Table of Contents

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, 2022

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)**	**10014** **(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: $66,379,178.

Class of Stock	Outstanding Shares as of March 27, 2023
Common Stock, $0.001 par value	129,763,114
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock, $0.001 par value	3,427,138

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

FORTRESS BIOTECH, INC.
ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

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 that 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. We have attempted to identify forward-looking statements by terminology including "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. Factors that could cause actual results to differ materially from those currently anticipated include those set forth under "Item 1A. Risk Factors" including, in particular, risks relating to:

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

We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law. 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 presentation should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

SUMMARY RISK FACTORS

Our business is subject to risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risk factors, the risk factors described in Item 1A, and the other reports and documents that we have filed with the Securities and Exchange Commission ("SEC"). As used below and throughout this filing (including in the risk factors described in Item 1A), the words "we", "us" and "our" may refer to Fortress Biotech, Inc. individually, to one or more of its subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context.

Risks Inherent in Drug Development

- Many of our product candidates are in early development stages and are subject to time and cost intensive regulation and clinical testing, which may result in the identification of safety or efficacy concerns. As a result, our product candidates may never be successfully developed or commercialized.
- Our competitors may develop treatments for our products' target indications, which could limit our product candidates' commercial opportunity and profitability.

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

- We have a history of operating losses and expect such losses to continue in the future.
- We have funded our operations in part through the assumption of debt, and the applicable lending agreements may restrict our operations. Further, the occurrence of any default event under an applicable loan document could adversely affect our business.
- Our research and development ("R&D") programs will require additional capital, which we may be unable to raise as needed and which may impede our R&D programs, commercialization efforts, or planned acquisitions.
- If we raise additional capital by issuing equity or equity-linked securities, our existing stockholders will be diluted.

Risks Pertaining to Our Existing Revenue Stream from Journey Medical Corporation ("Journey")

- Our operating income derives primarily from the sale of our partner company Journey's dermatology products, particularly Qbrexza, Accutane, Amzeeq, Zilxi, Targadox, Ximino, and Exelderm,. Any issues relating to the manufacture, sale, utilization, or reimbursement of Journey's products (including products liability claims) could significantly impact our operating results.
- A significant portion of Journey's sales derive from products that are without patent protection and/or are or may become subject to third party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse effect on our operating income. Four of Journey's marketed products, Qbrexza, Amzeeq, Zilxi and Ximino, 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. 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 as the Paragraph IV certification made by Perrigo pertaining to the patents covering Qbrexza, and subsequently, Amzeeq, and Zilxi, three products being commercialized by our partner company Journey. Such challenges may subject us to costly and time-consuming litigation and/or PTO proceedings.
- As a result of the loss of any patent protection from such litigation or PTO proceedings, or the "at-risk" launch by a generic competitor of our products, our products could be sold at significantly lower prices, and we could lose a significant portion of product sales in a short period of time, which could adversely affect our business, financial condition, operating results and prospects.

Risks Pertaining to the Commercialization of Product Candidates

- If our products are not broadly accepted by the healthcare community, the revenues from any such products are likely to be limited.
- We may not obtain the desired product labels or intended uses for product promotion, or favorable scheduling classifications desirable to successfully promote our products.
- Even if a product candidate is approved, it may be subject to various post-marketing requirements, including studies or clinical trials, the results of which could cause such products to later be withdrawn from the market.
- Any successful products liability claim related to any of our current or future product candidates may cause us to incur substantial liability and limit the commercialization of such products.

Risks Pertaining to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries

- We operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations.

General and Other Risks

- On October 31, 2022, we received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market LLC ("Nasdaq") indicating that the bid price of the Company's common stock, par value $0.001 per share (the "Common Stock"), had closed below $1.00 per share for 30 consecutive business days and, as a result, the Company is not in compliance with Nasdaq Listing Rule 5550(a)(2), which sets forth the minimum bid price requirement for continued listing on The Nasdaq Capital Market. Our Common Stock may be subject to delisting from The Nasdaq Capital Market if we are unable to regain compliance which may decrease the market liquidity and market price of our Common Stock.

PART I

Item 1. Business.

Overview

Fortress Biotech, Inc. ("Fortress" or the "Company") is a biopharmaceutical company dedicated to acquiring, developing and commercializing pharmaceutical and biotechnology products and product candidates, which we do through Fortress itself and through partner companies and subsidiaries. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who work in concert with our extensive network of key opinion leaders to identify and evaluate promising products and product candidates for potential acquisition . We have executed arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center, Fred Hutchinson Cancer Center, St. Jude Children's Research Hospital ("St. Jude"), Dana-Farber Cancer Institute, Nationwide Children's Hospital, Cincinnati Children's Hospital Medical Center, Columbia University, the University of Pennsylvania, Mayo Foundation for Medical Education and Research ("Mayo Clinic"), AstraZeneca plc, and Dr. Reddy's Laboratories, Ltd.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and financial expertise to help the partners achieve their goals. Partner companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out-licensings, sales transactions, and public and private financings. To date, four partner companies are publicly-traded, and 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. In October 2021, AstraZeneca purchased 100% of our partner Caelum for approximately $150 million upfront and up to $350 million in contingent regulatory and sales milestone payments.

Our subsidiary and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates are Aevitas Therapeutics, Inc. ("Aevitas"), 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") (formerly known as UR-1 Therapeutics, Inc.).

As used throughout this filing, the words "we", "us" and "our" may refer to Fortress individually, to one or more of its subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context. Generally, "subsidiary" refers to a private Fortress subsidiary, "partner company" refers to a public Fortress subsidiary, and "partner" refers to entities with whom one of the foregoing parties has a significant business relationship, such as an exclusive license or an ongoing product-related payment obligation. The context in which any such term is used throughout this document, however, may dictate a different construal from the foregoing.

Product Candidates and Other Intellectual Property

Commercialized Products

Through our partner company Journey we actively market the following branded dermatology products:

Qbrexza®: Qbrexza (glycopyrronium 2.4%) is a medicated cloth towelette for the treatment of primary axillary hyperhidrosis in adults and children 9 years and older.

Accutane®: Accutane (isotretinoin) is an oral capsule for the treatment of severe recalcitrant nodular acne.

Amzeeq®: Amzeeq (minocycline 4%) topical foam, is the first and only topical minocycline treatment for the inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and children 9 years and older.

Zilxi®: Zilxi (minocycline 1.5%) is a topical foam and the first and only topical minocycline treatment for inflammatory lesions of rosacea in adults.

Ximino®: Ximino (minocycline hydrochloride) is an oral minocycline drug for the treatment of moderate to severe acne.

Exelderm®: Exelderm (sulconazole nitrate) Cream and Solution are broad-spectrum antifungal intended for topical use.

Targadox®: Targadox (doxycycline hyclate) is an oral doxycycline drug for adjunctive therapy for severe acne.

Additionally, Journey sells three authorized generic products:

- minocycline hydrocholoride extended release capsules, launched in April 2020;
- sulconazole nitrate cream and solution, launched in January 2020; and
- doxycycline hyclate immediate release tablets, launched in May 2018.

Late Stage Product Candidates

Cosibelimab (Anti-PD-L1 mAb for CSCC)

Our partner company Checkpoint is currently evaluating its lead product candidate, cosibelimab, an anti-programmed death-ligand 1 ("PD-L1") antibody licensed from the Dana-Farber Cancer Institute, in an ongoing global, open-label, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts in locally advanced and metastatic cutaneous squamous cell carcinoma ("CSCC") intended to support one or more applications for marketing approval. Based on top-line and interim results in metastatic and locally advanced CSCC, respectively, Checkpoint submitted a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for these indications in January 2023, which application is filed and under review with a Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024. Additional information on the Phase 1 trial can be found on ClinicalTrials.gov using identifier NCT03212404. The information contained on this website is not included in, or incorporated by reference into, this Annual Report on Form 10-K.

In June 2022, Checkpoint announced interim results from a registration-enabling cohort of our multi-regional, Phase 1 clinical trial of cosibelimab in patients with locally advanced CSCC that are not candidates for curative surgery or radiation. Cosibelimab demonstrated a confirmed objective response rate ("ORR") of 54.8% (95% CI: 36.0, 72.7) based on independent central review of 31 patients enrolled in the cohort using Response Evaluation Criteria in Solid Tumors version 1.1 ("RECIST 1.1").

In January 2022, Checkpoint announced top-line results from a registration-enabling cohort of our multi-regional, Phase 1 clinical trial of cosibelimab in patients with metastatic CSCC. The cohort met its primary endpoint, with cosibelimab demonstrating a confirmed ORR of 47.4% (95% CI: 36.0, 59.1) based on independent central review of 78 patients enrolled in the metastatic CSCC cohort using RECIST 1.1.

Checkpoint also has 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 retains the right to develop and commercialize these assets in solid tumors.

In December 2021, Checkpoint announced the initiation of its' CONTERNO study, a multi-regional, open-label, multi-center, randomized Phase 3 trial of cosibelimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with non-small cell lung cancer ("NSCLC"). The February 2022 invasion of Ukraine and the ensuing response disrupted our ability to conduct clinical trials in the region. The substantially longer enrollment period in other planned countries made the conduct of the CONTERNO study no longer viable. Accordingly, Checkpoint expects that the study will be wound down and closed by the end of the first quarter of 2023.

CUTX-101 (Copper Histidinate injection for Menkes Disease)

Our partner company Cyprium is currently 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 also 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.

Cyprium also continues to asses and enroll prospective patients into its Intermediate-Size Patient Population Expanded Access Protocol. Additional information on the Expanded Access study and requirements can be found on ClinicalTrials.gov using identifier NCT04074512.

In February 2021, Cyprium announced the execution of an asset purchase agreement with Sentynl, a U.S.-based specialty pharmaceutical company owned by the Zydus Group. Pursuant to the asset purchase agreement, Sentynl paid Cyprium an upfront fee of $8.0 million upon execution, and Cyprium remains eligible to receive up to $12.0 million in additional future development cash milestones through New Drug Application ("NDA") approval. Cyprium is also eligible to receive up to $255.0 million in sales milestone payments (payable pursuant to five separate milestones). Royalties on CUTX-101 net sales ranging from the mid-single digits up to the mid-twenties are also payable. All of the foregoing milestone and royalty payments are subject to 50% diminution in the event Sentynl decides, at its option, to assume development control of CUTX-101 during the 45-day period beginning on September 30, 2023. Under the asset purchase agreement, Cyprium retains development responsibility of CUTX-101 (subject to the aforementioned right by Sentynl to assume development) and Sentynl will be responsible for commercialization of CUTX-101 as well as progressing newborn screening activities. Continued development of CUTX-101 is overseen by a Joint Steering Committee consisting of representatives from Cyprium and Sentynl. Cyprium will in any event retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.

In October 2021, Cyprium announced positive results from an efficacy and safety analysis of data integrated from two completed pivotal studies in patients with Menkes disease treated with CUTX-101, copper histidinate (CuHis). These data were presented as a virtual poster at the 2021 American Academy of Pediatrics National Conference & Exhibition.

On December 7, 2021, Cyprium announced the initiation of a rolling submission of its NDA to the FDA for CUTX-101 for the treatment of Menkes disease. Cyprium expects the rolling submission to complete in 2023.

Cyprium is currently in a dispute with its contract manufacturing organization (the "CMO"), regarding the CMO's attempt to terminate a Master Services Agreement (together with related work orders, the "MSA") between Cyprium and the CMO. Cyprium believes the CMO's grounds for purporting to terminate the MSA are without merit and is currently availing itself of all appropriate legal remedies in efforts to ensure that the CMO abides by its obligations under the MSA and/or to pursue monetary damages claims against the CMO. To that end, Cyprium obtained a temporary restraining order in August 2022 and a preliminary injunction in September 2022 from a court in New York State; the injunction invalidated the CMO's attempted termination of the MSA and prohibited the CMO from further attempts to terminate the MSA during the pendency of dispute resolution procedures, which are ongoing.

