sale through the Checkpoint 2023 S-3.

In 2023, Checkpoint closed on registered direct offerings in February, April, May and July and sold a total of 6,957,186 shares of common stock and 2,663,903 pre-funded warrants at prices ranging from $3.07 to $5.25. All pre-funded warrants were exercised in 2023. Each of these offerings included Series A warrants with a five-year term and Series B warrants with an 18-month term. Total Series A warrants were 9,621,089 and total Series B warrants were 9,621,089 with exercise prices ranging from $2.82 to $5.00. Total gross proceeds were $33.6 million, with net proceeds of $30.4 million.

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

Mustang

In April 2021, Mustang filed a shelf registration statement on Form S-3 (File No. 333-255476) which was declared effective in May 2021 (the "Mustang 2021 S-3"). Under the Mustang 2021 S-3, Mustang may sell up to a total of $200.0 million of its securities. During the year ended December 31, 2023, Mustang issued approximately 0.1 million shares of common stock at an average price of $3.15 per share for gross proceeds of $0.2 million under the ATM Agreement. In connection with these sales, Mustang paid aggregate fees of approximately $3,000 for net proceeds of approximately $0.2 million. As of December 31, 2023, approximately $195.6 million of the Mustang 2021 S-3 remained available for sales of securities.

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

Avenue

In November 2023, Avenue closed on a public offering of the issuance and sale of an aggregate of 16,633,400 units at a purchase price of $0.3006 per unit. Each unit consists of (i) one share of common stock (or pre-funded warrant in lieu of), and (ii) one Series A warrant to purchase one share of common stock, exercisable immediately upon issuance at a price of $0.3006 per share and expiring five years following the issuance date, and (iii) one Series B warrant to purchase one share of common stock, exercisable immediately upon issuance at a price of $0.3006 per share and expiring eighteen months following the issuance date (in aggregate, the "November 2023 Warrants"). The total gross proceeds from the offering were approximately $5.0 million with net proceeds of approximately $3.8 million after deducting commissions and other transaction costs, before giving effect to any exercises of the November 2023 Warrants.

In January 2023, Avenue entered into an agreement with a single institutional investor for the sale of 1,940,299 shares of common stock and pre-funded warrants for gross proceeds of approximately $3.0 million. In a concurrent private placement, Avenue also agreed to issue to the same investor a total of 1,940,299 warrants to purchase up to one share of common stock each at an exercise price of $1.55 per share for gross proceeds of approximately $0.2 million. Avenue received approximately $2.8 million in net proceeds across both transactions.

Debt

In December 2023, Journey announced it had entered into a credit agreement with SWK Funding LLC that provided a term loan facility in the original principal amount of $20 million. Of the $20 million, $15 million was funded upon closing, and the remaining $5.0 million may be drawn upon request by Journey within the first 12 months following credit agreement execution.

Cash Flows

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

($ in thousands)	Year Ended December 31, 2023	2022	Change
Total cash (used in)/provided by:			
Operating activities	$ (128,225)	$ (179,401)	$ 51,176
Investing activities	(2,103)	(22,928)	20,825
Financing activities	32,739	75,319	(42,580)
Net increase in cash and cash equivalents and restricted cash	$ (97,589)	$ (127,010)	$ 29,421

Operating Activities

Net cash used in operating activities decreased $51.2 million from the year ended December 31, 2022 to the year ended December 31, 2023. The decrease is primarily attributable to the decrease in net loss of $59.8 million for the year ended December 31, 2023 as compared to the year ended December 31, 2022, and the net decrease in cash from changes in operating assets and liabilities of $11.9 million offset by the increase in loss from deconsolidation and dissolution of subsidiaries of $4.1 million and a $3.1 million asset impairment loss.

Investing Activities

Net cash used by investing activities for the year ended December 31, 2022 of $22.9 million decreased $20.8 million to net cash used by investing activities of $2.1 million for the year ended December 31, 2023. The change is primarily due to Journey's purchase of the VYNE Therapeutics, Inc. ("VYNE") product licenses of $20.0 million and Mustang's property and equipment purchases of $2.7 million for the year ended December 31, 2022, offset by $6 million in proceeds from the sale of property and equipment recorded by Mustang for the uBriGene transaction.

Financing Activities

Net cash provided by financing activities was $75.3 million for the year ended December 31, 2022, compared to $32.7 million of net cash provided by financing activities for the year ended December 31, 2023, a decrease of $42.6 million. The decrease is primarily due to the repayment of partner company debt of $81.3 million, partially offset by proceeds from the issuance of common stock in public offerings of $22.1 million, and proceeds from new partner company debt of $14.5 million.

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

	For the Year Ended December 31, 2023					
($ in thousands)	**Fortress[1]**	**Avenue**	**Checkpoint**	**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 increase in cash and cash equivalents and restricted cash	$ (11,288)	$ (4,925)	$ (7,140)	$ (4,564)	$ (69,672)	$ (97,589)

	For the Year Ended December 31, 2022					
($ in thousands)	**Fortress[1]**	**Avenue**	**Checkpoint**	**JMC**	**Mustang**	**Total**
Statement of cash flows data:						
Total cash (used in)/provided by:						
Operating activities	$ (35,651)	$ (7,596)	$ (57,554)	$ (13,534)	$ (65,066)	$ (179,401)
Investing activities	24	—	—	(20,000)	(2,952)	(22,928)
Financing activities	(621)	10,541	14,887	16,456	34,056	75,319
Net increase in cash and cash equivalents and restricted cash	$ (36,248)	$ 2,945	$ (42,667)	$ (17,078)	$ (33,962)	$ (127,010)

Note 1: Includes Fortress and non-public subsidiaries.

Contractual Obligations

Our short-term and long-term contractual obligations as of December 31, 2023 include:

- Contractual payments related to our long-term debt (see Note 9, Debt and Interest, to our Consolidated Financial Statements included in “Part IV, Item 15, Exhibits and Financial Statement Schedules” 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, 2023, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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, 2023. 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, 2023, 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, 2023, 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

Information required by this item is incorporated by reference from the information contained under the sections "Corporate Governance," "Code of Business Conduct and Ethics," and "Our Executive Officers" in our Proxy Statement for the 2024 Annual Meeting of Stockholders.

The information under the heading "Executive Officers of Fortress" in Part I of this Annual Report on Form 10-K is also incorporated herein by reference.

Item 11. Executive Compensation

Information required by this item is incorporated by reference from the information contained under the sections "Executive Compensation," and "Director Compensation" in our Proxy Statement for the 2024 Annual Meeting of Stockholders.

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

Information required by this item is incorporated by reference from the information contained under the sections "Stock Ownership of Our Directors, Executive Officers, and 5% Beneficial Owners," "Outstanding Equity Awards at Fiscal Year-End," and "Equity Compensation Plan Information" in our Proxy Statement for the 2024 Annual Meeting of Stockholders.

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

Information required by this item is incorporated by reference from the information contained under the sections "Related-Person Transactions," and "Corporate Governance" in our Proxy Statement for the 2024 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services

During the year ended December 31, 2023, KPMG LLP audited the consolidated financial statements of the Registrant and its subsidiaries.

Information required by this item is incorporated by reference from the information contained under the section "Independent Registered Public Accounting Firm Fees and Other Matters" in our Proxy Statement for the 2024 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Financial Statements.

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

(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).
3.4	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, 2022).
3.9	Third 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 August 14, 2023.
4.1	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).
4.4	Description of Securities of Fortress Biotech, Inc.*

Exhibit Number	Exhibit Title
4.5	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).
4.6	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).
4.7	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.
10.2	Form of Stock Option Award Agreement (incorporated by reference to Exhibit 10.9 of the Registrant's Form 10 (file No. 000-54463) filed with the SEC on July 15, 2011).#
10.3	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).#
10.4	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).#
10.5	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).#
10.6	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). #
10.7	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).
10.8	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).#
10.9	Fortress Biotech, 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).#
10.10	Amendment to Fortress Biotech, 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).#
10.11	Amendment to the Fortress Biotech, 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).#
10.12	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).#

Exhibit Number	Exhibit Title
10.13	Development, Option and Stock Purchase Agreement by and among Caelum Biosciences, Inc., Alexion Pharmaceuticals, Inc., Fortress Biotech, Inc., and the several shareholders of Caelum Biosciences, Inc., dated January 30, 2019 (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (file No. 001-35366) filed with the SEC on May 10, 2019).
10.14	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).#
10.15	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).#
10.16	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).#
10.17	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).#
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 June 23, 2023).#
10.19	Credit Agreement entered into by and among Fortress Biotech, Inc. the lenders from time to time party thereto, and Oaktree Fund Administration, LLC on August 27, 2020 (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (file No. 001-35366) filed with the SEC on November 9, 2020).
10.20	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).#
10.21	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).#
10.22	Form of Securities Purchase Agreement, dated November 10, 2023, by and among the Registrant 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 November 14, 2023).
10.23	Form of Securities Purchase Agreement, dated December 29, 2023, by and among the Registrant 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 January 3, 2024).
10.24	Form of Placement Agency Agreement, dated November 10, 2023, by and among the Registrant and Roth Capital Partners, LLC (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 November 14, 2023).
10.25	Placement Agency Agreement, dated December 29, 2023, by and among the Registrant and Roth Capital Partners, LLC (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 January 3, 2024).

Exhibit Number	Exhibit Title
10.26	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).
21.1	Subsidiaries of the Registrant. *
23.1	Consent Independent Registered Accounting Firm (KPMG LLP, Short Hills, NJ). *
31.1	Certification of Chairman, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Chairman, President and Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
97.1	Clawback Policy of Fortress Biotech, Inc.*
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).*

Management contract or compensatory plan.

* Filed herewith.

**Furnished herewith.

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

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, 2023 and 2022, the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2023, 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.

Evaluation of accrued coupon liability

As discussed in Note 10 of the consolidated financial statements, the Company accrues for coupons on products for certain qualified commercially-insured parties. At December 31, 2023, the Company recorded $9,987 thousand in accrued coupon and rebates, which included the accrued coupon liabilities. The Company estimates the amount of its expected coupon redemptions for product that is still in the distribution channel and records the estimate as a reduction of revenue in the period the related product revenue is recognized. The Company's accrued coupon liability is primary based on historical company coupon redemption costs, cost per coupon claim, and estimates of product remaining in the distribution channel.

We identified the evaluation of the accrued coupon liability as a critical audit matter. There was a high degree of auditor judgment required in the evaluation of certain assumptions used in the determination of the accrued coupon liability, including the estimation of product in the distribution channel, coupon redemption costs, and the cost per coupon claims.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design of certain internal controls over the Company's accrued coupon process, including a control over the assumptions. We performed a risk assessment procedure to assess the sensitivity of changes in the estimate of distribution channel inventory on the accrued coupon liability. We tested the sales data and coupon redemption data used by management to calculate coupon redemption costs and cost of coupon claims by comparing the data to historical information. We developed an expectation of the accrued coupon liability based on an independent estimate of the product in the distribution channel and we compared our expectation to the Company's accrued coupon liability.

Accounting for and fair value of the warrant inducement transaction

As discussed in Notes 6 and 13 to the financial statements, in October 2023, Checkpoint Therapeutics, Inc. (Checkpoint), a consolidated subsidiary of the Company, entered into an inducement offer letter agreement with a holder of certain existing warrants. As part of the inducement, Checkpoint issued new unregistered Series A and Series B warrants. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $1.51 per share. The total gross proceeds from the inducement were approximately $11.1 million with net proceeds of approximately $10.0 million after deducting commissions and other transaction costs. Prior to the inducement, some of the existing warrants were liability classified and accounted for at fair value. At the date of the inducement, the Company revalued the existing liability classified warrants which resulted in a loss on common stock warrant liabilities. The other existing warrants, which were equity classified, were revalued to calculate the difference in fair value as a result of the change in exercise price, which was recorded as a deemed dividend. The Company also calculated the fair value of the Series A and Series B warrants and allocated that fair value to the existing warrants on a weighted basis. The Company used the Black-Scholes model to determine the estimated fair value of the warrants.

We identified the evaluation of the Company's accounting for the inducement transaction and the determination of the fair value of the warrants as a critical audit matter. Specifically, challenging and complex auditor judgment and specialized skills and knowledge were required in evaluating 1) the application of the relevant accounting guidance for equity and liability classified warrants and 2) the estimated fair value of the warrants due to the degree of subjectivity associated with the volatility assumption.

The following are the primary procedures we performed to address this critical audit matter. We inspected the Company's accounting analysis for the transaction. We involved professionals with specialized skills and knowledge, who assisted in inspecting the underlying agreements to understand the relevant terms and conditions of the transaction and evaluating whether the Company's accounting for the transaction is in accordance with the relevant accounting guidance. We also involved valuation professionals with specialized skills and knowledge who assisted in:

- developing an independent expectation of the volatility assumption based on consideration of implied share price volatility information
- developing an independent range of the fair value of the warrant liability for the December 2022 warrants, the fair value of the February 2023 equity classified warrants, and the fair value of both the Series A and Series B

warrants as of the inducement date using publicly available market data and the independently developed volatility assumption

- comparing the independently developed ranges of the fair value to the respective fair value of the warrant liability and the equity classified awards determined by the Company.

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

Short Hills, New Jersey
March 28, 2024

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

	December 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 80,927	$ 178,266
Accounts receivable, net	15,222	28,208
Inventory	10,206	14,159
Other receivables - related party	167	138
Prepaid expenses and other current assets	10,500	9,661
Total current assets	117,022	230,432
Property, plant and equipment, net	6,505	13,020
Operating lease right-of-use asset, net	16,990	19,991
Restricted cash	2,438	2,688
Intangible asset, net	20,287	27,197
Other assets	4,284	973
Total assets	**$ 167,526**	**$ 294,301**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	$ 73,562	$ 97,446
Income taxes payable	843	722
Common stock warrant liabilities	886	13,869
Operating lease liabilities, short-term	2,523	2,447
Partner company convertible preferred shares, short-term, net	3,931	2,052
Partner company line of credit	—	2,948
Partner company installment payments - licenses, short-term, net	3,000	7,235
Other short-term liabilities	163	996
Total current liabilities	84,908	127,715
Notes payable, long-term, net	60,856	91,730
Operating lease liabilities, long-term	18,282	21,572
Partner company installment payments - licenses, long-term, net	—	1,412
Other long-term liabilities	1,893	1,847
Total liabilities	**165,939**	**244,276**
Commitments and contingencies (Note 14)		
Stockholders' equity (deficit)		
Cumulative redeemable perpetual preferred stock, $0.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 15,093,053 and 7,366,283 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	15	7
Additional paid-in-capital	717,396	675,944
Accumulated deficit	(694,870)	(634,233)
Total stockholders' equity attributed to the Company	22,544	41,721
Non-controlling interests	(20,957)	8,304
Total stockholders' equity (deficit)	1,587	50,025
Total liabilities and stockholders' equity (deficit)	**$ 167,526**	**$ 294,301**

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

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

	Year Ended December 31, 2023	2022
Revenue		
Product revenue, net	$ 59,662	$ 70,995
Collaboration revenue	5,229	1,882
Revenue - related party	103	192
Other revenue	19,519	2,674
Net revenue	84,513	75,743
Operating expenses		
Cost of goods sold - product revenue	26,660	30,775
Research and development	101,747	134,199
Research and development - licenses acquired	4,324	677
Selling, general and administrative	94,124	113,656
Total operating expenses	226,855	279,307
Loss from operations	(142,342)	(203,564)
Other income (expense)		
Interest income	3,003	1,398
Interest expense and financing fee	(15,315)	(13,642)
Change in fair value of warrant liabilities	4,424	1,129
Other income (expense)	(3,403)	1,215
Total other income (expense)	(11,291)	(9,900)
Loss before income tax expense	(153,633)	(213,464)
Income tax expense	521	449
Net loss	**(154,154)**	**(213,913)**
Net loss attributable to non-controlling interests	93,517	127,338
Net loss attributable to Fortress	**(60,637)**	**$ (86,575)**
Preferred A dividends declared and paid	(8,032)	(8,032)
Net loss attributable to common stockholders	**$ (68,669)**	**(94,607)**
Net loss per common share attributable to common stockholders - basic and diluted	$ (8.47)	$ (15.97)
Weighted average common shares outstanding - basic and diluted	8,110,906	5,924,967

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

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

($ in thousands except for share amounts)	Series A Preferred Stock Shares		Common Stock Shares	Common Stock Amount	Common Shares Issuable	Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
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**

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

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, 2022

($ in thousands except for share amounts)	Series A Preferred Stock Shares		Common Stock Shares	Common Stock Amount	Common Shares Issuable	Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
Balance at December 31, 2021	**3,427,138**	**$ 3**	**6,762,368**	**$ 7**	**$ —**	**$ 656,127**	**$ (547,463)**	**$ 117,203**	**$ 225,877**
Stock-based compensation expense	—	—	—	—	—	22,987	—	—	22,987
Issuance of common stock related to equity plans	—	—	327,586	—	—	174	—	—	174
Issuance of common stock for at-the-market offering, net	—	—	276,329	—	—	6,053	—	—	6,053
Payment of Series A perpetual preferred stock dividends	—	—	—	—	—	(8,031)	—	—	(8,031)
Partner company's offering, net	—	—	—	—	—	3,205	—	—	3,205
Partner companies' at-the-market offering, net	—	—	—	—	—	16,370	—	—	16,370
Issuance of common stock under partner company's ESPP	—	—	—	—	—	206	—	—	206
Partner company's dividends declared and paid	—	—	—	—	—	(749)	—	—	(749)
Partner company's exercise of options for cash	—	—	—	—	—	142	—	—	142
Partner company's exercise of warrants for cash	—	—	—	—	—	148	—	—	148
Partner company's reclassification of warrant liability to equity	—	—	—	—	—	89	—	—	89
Partner company's repurchase of stock	—	—	—	—	—	(1,105)	—	—	(1,105)
Partner company's stock adjustment	—	—	—	—	—	(29)	—	—	(29)
Partner company's net settlement of shares withheld for taxes						(1,698)			(1,698)
Partner company's warrants issued in conjunction with debt	—	—	—	—	—	384	—	—	384
Partner company's retained earnings adjustment	—	—	—	—	—	195	(195)	—	—
Partner company's redemption of preferred shares	—	—	—	—	—	(85)	—	—	(85)
Non-controlling interest in subsidiaries	—	—	—	—	—	(18,439)	—	18,439	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	(127,338)	(127,338)
Net loss attributable to common stockholders	—	—	—	—	—	—	(86,575)	—	(86,575)
Balance at December 31, 2022	**3,427,138**	**$ 3**	**7,366,283**	**$ 7**	**$ —**	**$ 675,944**	**$ (634,233)**	**$ 8,304**	**$ 50,025**

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

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

	Year Ended December 31, 2023	2022
Cash Flows from Operating Activities:		
Net loss	$ (154,154)	$ (213,913)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation expense	2,230	3,109
(Gain) loss on sale of property and equipment	(1,466)	255
Bad debt expense	435	284
Amortization of debt discount	3,032	2,065
Accretion of partner company convertible preferred shares	757	—
Non-cash interest	353	770
Loss on extinguishment of debt	2,796	—
Amortization of acquired intangible assets	3,767	4,277
Reduction in the carrying amount of operating lease right-of-use assets	2,078	1,967
Stock-based compensation expense	17,029	22,987
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	266	—
Change in fair value of partner companies' warrant liabilities	(4,424)	(1,129)
Research and development - licenses acquired, expense	3,085	642
Loss from deconsolidation/dissolution of subsidiaries	4,127	—
Asset impairment loss	3,143	—
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:		
Accounts receivable	12,551	(5,380)
Inventory	3,953	1,744
Other receivables - related party	(29)	540
Prepaid expenses and other current assets	(848)	(2,595)
Other assets	(808)	344
Accounts payable and accrued expenses	(24,382)	8,349
Deferred revenue	—	(1,883)
Income taxes payable	121	377
Lease liabilities	(2,291)	(2,025)
Other long-term liabilities	(786)	(186)
Net cash used in operating activities	(128,225)	(179,401)
Cash Flows from Investing Activities:		
Purchase of research and development licenses	(3,035)	(340)
Purchase of property and equipment	(63)	(2,715)
Proceeds from sale of property and equipment	6,000	127
Other	(5)	—
Acquisition of VYNE products	—	(20,000)
Acquired intangible assets	(5,000)	—
Net cash used in investing activities	(2,103)	(22,928)

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

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

	Year Ended December 31, 2023	2022
Cash Flows from Financing Activities:		
Payment of Series A perpetual preferred stock dividends	$ (8,032)	$ (8,031)
Proceeds from issuance of common stock for public offering, net	22,078	—
Proceeds from issuance of common stock for at-the-market offering, net	2,041	6,053
Proceeds from issuance of common stock under ESPP	—	174
Exercise of warrants for cash	382	—
Proceeds from partner companies' ESPP	178	206
Partner company's dividends declared and paid	(736)	(749)
Partner company's redemption of preferred shares	(400)	(85)
Proceeds from partner companies' sale of stock and warrants, net	51,637	17,835
Proceeds from partner companies' at-the-market offering, net	4,620	16,370
Proceeds from exercise of partner companies' options and warrants, net	121	290
Partner company's net settlement of shares withheld for taxes	—	(1,698)
Partner company's cash payout for reverse stock split fractional shares	—	(6)
Payment of partner company's repurchase of stock	—	(1,105)
Payment of partner company's deferred financing cost	—	(119)
Repayment of partner company installment payments - licenses	(1,000)	(5,000)
Proceeds from partner company convertible preferred shares	854	2,533
Payment of debt issuance costs associated with partner company convertible preferred shares	(210)	(597)
Proceeds from partner companies' long-term debt, net	14,529	47,112
Repayment of partner companies' long-term debt	(50,375)	—
Proceeds from partner company's line of credit	28,000	5,000
Repayment of partner company's line of credit	(30,948)	(2,864)
Net cash (used in) provided by financing activities	32,739	75,319
Net decrease in cash and cash equivalents and restricted cash	(97,589)	(127,010)
Cash and cash equivalents and restricted cash at beginning of period	180,954	307,964
Cash and cash equivalents and restricted cash at end of period	$ 83,365	$ 180,954
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 7,945	$ 9,419
Cash paid (refunded) for income taxes	$ (55)	$ 858
Supplemental disclosure of non-cash financing and investing activities:		
Conversion of partner company annual maintenance fee to a promissory note	$ —	$ 268
Partner company's unpaid intangible assets	$ —	$ 4,740
Unpaid partner company's debt offering cost	$ —	$ 1,058
Unpaid partner company's offering cost	$ 263	$ 4
Partner company's retained earning adjustment	$ —	$ 195
Partner company's reclassification of warrant liability to equity	$ —	$ 89
Partner company derivative warrant liability associated with partner company convertible preferred shares	$ 33	$ 90
Partner company's warrants issued in conjunction with debt	$ —	$ 384
Unpaid research and development licenses acquired	$ 50	$ 325
Lease Liabilities arising from obtaining right-of-use assets	$ 923	$ 2,953

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

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 ("COH" or "City of Hope"), Fred Hutchinson Cancer Center, St. Jude Children's Research Hospital ("St. Jude"), Dana-Farber Cancer Institute, Nationwide Children's Hospital, Cincinnati Children's Hospital Medical Center, Columbia University, the University of Pennsylvania, Mayo Foundation for Medical Education and Research ("Mayo Clinic"), AstraZeneca plc and Dr. Reddy's Laboratories, Ltd.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and finance expertise to help the partners achieve their goals. Partner 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 have consummated strategic partnerships with industry leaders, including AstraZeneca plc as successor-in-interest to Alexion Pharmaceuticals, Inc. ("AstraZeneca") and Sentynl Therapeutics, Inc. ("Sentynl").

Our subsidiaries and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates are: Avenue Therapeutics, Inc. (Nasdaq: ATXI, "Avenue"), Baergic Bio, Inc. ("Baergic", a subsidiary of Avenue), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. (Nasdaq: CKPT, "Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Journey Medical Corporation (Nasdaq: DERM, "Journey" or "JMC"), Mustang Bio, Inc. (Nasdaq: MBIO, "Mustang"), Oncogenuity, Inc. ("Oncogenuity") and Urica Therapeutics, Inc. ("Urica"). Aevitas Therapeutics, Inc. ("Aevitas") was a consolidated subsidiary company until the sale of its primary asset to 4D Molecular Therapeutics in April 2023.

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.

Reverse Stock Split

On October 9, 2023, Fortress filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation, as amended, to effect the 1-for-15 Reverse Stock Split of the Company's shares of Common Stock (the "Reverse Stock Split"). The Reverse Stock Split was approved on August 10, 2023, by the Company's Board of Directors and by the Company's stockholders at a special meeting held on October 9, 2023. As a result of the Reverse Stock Split, every 15 shares of the Company's pre-reverse split Common Stock was combined and reclassified as one share of Common Stock. The proportionate voting rights and other rights of common stockholders were not affected by the Reverse Stock Split, other than as the result of payment for fractional shares. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise have held a fractional share of Common Stock received a cash payment in lieu thereof. In addition, there was no change to the authorized capital of the Company as a result of the reverse Stock Split and the number of authorized shares of common stock remained 200,000,000.

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

Liquidity and Capital Resources

Since inception, the Company's operations have been financed primarily through the sale of equity and debt securities, from the sale of subsidiaries/partner companies, and the proceeds from the exercise of warrants and stock options. The Company has incurred losses from operations and negative cash flows from operating activities since inception and expects to continue to incur substantial losses for the next several years as it continues to fully develop and prepare regulatory filings and obtain regulatory approvals for its existing and new product candidates. The parent Company's current cash and cash equivalents of $40.6 million are sufficient to fund the parent entity and private subsidiary operations for at least the next 12 months. However, the Company will need to raise additional funding through strategic relationships, public or private equity or debt financings, sale of a partner companies, grants or other arrangements to develop and prepare regulatory filings and obtain regulatory approvals for the existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for the potential products, sales and marketing capabilities. If such funding is not available or not available on terms acceptable to the Company, the Company's current development plans, and plans for expansion of its general and administrative infrastructure may be curtailed. Fortress also has the ability, subject to limitations imposed by Rule 144 of the Securities Act of 1933 and other applicable laws and regulations, to raise money from the sale of common stock of the public companies in which it has ownership positions.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The 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.