Intravenous (IV) Tramadol

Our partner company Avenue is developing intravenous Tramadol ("IV Tramadol"), 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 Complete Response Letter ("CRL") received in October 2020, resubmitted the NDA in February 2021. In August 2021 Avenue submitted a formal dispute resolution request ("FDRR"), of which we received notice of denial in March 2022 after an Advisory Committee meeting in February 2022. Avenue then participated in a Type A Meeting with the FDA in August 2022, which resulted in a collaborative discussion on study design and a potential path forward. Avenue incorporated the FDA's suggestions from the meeting minutes and submitted a detailed study protocol that could form the basis for the submission of a complete response to the Second CRL. Avenue announced on March 8, 2023 that the Company would participate in a Type C meeting with the FDA on March 9, 2023 to discuss a proposed study protocol to assess the risk of respiratory depression related to opioid stacking on IV Tramadol relative to an approved opioid analgesic and continues to evaluate next steps with regard to IV Tramadol.

MB-107 and MB-207 (Ex vivo Lentiviral Therapy for X-linked Severe Combined Immunodeficiency ("XSCID"))

Our partner company Mustang collaborates with St. Jude in the development of a first-in-class *ex vivo* lentiviral gene therapy for the treatment of XSCID, also known as bubble boy disease. In August 2018, Mustang entered into an exclusive worldwide license agreement with St. Jude for the development of this therapy. XSCID is the most common form of severe combined immune deficiency. This gene therapy is currently in two Phase 1/2 clinical trials involving two different autologous cell products: a multicenter trial of the MB-107 product in newly diagnosed infants sponsored by St. Jude (ClinicalTrials.gov Identifier: NCT01512888) 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).

MB-107 (for newly diagnosed infants with XSCID)

Interim Phase 1/2 data on treatment of newly diagnosed infants under the age of two with MB-107 were updated at an oral presentation at the American Society of Gene & Cell Therapy 25th Annual Meeting in May 2022. All patients were alive with stable vector marking in all cell lineages, and no evidence of clonal expansion or malignant transformation was observed.

In May 2020, Mustang submitted an Investigational New Product Drug Application ("IND") application with the FDA to initiate a pivotal non-randomized multicenter Phase 2 clinical trial of MB-107 in newly diagnosed infants with XSCID who are under the age of two. In response, the FDA identified Chemistry, Manufacturing and Controls ("CMC") hold issues that Mustang satisfactorily addressed in a December 2020 submission to the Agency, and the CMC hold was removed in January 2021.

MB-107 has received Orphan Drug Designation and Rare Pediatric Disease, and Regenerative Medicine Advanced Therapy ("RMAT") designations from the FDA. EMA has granted to MB-107 Priority Medicines ("PRIME") designation, Advanced Therapy Medicinal Product ("ATMP") classification, and Orphan Drug Designation.

MB-207 (for previously transplanted patients with XSCID)

The most recent peer-reviewed presentation of data from the MB-207 trial at the NIH occurred at the 61st Annual Meeting of the American Society of Hematology in December 2019. With the exception of one patient who died of a pre-existing lung condition after full immune reconstitution, all patients were alive with stable vector marking in all cell lineages, and no evidence of clonal expansion or malignant transformation was observed. In February 2021, Mustang announced an encouraging clinical update from this trial, including consistent safety and efficacy data.

Mustang filed an IND in the fourth quarter of 2021 for a pivotal non-randomized multicenter Phase 2 clinical trial of MB-207 in previously transplanted XSCID patients. In January 2022, the FDA issued a hold, pending CMC clearance, on Mustang's IND application.

The FDA has granted MB-207 Rare Pediatric Disease Designation and Orphan Drug Designation. The EMA has granted ATMP classification and Orphan Drug Designation to MB-207.

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. Olafernitib 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.

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. Checkpoint has met with the FDA to discuss the adequacy of the ongoing Phase 3 trial in China.

CAEL-101 (Light Chain Fibril-reactive 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.

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, 24-month escrow holdback amount and other miscellaneous transaction expenses. The agreement also provides for additional potential payments to Caelum shareholders totaling up to $350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive 42.4% of all possible proceeds of the transaction, totaling up to approximately $212 million.

Triplex (Vaccine for Cytomegalovirus)

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 found 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 efficacious in reducing CMV events in allogeneic stem cell transplant recipients (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 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 City of Hope National Medical Center ("COH") in April 2015. Helocyte secured an exclusive, worldwide license to Triplex from City of Hope National Medical Center ("COH") in April of 2015.

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 had 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. The trial is expected to commence in 2023.

CEVA101 (Cellular Therapeutic for Severe Traumatic Brain Injury)

Through our subsidiary Cellvation, we are developing CEVA101, a cellular product comprised of autologous Bone Marrow-derived Mononuclear Cells currently being developed for the treatment of severe traumatic brain injury ("TBI") in adults and children. In separate Phase 1 trials of adults and children with severe TBI, CEVA101 was observed to be safe, well-tolerated and efficacious (resulting in volumetric preservation versus time-matched controls, and in the case of children, reducing the Pediatric Intensity Level of Therapy or PILOT score, ClinicalTrials.gov Identifiers: NCT01575470 and NCT0254722).

In a randomized, placebo-controlled, multi-center Phase 2 study of children with severe TBI completed in November 2020, CEVA101 was similarly observed to be safe, well-tolerated and efficacious (resulting in volumetric preservation and a reduction in the PILOT score of those receiving CEVA101 versus those receiving placebo), (ClinicalTrials.gov Identifier: NCT01851083). A randomized, placebo-controlled Phase 2 study of CEVA101 for the treatment of severe TBI in adults is ongoing (ClinicalTrials.gov Identifier: NCT02525432). Cellvation received RMAT designation for CEVA101 in the treatment of severe TBI. Cellvation secured an exclusive worldwide license to CEVA101 (as well as CEVA-D and CEVA102) from University of Texas Health Science Center at Houston in October of 2016.

DFD-29 (Modified Release Oral Minocycline for Inflammatory Lesions 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. Journey initiated the Phase 3 trials in the first quarter of 2022, and completed enrollment in January 2023. Top-line data is expected in the first half of 2023, with a potential NDA filing anticipated in the second half of 2023.

Early Stage Product Candidates

Dotinurad

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.

In December 2022, Urica announced the expansion of our license to include additional territories in the Middle East and North Africa ("MENA") and Turkey territories.

Urica initiated a Phase 1 clinical trial in June 2022 to evaluate Dotinurad for the treatment of gout; we anticipate topline data in the first half of 2023.

MB-106 (CD20 CAR T for B-cell non-Hodgkin lymphoma ("B-NHL") and chronic lymphocytic leukemia("CLL"))

CD20 is a B-cell lineage-specific phosphoprotein that is expressed in high, homogeneous density on the surface of more than 95% of B-cell NHL. CD20 is stable on the cell surface with minimal shedding or internalization upon binding antibody and is present at only nanomolar levels as soluble antigen. It is well established as an effective immunotherapy target, with extensive studies demonstrating improved tumor responses and survival of B-NHL patients treated with rituximab and other anti-CD20 antibodies. MB-106 is a CD20-targeted third-generation autologous CAR T cell therapy is being developed by our partner company Mustang in a collaboration with Fred Hutch.

More than 80,000 new cases of NHL are diagnosed each year in the United States, and over 20,000 patients die of this group of diseases annually. Most forms of NHL including follicular lymphoma, mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytic lymphoma, and small lymphocytic lymphoma, which account collectively for ~45% of all cases of NHL, are incurable with available therapies, except for allogenic hematopoietic stem cell transplant ("allo-SCT"). However, many NHL patients are not suitable candidates for allo-SCT, and this treatment is also limited by significant rates of morbidity and mortality due to graft- versus-host disease.

Chronic lymphocytic leukemia/small lymphocytic lymphoma ("CLL/SLL") is a mature B cell neoplasm characterized by a progressive accumulation of monoclonal B lymphocytes. CLL is considered to be identical (i.e., one disease with different manifestations) to NHL SLL. CLL is the most common leukemia in adults in Western countries, accounting for approximately 25 to 35 percent of all leukemias in the United States. It is estimated that over 18,000 new cases of CLL/SLL will be diagnosed in the United States in 2023.

Most patients will have a complete or partial response to initial therapy. However, conventional therapy for CLL is not curative and most patients experience relapse. In addition, many patients will require a change in therapy due to intolerance. Since patients with CLL are generally elderly with a median age older than 70 years, and due to the relatively benign course of the disease in the majority of patients, only selected patients are candidates for intensive treatments such as allo-SCT. Innovative new treatments with a favorable safety profile are therefore urgently needed for patients with relapsed and refractory disease.

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 October 2022, Mustang treated the first patient in the Company-sponsored Phase 1/2 clinical study of MB-106 in patients with relapsed or refractory B cell NHL or CLL (Clinicaltrials.gov Identifier: NCT05360238). As of December 2022, Mustang dosed five patients at the starting dose level of their respective protocol arms. The study is also being supported by a grant of approximately $2 million from the National Cancer Institute ("NCI").

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 13,000 new glioblastoma cases were predicted in the U.S. for 2022. 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:

1. MB-101 with or without nivolumab and ipilimumab in treating patients with recurrent or refractory glioblastoma (currently enrolling patients; ClinicalTrials.gov Identifier: NCT04003649);

2. 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 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)

MB-108 is a next-generation oncolytic herpes simplex virus ("oHSV") in development at Mustang that is conditionally replication competent; that is, it can 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 multiforme in an ongoing Phase 1 trial (ClinicalTrials.gov Identifier: NCT03657576).

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-102 (CD123 CAR T Cell Program for BPDCN, AML and high-risk MDS)

Our partner company Mustang collaborates with COH and Fred Hutchinson Cancer Center ("Fred Hutch") in the development of proprietary, autologous, chimeric antigen receptor ("CAR") engineered T-cell ("CAR T") therapies. CAR T therapies use the patient's own T-cells to engage and destroy specific tumors. The process involves selecting specific T-cell subtypes, genetically engineering them to express chimeric antigen receptors and placing them back in the patient where they recognize and destroy cancer cells. We believe that harnessing the body's own immune system to treat cancer is a promising approach to cancer care that may prove curative across tumor types that have proved resistant to standard pharmacological and biological treatments.

MB-102 is a CAR T directed against CD123, a subunit of the heterodimeric interleukin-3-receptor ("IL-3R"), which is widely expressed on human hematologic malignancies including blastic plasmacytoid dendritic cell neoplasm ("BPDCN") and acute myeloid leukemia ("AML"). In addition, CD123 can be found on the surface of B cell acute lymphoblastic leukemia ("B-ALL"), hairy cell leukemia, myelodysplastic syndrome ("MDS"), chronic myeloid leukemia ("CML") and Hodgkin lymphoma.

Of these malignancies, Mustang is currently investigating CD123 as a target for adoptive cellular immunotherapy in BPDCN, since high CD123 expression is associated with enhanced cell proliferation, increased resistance of these cells to apoptosis, and poor clinical prognosis. Depending on the early results in this patient population, Mustang may broaden the inclusion criteria to include AML and high-risk MDS ("hrMDS"). CD123 is overexpressed in the vast majority of cases of AML and hrMDS and in essentially all cases of BPDCN.

In October 2020, Mustang announced the dosing of the first patient in a multicenter Phase 1/2 clinical trial of MB-102 in patients with relapsed or refractory BPDCN (Clinicaltrials.gov Identifier: NCT04109482).