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 product returns, coupons, rebates, chargebacks, discounts, allowances and distribution fees paid by Journey to certain wholesalers, 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, prompt pay discounts, specialty pharmacy discounts, managed care rebates, product returns, government rebates 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 complex series of judgements about future events and uncertainties and can rely heavily 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 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 of inventory 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. The rate is estimated by using historical sales information, including its visibility and estimates into the inventory remaining in the distribution channel.

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. 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 financial instruments 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, such as accounts payable, accrued expenses and other current liabilities.

Segment Reporting

The Company operates in two operating and reportable segments, Dermatology Product Sales and Pharmaceutical and Biotechnology Product Development. The Company evaluates the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

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, 2023 and 2022, 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 Certificate of Deposit Account Registry Service ("CDARS") accounts to maximize FDIC insurance coverage across its holdings. As of December 31, 2023, 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. The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

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.

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. 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 payment 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 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 for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset 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 are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. During the year ended December 31, 2023, 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 selling, general and administrative expenses on the consolidated statements of operations. The Company did not record any impairment loss on long-lived assets for the year ended December 31, 2022.

Restricted Cash

The Company records cash held in trust or pledged to secure certain debt obligations as restricted cash. As of December 31, 2023, the Company had $2.4 million of restricted cash representing pledges to secure letters of credit in connection with certain office leases and an undertaking posted by Cyprium to secure potential damages in an injunctive proceeding. As of December 31, 2022, the Company had $2.7 million of restricted cash representing pledges to secure letters of credit in connection with certain office leases.

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

	December 31,	
	2023	2022
Cash and cash equivalents	$ 80,927	$ 178,266
Restricted cash	2,438	2,688
Total cash and cash equivalents and restricted cash	$ 83,365	$ 180,954

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 $0.3 million and $0.4 million at December 31, 2023 and 2022, respectively.

Accounts Receivable, Net

The Company's accounts receivable consists of amounts due from customers to Journey related to dermatological product sales and have standard 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 $0.5 million and $0.4 million at December 31, 2023 and 2022, 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.

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.

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. The Company continues to account for leases in the prior period consolidated financial statements under ASC Topic 840, *Leases*.

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, 2023 and December 31, 2022, the Company has recorded a liability related to an uncertain tax position of $0.8 million and $0.7 million, respectively. The 2019 through 2021 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, 2023 and December 31, 2022, the Company accrued interest related to uncertain tax positions of $0.1 million and approximately $32,000, 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) by the weighted-average number of shares of Common Stock outstanding during the period, not including unvested restricted stock, and without consideration for Common Stock equivalents. Diluted net loss per share is the same as the basic loss per share due to net losses 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. Early adoption will be permitted. The Company is currently evaluating the impact of the new standard on its consolidated 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 statements.

3. Asset Purchase Agreements

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.

Mustang

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

On May 18, 2023, Mustang entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with uBriGene, as amended by a first amendment thereto, dated June 29, 2023, and further amended by a second amendment thereto, dated as of July 28, 2023 (collectively the "Amended Asset Purchase Agreement"), pursuant to which Mustang agreed, subject to the terms and conditions therein, to sell its leasehold interest in its cell processing facility located in Worcester, MA (the "Facility") and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility to uBriGene. On July 28, 2023, the closing date, pursuant to the terms and conditions of the Amended Asset Purchase Agreement, Mustang completed the sale of Mustang's assets primarily relating to the manufacturing and production of cell and gene therapies to uBriGene for base consideration of $6.0 million. Mustang recorded a gain of $1.5 million in connection with the sale of the assets and recorded approximately $0.3 million of the base consideration as deferred income, to be recognized upon the transfer of the lease. Certain assets, including Mustang's lease of the Facility and related contracts did not transfer to uBriGene on the Closing date. uBriGene will be obligated to pay to Mustang a contingent amount of $5.0 million less certain severance obligations and payments payable in connection with the transfer of certain contracts related to the transferred assets, if Mustang, within two years of the closing date: (i) completes one or more issuances of equity securities in an aggregate gross amount equal to or greater than $10.0 million after the closing and (ii) obtains consent of the landlord to the proposed lease transfer within two years after the closing date.

The Asset Purchase Agreement contemplates that Mustang will seek to procure the consent and approval of the landlord of the Facility, WCS-377 Plantation Street, Inc. (the "Landlord"), and the Landlord informed Mustang that it will not consider the lease transfer request until receipt of the final determination letter from with the U.S. Committee on Foreign Investment in the United States ("CFIUS"), although there can be no guarantee that, even if CFIUS does approve the below-described Facility Transaction, the Landlord will approve the lease transfer. In connection with the sale of its leasehold interest in the Facility and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility (the "Facility Transaction") to uBriGene and an indirect, wholly owned subsidiary of uBriGene (Jiangsu) Biosciences Co., Ltd., a Chinese contract development and manufacturing organization, Mustang and uBriGene previously submitted a voluntary notice with CFIUS. The current 45-day review period will conclude no later than March 28, 2024. If CFIUS does not conclude its review by March 28, 2024, the proceeding will transition to a subsequent 45-day phase as CFIUS further investigates the Transaction. Unless and until the lease is transferred to uBriGene, Mustang will retain its facility lease and facility personnel, and will continue to occupy the leasehold premises and manufacture there its lead product candidates, including MB-106.

As contemplated by the Amended Asset Purchase Agreement, on the Closing Date, Mustang and uBriGene entered into a Manufacturing Services Agreement (the "Manufacturing Services Agreement"). Under the Manufacturing Services Agreement, Mustang contracted uBriGene to manufacture Mustang's lead product candidates, including MB-106, and Mustang committed to spend at least $8 million over a period of two years after the closing of the transaction to purchase manufacturing and related services (the "Manufacturing Services") from uBriGene (the "Minimum Commitment"). Mustang paid uBriGene 25% of the Minimum Commitment at the time of signing of the Manufacturing Services Agreement and will pay the remainder of the Minimum Commitment over the following two years. Subject to Mustang's payment of its Minimum Commitment, uBriGene will provide to Mustang a manufacturing rebate, payable in cash at the end of the second year of the Manufacturing Services Agreement term, for any amounts paid for Manufacturing Services in excess of the Minimum Commitment (but in no event will such rebate exceed $3 million). In connection with the Manufacturing Services Agreement, Mustang will provide uBriGene with the customary licenses to use intellectual property rights specific to Mustang's cell and gene therapies to the extent reasonably necessary for uBriGene's performance under the Manufacturing Services Agreement. Mustang intends to expense manufacturing costs under the Manufacturing Services Agreement and the sub-contracting Manufacturing Services Agreement, pursuant to which uBriGene contracted with Mustang to perform the Manufacturing Services to be performed by uBriGene under the Manufacturing Services Agreement and account for reimbursed costs associated with the agreements as an offset to such expense. For the year ended December 31, 2023, Mustang has expensed $4.1 million of manufacturing costs under the Manufacturing Services Agreement.

In addition, as contemplated by the Asset Purchase Agreement, on the closing date, Mustang and uBriGene entered into a sub-contracting Manufacturing Services Agreement (the "Sub-Contracting CDMO Agreement"). Under the terms of the Sub-Contracting CDMO Agreement, Mustang will manufacture its lead product candidates, including MB-106, and may from time to time manufacture other products as requested by uBriGene. In addition, under the Sub-Contracting CDMO Agreement, Mustang and uBriGene agreed to establish a joint steering committee comprising two representatives from each of Mustang and uBriGene to review, discuss and decide on operational matters relating to the services to be performed by Mustang under such agreement, including matters relating to expenses. For the year ended December 31, 2023, Mustang received $2.4 million in reimbursed costs and has a receivable of $3.2 million associated with the Sub-Contracting CDMO Agreement.

Because the Facility was not assigned to uBriGene within 120 days following July 28, 2023, so long as the lease has not been so assigned, uBriGene may deliver a notice to Mustang indicating its intention to enter into good faith negotiations (the "Repurchase Notice") to provide for Mustang to repurchase the associated assets relating to the manufacturing and production of cell and gene therapies at the Facility, re-assume the transferred liabilities and resume all transferred operations. Upon receipt of such Repurchase Notice, Mustang and uBriGene have agreed to use our best commercial efforts to negotiate in good faith the terms of any such Repurchase Transaction.

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 are 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 years ended December 31, 2023 and 2022, the Company recognized revenue from this arrangement of $0.7 million and $1.9 million, respectively.

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 the closing of financings that occurred in 2023 and 2022, Avenue made payments totaling $0.5 million to InvaGen.

4. Inventory

Inventory consisted of the following:

($ in thousands)	December 31, 2023	2022
Raw materials	$ 4,640	$ 6,454
Work-in-process	884	395
Finished goods	4,987	7,739
Inventory reserve	(305)	(429)
Total inventories	$ 10,206	$ 14,159

5. Property and Equipment

Fortress' property and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	December 31, 2023	2022
Computer equipment	3	$ 595	$ 739
Furniture and fixtures	5	1,017	1,387
Machinery & equipment	5	—	8,632
Leasehold improvements	15	13,175	13,175
Buildings	40	581	581
Construction in progress	N/A	29	952
Total property and equipment		15,397	25,466
Less: Accumulated depreciation		(8,892)	(12,446)
Property, plant and equipment, net		$ 6,505	$ 13,020

Fortress' depreciation expense for the years ended December 31, 2023 and 2022 was $2.2 million and $3.1 million, respectively, and was recorded in research and development, and selling, general and administrative expense in the Consolidated Statements of Operations.

6. Fair Value Measurements

Fair Value of Aevitas

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

Common Stock Warrant Liabilities

($ in thousands)	Warrants liabilities
Balance at December 31, 2021	$ —
Checkpoint Series A & B common stock warrants	7,640
Checkpoint placement agent warrants	278
Avenue common stock warrants	8,278
Urica placement agent warrants	90
Change in fair value of common stock warrants - Avenue	(5,669)
Change in fair value of common stock warrants - Checkpoint	3,252
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

Checkpoint

On December 16, 2022, Checkpoint closed on an offering for the sale of shares of its common stock and pre-funded warrants as part of a registered direct offering (the "December 2022 Registered Direct Offering"). The common stock and the pre-funded warrants were sold together with December 2022 Common Stock Warrants and placement agent warrants. Net proceeds to Checkpoint from the December 2022 Registered Direct Offering were $6.7 million after deducting commissions and other transaction costs (see Note 13).

Checkpoint deemed the December 2022 common warrants and placement agent warrants to be classified as liabilities on the balance sheet as they contain terms for redemption of the underlying security that are outside its control. The common warrants and placement agent warrants were recorded at the time of closing at a fair value, determined by using the Black-Scholes model. As the total fair value of the common stock warrant liability exceeded the total net proceeds, no proceeds were allocated to the common stock and pre-funded warrants issued as part of this transaction. Checkpoint revalued the December 2022 common warrants and placement agent warrants at December 31, 2022 resulting in a fair value of $11.2 million. Checkpoint also revalued the December 2022 Common Stock Warrants and December 2022 Placement Agent Warrants at each reporting period in 2023, resulting in gains throughout the year.

In February 2023, Checkpoint closed on an offering for the sale of shares of its common stock and pre-funded warrants as part of a registered direct offering (the "February 2023 Registered Direct Offering"). The common stock and pre-funded warrants were sold together with February 2023 Common Stock Warrants and placement agent warrants (collectively, the "February 2023 Common Stock Warrants"). The total gross proceeds from the February 2023 Registered Direct Offering were approximately $7.5 million with net proceeds of approximately $6.7 million after deducting approximately $0.8 million in commissions and other transaction costs. The February 2023 Common Stock Warrants and placement agent warrants met the criteria for equity classification.

In October 2023, Checkpoint entered into an inducement offer letter agreement (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 the Checkpoint's common stock at a reduced exercise price of $1.76 per share. The exercised warrants included the December 2022 Common Stock Warrants with an original exercise price of $4.075 per share and the February Common Stock Warrants with an original exercise price of $5.00 per share. These warrants were issued as part of the December 2022 Registered Direct Offering and February 2023 Registered Direct Offering. As part of the October 2023 Inducement, Checkpoint agreed to issue new unregistered Series A Warrants to purchase up to 6,325,354 shares of Common Stock and new unregistered Series B Warrants to purchase up to 6,325,354 shares of Common Stock (the October 2023 Common Stock Warrants"). Checkpoint also issued the placement agent warrants to purchase up to 379,521 shares of common stock with an exercise price of $2.20 per share. The total gross proceeds from the October 2023 Inducement were approximately $11.1 million with net proceeds of approximately $10.0 million after deducting approximately $1.1 million in commissions and other transaction costs. The October 2023 Common Stock Warrants and placement agent warrants met the criteria for equity classification.