MB-104 (CS1 CAR T for Multiple Myeloma and Light Chain Amyloidosis)

Another Mustang program is a CAR T directed against CS1 (also known as CD319, CRACC and SLAMF7), which was identified as a natural killer ("NK") cell receptor regulating immune functions. It is also expressed on B cells, T cells, dendritic cells, NK-T cells, and monocytes. CS1 is overexpressed in multiple myeloma ("MM") and AL amyloidosis, which makes it a good target for immunotherapy. A humanized anti-CS1 antibody, elotuzumab (Empliciti®), is approved in combination with other medications for the treatment of adult patients with MM who have received prior therapies. Despite great advances in treatment, MM remains an incurable malignancy of plasma cells. AL is a protein deposition disorder that is a result of a plasma cell dysplasia, similar to MM. Immunotherapy is an attractive approach for AL because of the low burden of disease. Our academic partners at COH have developed a novel second generation CS1-specific CAR T cell therapy. In preclinical studies, they have demonstrated efficacy of these CAR T cells, both *in vitro* and *in vivo*, within the context of clinically relevant models of MM and AL. COH is evaluating the safety of this CS1-specific CAR T cell therapy in a Phase 1 trial (ClinicalTrials.gov Identifier: NCT03710421). Once COH has established a safe and effective dose for MB-104 in this trial, Mustang expects to file an IND for a multicenter Phase 1/2 trial for the treatment of patients with MM.

MB-103 (HER2 CAR T for GBM & Metastatic Breast Cancer to Brain)

HER2/neu (often shortened to "HER2") is a growth-promoting protein on the outside of all breast cells. Breast cancer cells with higher than normal levels of HER2 are called HER2-positive ("HER2+"). These cancers tend to grow and spread faster than other breast cancers. Breast cancer is the most commonly diagnosed cancer in women, with over 42,000 women in the United States expected to die from advanced metastatic disease in 2020. Approximately 20% to 25% of breast cancers overexpress HER2, which is an established therapeutic target of both monoclonal antibodies ("mAbs") and receptor tyrosine kinase inhibitors. With the advent of effective mAbs directed against HER2, the median overall survival of patients with metastatic HER2+ breast cancer has improved. However, management of metastatic disease in the CNS observed in up to 50% of HER2+ breast cancer patients continues to be a clinical challenge in large part due to the inability of mAbs to sufficiently cross the blood-brain barrier. Although small-molecule inhibitors of HER2 exist and have been clinically approved, their single-agent efficacy in the context of metastatic disease to the brain has been limited. While HER2-targeted therapy in combination with conventional agents has shown some promise for the treatment of patients with metastatic breast cancer, control of brain metastases remains a significant unmet clinical need, as most patients survive less than two years following CNS involvement.

CAR-based T-cell immunotherapy is being actively investigated for the treatment of solid tumors, including HER2+ cancers. Mustang's academic partners at COH have developed a second-generation HER2-specific CAR T-cell for the treatment of refractory/relapsed HER2+ GBM, as well as for the treatment of brain and/or leptomeningeal metastases from HER2+ cancers. COH's preclinical data demonstrate effective targeting of breast cancer brain metastases with intraventricular delivery of HER2-directed CAR T cells. COH is evaluating the safety of this HER2-specific CAR T cell therapy in two phase 1 trials that commenced in the fourth quarter of 2018 (ClinicalTrials.gov Identifiers: NCT03389230 and NCT03696030).

MB-105 (PSCA CAR T for Prostate & Pancreatic Cancers)

Prostate stem-cell antigen ("PSCA") is a glycosylphosphatidylinositol-anchored cell membrane glycoprotein. In addition to being highly expressed in the prostate it is also expressed in the bladder, placenta, colon, kidney, and stomach. Prostate cancer may be amenable to T cell-based immunotherapy since several tumor antigens, including PSCA, are widely over-expressed in metastatic disease. Mustang's academic partners at COH have developed a second-generation PSCA-specific CAR T cell therapy that has demonstrated robust *in vitro* and *in vivo* anti-tumor activity in patient-derived, clinically relevant, bone-metastatic prostate cancer xenograft models. COH is evaluating the safety of this PSCA-specific CAR T cell therapy in a Phase 1 trial treating patients with PSCA+ metastatic castration-resistant prostate cancer (ClinicalTrials.gov Identifier: NCT03873805).

In October 2020, Mustang announced initial data from the Phase 1 clinical trial in patients with PSCA+-positive castration-resistance prostate cancer ("CRPC"). In a presentation at the Annual Prostate Cancer Foundation Scientific Retreat, the COH principal investigator reported results from a highly refractory patient treated with MB-105 who experienced a 94 percent reduction in prostate-specific antigen (PSA), near complete reduction of measurable soft tissue metastasis by computerized tomography, and improvement in bone metastases by magnetic resonance imaging. Data presented in February 2022 indicate that PSCA-CAR T-cell therapy is feasible in patients with metastatic castration-resistant prostate cancer ("mCRPC") with a dose-limiting toxicity of cystitis, and shows preliminary anti-tumor effect at a dose of 100M cells plus lymphodepletion.

AJ201 (novel AR degrader and Nrf1 and Nrf2 activator)

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).

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.

BAER-101 (novel α2/3–subtype-selective GABA A positive allosteric modulator ("PAM"))

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.

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 continues to take place at Mayo Clinic.

AAV-ATP7A Gene Therapy

Through our subsidiary Cyprium, we are developing adeno-associated virus ("AAV") gene therapy ("AAV-ATP7A"). 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.

AVTS-001 Gene Therapy

Through our subsidiary Aevitas, we are developing AVTS-001, an AAV gene therapy to treat diseases associated with a dysregulated complement system via AAV delivery of functional short Factor H. Aevitas has licensed an engineered, fully functional shortened version of Factor H which can be packaged by AAV, from the University of Pennsylvania. Aevitas also has a collaboration 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 enhances 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 TBI.

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 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 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 rely 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 us. 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, including Galderma Laboratories, Almirall, Novan Health, 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 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 a 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.

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.

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.

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.

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 and individual United States Attorney offices within the Department of Justice, and state and local governments.

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 our products 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 Affordable Care Act ("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 following the 2020 election and subsequent change of Administration.

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, 2022, we had 187 full-time employees at Fortress and our subsidiaries and partner companies. Journey relies on professional employer organizations and staffing organizations for the employment of its field sales force, which totaled 74 at December 31, 2022. 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, 2022.

Name	Age	Position
Lindsay A. Rosenwald, M.D.	67	Chairman of the Board of Directors, President and Chief Executive Officer
David Jin	32	Chief Financial Officer
George Avgerinos, Ph.D.	69	Senior Vice President, Biologics Operations
Michael S. Weiss	56	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). 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 take several years, and it is unlikely that our product candidates, even if successfully developed and approved by the FDA and/or foreign equivalent regulatory bodies, would be commercially available for several years. Only a small percentage of drugs under development successfully obtain regulatory approval and are successfully commercialized. Accordingly, even if we are able to obtain the requisite financing to fund development programs, we cannot be sure that any of our product candidates will be successfully developed or commercialized, which could result in the failure of our business and a loss of your investment.

Pharmaceutical development has inherent risks. Before we may seek regulatory approval for the commercial sale of any of our products, we will be required to demonstrate, through well-controlled clinical trials, that our product candidates are effective and have a favorable benefit-risk profile for their target indications. Success in early clinical trials is not necessarily indicative of success in later stage clinical trials, during which product candidates may fail to demonstrate sufficient safety or efficacy, despite having progressed through initial clinical testing, which may cause significant setbacks. Further, we may need to conduct additional clinical trials that are not currently anticipated. As a result, product candidates that we advance into clinical trials may never receive regulatory approval.

Even if any of our product candidates are approved, regulatory authorities may approve any such product candidates for fewer or more limited indications than we request, may place limitations on our ability to commercialize products at the intended price points, may grant approval contingent on the product's performance in costly post-marketing clinical trials, or may approve a label that does not include the claims necessary or desirable for the successful commercialization of that product candidate. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of the product. In addition, the Drug Enforcement Agency ("DEA"), or foreign equivalent, may schedule one or more of our product candidates under the Controlled Substances Act, or its foreign equivalent, which could impede such product's commercial viability. Any of these scenarios could impact the commercial prospects for one or more of our current or future product candidates.

The extensive regulation to which our product candidates are subject may be costly and time consuming, cause anticipated delays, and/or prevent the receipt of the required approvals for commercialization.

The research and clinical development, testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of any product candidate, including our product candidates, is subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market a product candidate until the FDA approves such product candidate's BLA or NDA. The approval process is uncertain, expensive, often spans many years, and can vary substantially based upon the type, complexity and novelty of the products involved. In addition to significant and expansive clinical testing requirements, our ability to obtain marketing approval for product candidates depends on the results of required non-clinical testing, including the characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our manufacturing processes, testing procedures or equipment and facilities are inadequate to support approval. Further, the FDA has substantial discretion in the pharmaceutical approval process and may change approval policies or interpretations of regulations at any time, which could delay, limit or preclude a product candidate's approval.

The FDA and other regulatory agencies may delay, limit or refuse approval of a product candidate for many reasons, including, but not limited to:

- disagreement with the trial design or implementation of our clinical trials, including proper use of clinical trial methods and methods of data analysis;
- an inability to establish sufficient data and information to demonstrate that a product candidate is safe and/or effective for an indication;
- the FDA's rejection of clinical data from trials conducted by individual investigators or in countries where the standard of care is potentially different from that of the United States;
- the FDA's determination that clinical trial results do not meet the statistical significance levels required for approval;
- a disagreement by the applicable regulator regarding the interpretation of preclinical study or trial data;
- determination by the FDA that our manufacturing processes or facilities or those of third-party manufacturers with which we or our collaborators contract for clinical supplies or plan to contract for commercial supplies, do not satisfactorily comply with cGMPs; or

- a change to the FDA's approval policies or interpretation of regulations rendering our clinical data, product characteristics, or benefit-risk profile insufficient or unfavorable for approval.

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

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

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

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

Any regulatory approval is limited to the indications for use and related treatment of those specific diseases set forth in the approval for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

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

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

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

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

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

On August 27, 2020, we entered into the $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"). 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 $203.6 million and $188.5 million for the years ended December 31, 2022 and 2021, respectively. At December 31, 2022, we had an accumulated deficit of approximately $634.2 million. We expect to make substantial expenditures and incur increasing operating costs and interest expense in the future, and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates and finance investments in certain of our existing and new subsidiaries in accordance with our growth strategy. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity.

Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if:

- one or more of our development-stage product candidates is approved for commercial sale and we decide to commercialize such product(s) ourselves, due to the need to establish the necessary commercial infrastructure to launch and commercialize this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for manufacturing, testing, warehousing, distribution, cash collection and related commercial activities;

- we are required by the FDA or a foreign regulatory authority to perform studies in addition to those currently expected;

- there are any delays in completing our clinical trials or the development of any of our product candidates;
- we execute other collaborative, licensing or similar arrangements, depending on the timing of payments we may make or receive under these arrangements;
- there are variations in the level of expenses related to our future development programs;
- we become involved in any product liability or intellectual property infringement lawsuits; and
- there are any regulatory developments affecting our competitors' product candidates.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage products, and we do not know when, or if, we will generate any revenue from such development-stage products. Our ability to generate revenue from such development-stage products depends on a number of factors, including, but not limited to, our ability to:

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

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

To fund our operations and service our debt securities, which may be deemed to include our Series A Preferred Stock, we will be required to generate a significant amount of cash. Our ability to generate cash depends on a number of factors, some of which are beyond our control, and any failure to meet our debt obligations would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Common Stock and/or Series A Preferred Stock to decline.