The December 2022 Common Stock Warrants, which were liability classified, were revalued on October 4, 2023 using Black-Scholes Model to calculate the difference in fair value as a result of the change in exercise price. The difference in fair value of $1.2 million was recorded as a loss on common stock warrant liabilities in the Consolidated Statements of Operations. The issuance of the October 2023 Common Stock Warrants was also considered as part of the cost of the inducement and were valued using Black-Scholes Model and allocated between the December 2022 Common Stock Warrants and The February 2023 Common Stock Warrants on a weighted basis. The approximately $7.7 million allocated to the December 2022 Common Stock Warrants was recorded as loss on common stock warrant liabilities in the Consolidated Statements of Operations with a corresponding offset to additional paid-in-capital.

The February 2023 Common Stock Warrants, which were equity classified and treated under ASC 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity*, were revalued using Black-Scholes Model to calculate the difference in fair value as a result of the change in exercise price. The difference in fair value of $1.1 million was deemed to be a dividend and recorded to additional paid-in-capital by Checkpoint because Checkpoint had an accumulated deficit on the exercise date. The approximately $6.3 million allocated to the February 2023 Common Stock Warrants from the issuance of the October 2023 Common Stock Warrants was also deemed to be a dividend and recorded to additional paid-in-capital by Checkpoint because Checkpoint had an accumulated deficit on the exercise date.

($ in thousands)		**Checkpoint Warrant Liability**
Common stock warrant liabilities at December 31, 2021	$	-
Issuance of Checkpoint common warrants		7,640
Issuance of placement agent warrants		278
Change in fair value of common stock warrant liabilities		3,252
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

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

Checkpoint Warrants	December 31, 2023	October 4, 2023	December 31, 2022
Exercise price	$ 5.41	$ 1.76	$ 4.08 - 5.41
Volatility	96.4 %	91.4 - 99.6 %	82.4 - 89.4 %
Expected life	4.0	0.7 - 4.2	1.5 - 5.0
Risk-free rate	3.8 %	4.7 - 5.4 %	4.0 - 4.7 %

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") (see Note 13). 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. The October 2022 Warrants were valued using the Monte Carlo simulation approach. 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 $1.55, 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, 2023.

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

($ in thousands)	Avenue Warrant Liability
Common stock warrant liabilities at December 31, 2021	$ -
Issuance of Avenue common warrants	8,278
Change in fair value of common stock warrant liabilities	(5,669)
Common Stock Warrant liabilities at December 31, 2022	2,609
Issuance of Avenue common warrants	2,235
Change in fair value of common stock warrant liabilities	(4,258)
Common Stock Warrant liabilities at December 31, 2023	$ 586

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, 2023	January 31 2023	December 31 2022
Stock price	$ 0.16	$ 1.38	$ 1.16
Risk-free interest rate	3.84 - 4.23 %	3.90 %	4.02 %
Expected dividend yield	—	—	—
Expected term in years	2.1 - 3.8	3.00	4.78
Expected volatility	148 - 175 %	160 %	93 %

Urica

Urica's contingently issuable placement agent warrants were issued in connection with Urica's first close of their preferred offering in December 2022 (see Note 9). A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Urica's warrant liability that are categorized within Level 3 of the fair value hierarchy was as follows:

	December 31, 2023	2022
Risk-free interest rate	3.93 %	3.94 %
Expected dividend yield	—	—
Expected term in years	0.5	1.5
Expected volatility	153.6 %	70.7 %

At December 31, 2023 and 2022, the value of Urica's contingent payment warrant was $0.2 million and $0.1 million, respectively, and was recorded on the consolidated balance sheet.

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 has no alternate use. Expense recognized was $4.3 million (primarily Avenue) and $0.7 million, for the years ended December 31, 2023 and 2022, respectively. The purchase prices of the licenses acquired were classified as research and development-licenses acquired in the consolidated statements of operations.

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, of which $2.0 million was paid on April 27, 2023 and $1 million was paid on September 8, 2023.

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

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

In connection with the signing of the AnnJi License Agreement, Avenue issued 831,618 shares of its common stock to AnnJi ("First Tranche Shares") and recognized expense of $0.9 million; and issued 276,652 shares of common stock ("Second Tranche Shares"), recorded at a fair value of $0.3 million, on September 26, 2023 upon enrollment of the eighth patient in the ongoing Phase 1b/2a SBMA clinical trial. 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.

Journey

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 ¥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 $19.0 million as other revenue in the consolidated statements of operations during the year ended December 31, 2023.

In June 2021, Journey entered a license, collaboration, and assignment agreement (the "DFD-29 Agreement") to obtain global rights for the development and commercialization of a late-stage development modified release oral minocycline for the treatment of rosacea ("DFD-29") with Dr. Reddy's Laboratories, Ltd ("DRL"); provided, that DRL retained certain rights to the program in select markets including Brazil, Russia, India and China. Pursuant to the terms and conditions of the DFD-29 Agreement, Journey paid $10.0 million. Based on the development and commercialization of DFD-29, additional contingent regulatory and commercial milestone payments totaling up to $158.0 million may also become payable by Journey. Journey is required to pay royalties ranging from approximately ten percent to fifteen percent on net sales of the DFD-29 product, subject to certain reductions. Additionally, Journey was required to fund and oversee the Phase 3 clinical trials beginning upon the license of DFD-29 in 2021. The Phase 3 clinical trials substantially concluded in July 2023 upon Journey's receipt of positive topline results from the trials. From inception to date Journey has incurred approximately $23.8 million in costs associated with the development of DFD-29.

On March 31, 2021, Journey acquired global rights to Qbrexza®, a prescription cloth towelette to treat primary axillary hyperhidrosis in patients nine years of age or older. 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 from approximately 40% to 30%. Thereafter for a period of eight years royalties are approximately 12.0% to 19.0%. Royalty amounts are subject to 50% diminution in the event of loss of exclusivity due to generic competition.

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. The license agreement includes contingent regulatory and commercial milestone payments totaling up to $88 million with subsequent sales royalties ranging from approximately 7% to approximately 10% payable on net sales of dotinurad. Urica paid a $3.0 million milestone payment in December 2021 upon IND submission of dotinurad. In December 2022 Urica Therapeutics 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.

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 $439.5 million, of which $285.2 million relates to Mustang agreements. The license agreements also have sales-based milestone payments that total approximately $337.9 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. 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 selling, general and administrative expenses on the consolidated statements of operations. The Company did not record any impairment loss on long-lived assets for the year ended December 31, 2022.

Agreement with VYNE Therapeutics Inc.

In January 2022, Journey entered into an agreement with VYNE Therapeutics, Inc. ("VYNE") to acquire two FDA-Approved Topical Minocycline Products, Amzeeq (minocycline) topical foam, 4%, and Zilxi (minocycline) topical foam, 1.5%, and a Molecule Stabilizing Technology™ proprietary platform from VYNE for an upfront payment of $20.0 million and an additional $5.0 million payment on the one-year anniversary of the closing (the "VYNE Product Acquisition Agreement"). This expanded Journey's product portfolio to eight marketed branded dermatology products. Journey also acquired certain associated inventory.

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

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

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

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

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

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

The intangible assets were valued using an income approach, while the inventory was valued using a final sales value less cost to dispose approach.

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 agreed to pay $5.0 million, comprised of an upfront payment of $1.0 million paid upon execution, with additional milestone payments totaling $4.0 million. To date, Journey has paid all milestone payments. 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.

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

($ in thousands)	Estimated Useful Lives (Years)	Year Ended December 31, 2023	2022
Intangible assets – product licenses	3 to 9	$ 37,925	$ 37,925
Accumulated amortization		(14,495)	(10,728)
Impairment loss		(3,143)	—
Net intangible assets		$ 20,287	$ 27,197

The future amortization of these intangible assets is as follows:

($ in thousands)	Total Amortization
December 31, 2024	$ 3,257
December 31, 2025	3,257
December 31, 2026	2,471
December 31, 2027	1,775
Thereafter	5,585
Sub-total	$ 16,345
Asset not yet placed in service	3,942
Total	$ 20,287

9. Debt and Interest

Debt

Total debt consists of the following:

($ in thousands)	December 31, 2023	December 31, 2022	Interest rate	Maturity
Oaktree Note	$ 50,000	$ 50,000	11.0 %	August - 2025
SWK Term Loan	15,000	—	15.1 %	December - 2027
EWB Term Loan	—	20,000	10.2 %	January - 2026
Runway Note	—	31,050	13.8 %	April - 2027
Less: Discount on notes payable	(4,144)	(9,320)		
Total notes payable	$ 60,856	$ 91,730		

Oaktree Note

On August 27, 2020 (the "Oaktree Closing Date"), Fortress, as borrower, entered into the $60.0 million senior secured credit agreement with Oaktree (the "Oaktree Agreement" and the debt thereunder, the "Oaktree Note") with Oaktree Fund Administration, LLC and the lenders from time-to-time party thereto (collectively, "Oaktree"). The Oaktree Note bears interest at a fixed annual rate of 11.0%, payable quarterly and maturing on the fifth anniversary of the Oaktree Closing Date, August 27, 2025, the ("Maturity Date"). The Company is required to make quarterly interest-only payments until the Maturity Date, at which point the outstanding principal amount is due. The Company may voluntarily prepay the Oaktree Note at any time subject to a Prepayment Fee. The Company is also required to make mandatory prepayments of the Oaktree Note under various circumstances. No mandatory prepayments were required in the years ended December 31, 2023 or 2022. No amounts paid or prepaid may be reborrowed without Oaktree consent.

The Oaktree Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, affiliate transactions, investments, acquisitions, mergers, dispositions, prepayment of permitted indebtedness, and dividends and other distributions, subject to certain exceptions. These affirmative and negative covenants apply in different instances to Fortress itself, its private subsidiaries, its public subsidiaries, or certain combinations of the foregoing. The limitations on dividends and other distributions have the practical effect of preventing any further issuances by the Company or its private subsidiaries of equity securities with cash dividends or redemption features.

In addition, the Oaktree Agreement contains certain financial covenants, including, among other things, (i) maintenance of minimum liquidity and (ii) a minimum revenue test that requires Journey's annual revenue to be equal to or to exceed annual revenue projections set forth in the agreement. Failure by the Company or Journey, as applicable, to comply with the financial covenants will result in an event of default, subject to certain cure rights of the Company. The Company was in compliance with all applicable covenants under the Oaktree Note as of December 31, 2023.

The Oaktree Agreement contains customary events of default, in certain circumstances subject to customary cure periods. These events of default apply in different instances to Fortress itself, its private subsidiaries, its public subsidiaries, or a certain combination of the foregoing. 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 Oaktree Agreement, in addition to other remedies available to the lenders as secured creditors of the Company.

The Oaktree Agreement grants a security interest in favor of the Agent, for the benefit of the lenders, in substantially all of the Company's assets (consisting principally of the Company's shareholdings in, and in some cases debt owing from, its subsidiaries and partner companies) as collateral securing the Company's obligations under the Oaktree Agreement, except for: (i) certain interests in controlled foreign corporation subsidiaries of the Company; (ii) the Company's holdings in Avenue; and (iii) those portions of the Company's holdings in certain subsidiaries and partner companies that are encumbered by pre-existing equity pledges to certain of the Company's officers. None of Fortress' subsidiaries or partner companies is a party to the Oaktree Agreement, and the collateral package does not include the assets of any such subsidiaries or partner companies.

Pursuant to the terms of the Oaktree Agreement, on the Oaktree Closing Date the Company paid Oaktree an upfront commitment fee equal to 3% of the $60.0 million, or $1.8 million. In addition, the Company paid a $35,000 Agency fee to the Agent, which was due on the Oaktree Closing Date and will be due annually, together with fees of $2.5 million directly to third parties involved in the transaction, and issued warrants to Oaktree and certain of its affiliates to purchase up to 116,624 shares of common stock of the Company (see Note 13) with a relative fair value of $4.4 million. The Company recorded the fees totaling $8.7 million ($1.8 million to Oaktree, $2.5 million of expenses paid to third-parties and $4.4 million representing the relative fair value of the Oaktree Warrants) to debt discount, to be amortized over the term of the Oaktree Note. For the years ended December 31, 2023 and 2022, the Company amortized $2.1 million and $1.5 million, respectively, of debt discount associated with the Oaktree Note.

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. The remaining $5.0 million may be drawn upon request by Journey within 12 months after the SWK Closing Date. Loans under the Credit Facility (the "Term Loans") mature on December 27, 2027 unless the Credit Facility is otherwise terminated pursuant to the terms of the Credit Agreement. The Term Loans accrue interest which is payable quarterly in arrears. The Term Loans bear interest at a rate per annum equal to the three-month term SOFR (subject to a SOFR floor of 5%) plus 7.75%. The interest rate resets quarterly.

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. If the total revenue of Journey, measured on a trailing twelve-month basis, is greater than $70.0 million as of December 31, 2025, principal repayment is not required until 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.

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 for the fiscal year ended December 31, 2023 was 15.1%.

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, 2023, 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 $2.4 million and $2.7 million as of December 31, 2023 and December 31, 2022, respectively, securing rent deposits for lease facilities and an undertaking posted by Cyprium to secure potential damages in 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).

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

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

The Urica Preferred 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 % 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).

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,					
	2023			2022		
($ in thousands)	*Interest*	*Fees*	Total	*Interest*	*Fees*	Total
Oaktree Note	5,561	2,073	7,634	5,561	1,532	7,093
Partner company convertible preferred shares	1,023	503	1,526	—	—	—
Partner company installment payments - licenses	353	—	353	770	—	770
Partner company notes payable[1]	4,856	492	5,348	4,021	533	4,554
Other	122	332	454	65	—	65
Total Interest Expense and Financing Fee	$ 11,915	$ 3,400	$ 15,315	$ 10,417	$ 2,065	$ 12,482

Note 1: Imputed interest expense related to Ximino, Accutane, Anti-itch product license and VYNE product licenses (see Note 8); includes loss on extinguishment of $2.8 million recorded by Mustang related to payoff of the Runway Note on April 11, 2023.

10. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

($ in thousands)	December 31, 2023	2022
Accounts payable	$ 34,810	$ 57,244
Accrued expenses:		
Professional fees	1,681	1,693
Salaries, bonus and related benefits	8,531	9,772
Research and development	11,644	7,390
Research and development - license maintenance fees	—	632
Research and development - milestones	—	4,600
Accrued royalties payable	2,015	2,627
Accrued coupon and rebates	9,987	7,604
Return reserve	4,077	3,689
Accrued interest	—	342
Other	817	1,853
Total accounts payable and accrued expenses	$ 73,562	$ 97,446

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). Fortress' ownership in Baergic was transferred to Avenue as of November 7, 2022 (see Note 14). Tamid was dissolved in the year ended December 31, 2023 due to inactivity.

The Company's ownership interest in its consolidated subsidiaries in 2023 was similar to 2022, except for Checkpoint which decreased from 18% to 9% and Journey, which decreased from 56% to 50%.

12. Net Loss per Common Share

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

The Company updated its presentation of net loss attributable to common stockholders and its net loss per share as an immaterial correction to reflect the preferred stock dividend of $2.0 million per quarter. The statement of changes in stockholders' equity (deficit) and statement of cash flows reflected the dividend and as such are not impacted by this change in presentation. For the year ended December 31, 2022, in addition to being retroactively adjusted to give effect to the Reverse Stock Split (see Note 1), the net loss attributable to Fortress increased from ($86.6) million to ($94.6) million and the net loss per share increased from ($14.61) to ($15.97) per share to reflect the preferred stock dividend.

The following shares of potentially dilutive securities, weighted during the years ended December 31, 2023 and 2022 have been excluded from the computations of diluted weighted average shares outstanding as the effect of including such securities would be anti-dilutive:

	Year Ended December 31,	
	2023	2022
Warrants to purchase Common Stock	873,065	233,057
Options to purchase Common Stock	32,601	48,317
Unvested Restricted Stock	1,362,880	1,225,000
Unvested Restricted Stock Units	151	2,608
Total	2,268,697	1,508,982

13. Stockholders' Equity

Reverse Stock Split

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

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

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 15,093,053 and 7,366,283 shares of Common Stock were outstanding as of December 31, 2023 and 2022, 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, 2023 and 2022, 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. The Company recorded approximately $8.0 million and $8.0 million of dividends in Additional Paid in Capital on the Consolidated Balance Sheets as of December 31, 2023 and 2022, respectively.

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. As of December 31, 2023, no Series A Preferred Stock shares have been 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"); 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 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, 2023, the Company had four equity compensation plans: the Fortress Biotech, Inc. 2007 Stock Incentive Plan, the Fortress Biotech, Inc. 2013 Stock Incentive Plan, as amended (collectively, the "Plans"), the Fortress Biotech, Inc. 2012 Employee Stock Purchase Plan (the "ESPP") and the Fortress Biotech, Inc. Long Term Incentive Plan (the "LTIP"). In the years ended December 31, 2023 and 2022, the Company's Board of Directors and stockholders approved increases of 0.5 million and 0.2 million shares, respectively, to the Plans, bringing the aggregate total of authorized shares available under the Plans to 1.9 million shares. A total of 1,858,879 shares have been granted under the Plans, net of cancellations, and 74,454 shares remained available for issuance as of December 31, 2023.

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, 2023:

Partner Company	Stock Plan	Shares Authorized	Shares available at December 31, 2023
Avenue	Avenue Therapeutics, Inc. 2015 Stock Plan	5,266,666	3,352,489
Cellvation	Cellvation Inc. 2016 Incentive Plan	2,000,000	300,000
Checkpoint	Checkpoint Therapeutics, Inc. Amended and Restated 2015 Stock Plan	6,000,000	3,510,830
Cyprium	Cyprium Therapeutics, Inc. 2017 Stock Plan	2,000,000	675,000
Helocyte	DiaVax Biosciences, Inc. 2015 Incentive Plan	2,000,000	341,667
Journey	Journey Medical Corporation 2015 Stock Plan	7,642,857	1,487,994
Mustang	Mustang Bio, Inc. 2016 Incentive Plan	733,333	282,334
Oncogenuity	FBIO Acquisition Corp. VII 2017 Incentive Plan	2,000,000	1,200,000
Urica	FBIO Acquisition Corp. VIII 2017 Incentive Plan	4,000,000	204,510

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 and vest in three equal annual installments commencing on the grant date.

The Company estimates the fair value of stock option grants using a Black-Scholes option pricing model. In applying this model, the Company uses the following assumptions:

- *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 Company utilizes the trading history of its Common Stock to determine the expected stock price volatility for its Common Stock.
- *Expected Term*: Due to the limited exercise history of the Company's stock options, the Company determined the expected term based on the Simplified Method under SAB 107 and the expected term for non-employees is the remaining contractual life for both options and warrants.
- *Expected Dividend Rate*: The Company has not paid and does not anticipate paying any cash dividends in the near future on its 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 and restricted Common Stock awards and warrants for the years ended December 31, 2023 and 2022:

($ in thousands)	Year Ended December 31, 2023	2022
Employee and non-employee awards	$ 8,369	$ 9,934
Executive awards of Fortress Companies' stock	1,576	2,718
Partner Companies:		
Avenue	907	649
Checkpoint	2,897	2,924
Mustang	567	2,283
Journey	2,606	4,425
Other	107	54
Total stock-based compensation expense	$ 17,029	$ 22,987

For the years ended 2023 and 2022, $3.2 million and $4.4 million was included in research and development expenses, and $13.8 million and $18.5 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	Weighted average exercise price	Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Options vested and expected to vest at December 31, 2022	176,732	$ 22.08	$ 230,000	5.64
Forfeited	(133,503)	8.14	—	—
Expired	(24,333)	99.78	—	—
Options vested and expected to vest at December 31, 2023	18,896	$ 20.55	$ —	1.76
Options vested and exercisable at December 31, 2023	18,896	$ 20.55	$ —	1.76

During the years ended December 31, 2023 and 2022, there were no exercises of 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, 2022
Risk-free interest rate	3.78 %
Expected dividend yield	—
Expected term in years	7.0
Expected volatility	78.48 %

As of December 31, 2023, the Company had no unrecognized stock-based compensation expense related to options.

Restricted Stock

Consolidated stock-based compensation expense from restricted stock awards and restricted stock units for the years ended December 31, 2023 and 2022 was $16.0 million and $21.9 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 will be measured and recorded if and when it becomes probable that the milestone will be achieved.

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.

During 2022, the Company granted 0.3 million restricted shares of its Common Stock to executives and directors of the Company and 0.1 million restricted stock units to employees and non-employees of the Company. The fair value of the restricted stock awards issued during 2022 of $7.0 million and the fair value of the restricted stock unit awards issued during 2022 of $2.1 million were valued on the grant date using the Company's stock price as of the grant date. The 2022 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:

	Number of shares	Weighted average grant price
Unvested balance at December 31, 2022	1,370,001	$ 35.44
Restricted stock granted	173,904	9.90
Restricted stock vested	(181,831)	36.01
Restricted stock units granted	169,466	3.59
Restricted stock units forfeited	(19,182)	42.05
Restricted stock units vested	(53,658)	48.80
Unvested balance at December 31, 2023	1,458,700	$ 28.05

The total fair value of restricted stock units and awards that vested during the years ended December 31, 2023 and 2022 was $9.6 million and $7.3 million, respectively. As of December 31, 2023, the Company had unrecognized stock-based compensation expense related to all unvested restricted stock and restricted stock unit awards of $10.6 million and $1.4 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 1.6 years and 1.7 years, respectively. This amount 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 year ended December 31, 2023 and 2022, certain non-employee directors elected to defer an aggregate of approximately 27,000 and 22,000 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, 2023, 0.1 million shares have been purchased and 0.1 million shares are available for future sale under the Company's ESPP. The Company recognized share-based compensation expense of approximately $11,000 and $0.1 million for the years ended December 31, 2023 and 2022, 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, 2021	300,374	$ 47.96	$ 68,800	3.93
Expired	(173,086)	48.97	—	
Outstanding as of December 31, 2022	127,288	$ 46.58	$ —	7.45
Granted	5,885,000	1.70		
Exercised	(225,000)	1.70		
Outstanding as of December 31, 2023	5,787,288	$ 1.88	$ 7,794,450	4.91
Exercisable as of December 31, 2023	5,787,288	$ 1.88	$ 7,794,450	4.91

In connection with the Oaktree Note (see Note 9), the Company had issued warrants to Oaktree and certain of its affiliates to purchase up to approximately 0.1 million shares of Common Stock at a purchase price of $48.00 per share (the "Oaktree Warrants"). Oaktree is entitled to additional warrants if at any time prior to the expiration of the Oaktree Warrants the Company issues equity, warrants or convertible notes (collectively known as "Security Instruments") at a price that is less than 95% of the market price of the Company's Common Stock on the trading day prior to the issuance of the Security Instruments. The Oaktree Warrants expire on August 27, 2030 and may be net exercised at the holder's election. The Company filed registration statement No. 333-249983 on Form S-3 to register the resale of the shares of Common Stock issuable upon exercise of the Oaktree Warrants that was declared effective by the SEC on November 20, 2020.

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

The Oaktree Warrants were reported as a component of additional paid in capital within Stockholders' equity, and the value ascribed to the warrants was recorded as debt discount of the Oaktree Note and is amortized utilizing the effective interest method over the term of the Oaktree Note. The modification of the warrants resulted in a change in value of $0.3 million which was recorded as interest expense in the condensed consolidated statement of operations for the year ended December 31, 2023.

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 result in performance-based compensation that is deductible without limit under Section 162(m) of the Internal Revenue Code of 1986, as amended.

On January 1, 2023 and 2022, the Compensation Committee granted 81,286 and 73,532 shares each to Dr. Rosenwald and Mr. Weiss, respectively. These equity grants, made in accordance with the LTIP, represent 1% of total outstanding shares of the Company as of the dates of such grants. The shares will vest in full if the employee is either in the service of the Company as an employee, Board member or consultant (or any combination of the foregoing) on the tenth anniversary of the LTIP, or the eligible employee has had an involuntary Separation from Service (as defined in the LTIP). The only other vesting condition – one based on achievement of an increase in the Company's market capitalization – has already been achieved, with respect to each annual award under the LTIP. The shares awarded under the LTIP will also vest in full (and the Company's repurchase option on each tranche of shares granted thereunder will accordingly lapse) upon the occurrence of a Corporate Transaction (as defined in the LTIP) if the eligible employee is in service to the Company on the date of such Corporate Transaction. The fair value of each grant on the grant date was approximately $0.8 million for the 2023 grant and $2.8 million for the 2022 grant. For the year ended December 31, 2023 and 2022, the Company recorded stock compensation expense related to LTIP grants of approximately $5.8 million and $5.3 million, respectively, on the consolidated statement of operations.

Capital Raises

2021 Shelf

On July 23, 2021, the Company filed a shelf registration statement (File No. 333-255185***)*** on Form S-3, which was declared effective on July 30, 2021 (the "2021 Shelf"). Approximately $100.1 million of securities remain available for sale under the 2021 Shelf as of December 31, 2023. The Company's shelf registration statement (File No. 333-238327) on Form S-3 filed in 2020 expired on May 26, 2023.

Common Stock At the Market Offering

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 gross proceeds of $2.2 million. In connection with these sales, the Company paid aggregate fees of $0.1 million.

For the year ended December 31, 2022, the Company issued approximately 0.3 million shares of common stock at an average price of $22.58 per share for gross proceeds of $6.2 million. In connection with these sales, the Company paid aggregate fees of $0.2 million.