Prevailing economic conditions and financial, business and other factors, many of which are beyond our control, may affect our ability to make payments on our debt. If we do not generate sufficient cash flow to satisfy our debt obligations, we may have to undertake alternative financing plans, such as refinancing or restructuring our debt, selling assets, reducing or delaying capital investments or seeking to raise additional capital. Alternatively, as we have done in the past, we may also elect to refinance certain of our debt, for example, to extend maturities. Our ability to restructure or refinance our debt will depend on the capital markets and our financial condition at such time. If we are unable to access the capital markets, whether because of the condition of those capital markets or our own financial condition or reputation within such capital markets, we may be unable to refinance our debt. In addition, any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. Our inability to generate sufficient cash flow to satisfy our debt obligations or to refinance our obligations on commercially reasonable terms, or at all, could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Common Stock and/or debt securities to decline.

Repayment of our indebtedness is dependent in part on the generation of cash flow by Journey and its ability to make such cash available to us, by dividend, debt repayment or otherwise. Journey may not be able to, or may not be permitted to, make distributions to enable us to make payments in respect of our indebtedness. Each of our subsidiaries, 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 stock prices of our securities. If additional funds are required to support our operations and such funds cannot be obtained on favorable terms, we may not be able to develop products, which will adversely impact our growth strategy.

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2022 and 2021, we incurred R&D expenses of approximately $134.2 million and $113.2 million, respectively. We expect to continue to spend significant amounts on our growth strategy. We believe that our current cash and cash equivalents will enable us to continue to fund operations in the normal course of business for at least the next 12 months from the filing of this 10-K. Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, however, we expect to seek to finance potential cash needs.

Our ability to obtain additional funding when needed, changes to our operating plans, our existing and anticipated working capital needs, the acceleration or modification of our planned R&D activities, expenditures, acquisitions and growth strategy, increased expenses or other events may affect our need for additional capital in the future and require us to seek additional funding sooner or on different terms than anticipated. In addition, if we are unable to raise additional capital when needed, we might have to delay, curtail or eliminate one or more of our R&D programs and commercialization efforts and potentially change our growth strategy. The terms of our existing debt arrangements, including that with Oaktree, have and will continue to inhibit our and our subsidiaries' abilities to raise capital.

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

As part of our growth strategy, we have made and will likely continue to make substantial financial and operational commitments in our subsidiaries, which often have limited or no operating history, 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.

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 preferred stock that is convertible into Common Stock), the share ownership of existing stockholders will be diluted. We have also entered into financing arrangements to raise capital for our subsidiaries under which Fortress Common Stock is or may be issuable to investors in lieu of cash, upon certain conditions being met; in the event such issuances take place, they will also be dilutive of the stakes of existing stockholders. Any future debt financings may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain financial commitments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing or sublicensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Risks Pertaining to Our Existing Revenue Stream from Journey Medical Corporation

Future revenue based on sales of our dermatology products, especially Qbrexza, Accutane, Amzeeq, Zilxi, Ximino, Targadox, and Exelderm, may be lower than expected or lower than in previous periods.

The vast majority of our operating income for the foreseeable future is expected to come from the sale of our dermatology products through our partner company Journey. Any setback that may occur with respect to such products could significantly impair our operating results and/or reduce our revenue and the value of our Securities. Setbacks for such products could include, but are not limited to, issues related to: supply chain, shipping; distribution; demand; manufacturing; product safety; product quality; marketing; government regulation, including but not limited to pricing or reimbursement; licensing and approval; intellectual property rights; competition with existing or new products, including third-party generic competition; product acceptance by physicians, other licensed medical professionals, and patients; and higher than expected total rebates, returns or recalls. Also, a significant portion of Journey's sales derive from products that are without patent protection and/or are or may become subject to third party generic competition; the introduction of new competitor products, or increased market share of existing competitor products, could have a significant adverse effect on our operating income.

We face challenges as our products face generic competition and/or losses of exclusivity.

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

A significant portion of our sales derive from products that are without patent protection and/or are or may become subject to third-party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse impact on our operating income. Four of our marketed products, Qbrexza, Amzeeq, Zilxi and Ximino, as well as 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 under third-party reimbursement programs, or substituted by pharmacies. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care.

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

Journey's field sales force has been and is expected to continue to be an important contributor to our commercial success. Any disruptions to our relationship with such field sales force or the professional employer organization that employs our field sales force, could materially adversely affect our product sales. 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 and financial condition.

Reimbursement for our products and product candidates may be limited or unavailable in certain market segments, which could make it difficult for us to sell our products profitably.

We have obtained approval for some products, and intend to seek approval for other product candidates, to commercialize in both the United States and in countries and territories outside the United States. If we obtain approval in one or more foreign countries, we will be subject to rules and regulations in those countries relating to such products. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future healthcare reform measures.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which pharmaceuticals they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination regarding whether a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- experimental or investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require that we provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability. Additionally, while we may seek approval of our products in combination with each other, there can be no guarantee that we will obtain coverage and reimbursement for any of our products together, or that such reimbursement will incentivize the use of our products in combination with each other as opposed to in combination with other agents which may be priced more favorably to the medical community.

Legislative and regulatory changes to the healthcare systems of the United States and certain foreign countries could impact our ability to sell our products profitably. Several federal agencies including FDA, CMS and HHS, in addition to state and local governments, regulate drug product development and marketing. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products by revising the payment methodology for many products reimbursed by Medicare, resulting in lower rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. In addition, this law provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this law and future laws could decrease the coverage and price that we will receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Therefore, any limitations in reimbursement that results from the MMA may result in reductions in payments from private payors.

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

The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015.

At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA.

The Bipartisan Budget Act of 2018, the "BBA," which set government spending levels for Fiscal Years 2018 and 2019, revised certain provisions of the ACA. Specifically, beginning in 2019, the BBA increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70%, ultimately increasing the liability for brand drug manufacturers. Further, this mandatory manufacturer discount applied to biosimilars beginning in 2019.

In the United States there is significant interest in containing healthcare costs and increasing the scrutiny of pharmaceutical pricing practices. Congress has continually explored legislation intended to address the cost of prescription drugs. Notably, the major committees of jurisdiction in the Senate (Finance Committee, Health, Education, Labor and Pensions Committee, and Judiciary Committee), regularly evaluate and hold hearings on legislation intended to address various elements of the prescription drug supply chain and prescription drug pricing. Proposals include a significant overhaul of the Medicare Part D benefit design, addressing patent "loopholes", and efforts to cap the increase in drug prices, create drug price, and efforts to allow the Secretary of HHS to negotiate drug prices with prescription drug manufacturers.

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

The former Trump Administration took several regulatory steps and proposed numerous prescription drug cost control measures. Similarly, the Biden Administration has identified promoting competition and lowering drug prices as a priority.

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

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

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

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

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

Risks Pertaining to our Business Strategy, Structure and Organization

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

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

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

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

Any collaboration or divestiture we pursue, whether we are able to complete it or not, may be complex, time consuming and expensive, may divert from management's attention, may have a negative impact on our customer relationships, cause us to incur costs associated with maintaining the business of the targeted collaboration or divestiture during the transaction process and also to incur costs of closing and disposing the affected business or transferring the operations of the business to other facilities. In addition, if such transactions are not completed for any reason, the market price of our Common Stock may reflect a market assumption that such transactions will occur, and a failure to complete such transactions could result in a negative perception by the market of us generally and a decline in the market price of our Common Stock.

We act, and are likely to continue acting, as guarantor and/or indemnitor of the obligations, actions or inactions of certain of our subsidiaries and partner companies. We have also entered into, and may again enter into, certain arrangements with our subsidiaries, partner companies and/or third parties pursuant to which a substantial number of shares of our Common Stock may be issued. Depending on the terms of such arrangements, we may be contractually obligated to pay substantial amounts to third parties, or issue a substantially dilutive number of shares of our Common Stock, based on the actions or inactions of our subsidiaries and/or partner companies, regulatory agencies or other third parties.

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

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 Fortress Common Stock or perpetual preferred stock if certain events occur or do not occur, which could lead to a depletion of resources or dilution to our Common Stock, or both.

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 companiess, 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 results of operations.

Certain of our executives, directors and principal stockholders, whose interests may be adverse to those of our other stockholders, can control our direction and policies.

Certain of our executive officers, directors and stockholders own nearly or more than 10% of our outstanding Common Stock and, together with their affiliates and related persons, beneficially own a significant percentage of our capital stock. If these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. In addition, this concentration of ownership might adversely affect the market price of our Common Stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

If we acquire, or enter into joint ventures with or obtain a controlling interest in, companies in the future, our operating results and the value of our Securities may be adversely affected, thereby diluting stockholder value, disrupting our business and/or diminishing the value of our holdings in our partner companies.

As part of our growth strategy, we might acquire, enter into joint ventures with, or obtain significant ownership stakes in other companies. Acquisitions of, joint ventures with and investments in other companies involve numerous risks, including, but not necessarily limited to:

- risk of entering new markets in which we have little to no experience;
- diversion of financial and managerial resources from existing operations;
- successfully negotiating a proposed acquisition or investment timely and at a price or on terms and conditions favorable to us;
- the impact of regulatory reviews on a proposed acquisition or investment;
- the outcome of any legal proceedings that may be instituted with respect to the proposed acquisitions or investment;
- with respect to an acquisition, difficulties in integrating operations, technologies, services and personnel; and
- potential inability to maintain relationships with customers of the companies we may acquire or invest in.

If we fail to properly evaluate potential acquisitions, joint ventures or other transaction opportunities, we might not achieve the anticipated benefits of any such transaction, we might incur higher costs than anticipated, and management resources and attention might be diverted from other necessary or valuable activities.

Russian military action in Europe may impact foreign countries in which certain of our partner companies may have enrolled, or had planned to enroll patients in clinical trials, and any such clinical trials may be delayed or suspended.

In February 2022, Russia commenced a military invasion of Ukraine. Russia's invasion and the ensuing response by Ukraine may disrupt our partner companies' ability to conduct clinical trials in Russia, Ukraine, Belarus, and Georgia, and potentially other neighboring countries. Although the impact of Russia's military action is highly unpredictable, certain clinical trial sites may be affected, including those of our partner company Checkpoint in Russia, Ukraine, Belarus, and Georgia. Those clinical trial sites may suspend or terminate trials, and patients could be forced to evacuate or choose to relocate, making them unavailable for initial or further participation in clinical trials. Alternative sites to fully and timely compensate for clinical trial activities in these areas may not be available, and we may need to find other countries to conduct these clinical trials. Clinical trial interruptions may delay our plans for clinical development and approvals for our product candidates, which could increase costs and jeopardize our ability to commence product sales and generate.

Risks Pertaining to Reliance on Third Parties

We rely predominantly on third parties to manufacture the majority of our preclinical and clinical pharmaceutical supplies, and we expect to continue to rely heavily on such third parties and other contractors to produce commercial supplies of our products. Further, we rely solely on third parties to manufacture Journey's commercialized products. Such dependence on third-party suppliers could adversely impact our businesses.

We depend heavily on third party manufacturers for product supply. If our contract manufacturers cannot successfully manufacture material that conforms to applicable specifications and FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for those products. Our third-party suppliers will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA and comparable agencies and authorities in other jurisdictions to confirm such compliance. In the event that the FDA or such other authorities determine that our third-party suppliers have not complied with cGMPs or comparable regulations, the relevant clinical trials could be terminated or subjected to 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, 2022, we had an accumulated deficit of approximately $634.2 million. We may need to rely on third parties for activities critical to the product candidate development process, including but not necessarily limited to:

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

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

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

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

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

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

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

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities or potential liability. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with 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 ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If any of our relationships with these third-party contract research organizations or site management organizations terminates, we may not be able to enter into arrangements with alternative contract research organizations or site management organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization or site management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or site management organizations, there can be no assurance that we will not encounter similar challenges or delays in the future.

We rely on clinical and pre-clinical data and results obtained from and by third parties that could ultimately prove to be inaccurate or unreliable.

As part of our strategy to mitigate development risk, we generally intend on developing product candidates with previously validated mechanisms of action and seek to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical and pre-clinical data and other results produced or obtained by third parties, which may ultimately prove to be inaccurate or unreliable. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidates or acquired products, we could make inaccurate assumptions and conclusions about our current or future product candidates and our research and development efforts could be compromised.

Collaborative relationships with third parties could cause us to expend significant resources and/or incur substantial business risk with no assurance of financial return.

We anticipate substantial reliance on strategic collaborations for marketing and commercializing our existing product candidates and we may rely even more on strategic collaborations for R&D of other product candidates. We may sell product offerings through strategic partnerships with pharmaceutical and biotechnology companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited.

If we enter into R&D collaborations during the early phases of drug development, success will, in part, depend on the performance of research collaborators. We may not directly control the amount or timing of resources devoted by research collaborators to activities related to product candidates. Research collaborators may not commit sufficient resources to our R&D programs. If any research collaborator fails to commit sufficient resources, the preclinical or clinical development programs related to the collaboration could be delayed or terminated. Also, collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to collaborators or to observe other obligations in agreements with them, the collaborators may have the right to terminate or stop performance of those agreements.

Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaboration proposals based upon their assessment of our financial, regulatory or intellectual property positions. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of product candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, the related product revenues that might follow are likely to be lower than if we directly marketed and sold products. Such collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on, and such collaborations could be more attractive than the one with us for any future product candidate.

Management of our relationships with collaborators will require:

- significant time and effort from our management team;
- coordination of our marketing and R&D programs with the respective marketing and R&D priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

The contractual provisions we may be forced to agree upon in services, manufacturing, supply and other agreements may be inordinately one-sided, vis-à-vis current or historical standard market terms (especially as pertains contractual liability and indemnification paradigms), and as a result we may be subject to liabilities that are not attributable to our own actions or the actions of our personnel.

There is a finite number of service providers who can perform the services or produce the materials or product candidates that we need, and we therefore often have a limited number of options in choosing such service providers. The standard market terms in many of the agreements into which we customarily enter with such service providers are subject to evolution over time, often-times in favor of our counterparties. Also, some such agreements are "adhesion contracts" under which our contractual counterparties refuse to entertain any modifications to their template documentation. One area where service providers often have and exert leverage over us is the negotiation of liability language – specifically in broadly-scoped indemnification by us of service providers and/or the application of liability damages "caps" to certain of such service providers' indemnification obligations. In any circumstance where we've been compelled to agree to such language, it is conceivable that we will be liable to third parties for liabilities in excess of such caps that are attributable to the actions, forbearances and/or culpability of such service providers and their indemnitiees (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 but do not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that any such product candidates generate from sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally would also be necessary for commercial success. The degree of market acceptance of any approved products would depend on a number of factors, including, but not necessarily limited to:

- the efficacy and safety as demonstrated in clinical trials;

- the timing of market introduction of such product candidate as well as competitive products;

- the clinical indications for which the product is approved;

- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;

- the potential and perceived advantages of product candidates over alternative treatments;

- the safety of product candidates in a broader patient group (i.e., based on actual use);

- the availability, cost and benefits of treatment, in relation to alternative treatments;

- the availability of adequate reimbursement and pricing by third parties and government authorities;

- changes in regulatory requirements by government authorities for our product candidates;

- the product labeling or product insert required by the FDA or regulatory authority in other countries, including any contradictions, warnings, drug interactions, or other precautions;

- changes in the standard of care for the targeted indications for our product candidate or future product candidates, which could reduce the marketing impact of any labeling or marketing claims that we could make following FDA approval;
- relative convenience and ease of administration;
- the prevalence and severity of side effects and adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

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

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

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

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for one or more of our product candidates or a future product candidate we may license or acquire and may have to limit their commercialization.

The use of one or more of our product candidates and any future product candidate we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- suspension or termination of clinical trial sites or entire trial programs;
- decreased demand for any product candidates or products that we may develop;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;

- substantial monetary awards to patients or other claimants;
- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our product candidate or future product candidates.

Our partner company Journey acquired an isotretinoin product and began marketing that product under the Accutane® brand name in Q2 2021. Isotretinoin has a black box warning for use in pregnant women. Isotretinoin also has warnings for side effects related to psychiatric disorders and inflammatory bowel disease, among others. Historically, isotretinoin has been the subject of significant product liability claims, mainly related to irritable bowel disease . Currently, there is no significant isotretinoin product liability litigation. The federal multi-district litigation ("MDL") court dismissed all remaining federal isotretinoin cases in 2014 after ruling that the warning label on the drug was adequate. The MDL dissolved in 2015, which effectively put an end to federal lawsuits. Cases continued in New Jersey state court until 2017, when the trial court judge dismissed the remaining the isotretinoin product liability cases. Thus, should a product liability claim against Journey be brought related to its isotretinoin product, we have substantial defenses. However, it is not feasible to predict the ultimate outcome of any litigation, and we could in the future be required to pay significant amounts as a result of settlement or judgments should such new product liability claims be brought.

We will obtain limited product liability insurance coverage for all of our upcoming clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. When needed we intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for one or more of our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

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

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

- restrictions on product manufacturing, distribution or use;

- restrictions on the labeling or marketing of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- recalls or other withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- fines;
- suspension or withdrawal of marketing or regulatory approvals;
- refusal to permit the import or export of products;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

If we or our suppliers, third-party contractors, clinical investigators or collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we or our collaborators may be subject to the actions listed above, including losing marketing approval for products when and if any of them are approved, resulting in decreased revenue from milestones, product sales or royalties.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product cannot be marketed in the U.S. or other countries until the relevant governmental authority has completed a rigorous and extensive regulatory review process, including approval of a brand name. Any brand names we intend to use for our product candidates in the U.S. will require approval from the FDA regardless of whether we have secured a formal trademark registration from the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Pertaining to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere play a primary role in the recommendation and prescription of our product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, which requires manufacturers of certain drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to "covered recipients," which include physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals) and applicable manufacturers. Applicable group purchasing organizations also are required to report annually to CMS the ownership and investment interests held by the physicians and their immediate family members. The SUPPORT for Patients and Communities Act added to the definition of covered recipient practitioners including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse-midwives effective in 2022; 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 $136.1 million as of December 31, 2022. Any sale of a substantial number of shares of our Common Stock or our Series A Preferred Stock could cause a drop in the trading price of our Common Stock or 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, including without limitation the COVID-19 virus, may also impede our employees' and consultants' abilities to provide services in-person and/or in a timely manner; hinder our ability to raise funds to finance our operations on favorable terms or at all; and trigger effectiveness of "force majeure" clauses under agreements with respect to which we receive goods and services, or under which we are obligated to achieve developmental milestones on certain timeframes. Disputes with third parties over the applicability of such "force majeure" clauses, or the enforceability of developmental milestones and related extension mechanisms in light of such business interruptions, may arise and may become expensive and time-consuming.

Our ability to use our pre-change NOLs and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

We may, from time to time, carry net operating loss carryforwards ("NOLs") as deferred tax assets on our balance sheet. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage- point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use all of its pre-change NOLs and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership, some of which changes are outside our control. As a result, our ability to use our pre-change NOLs and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We, and/or third parties on our behalf, may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations may also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our respective resources, and clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted in connection with the storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

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

The COVID-19 pandemic has caused considerable disruptions at FDA, namely with respect to diverting FDA's attention and resources to facilitate vaccine development and ensure rapid review and emergency use authorization of vaccines intended to prevent COVID-19. Continued focus on COVID-19 countermeasures, and the reorganization and rededication or critical resources, both at FDA and within similar governmental authorities across the world, may impact the ability of new products and services from being developed or commercialized in a timely manner.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. Also, if we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our Securities.

As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act ("SOX"), as well as rules subsequently implemented by the SEC, and the rules of the Nasdaq Stock Exchange. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

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

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

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

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

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

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

On October 31, 2022, the Company received a letter from the Staff of Nasdaq indicating that the bid price of the Company's Common Stock had closed below $1.00 per share for 30 consecutive business days and, as a result, the Company is not in compliance with Nasdaq Listing Rule 5550(a)(2), which sets forth the minimum bid price requirement for continued listing on The Nasdaq Capital Market. Nasdaq's notice has no immediate effect on the listing of the Company's Common Stock on Nasdaq. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company is afforded a 180-calendar day grace period, through May 1, 2023, to regain compliance with the bid price requirement. Compliance can be achieved by evidencing a closing bid price of at least $1.00 per share for a minimum of ten (10) consecutive business days, although the Staff may, in its discretion, require compliance for a longer period of time (generally no more than 20 consecutive business days) during the 180-calendar day grace period.

If the Company does not regain compliance with the bid price requirement by May 1, 2023, the Company may be eligible for an additional 180-calendar day compliance period so long as it satisfies the criteria for initial listing on Nasdaq and the continued listing requirement for market value of publicly held shares and the Company provides written notice to Nasdaq of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. In the event the Company is not eligible for the second grace period, the Nasdaq staff will provide written notice that the Common Stock is subject to delisting; however, the Company may request a hearing before the Nasdaq Hearings Panel (the "Panel"), which request, if timely made, would stay any further suspension or delisting action by the Staff pending the conclusion of the hearing process and expiration of any extension that may be granted by the Panel. There can be no assurance that the Company would be successful in its efforts to maintain the Nasdaq listing.

The Company intends to closely monitor the closing bid price of the Common Stock and consider all available options to remedy the bid price deficiency, but no decision regarding any action has yet been made. If we were unable to meet the continued listing requirements of the Nasdaq, our Common Stock could be delisted from the Nasdaq. Any such delisting of our Common Stock could have an adverse effect on the market price of, and the efficiency of the trading market for, our Common Stock, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and less coverage of us by securities analysts, if any. Also, if in the future we were to determine that we need to seek additional equity capital, being delisted from Nasdaq could have an adverse effect on our ability to raise capital in the public or private equity markets.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Neither we nor any of our subsidiaries or partner companies own any real estate. We lease office space and other facilities as set forth in the table below. We believe that our existing facilities are adequate to support our current requirements. We also believe that we will be able to obtain suitable additional facilities on commercially reasonable terms on an "as needed basis."

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, office space	27,043
Mustang	Worcester, MA	Office space	26,503

Item 3. Legal Proceedings

To our knowledge, there are no legal proceedings pending against us, other than routine actions and administrative proceedings, and other actions not deemed material are not expected to have a material adverse effect on our financial condition, results of operations, or cash flows. In the ordinary course of business, however, the Company may be subject to both insured and uninsured litigation. Suits and claims may be brought against the Company by customers, suppliers, partners and/or third parties (including tort claims for personal injury arising from clinical trials of the Company's product candidates and property damage) alleging deficiencies in performance, breach of contract, etc., and seeking resulting alleged damages.

Item 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

We became a public company on November 17, 2011. 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 28, 2023, there were approximately 433 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.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

Unregistered Sales of Equity Securities

None.

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 "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 dedicated to acquiring, developing and commercializing pharmaceutical and biotechnology products and product candidates, which we do through Fortress itself and through partner companies and subsidiaries. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who work in concert with our extensive network of key opinion leaders to identify and evaluate promising products and product candidates for potential acquisition by new or existing partner companies. We have executed arrangements with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center, Fred Hutchinson Cancer Center, St. Jude Children's Research Hospital ("St. Jude"), Dana-Farber Cancer Institute, Nationwide Children's Hospital, Cincinnati Children's Hospital Medical Center, Columbia University, the University of Pennsylvania, Mayo Foundation for Medical Education and Research ("Mayo Clinic"), AstraZeneca plc and Dr. Reddy's Laboratories, Ltd.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and financial expertise to help the partners achieve their goals. Partner companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out-licensings, sales transactions, and public and private financings. To date, four partner companies are publicly-traded, and 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. On October 5, 2021, AstraZeneca purchased 100% of our partner Caelum for approximately $150 million upfront and up to $350 million in contingent regulatory and sales milestone payments.