February 2023 Registered Direct Offering and Concurrent Private Placement

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

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

November 2023 Public Offering

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

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. 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. 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, 2023, Journey issued approximately 0.7 million shares of common stock at an average price of $6.189 per share for gross proceeds of $4.6 million under the Journey ATM. In connection with these sales, Journey paid aggregate fees of $0.1 million. At December 31, 2023, 4,151,297 shares remain available for issuance under the Journey 2022 S-3.

Checkpoint 2020 and 2023 Shelf Registration Statements and At the Market Offering

In March 2023, the Checkpoint 2023 S-3 (File No. 333-270843), which was declared effective May 5, 2023. Under the Checkpoint 2023 S-3, Checkpoint may sell up to a total of $150 million of its securities. As of December 31, 2023, approximately $91.7 million of the securities remains available for sale through the Checkpoint 2023 S-3.

There were no sales under the Checkpoint 2020 ATM in the year ended December 31, 2023. During the year ended December 31, 2022, Checkpoint sold a total of 532,816 shares of common stock under the Checkpoint 2020 ATM for aggregate total gross proceeds of approximately $10.1 million at an average selling price of $18.99 per share, resulting in net proceeds of approximately $9.9 million after deducting commissions and other transaction costs.

Checkpoint Registered Direct Offerings

In 2023, Checkpoint made registered direct offerings in February, April, May and July and sold a total of 6,957,186 shares of common stock and 2,663,903 pre-funded warrants at prices ranging from $3.07 to $5.25. All pre-funded warrants were exercised in 2023. Each of these offerings included Series A warrants with a five-year term and Series B warrants with an 18-month term. Total Series A warrants were 9,621,089 and total Series B warrants were 9,621,089 with exercise prices ranging from $2.82 to $5.00. Total gross proceeds were $33.6 million, with net proceeds of $30.4 million.

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

In December 2022, Checkpoint closed on the December 2022 Registered Direct Offering with a single institutional investor for the issuance and sale of 950,000 shares of its common stock and 784,105 pre-funded warrants for one share of Checkpoint's common stock. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 1,734,105 shares of common stock and Series B warrants to purchase up to 1,734,105 shares of common stock, at a purchase price of $4.325 per share of common stock. The Series A warrants will expire in five years and the Series B warrants will expire in eighteen months, and both have an exercise price of $4.075 per share. Net proceeds from the registered direct offering were $6.7 million and allocated to the common stock warrant liabilities (see Note 6).

Pursuant to the Founders Agreement, Checkpoint issued to Fortress 2.5% of the aggregate number of shares of Checkpoint common stock issued in the offerings noted above. Accordingly, Checkpoint issued 398,660 shares and 56,671 shares to Fortress for the year ended December 31, 2023 and 2022, respectively.

Mustang 2020 and 2021 Shelf Registration Statements and At-the-Market Offering

On April 23, 2021, Mustang filed a shelf registration statement (File No. 333-255476) on Form S-3 (the "Mustang 2021 S-3"), which was declared effective on May 24, 2021. Through the Mustang 2021 S-3, Mustang may sell up to a total of $200 million of its securities. As of December 31, 2023, approximately $195.6 million of the Mustang 2021 S-3 remained available for sales of securities.

On July 2018, Mustang entered into an At-the-Market Issuance Sales Agreement (the "Mustang ATM") relating to the sale of shares of common stock pursuant to the Mustang 2021 S-3. Under the Mustang ATM, Mustang pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. On April 14, 2023, the Mustang ATM was amended to add the limitations imposed by General Instruction I.B.6 to Form S-3.

During the year ended December 31, 2023, Mustang issued approximately 0.1 million shares of common stock at an average price of $3.15 per share for gross proceeds of $0.2 million under the ATM Agreement. In connection with these sales, Mustang paid aggregate fees of approximately $3,000 for net proceeds of approximately $0.2 million.

During the year ended December 31, 2022, Mustang issued approximately 0.5 million shares of common stock at an average price of $12.61 per share for gross proceeds of $6.6 million under the Mustang ATM. In connection with these sales, Mustang paid aggregate fees of approximately $0.1 million for net proceeds of approximately $6.5 million.

Mustang Registered Direct Offering

In October 2023, Mustang closed on the October 2023 Registered Direct Offering with a single institutional accredited investor for the issuance and sale of an aggregate of (i) 920,000 shares of its common stock and (ii) pre-funded warrants to purchase up to 1,688,236 shares of its common stock at a purchase price of $1.70 per share and $1.699 per pre-funded warrant in a registered direct offering priced at-the-market under the rules of The Nasdaq Stock Market LLC. In a concurrent private placement, Mustang issued and sold 2,588,236 unregistered warrants to purchase shares of common stock. The unregistered warrants have an exercise price of $1.58, were exercisable immediately upon issuance and will

expire five and one-half years following the issuance date. The total gross proceeds from the offerings were approximately $4.4 million before deducting approximately $0.5 million in placement agency fees and offering expenses.

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 recorded the value of 1,297 as shares issuable at December 31, 2023 and issued 13,131 common shares to Fortress for the year ended December 31 2022.

Avenue Registered Direct, Private Placement and PIPE

In November 2023, Avenue closed on a public offering of the issuance and sale of an aggregate of 16,633,400 units at a purchase price of $0.3006 per unit (the "November 2023 Offering"). Each unit consists of (i) one share of common stock (or pre-funded warrant in lieu of), and (ii) one Series A warrant to purchase one share of common stock, exercisable immediately upon issuance at a price of $0.3006 per share and expiring five years following the issuance date, and (iii) one Series B warrant to purchase one share of common stock, exercisable immediately upon issuance at a price of $0.3006 per share and expiring eighteen months following the issuance date (in aggregate the "November 2023 Warrants"). The total gross proceeds from the offering were approximately $5.0 million with net proceeds of approximately $3.8 million after deducting commissions and other transaction costs. In January 2024, Avenue entered into an inducement offer letter agreement with certain investors in the November 2023 Offering who agreed to exercise certain outstanding November 2023 Warrants to purchase up to an aggregate of 14,600,000 shares of Avenue common stock at their exercise price of $0.3006 per share (see Note 20).

In connection with the Avenue September 2023 Private Placement (see Note 16), Avenue entered into a registration rights letter agreement (the "Avenue Registration Rights Letter Agreement") with Fortress and the Company's Chairman, President and Chief Executive Officer, a director on the board of directors of Avenue (the "Avenue Private Placement Investors"). Avenue will file, on or prior to September 8, 2024, a resale registration statement to register the resale of the Avenue September 2023 Private Placement Shares.

In January 2023, Avenue agreed to issue and sell (i) 448,000 shares of Avenue's common stock at a price per share of $1.55, and (ii) pre-funded warrants to purchase 1,492,299 shares of common stock, at a price equal to the price per share, less $0.001 (the "Avenue January 2023 Registered Direct Offering"). The Avenue Pre-Funded Warrants had an exercise price of $0.001 per share.

Also in January 2023, Avenue entered into a private placement offering ("Avenue January 2023 Private Placement") of January 2023 Warrants to purchase 1,940,299 shares of Avenue common stock, each with an exercise price of $1.55 per share. Avenue agreed to issue and sell the January 2023 Warrants at an offering price of $0.125 per January 2023 Warrant to purchase one share of Avenue common stock. The gross proceeds across the Avenue January 2023 Registered Direct Offering and the Avenue January 2023 Private Placement were $3.2 million and net proceeds were $2.8 million.

On October 11, 2022, Avenue announced the closing of an underwritten public offering of 3,636,365 common and pre-funded units. Each unit consists of one share of common stock or one pre-funded warrant and one warrant to purchase one share of common stock. Each unit was sold for a purchase price of $3.30 per common unit (or $3.2999 per pre-funded unit after reducing $0.0001 attributable to the exercise price of the pre-funded warrants). Avenue also simultaneously closed on the sale of an additional 545,454 warrants to purchase common stock, which were sold pursuant to a partial exercise of the underwriter's over-allotment option. Avenue received net proceeds of approximately $10.3 million at closing, before giving effect to any warrant exercises. This transaction, along with Avenue's repurchase of 100% of the Avenue shares held by InvaGen for a purchase price of $3.0 million in October 2022 (see Note 3), resulted in the November 2022 consummation of the Contribution Agreement between Fortress and Avenue (see Note 16).

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 52,419 shares and recorded 415,718 shares issuable for the year ended December 31, 2023, and recorded 90,909 shares issuable to Fortress for the year ended December 31, 2022.

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. 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. At December 31, 2023, the Company had operating lease liabilities of $20.8 million and right of use assets of $17.0 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, 2023 and 2022 was $1.9 million and $2.0 million, respectively. The components of lease cost are as follows:

	Year Ended December 31,	
($ in thousands)	**2023**	**2022**
Operating lease cost	$ 3,236	$ 3,524
Shared lease costs	(2,086)	(2,127)
Variable lease cost	761	648
Total lease expense	$ 1,911	$ 2,045

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

	Year Ended December 31,	
($ in thousands)	**2023**	**2022**
Operating cash flows from operating leases	$ (3,549)	$ (3,473)
Right-of-use assets exchanged for new operating lease liabilities	$ 923	$ 2,953
Weighted-average remaining lease term – operating leases (years)	4.2	4.7
Weighted-average discount rate – operating leases	6.5 %	6.6 %

($ in thousands)	**Future Lease Liability**
Year Ended December 31, 2024	3,796
Year Ended December 31, 2025	3,799
Year Ended December 31, 2026	3,535
Year Ended December 31, 2027	3,191
Other	11,669
Total operating lease liabilities	25,990
Less: present value discount	(5,185)
Net operating lease liabilities, short-term and long-term	$ 20,805

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

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, 2023 and 2022, the Company paid a matching contribution of $1.1 million and $1.1 million, respectively.

16. Related Party Transactions

The Company's Chairman, President and Chief Executive Officer, individually and through certain trusts over which he has voting and dispositive control, beneficially owned approximately 17.2% and 10.5% of the Company's issued and outstanding Common Stock as of December 31, 2023 and 2022, respectively. The Company's Executive Vice Chairman, Strategic Development individually owns approximately 7.5% and 11.2% of the Company's issued and outstanding Common Stock at December 31, 2023 and 2022, respectively.

Avenue September 2023 Private Placement

In September 2023, Avenue entered into an unwritten agreement with the Avenue Private Placement Investors, pursuant to which Avenue agreed to issue and sell 767,085 shares (the "Avenue September 2023 Private Placement Shares") of Avenue common stock for an aggregate purchase price of approximately $550,000 in a private placement transaction (the "Avenue September 2023 Private Placement). The Avenue common shares were purchased by the Avenue Private Placement Investors at a price per Avenue September 2023 Private Placement Share of $0.717, which was the "consolidated closing bid price" of the Avenue common stock on Nasdaq as of September 7, 2023, in compliance with Nasdaq Listing Rule 5365(c). The net proceeds to Avenue from the Avenue September 2023 Private Placement were approximately $550,000. Avenue did not incur any underwriting or placement agent fees associated with the Avenue September 2023 Private Placement. Avenue intends to use the net proceeds from the Avenue September 2023 Private Placement for working capital and other general corporate purposes.

Shared Services Agreement with 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, the Company invoiced TGTX $0.4 million and $0.4 million, and received payments of $0.4 million and $0.4 million for the years ended December 31, 2023 and 2022, respectively.

Desk Share Agreement with TGTX

The Desk Share Agreement with TGTX, as amended, requires TGTX to pay 65% of the average annual rent. 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, 2023 and 2022, the Company had paid $2.8 million and $2.7 million in rent, respectively, and invoiced TGTX approximately $1.8 million and $1.9 million respectively, for their prorated share of the rent base. At December 31, 2023, there were no amounts due from TGTX related to this arrangement.

From 2018 until 2022, TGTX employees occupied desks in the Waltham, MA office under the Desk Share Agreement. TGTX paid their share of the rent based on actual percentage of the office space occupied on a month by month basis. For the year ended December 31, 2022, the Company had paid approximately $0.2 million in rent for the Waltham, MA office, and invoiced TGTX approximately $0.1 million. The Desk Share Agreement with TGTX terminated on December 31, 2022.

Checkpoint Collaborative Agreements with TGTX

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

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 year ended December 31, 2023 and 2022, the Company's employees have provided services to Journey totaling approximately $0.1 million and $0.1 million, respectively. At December 31, 2023, approximately $0.2 million is due from Journey related to this arrangement.