Our subsidiary and partner companies that are pursuing development and/or commercialization of biopharmaceutical products and product candidates are Aevitas Therapeutics, Inc. ("Aevitas"), 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", formerly UR-1 Therapeutics, Inc.).

Recent Events

Marketed Dermatology Products

- In 2022, Journey's commercial portfolio generated net revenue of $71.0 million, compared to net revenue of $63.1 million in 2021.

- At December 31, 2022, Journey currently had 74 field sales representatives dedicated to marketing and promoting their dermatology product portfolio.
- In January 2022, Journey received notice from its exclusive out-licensing partner in Japan, Maruho Ltd. ("Maruho"), that Japan's Ministry of Health, Labor and Welfare approved Rapifort® Wipes 2.5% (glycopyrronium tosylate hydrate) for the treatment of primary axillary hyperhidrosis. This approval triggered a milestone payment of $10.0 million to Journey, $7.5 million of which was paid to Dermira pursuant to the terms of the Asset Purchase Agreement between Journey and Dermira for Qbrexza, resulting in net proceeds of $2.5 million paid to Journey.
- In January 2022, JMC acquired Amzeeq (minocycline) topical foam, 4%, and Zilxi (minocycline) topical foam, 1.5%, two U.S Food and Drug Administration ("FDA") approved Topical Minocycline Products and Molecule Stabilizing Technology (MST)™ from Vyne Therapeutics, Inc., which expanded Journey's product portfolio of actively marketed branded dermatology products to eight.
- In May 2022, Journey received notice from Maruho that its commercial launch of Rapifort was initiated and Journey began receiving royalty payments from Maruho of 10% of net sales of Rapifort in Japan in the second quarter of 2022.
- In May 2022, Journey announced that it had entered into three separate settlement agreements (the "Settlement Agreements") with Padagis for patent infringement lawsuits that Journey filed to enforce the patents covering Qbrexza®, Amzeeq®, and Zilxi®. Pursuant to the terms of the Settlement Agreements, Padagis is prohibited from launching generic versions of Qbrexza®, Amzeeq® and Zilxi® until August 15, 2030, July 1, 2031, and April 1, 2027, respectively. Each of the aforementioned lawsuits were dismissed on May 19, 2022. Additionally, in December 2022, Journey settled the Qbrexza patent infringement lawsuit that Journey filed against Teva Pharmaceuticals.

Late Stage Product Candidates

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

- Journey completed enrollment in its DFD-29 Phase 3 clinical program for the treatment of papulopustular rosacea. Topline data from the two DFD-29 Phase 3 clinical studies are expected to be announced in the first half of 2023. Journey plans to submit the New Drug Application ("NDA") for DFD-29 in the second half of 2023 and FDA approval is anticipated in the second half of 2024.
- In the Phase 2 clinical trials, DFD-29 (40mg) demonstrated nearly double the efficacy when compared against Oraycea® (European equivalent of Oracea®) on both co-primary endpoints. For the first co-primary endpoint, Investigator's Global Assessment ("IGA") treatment success, Oraycea had a 33.33% IGA treatment success rate, while DFD-29 achieved a 66.04% IGA treatment success rate. For the second co-primary endpoint, the change in total inflammatory lesion count, Oraycea had a 10.5 reduction in inflammatory lesions, while DFD-29 achieved a 19.2 reduction in inflammatory lesions.
- In March 2023, Journey announced completion of treatment in the Phase 1 clinical trial assessing the impact of DFD-29 on the microbial flora of healthy adults. No significant safety issues were noted during the study.

CUTX-101 (Copper Histidinate injection for Menkes Disease)

- In 2021, our subsidiary Cyprium signed a Development and Asset Purchase Agreement with Sentynl, a subsidiary of Zydus Lifesciences Ltd., for CUTX-101 for the treatment of Menkes disease. Under the terms of the agreement, Cyprium received $8 million upfront to fund the development of CUTX-101 and could receive up to $12 million in regulatory milestone payments related to the NDA submission and approval process and is eligible to receive sales milestones totaling up to $255.0 million in the aggregate, plus royalties. Royalties start from mid-single digits, scaling up to 25% on sales exceeding $100 million annually. All of the foregoing milestone and royalty payments are subject to 50% diminution in the event Sentynl decides, at its option, to assume development control of CUTX-101 during the 45-day period beginning on September 30, 2023. Cyprium will in any event retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101. Cyprium is responsible for the development of CUTX-101 (subject to the aforementioned righ by Sentynl to assume development), and Sentynl will be responsible for commercialization of CUTX-101, as well as progressing newborn screening activities.

- In December 2021, Cyprium initiated the rolling submission of an NDA to the FDA for CUTX-101. The rolling submission of the NDA for CUTX-101 is ongoing and is expected to be completed in 2023.
- Cyprium is currently in a dispute with its contract manufacturing organization (the "CMO"), regarding the CMO's attempt to terminate a Master Services Agreement (together with related work orders, the "MSA") between Cyprium and the CMO. Cyprium believes the CMO's grounds for purporting to terminate the MSA are without merit and is currently availing itself of all appropriate legal remedies in efforts to ensure that the CMO abides by its obligations under the MSA and/or to pursue monetary damages claims against the CMO. To that end, Cyprium obtained a temporary restraining order in August 2022 and a preliminary injunction in September 2022 from a court in New York State. The injunction enjoined the CMO from terminating the MSA and prohibited the CMO from further attempts to terminate the MSA during the pendency of dispute resolution procedures.
- CUTX-101 was sourced by Fortress and is currently in development at our partner company, Cyprium.

CAEL-101 (Light Chain Fibril-reactive 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, net of the ten percent, 24-month escrow holdback amount and other miscellaneous transaction expenses. The agreement also provides for additional potential payments to Caelum shareholders totaling up to $350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive 42.4% of all proceeds of the transaction, totaling up to approximately $212 million.
- There are two ongoing Phase 3 studies of CAEL-101 for AL amyloidosis. (ClinicalTrials.gov identifiers: NCT04512235 and NCT04504825).
- AstraZeneca has indicated an expected Biologics License Application ("BLA") submission in 2024.
- CAEL-101 was sourced by Fortress and was developed by Caelum (founded by Fortress) until its acquisition by AstraZeneca in October 2021.

Cosibelimab (Anti-PD-L1 mAb for CSCC and NSCLC)

- Our partner company, Checkpoint submitted a BLA to the FDA for cosibelimab as a treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") in January 2023 and the BLA was accepted in March 2023 with a Prescription Drug User Fee Act ("PDUFA") date of January 3, 2024. With a compelling safety profile and its unique mechanism of action, we believe cosibelimab has the potential to be a market disruptive product in the $30 billion and growing PD-(L)1 class.
- In January 2022, Checkpoint announced topline results from its registration-enabling cohort of a multi-regional, Phase 1 clinical trial in patients with metastatic cSCC. The cohort met its primary endpoint, with cosibelimab demonstrating a confirmed objective response rate of 47.4% (95% CI: 36.0, 59.1) based on independent central review of 78 patients enrolled in the metastatic cSCC cohort using Response Evaluation Criteria in Solid Tumors version 1.1 criteria.
- In May 2022, Checkpoint announced that it received Pediatric Investigation Plan ("PIP") product-specific waivers from the European Medicines Agency ("EMA") and the U.K. Medicines & Healthcare products Regulatory Agency ("MHRA") for cosibelimab in cSCC. The waivers remove the requirement to conduct pediatric clinical studies to support cosibelimab marketing authorization applications in Europe.
- In June 2022, Cjeckpoint announced interim results from it's registration-enabling cohort of its multi-regional, Phase 1 clinical trial of cosibelimab in metastatic cSCC were presented at the 2022 American Society of Clinical Oncology Annual Meeting. Data highlights presented include confirmed objective response rate ("ORR") by independent central review in the modified intent-to-treat population of 48.7% (95% CI, 37.0-60.4) and 13.2% of patients achieved a complete response in target lesions. Cosibelimab was generally well tolerated with no unexpected safety signals.
- Also in June 2022, Checkpoint announced interim results from it's registration-enabling cohort of its multi-regional, Phase 1 clinical trial of cosibelimab in patients with locally advanced cSCC that are not candidates for curative surgery or radiation. As of the March 2022 data cutoff, the confirmed ORR by independent central review in 31 patients was 54.8% (95% CI: 36.0, 72.7).

- In July 2022, Checkpoint successfully completed two pre-BLA meetings with the FDA (chemistry, manufacturing and controls ("CMC") and clinical/non-clinical). Based upon favorable interactions with the agency, the January 2023 BLA submission included both the metastatic and locally advanced cutaneous squamous cell carcinoma indications.
- Cosibelimab was sourced by Fortress and is currently in development at Checkpoint.

MB-107 and MB-207 (Ex vivo Lentiviral Therapies for X-linked Severe Combined Immunodeficiency ("XSCID"))

- The timeline for initiating the MB-107 pivotal non-randomized multicenter Phase 2 trial under Mustang IND has been extended due to unanticipated issues related to the materials used in manufacturing. These issues were communicated to the FDA, and Mustang received a written response on August 26, 2022. The FDA response provided additional direction, enabling us to effectively continue to work with our outside suppliers. We are working towards enrolling the first patient in this trial in 2023.
- In order to lift the clinical hold on the MB-207 pivotal non-randomized multicenter Phase 2 trial under Mustang IND and receive an FDA safe-to-procced for the IND, we believe the most critical activities will be to (1) perform process validation manufacturing runs using healthy donor material and (2) ensure qualification of all assays related to the product release. Following completion of these activities and the earliest release of the clinical hold by FDA, we expect to enroll the first patient in the planned Phase 2 clinical trial in 2023.
- The MB-107 multicenter Phase 1/2 clinical trial under St. Jude IND remains open to accrual.
- As a result of the study stopping rules, the MB-207 single-center Phase 1/2 clinical trial under NIH IND was suspended in 2022 due to the presence of clonal expansion in the myeloid lineage in 10% of the treated patients, although to date there have been no observations of insertional mutagenesis or malignancies. All patients continue to be followed and remain clinically stable with no significant hematological abnormalities. Upon review of these data, the FDA agreed that the risk-benefit ratio of both MB-107 and MB-207 remains favorable to support moving forward with Mustang-sponsored pivotal multicenter Phase 2 clinical trials once Mustang has appropriately addressed other items flagged by the Agency, as noted above.
- MB-107 and MB-207 were sourced by Fortress and are currently in development at our partner company, Mustang.

Triplex (Cytomegalovirus ("CMV") vaccine)

- In August 2022, we 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.
- In February 2023, we announced that data from a Phase 1 pilot study published in the *American Journal of Hematology* demonstrated the feasibility, safety, immunological response and potential efficacy associated with vaccination of a hematopoietic cell transplant ("HCT") donor with CMV vaccine Triplex to enhance protective CMV-specific T cells in immunosuppressed recipients of allogeneic HCT. This data was also presented at the 2023 Tandem Meetings: Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR, in February 2023, in Orlando, Florida. A Phase 2 clinical trial is planned to evaluate the the vaccination of HCT donors to enhance protective CMV-specific T cell immunity in HCT recipients.
- 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 HIV; and in combination with a CAR T cell therapy for adults with non-Hodgkin lymphoma ("NHL").
- Triplex was sourced by Fortress and is currently in development at our partner company, Helocyte.

IV Tramadol

- In September 2022, our partner company Avenue received the official meeting minutes from the FDA regarding a meeting conducted in August 2022, for IV Tramadol. At the meeting, Avenue presented a study design for a single safety clinical trial that Avenue believes could address the concerns regarding risks related to opioid stacking. The FDA stated that the proposed study design appears reasonable and agreed on various study design aspects with the expectation that additional feedback would be provided to Avenue upon review of a more detailed study protocol. Avenue incorporated the FDA's suggestions from the meeting minutes and submitted a detailed study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol.
- In March 2023, we announced Avenue's participation in a Type C meeting with the FDA to discuss the proposed study protocol to asses the risk of respiratory depression related to opioid stacking on IV Tramadol relative to an approved opioid analgesic.
- IV Tramadol was sourced by Fortress and is currently in development at Avenue.

Early Stage Product Candidates

Dotinurad (Urate Transporter (URAT1) Inhibitor)

- In May 2022, our subsidiary company Urica initiated a Phase 1 clinical trial to evaluate dotinurad in healthy volunteers in the United States. Dotinurad is in development for the treatment of gout. We anticipate topline data from the Phase 1 trial in the first half of 2023.
- 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 October 2022, Urica strengthened its leadership team by appointed Jay D. Kranzler, M.D., Ph.D. as Chairman and Chief Executive Officer, and Vibeke Strand, M.D., MACR, FACP, Adjunct Clinical Professor, Division of Immunology/Rheumatology, Stanford University, to Urica's Board of Directors.
- In December 2022, Urica expanded its exclusive license agreement with Fuji Yakuhin Co. Ltd. ("Fuji") for the development of dotinurad to include the Middle East and North Africa ("MENA") and Turkey territories. The agreement builds upon the exclusive license agreement between Urica and Fuji previously announced in May of 2021 to develop dotinurad in the United States, United Kingdom, European Union and Canada.
- Dotinurad was sourced by Fortress and is currently in development at our partner company, Urica.

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

- In 2023, Mustang plans to file an IND for the combination of MB-101 CAR T therapy and MB-108 oncolytic virus therapy for the treatment of glioblastoma and anaplastic astrocytoma. This combination will be referred to as MB-109.
- MB-101 was sourced by Fortress and is currently in development at Mustang.

MB-105 (PSCA-targeted CAR T cell therapy)

- In February 2022, Phase 1 data on MB-105, a PSCA-targeted CAR T administered systemically to patients with PSCA-positive metastatic castration-resistant prostate cancer (mCRPC), were presented by City of Hope at the 2022 American Society of Clinical Oncology Genitourinary Cancers Symposium.
- MB-105 was sourced by Fortress and is currently in development at Mustang.

MB-102 (CD123 CAR T Cell Program for BPDCN, AML and high-risk MDS)

- In December 2022, Mustang announced that the safety review team (SRT), after thoroughly reviewing the safety data from Dose Level 1 (100 x 10^6 CAR T cells), unanimously recommended dose escalation to Dose Level 2 (300 x 10^6 CAR T cells). Mustang anticipates initiation of the Dose Level 2 cohort in 2023.
- MB-102 was sourced by Fortress and is currently in development at our partner company, Mustang.

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

- In April 2022, we announced that interim Phase 1/2 data on MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-NHL and CLL, were presented at the 2022 Tandem Meetings I Transplantation & Cellular Therapy Meetings of the American Society of Transplantation and Cellular Therapy and Center for International Blood & Marrow Transplant Research. Data demonstrated high efficacy and a very favorable safety profile in all patients (n=25). Five dose levels were used during the study, and complete responses were observed at all dose levels. Durable responses were observed in a wide range of hematologic malignancies including follicular lymphoma ("FL"), CLL, diffuse large B-cell lymphoma ("DLBCL") and Waldenstrom macroglobulinemia ("WM"). An ORR of 96% and a complete response ("CR") rate of 72% were observed in all patients across all dose levels.
- Also in April 2022, MB-106 data focused on CLL were presented at the 4th International Workshop on CAR-T and Immunotherapies.
- In June 2022, we announced that MB-106 data were presented in an oral session at the European Hematology Association 2022 Hybrid Congress. Dr. Mazyar Shadman of Fred Hutch presented updated interim data from the ongoing Phase 1/2 clinical trial for B-NHL and CLL. Data presented include a 94% ORR and 78% CR rate in patients with FL. Overall, for the 26 patients treated on the trial, there was a 96% ORR and 73% CR, including complete responses in both DLBCL patients, both WM patients, and both patients previously treated with CD19-targeted CAR-T therapy (1 DLBCL patient and 1 FL patient).
- Also in June 2022, we announced that the FDA granted Orphan Drug Designation to MB-106 for the treatment of WM, a rare type of B-NHL. Our partner company Mustang Bio, Inc. ("Mustang"), which is developing MB-106, plans to treat additional WM patients in the Mustang Bio-sponsored Phase 1 portion of its multicenter trial to potentially support an accelerated Phase 2 strategy for this indication.
- In October 2022, we announced that the first patient was treated in Mustang's multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106.
- Also in October 2022, we announced that results from the WM cohort and other interim data from the ongoing Phase 1/2 clinical trial of MB-106 at Fred Hutch were presented at the 11th International Workshop for Waldenstrom's Macroglobulinemia that took place in Madrid, Spain. Mustang plans to treat additional WM patients in the Mustang Bio-sponsored Phase 1 portion of its multicenter trial to potentially support an accelerated Phase 2 strategy for WM.
- Additionally, in October 2022, we shared interim data from 28 patients treated in the initial, ongoing Phase 1/2 investigator-sponsored clinical trial at Fred Hutch. These data continue to support MB-106 as a viable CAR T cell therapy for B-NHLs and CLL. An overall response rate of 96% and CR rate of 75% were observed in a wide range of hematologic malignancies including follicular lymphoma, CLL, diffuse large B-cell lymphoma and WM. Twelve patients have experienced CR for more than 12 months (10 ongoing), including four patients with CR for more than two years and the longest patient with CR at 33 months. Six patients with initial partial response ("PR") at 28 days post-treatment improved to CR, presumably due to the demonstrated persistence of CAR T cells in these patients, and all remain in ongoing CR. All three patients previously treated with CD19 CAR T cell therapy responded to treatment with MB-106. A favorable safety profile for MB-106 as an outpatient therapy remains with no cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome ≥ Grade 3.
- In December 2022 we announced that six patients had been enrolled in Mustang's multicenter Phase 1/2 clinical trial and five patients had been infused at the starting dose levels of their respective protocol arms. We have since treated the first WM in the indolent lymphoma arm of the trial, and we expect to provide first safety and efficacy data from that arm in the second quarter of 2023, with a more substantial data set from all three arms in the fourth quarter of 2023. Finally, we anticipate that the indication for the first pivotal Phase 2 trial will be relapsed/refractory WM, with the first patient treated on that trial in the first quarter of 2024.
- MB-106 was sourced by Fortress and is currently in development at Mustang.

MB-108 (HSV-1 Oncolytic Virus C134)

- The Phase 1 trial of MB-108 at the University of Alabama at Birmingham ("UAB") has been on clinical hold since September 2022 due to toxicity, and UAB expects FDA clearance in 2023 in order to resume enrolling patients at a lower dose level.
- In 2023, Mustang plans to file an IND for the combination of MB-101 CAR T therapy and MB-108 oncolytic virus therapy for the treatment of glioblastoma and anaplastic astrocytoma. This combination will be referred to as MB-109.
- MB-108 was sourced by Fortress and is currently in development at our partner company, Mustang.

MB-109 (MB-101 (IL13Rα2-targeted CAR T Cell Therapy) + MB-108 oncolytic virus)

- In April 2022, we announced interim data from two ongoing investigator-sponsored Phase 1 clinical trials evaluating two clinical candidates, MB‑101 (IL13Rα2‑targeted CAR T cell therapy licensed from City of Hope) and MB-108 (herpes simplex virus type 1 oncolytic virus licensed from Nationwide Children's Hospital) for the treatment of recurrent glioblastoma ("rGBM"). The data were from a late-breaking poster presented at the American Association for Cancer Research Annual Meeting 2022. Preclinical data also presented support the safety of administering these two therapies sequentially to optimize treatment in a regimen designated as MB-109. The combination leverages MB-108 to make cold tumors "hot," thereby improving the efficacy of MB-101 CAR T cell therapy. Mustang expects to file an IND in 2023 to initiate an MB-109 Phase 1 clinical trial.
- MB-101 and MB-108 were sourced by Fortress and they are currently in development at Mustang Bio.

***In vivo* CAR T Platform Technology**

- We continue to collaborate with the Mayo Clinic to progress our exclusively licensed novel *in vivo* CAR T technology platform 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.
- We anticipate the publication of proof-of-concept research in a murine tumor model in 2023.
- The novel CAR T technology was sourced by Fortress and is currently in development at Mustang.

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

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

BAER-101 (novel α2/3–subtype-selective GABA A positive allosteric modulator ("PAM"))

- In November 2022, Baergic became a majority-owned subsidiary of Avenue through the consummation of the Share Contribution Agreement between Fortress and Avenue.
- Baergic intends to explore BAER-101 in a number of CNS disorders where patients are not adequately treated.
- BAER-101 was sourced by Fortress and is currently in development at Baergic.

General Corporate

- In March 2022, Mustang completed a $75 million debt financing with Runway Growth Capital. $30 million was funded upon closing with the additional $45 million available upon Mustang achieving certain milestones.

- In July 2022, we announced that David Jin, who has served as Vice President of Corporate Development since May 2020, was also appointed as Chief Financial Officer effective August 16, 2022.
- In September 2022, Avenue effected a 1-for-15 reverse stock split to bring the company in compliance with the minimum bid price listing requirements of The Nasdaq Capital Market.
- In October 2022, Avenue closed a $12 million underwritten public offering of units consisting of one share of Avenue common stock and one warrant to purchase a share of Avenue common stock. Avenue received net proceeds of approximately $10.4 million at closing after deducting underwriting discounts and commissions and other expenses of the offering.
- Fortress' Board of Directors declared the regular monthly dividend of $0.1953125 per share on the Company's Series A Preferred Stock for each month in 2022. Dividends were paid in cash. Going forward, future notifications related to dividends for the Series A Preferred Stock will be disclosed on the Fortress website in the Investors section on the FBIOP Announcements page under Resources, https://www.fortressbiotech.com/investors/resources/fbiop-announcements. In addition, investors will also be able to find Form 8937s related to FBIOP on the same page.
- On October 31, 2022, Fortress received a letter from the Listing Qualifications Staff of Nasdaq indicating that the bid price of the Company's common stock had closed below $1.00 per share for 30 consecutive business days and, as a result, Fortress is not in compliance with Nasdaq minimum bid price requirement. Nasdaq's notice has no immediate effect on the listing of the common stock on Nasdaq, although a failure to maintain our listing on Nasdaq could have a material adverse effect on the Company (see risk factors described in Item 1A.). The Company intends to closely monitor the closing bid price of the Common Stock and consider all available options to remedy the bid price deficiency, but no decision regarding any action has yet been made.
- In November 2022, Avenue announced the completion of the acquisition of Baergic from Fortress, pursuant to a Share Contribution Agreement.
- In December 2022, Checkpoint effected a 1-for-10 reverse stock split of its common stock in order to improve the marketability and liquidity of Checkpoint's common stock and to remain in compliance with all of Nasdaq's continued listing requirements, including the minimum bid price rules.
- Also in December 2022, Checkpoint completed a registered direct offering priced At-the-Market under Nasdaq rules for total gross proceeds of approximately $7.5 million.
- Additionally in December 2022, Fortress appointed Dr. Lucy Lu, M.D. to its Board of Directors.