Contribution Agreement with Avenue

On May 11, 2022, the Company entered into a stock contribution agreement (the "Contribution Agreement") with Avenue, pursuant to which the Company agreed to transfer ownership of 100% of its shares (common and preferred) in Baergic to Avenue. Under the Contribution Agreement, the Company also agreed to assign to Avenue certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement, by and between Fortress and Baergic, dated as of March 9, 2017, and Management Services Agreement, by and between Fortress and Baergic, dated as of March 9, 2017. Consummation of the transactions contemplated by the Contribution Agreement was subject to the satisfaction of certain conditions precedent, including, inter alia: (i) the closing of an equity financing by Avenue resulting in gross proceeds of at least $7.5 million, (ii) the agreement by minority Avenue shareholder InvaGen to (A) have 100% of its shares in Avenue repurchased by Avenue and (B) terminate certain of the agreements to which it was party with Avenue and/or the Company in connection with InvaGen's 2019 equity investment in Avenue, which eliminated certain negative consent rights of InvaGen over Avenue and restore certain rights and privileges of Fortress in Avenue; and (iii) the sustained listing of Avenue's common stock on the Nasdaq Capital Market. On October 11, 2022, Avenue announced the closing of an underwritten public offering in which it received net proceeds of approximately $10.4 million (see Note 13). The offering, together with the October 2022 repurchase of Avenue common shares held by InvaGen, resulted in the consummation of the Contribution Agreement in November 2022 (see Note 3). As a result, Baergic became a majority-controlled and owned subsidiary company of Avenue.

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, 2023, there are 300,600 shares of Cyprium PPS outstanding.

Pursuant to the terms of the Cyprium PPS, shareholders on the record date are entitled to receive a monthly cash dividend of $0.19531 per share which yields an annual dividend of $2.34375 per share. The Cyprium PPS will automatically be redeemed upon the first (and only the first) bona fide, arm's-length sale of a Priority Review Voucher (a "PRV Sale") issued by the FDA in connection with the approval of CUTX-101, 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.

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

Founders Agreement 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 a Change in Control (as defined in the Founders Agreement) occurs. In connection with each Founders Agreement the Company receives 250,000 Class A Preferred shares (except for that with Checkpoint, in which the Company holds Class A Common Stock).

The Class A Preferred Stock (Class A Common Stock with respect to Checkpoint) 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 Class A Preferred Stock (Class A Common Stock with respect to Checkpoint) 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 Class A Preferred Stock (Class A Common Stock with respect to Checkpoint) are convertible and the denominator of which is the number of shares of outstanding Class A Preferred Stock (Class A Common Stock with respect to Checkpoint). Thus, the Class A Preferred Stock (Class A Common Stock with respect to Checkpoint) will at all times constitute a voting majority. Each share of Class A Preferred Stock (Class A Common Stock with respect to Checkpoint) 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 Class A Preferred Stock (and the Class A Common Stock with respect to Checkpoint), 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") until the date all outstanding Class A Preferred Stock (Class A Common Stock with respect to Checkpoint) 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 Class A Preferred Stock (Class A Common Stock with respect to Checkpoint) 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 would survive 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 and the partner companies'/subsidiaries' certificates of incorporation.

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

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

Note 2: Pursuant to the terms of the agreement between Avenue and InvaGen Pharmaceuticals, Inc. during the term of the Avenue SPMA PIK dividends were not be paid or accrued. Upon the repurchase of the securities held by InvaGen, such PIK dividends have resumed.

Note 3: Pursuant to the Share Contribution Agreement between Fortress and Avenue, under which Baergic became a majority-controlled and owned subsidiary of Avenue, Fortress also assigned to Avenue the Founders Agreement previously between Fortress and Baergic, such that Baergic's annual PIK dividend is now payable to Avenue.

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

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

Equity Fees

The following table summarizes, by subsidiary, 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, 2023 and 2022 ($ in thousands):

Partner company	PIK Dividend Date	Year Ended December 31, 2023	2022
Aevitas	July 28	$ —	$ 23
Avenue	January 1	271	268
Baergic[1]	December 17	—	—
Cellvation	October 31	10	10
Checkpoint	January 1	3,418	1,885
Cyprium	January 1	304	422
Helocyte	January 1	120	90
Mustang	January 1	477	1,109
Oncogenuity	May 8	9	8
Urica	November 25	501	51
Fortress		(5,110)	(3,866)
Total		$ —	$ —

Note 1: Pursuant to the Share Contribution Agreement between Fortress and Avenue, under which Baergic became a majority-controlled and owned subsidiary of Avenue, Fortress also assigned to Avenue the Founders Agreement previously between Fortress and Baergic, such that Baergic's annual PIK dividend is now payable to Avenue.

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 (5) years. 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**	**2023**	**2022**
Aevitas[1]	July 28, 2017	$ —	$ 500
Avenue	February 17, 2015	500	83
Baergic[2]	March 9, 2017	—	417
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	1,000
Oncogenuity	February 10, 2017	500	500
Urica	November 7, 2017	500	500
Fortress		(4,000)	(5,000)
Consolidated (Income)/Expense		$ —	$ —

Note 1: Aevitas was deconsolidated in April 2023 as a result of the Asset Purchase Agreement with 4DMT (see Note 3).

Note 2: Pursuant to the Share Contribution Agreement between Fortress and Avenue, under which Baergic became a majority-controlled and owned subsidiary of Avenue, Fortress also assigned to Avenue the Founders Agreement previously between Fortress and Baergic, such that Baergic's annual MSA is now payable to Avenue.

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.

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.

The components of the income tax provision are as follows:

($ in thousands)	Year Ended December 31, 2023	2022
Current		
Federal	$ 33	$ —
State	254	449
Deferred		
Federal	194	—
State	39	—
Total	$ 521	$ 449

For the years ended December 31, 2023 and 2022, income tax expense was $0.5 million and $0.4 million, respectively, resulting in an effective income tax rate of -0.3% and -0.2%. The income tax expense in 2023 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 $366.4 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:

($ in thousands)	As of December 31, 2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 211,329	$ 198,250
Amortization of license fees	33,996	30,151
Amortization of in-process R&D	315	334
Stock compensation	13,184	13,754
Lease liability	6,477	7,011
Accruals and reserves	3,897	3,402
Tax credits	37,894	33,501
Startup costs	40	42
Unrealized gain/loss on investments	55	406
Section 174 R&D expenditure capitalization	59,238	34,170
State taxes	33	192
Business interest limitation	2,880	2,359
Reserve on Sales Return, Discount and Bad Debt	4,556	2,286
Total deferred tax assets	373,895	325,858
Less: valuation allowance	(366,375)	(317,959)
Net deferred tax assets	$ 7,520	$ 7,899
Deferred tax liabilities:		
Section 483 imputed interest	$ (25)	$ (92)
Debt issuance costs	(297)	(347)
Right of use asset	(5,289)	(5,835)
Basis in subsidiary	(2,142)	(1,625)
Total deferred tax liabilities, net	$ (233)	$ —

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

	For the Year Ended December 31, 2023	2022
Percentage of pre-tax income:		
U.S. federal statutory income tax rate	21.0 %	21.0 %
State taxes, net of federal benefit	10.6 %	6.7 %
Credits	3.1 %	4.6
Non-deductible items	(0.9)%	(0.5)%
Provision to return	(0.7)%	1.8 %
Stock based compensation shortfall	(2.0)%	(1.4)%
Change in state rate	4.1 %	(1.6)%
Change in valuation allowance	(31.5)%	(31.3)%
Change in subsidiary basis	(1.0)%	— %
Deconsolidation/dissolution of subsidiaries	(2.4)%	— %
Adjustment for warrants	0.9 %	0.1 %
Section 162(m) compensation disallowance	(1.2)%	(0.8)%
Other	(0.3)%	1.2 %
Effective income tax rate	(0.3)%	(0.2)%

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, 2023 and 2022. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2023 and 2022. The valuation allowance increased by a net $48.4 million during the current year.

The Company has incurred net operating losses ("NOLs") since inception. At December 31, 2023, the Company had federal NOLs of $714.4 million, which will begin to expire in the year 2032, state NOLs of $970.0 million, which will begin to expire in 2026, and federal income tax credits of $33.8 million and state income tax credits of $5.2 million, which will begin to expire in 2028. Approximately $518.9 million of the federal NOLs and $16.2 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, 2022, the company added $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 $0.1 million and approximately $32,000 of such interest as of December 31, 2023 and 2022, 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, 2020, 2021 and 2022 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 operates in two reportable segments, Dermatology Product Sales and Pharmaceutical and Biotechnology Product Development. The accounting policies of the Company's segments are the same as those described in Note 2. The following tables summarize, for the periods indicated, operating results from continued operations by reportable segment:

Year Ended December 31, 2023	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net revenue	$ 79,181	$ 5,332	$ 84,513
Cost of goods - product revenue	(26,660)	—	(26,660)
Research and development	(7,541)	(98,530)	(106,071)
Selling, general and administrative	(47,053)	(47,071)	(94,124)
Other expense	(1,559)	(9,732)	(11,291)
Income tax expense	(221)	(300)	(521)
Segment loss	$ (3,853)	$ (150,301)	$ (154,154)

Year Ended December 31, 2022	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net revenue	$ 73,669	$ 2,074	$ 75,743
Cost of goods - product revenue	(30,775)	—	(30,775)
Research and development	(10,943)	(123,933)	(134,876)
Selling, general and administrative	(59,503)	(54,153)	(113,656)
Other expense	(2,048)	(7,852)	(9,900)
Income tax (expense) benefit	—	(449)	(449)
Segment loss	$ (29,600)	$ (184,313)	$ (213,913)

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

($ in thousands) December 31, 2023	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Total Assets
Intangible assets, net	$ 20,287	$ —	$ 20,287
Tangible assets	56,561	90,678	147,239
Total segment assets	$ 76,848	$ 90,678	$ 167,526

($ in thousands) December 31, 2022	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Total Assets
Intangible assets, net	$ 27,197	$ —	$ 27,197
Tangible assets	77,964	189,140	267,104
Total segment assets	$ 105,161	$ 189,140	$ 294,301

19. Revenues from Contracts and Significant Customers

Disaggregation of Total Revenues

All of Journey's product revenues are recorded in the U.S. The Company's collaboration revenue is from Cyprium's agreement with Sentynl (see Note 3). The Company's related party revenue is from Checkpoint's collaborations with TGTX (see Note 16).

The table below summarizes the Company's revenue for the years ended December 31, 2023 and 2022:

	Year Ended December 31, 2023	2022
Revenue		
Qbrexza	$ 25,410	$ 26,715
Accutane	20,168	18,373
Amzeeq	6,201	7,242
Zilxi	1,962	2,273
Targadox	3,204	7,972
Exelderm	2,395	3,463
Ximino	287	4,957
Luxamend	35	—
Collaboration revenue	5,229	1,882
Revenue – related party	103	192
Other revenue	19,519	2,674
Total net revenue	$ 84,513	$ 75,743

Other revenue for the year ended December 31, 2023, includes royalties on sales of Rapifort® Wipes 2.5% ("Rapifort") in Japan, from Maruho, Journey's exclusive out-licensing partner in Japan, and also reflects a net $19.0 million payment from Maruho under the New License Agreement. Other revenue for the year ended December 31, 2022, included a net $2.5 million milestone payment from Maruho Co., Ltd, upon receipt of marketing and manufacturing approval for Rapifort, as well as $0.2 million in royalties from Maruho on sales of Rapifort in Japan.

Significant Customers

For the years ended December 31, 2023 and 2022, none of Journey's Dermatology Products customers accounted for more than 10.0% of its total gross product revenue.

For the year ended December 31, 2023, one of Journey's customers accounted for more than 10% of its total accounts receivable balance at 13%. For the year ended December 31, 2022, two of Journey's Dermatology Products customers accounted for more than 10% of its total accounts receivable balance at 16.7% and 10.4%.

20. Subsequent Events

January 2024 Private Placement - Avenue

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 1,940,299 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 "Inducement Letters") 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 14,600,000 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 $1.55 per share, and the November 2023 Warrants had an exercise price of $0.3006 per share. Pursuant to the Inducement Letters, (i) the January 2023 Investor agreed to exercise its January 2023 Warrants for cash at a reduced exercise price of $0.3006 per share and (ii) the November 2023 Investors agreed to exercise their November 2023 Warrants for cash at the existing exercise price of $0.3006, in each case in consideration for Avenue's agreement to issue in a private placement (x) Series A Warrants to purchase up to 16,540,299 shares of Avenue Common Stock and (y) Series B Warrants to purchase up to 16,540,299 shares of Avenue Common Stock. The gross proceeds to Avenue from the exercise of the warrants is approximately $5.0 million, before deducting placement agent fees and estimated offering costs.

Registered Direct Offering – Checkpoint

In January 2024, Checkpoint closed on a registered direct offering (the "January 2024 Registered Direct Offering") with a single institutional investor for the issuance and sale of 1,275,000 shares of its common stock and 6,481,233 Pre-Funded Warrants. Each Pre-Funded Warrant was exercisable for one share of Checkpoint common stock. The Checkpoint common stock and the Pre-Funded Warrants were sold together with common stock warrants (the "January 2024 Common Warrants") to purchase up to 7,756,233 shares of Checkpoint common stock, at a purchase price of $1.805 per share of common stock and $1.8049 per Pre-Funded Warrant. The Pre-Funded Warrants are funded in full at closing except for a nominal exercise price of $0.0001 and are exercisable commencing on the closing date and will terminate when such Pre-Funded Warrants are exercised in full. The 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 January 2024 Registered Direct Offering were $12.8 million after deducting commissions and other transaction costs. As of March 19, 2024, 2,661,233 Pre-Funded warrants from the January 2024 Registered Direct Offering were fully exercised.

Nasdaq Hearing Panel Meeting - Avenue

On February 15, 2024, Avenue met with the Nasdaq Hearings Panel regarding the outstanding Nasdaq deficiencies and on March 11, 2024, the Nasdaq Hearings Panel informed Avenue that it granted Avenue's request for an extension until May 20, 2024 to demonstrate compliance with the Stockholders' Equity Requirement and Minimum-Bid Price Requirement. Avenue is considering all options available to it to regain compliance with these rules; however, there can be no assurance that Avenue will be able to evidence compliance with the Stockholders' Equity Requirement and the Minimum-Bid Price Requirement within the extension period granted by the Panel.

Registered Direct Offering – Fortress

In January 2024, Fortress closed on a registered direct offering for the issuance and sale 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, are immediately exercisable, and will 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 $10.2 million.

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

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 28, 2024

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 (*Principal Executive Officer*)	March 28, 2024
/s/ David Jin David Jin	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	March 28, 2024
/s/ Eric K. Rowinsky, M.D. Eric K. Rowinsky, M.D.	Vice Chairman of the Board of Directors	March 28, 2024
/s/ Michael S. Weiss Michael S. Weiss	Executive Vice Chairman, Strategic Development and Director	March 28, 2024
/s/ Jimmie Harvey, Jr., M.D. Jimmie Harvey, Jr., M.D.	Director	March 28, 2024
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director	March 28, 2024
/s/ Dov Klein Dov Klein	Director	March 28, 2024
/s/ J. Jay Lobell J. Jay Lobell	Director	March 28, 2024
/s/ Kevin L. Lorenz, J.D. Kevin Lorenz	Director	March 28, 2024
/s/ Lucy Lu, M.D. Lucy Lu, M.D.	Director	March 28, 2024

Exhibit 4.4

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 amended and restated 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 amended and restated 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 current date, 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 defined below). At present, 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, 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 Series A Preferred Stock ("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 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.

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

Oaktree Warrants

As of December 31, 2023, there were 116,624 warrants to purchase our Common Stock (the "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 Oaktree Warrants allow for Oaktree and certain of its affiliates to purchase up to 116,624 shares of our Common Stock.

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

Exercisability

The Oaktree Warrants became exercisable immediately upon issuance for a period of ten (10) years. The 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 Oaktree Warrant is exercisable for one share of our Common Stock (subject to adjustment, as discussed below). The holders of the Oaktree Warrants do not have the right to exercise any portion of the 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 Oaktree Warrants was originally $48.00 per share. On June 13, 2023, the Company lowered the exercise price of the Oaktree Warrants to $8.136 per share. The exercise price and the number of shares of Common Stock issuable upon exercise of the 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 Oaktree Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holders of the Oaktree Warrants do not have the rights or privileges of holders of our Common Stock, including any voting rights, until they exercise their Oaktree Warrants.

Fractional Shares

No fractional shares of Common Stock will be issued upon the exercise of the 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 Oaktree Warrants may be offered for sale, sold, transferred or assigned without our consent.

Governing Law

The Oaktree Warrants are governed by New York law.

Consulting Warrants

As of December 31, 2023, there were 6,664 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 6,664 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, 2023, there were 5,660,000 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 5,660,000 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 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 exercised. 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 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.

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.

EXHIBIT 21.1

SUBSIDIARIES OF FORTRESS BIOTECH, INC.

Subsidiaries of Fortress Biotech, Inc. at December 31, 2023, 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)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-238327, 333-249983, 333-255185, 333-258145, and 333-269687) on Form S-3 and (Nos. 333-184616, 333-194588, 333-206645, 333-221485, 333-233195, 333-249985, 333-267977, 333-274781, and 333-274782) on Form S-8 of our report dated March 28, 2024, with respect to the consolidated financial statements of Fortress Biotech, Inc.

KPMG LLP

Short Hills, NJ

March 28, 2024

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lindsay A. Rosenwald, M.D. certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2023 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 28, 2024

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

EXHIBIT 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Jin, certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2023 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 28, 2024

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

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Fortress Biotech, Inc. (the "Company") for the period ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lindsay A. Rosenwald, M.D., Chairman, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 28, 2024

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

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Fortress Biotech, Inc. (the "Company") for the period ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Jin, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 28, 2024

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

Exhibit 97.1

FORTRESS BIOTECH, INC.

Clawback Policy
Effective as of October 2, 2023

The Board of Directors ("Board") of Fortress Biotech, Inc. ("**Company**") believes that it is in the best interests of the Company and its shareholders to adopt this Clawback Policy ("**Policy**") which provides for the recoupment of certain executive compensation in the event of an Accounting Restatement (as defined below).

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Securities Exchange Act of 1934, as amended ("**Exchange Act**"), and final rules and amendments adopted by the Securities and Exchange Commission ("**SEC**") to implement the aforementioned legislation, and Rule 5608 of the Nasdaq Stock Exchange's listing standards.

This policy shall be effective as of October 2, 2023, the Effective Date of Rule 5608 of the Nasdaq Stock Exchange's listing standards (the "**Effective Date**") and applies to all Covered Officers (as defined below) of Fortress Biotech, Inc.

Administration

This Policy shall be administered by the Compensation Committee of the Board (if composed entirely of independent directors) or if so designated by the Board, a separate committee of the Board, consisting of a majority of the independent directors serving on the board (as applicable, the "**Administrator**"). The Administrator is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy. Any determinations made by the Administrator shall be final and binding on all affected individuals and need not be uniform with respect to each individual covered by the Policy. In the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board, such as the Audit Committee or the Compensation Committee, as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority.

Subject to any limitation under applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

Definitions

For purposes of this Policy, the following definitions will apply:

"**Accounting Restatement**" means an accounting restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, including those that either (a) correct an error in a previously issued financial statement that is material to such previously issued financial statement or (b) correct an error that is not material to a previously issued financial statement but would result in a material misstatement if left uncorrected in a current report or the error correction was not recognized in the current period.

"**Administrator**" has the meaning set forth in the "Administration" section above.

"Board" means the Company's Board of Directors.

"**Clawback Exception**" has the meaning ascribed to such term in the "Clawback Exceptions" section below.

"**Covered Officer**" means the Company's officers for purposes of Section 16 under the Exchange Act during any portion of the performance period of the Incentive-Based Compensation.

"**Excess Compensation**" means any amount of Incentive-Based Compensation Received by a Covered Officer that exceeds the amount of Incentive-Based Compensation that otherwise would have been received had it been determined based on the restated financial information or properly calculated financial measure. Excess Compensation shall be calculated on a pre-tax basis.

"**Incentive-Based Compensation**" means any non-equity incentive plan awards, bonuses paid from a bonus pool, cash awards, equity or equity-based awards, or proceeds received upon sale of shares acquired through an incentive plan; provided that such compensation is granted, earned, and/or vested based wholly or in part on the attainment of a financial performance measure, as determined in accordance with Section 10D of the Exchange Act and the Nasdaq Stock Exchange listing standards (the "**Clawback Rules**"). Incentive-Based Compensation does not include any salaries, discretionary bonuses, non-equity incentive plan awards earned upon satisfying a strategic measure or operational measure (e.g., completion of a project), or equity-based awards that are not contingent on achieving any financial reporting measure (e.g., time vested stock options, restricted stock or restricted stock units).

"**Look-Back Period**" means the three (3) completed fiscal years immediately preceding the earlier of the date on which (a) the Board or appropriate committee concludes, or reasonably should have concluded, that an Accounting Restatement is required or (b) a regulator directs an Accounting Restatement.

"**Received**" means any Incentive-Based Compensation that is received during the fiscal year in which the applicable financial reporting measure upon which the payment is based is achieved, even if payment or grant of the Incentive-Based Compensation occurs after the end of such period.

Clawback Due to Accounting Restatement

In the event the Company is required to prepare an Accounting Restatement, the Administrator shall require reimbursement or forfeiture ("**clawback**") of any Excess Compensation Received by any Covered Officer (current or former) during the applicable Look-Back Period, regardless of whether the Covered Officer engaged in misconduct or was otherwise directly or indirectly responsible, in whole or in part, for the Accounting Restatement.

In the event the Administrator cannot determine the Excess Compensation from the information in the Accounting Restatement or from the recalculated financial measure, then it will make its determination based on a reasonable estimate of the effect of the Accounting Restatement or recalculation. Such determination will be final and binding.

If a Clawback Exception applies with respect to a Covered Officer, the Company may forgo the recovery described in this Section from such Covered Officer.

Clawback Method

The Administrator may determine, in its sole discretion, the method for the clawback of any amounts due under this Policy, which may include without limitation direct payment from the Covered Officer, recovery over time, the forfeiture or reduction of future pay or awards, or any other method that will provide for recovery within a reasonable manner and without undue delay. The Company may enter into deferred payment plans with Covered Officers to effectuate clawback to avoid unreasonable economic hardship. Any amounts due under this Policy may be deducted as an offset from amounts due to the Covered Officer from the Company, except to the extent such set-off is prohibited by law or would violate Section 409A of the Internal Revenue Code of 1986, as amended and the regulations thereunder.

Clawback Exceptions

The Company will be required, in the event of an Accounting Restatement, to recover all Excess Compensation received by a Covered Officer during the Look-Back Period unless: (i) one of the following conditions is met; and (ii) the Committee has made a determination that recovery would be impracticable in accordance with Rule 10D-1 of the Exchange Act:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount

to be recovered (and the Company has already made a reasonable attempt to recover such erroneously awarded Excess Compensation from such Covered Officer, has documented such reasonable attempt(s) to recover, and has provided such documentation to the Nasdaq Stock Exchange);

(ii) recovery would violate home country laws that existed at the time of adoption of the rule and the Company receives an opinion of counsel to that effect; or

(iii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code and regulations thereunder. For purposes of clarity, this Clawback Exception only applies to tax-qualified retirement plans and does not apply to other plans, including long term disability, life insurance, and supplemental executive retirement plans, or any other compensation that is based on Incentive-Based Compensation in such plans, such as earnings accrued on notional amounts of Incentive-Based Compensation contributed to such plans.

General

The Company shall not indemnify any Covered Officer against the loss of any covered compensation as a result of the application of this Policy.

This Policy is in addition to (and not in lieu of) any right of repayment, forfeiture or right of offset against any employees that is required pursuant to any statutory repayment requirement (regardless of whether implemented at any time prior to or following the adoption or amendment of this Policy), including Section 304 of the Sarbanes-Oxley Act of 2002. Any amounts paid to the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 shall be considered in determining any amounts recovered under this Policy.

The terms of this Policy shall be binding and enforceable against all Covered Officers subject to this Policy and their beneficiaries, heirs, executors, or other legal representatives. If any provision of this Policy or the application of such provision to any Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision (or the application of such provision) valid, legal or enforceable.

Each Covered Officer shall sign and return to the Company, within the later of: (i) 60 calendar days following the Effective Date or (ii) 30 calendar days following the date the individual becomes a Covered Officer, the Acknowledgement and Agreement Form attached hereto as Exhibit A, pursuant to which the Covered Officer agrees to be bound by, and to comply with, the terms and conditions of this Policy.

To the extent the Clawback Rules require recovery of Incentive-Based Compensation in additional circumstances beyond those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Clawback Rules.

The Board may amend this Policy from time-to-time in its discretion and as necessary to comply with any rules or standards adopted by the SEC and the listings standards of any national securities exchange on which the Company's securities are listed.

Exhibit A

Fortress Biotech, Inc. (the "Company")
Clawback Policy

Acknowledgement and Agreement Form

I, the undersigned, acknowledge and agree that I have received and reviewed the Clawback Policy of Fortress Biotech, Inc. (the "**Policy**"), effective as of October 2, 2023, as adopted by the Company's Board of Directors.

Furthermore, I acknowledge and agree:

- that I am fully bound by, and subject to, all of the terms and conditions of the Policy, as may be amended, restated, supplemented or otherwise modified from time to time.
- that I have been designated as a "Covered Officer" as defined in the policy.
- that my execution of this Acknowledgement and Agreement Form is in consideration of, and is a condition to, my continued employment (if currently an employee) and my receipt of future awards from the Company, though nothing in this Acknowledgement and Agreement Form shall obligate the Company to make any particular award.

In the event of any inconsistency between the Policy and the terms of any employment agreement to which I am a party, or to the terms of any compensation plan, program, agreement or arrangement under which any incentive-based compensation covered by the Policy is payable, the terms of this Policy shall govern and shall be deemed incorporated into all such plans, programs, agreements (including any employment agreements) or arrangements, including and without limitation, those granted or awarded prior to the date hereof and those granted or awarded in the future.

In the event any Incentive-Based Compensation (as defined in the Policy) is subject to recoupment or recovery under the terms of the Policy, I will promptly take any action necessary to effectuate the recoupment or recovery of such compensation by the Company.

COVERED OFFICER

_____
Signature

_____
Print Name

_____
Date