Subsequent Events

- In January 2023, Avenue completed a registered direct offering of Avenue common stock and concurrent private placement of warrants to purchase Avenue common stock priced At-the-Market under Nasdaq rules for total gross proceeds of approximately $3.3 million.
- Also in January 2023, Checkpoint submitted a BLA to the FDA for cosibelimab as a treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma. In March 2023, Checkpoint announced the BLA was accepted, with a PDUFA goal date of January 3, 2024.
- In February 2023, Fortress completed a registered direct offering priced At-the-Market under Nasdaq rules for total gross proceeds of approximately $13.9 million, and a concurrent private placement with investors in the registered direct offering for the pro rata rights to acquire, in the aggregate, securities exercisable into common stock in certain future operating subsidiaries that consummate a specified corporate development transaction within the next five years.
- Also in February 2023, Checkpoint completed a registered direct offering of Checkpoint common stock priced At-the-Market under Nasdaq rules and a concurrent private placement of two series of warrants to purchase Checkpoint common stock, for total gross proceeds of approximately $7.5 million.
- In March 2023, Avenue announced its exclusive license agreement with AnnJi Pharmaceutical Co., Ltd. for intellectual property related to AJ201, a clinical asset currently in a Phase 1b/2a study in the U.S. for the treatment of spinal and bulbar muscular atrophy, also known as Kennedy's disease.

Critical Accounting Policies and Use of Estimates

Our consolidated financial statements 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, chargebacks, discounts, 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, investments, accrued expenses, provisions for income taxes 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 elsewhere in this Report, 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, governmental rebate programs 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. In addition, estimates associated with U.S. Medicare and Medicaid governmental rebate programs are at risk for material adjustment because of the extensive time delay.

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 16.08% at December 31, 2022.

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.

Stock-Based Compensation

We expense 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. We estimate 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.

We will continue to use judgment in evaluating the expected volatility, expected terms and interest rates utilized for our stock-based compensation expense calculations on a prospective basis. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different. We expect to continue to grant options and other stock-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

Recent Accounting Pronouncements

See Note 2 to the Consolidated Financial Statements.

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.

Results of Operations

General

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 milestone payment and royalties from Maruho Co., Ltd. ("Maruho") related to the manufacturing and marketing approval and sales of Rapifort® Wipes 2.5% in Japan, $1.9 million relates to Cyprium's collaboration revenue with Sentynl, and $0.2 million of revenue relates to Checkpoint's collaborative agreements with TGTX, a related party. For the year ended December 31, 2021 we generated $68.8 million of net revenue, of which $63.1 million relates to the sale of Journey branded and generic products, $5.4 million relates to Cyprium's collaboration revenue with Sentynl and $0.3 million relates to Checkpoint's collaborative agreements with TGTX. At December 31, 2022, we had an accumulated deficit of $625.9 million primarily as a result of research and development expenses, purchases of in-process research and development and selling, general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our current non-marketed product candidates are at various stages of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate significant revenues.

We had $30.8 million and $32.1 million of costs of goods sold in connection with the sale of JMC branded and generic products for the years ended December 31, 2022 and 2021, respectively.

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.

Also included in research and development is the total purchase price for licenses acquired during the period.

For the years ended December 31, 2022 and 2021, research and development expenses were approximately $134.2 million and $113.2 million, respectively. Additionally, during the years ended December 31, 2022 and 2021, we incurred approximately $0.7 million and $15.6 million, respectively, in costs related to the acquisition of licenses.

The table below provides a summary of research and development costs associated with the development of our licenses by entity, for the years ended December 31, 2022 and 2021:

($ in thousands)	Year Ended December 31, 2022	Year Ended December 31, 2021	% of total 2022	% of total 2021
Research & Development				
Fortress	$ 2,360	$ 2,593	2 %	2 %
Partner Companies:				
Avenue	2,381	1,255	2 %	1 %
Checkpoint	47,940	41,855	36 %	37 %
JMC	10,943	2,739	8 %	2 %
Mustang	62,030	49,631	46 %	44 %
Other[1]	8,545	15,167	6 %	14 %
Total Research & Development Expense	**$ 134,199**	**$ 113,240**	**100 %**	**100 %**

Note 1: Includes the following subsidiaries: Aevitas, Baergic (through November 7, 2022), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

Noncash, stock-based compensation expense included in research and development for the years ended December 31, 2022 and 2021, was $4.4 million and $4.3 million, respectively.

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, 2022 and 2021, selling, general and administrative expenses were $113.7 million and $86.8 million, respectively. Stock based compensation expense included in selling, general and administrative expenses in 2022 and 2021 was $18.5 million and $15.2 million, respectively.

The table below provides a summary by entity of selling, general and administrative expenses for the years ended December 31, 2022 and 2021, respectively:

($ in thousands)	Year Ended December 31, 2022	Year Ended December 31, 2021	% of Total 2022	% of Total 2021
Selling, General & Administrative				
Fortress	$ 26,919	$ 26,062	24 %	30 %
Partner Companies:				
Avenue	5,013	2,484	4 %	3 %
Checkpoint	7,782	7,006	6 %	8 %
JMC[1]	59,503	39,895	53 %	46 %
Mustang	10,740	8,866	10 %	10 %
Other[2]	3,699	2,530	3 %	3 %
Total Selling, General & Administrative Expense	**$ 113,656**	**$ 86,843**	**100 %**	**100 %**

Note 1: Includes field sales force costs for the year ended December 31, 2022 and 2021 of $23.5 million and $16.0 million, respectively. During the course of 2022, JMC expanded their field sales force to support their increased product portfolio.

Note 2: Includes the following subsidiaries: Aevitas, Baergic (through November 7, 2022), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

Comparison of Years Ended December 31, 2022 and 2021

($ in thousands)	Year Ended December 31, 2022	Year Ended December 31, 2021	Change $	Change %
Revenue				
Product revenue, net	$ 70,995	$ 63,134	$ 7,861	12 %
Collaboration revenue	1,882	5,389	(3,507)	(65)%
Revenue – related party	192	268	(76)	(28)%
Other revenue	2,674	—	2,674	100 %
Net revenue	75,743	68,791	6,952	10.1 %
Operating expenses				
Cost of goods sold – product revenue	30,775	32,084	(1,309)	(4)%
Research and development	134,199	113,240	20,959	19 %
Research and development – licenses acquired	677	15,625	(14,948)	(96)%
Selling, general and administrative	113,656	86,843	26,813	31 %
Wire transfer fraud loss	—	9,540	(9,540)	(100)%
Total operating expenses	279,307	257,332	21,975	9 %
Loss from operations	(203,564)	(188,541)	(15,023)	8 %
Other income (expense)				
Interest income	1,398	649	749	115 %
Interest expense and financing fee	(13,642)	(15,308)	1,666	(11)%
Foreign exchange loss	(89)	—	(89)	100 %
Change in fair value of investments	—	39,294	(39,294)	(100)%
Change in fair value of warrant liabilities	1,129	(447)	1,576	(353)%
Grant income	1,304	—	1,304	100 %
Total other income (expense)	(9,900)	24,188	(34,088)	(141)%
Loss before income tax expense	(213,464)	(164,353)	(49,111)	30 %
Income tax expense	449	473	(24)	(5)%
Net loss	**(213,913)**	**(164,826)**	**(49,087)**	**30 %**
Less: net loss attributable to non-controlling interest	127,338	100,123	27,215	27 %
Net loss attributable to common stockholders	**$ (86,575)**	**$ (64,703)**	**$ (21,872)**	**34 %**

For the year ended December 31, 2022, the net increase in revenue of $7.0 million or 10% is due to Journey's expanded product portfolio, which resulted in a net product revenue increase of $7.9 million, and the increase in other revenue of $2.7 million resulting from the $2.5 million milestone payment from Maruho triggered by Maruho's receipt of manufacturing and marketing approval in Japan of Rapifort® Wipes 2.5% and $0.2 million in royalties, also from Maruho. Collaboration revenue related to Cyprium's agreement with Sentynl decreased $3.5 million due to the extension of Cyprium's NDA submission timeline, offset by a decrease in revenue from a related party of $0.1 million related to Checkpoint's collaboration agreement with TG Therapeutics for patent cost reimbursement. Journey's increased net product revenues are a result of the growth of Journey's marketed products acquired in 2021, Qbrexza and Accutane, as well as incremental growth from Amzeeq and Zilxi, acquired in January 2022, offset by a decrease in net sales of Journey's legacy products primarily as a result of generic competition and also contract manufacturer product shortages in 2022 that were resolved by the third quarter of 2022.

Cost of goods sold decreased by $1.3 million or 4% in 2022 due to decreased inventory step-up charges of approximately $5.9 million resulting from reduced costs related to the Amzeeq and Zilxi product acquisitions in January 2022 as compared to the charges related to the Qbrexza acquisition in the second quarter of 2021. In addition, royalty expenses decreased by $1.7 million, or 12%, mainly due to the decrease in Targadox sales from period-to-period. These reductions were offset in part by higher product costs of $1.8 million, driven by: increased product sales volume from period-to-period, increased license amortization and Prescription Drug User Fee Act fees of $1.86 million and $0.6 million respectively, related to our acquired intangible assets from the acquisition of Amzeeq and Zilxi, and increased costs of approximately $1.7 million related to freight, destruction, product validation and stability testing costs. Additionally, incremental costs of $0.4 million related to the establishment of expired product and other inventory reserves were charged against operations through cost of goods sold for the year ended December 31, 2022.

Research and development expenses increased $21.0 million, or 19%, from the year ended December 31, 2021 to the year ended December 31, 2022. The following table shows research and development spending for Fortress and each partner company:

($ in thousands)	Year Ended December 31, 2022	2021	Change $	Change %
Research & Development				
Stock-based compensation				
Fortress	$ 1,592	$ 1,152	$ 440	38 %
Partner Companies:				
Avenue	297	172	125	73 %
Checkpoint	888	684	204	30 %
JMC	73	—	73	100
Mustang	1,583	2,278	(695)	(30)%
Other[1]	10	21	(11)	(55)%
Sub-total stock-based compensation expense	4,443	4,307	136	158 %
Other Research & Development				
Fortress	768	1,441	(673)	(47)%
Partner Companies:				
Avenue	2,084	1,083	1,001	92 %
Checkpoint	47,052	41,171	5,881	14 %
JMC	10,870	2,739	8,131	297 %
Mustang	60,447	47,353	13,094	28 %
Other[1]	8,535	15,146	(6,611)	(44)%
Total Research & Development Expense	**$ 134,199**	**$ 113,240**	**$ 20,959**	**19 %**

Note 1: Includes the following subsidiaries: Aevitas, Baergic (through November 7, 2022), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

The increase in stock-based compensation at Fortress, Avenue and Checkpoint is due to new equity grants to key employees and consultants in 2022, while the decrease in Mustang's stock-based compensation is due to the effect of fully vested equity grants to key employees and consultants.

The increase in research and development spending is due in part to Mustang's increase in employee compensation costs of $4.3 million as research and development headcount supporting clinical program development, increased laboratory supply costs of $2.7 million, increased lentiviral vector manufacturing costs of $1.7 million to support Mustang-sponsored clinical trials, and $2.6 million in increased sponsored research and clinical trial costs. Journey's increased research and development costs are due to clinical trial expenses to develop DFD-29, for which their Phase 3 clinical trials are 100% enrolled as of January 2023. Checkpoint's increase in research and development spending is attributable to an $8.3 million increase in manufacturing costs of product candidates, $3.0 million increase in headcount costs, and $1.7 million increased regulatory costs, offset by a decrease in milestone payments of $6.4 million related to the 2021 non-refundable milestone payment that was triggered by the first patient dosed in a Phase 3 clinical study of cosibelimab, and a $1.8 million decrease in clinical costs due to the closing of the CONTERNO study, initiated in December 2021, due to the ongoing conflict in Ukraine and the disruption of clinical trial sites in the region. Avenue's increase in research and development spend in 2022 is primarily attributable to costs related to the FDA Advisory Committee Meeting for IV Tramadol in early 2022. The decrease in "Other" is attributable to a decrease of $3.2 million in costs incurred by Cyprium for its rolling NDA submission for CUTX-101, a decrease of $1.2 million of costs incurred by Urica for the dotinurad clinical program, and reduced costs at Oncogenuity and Aevitas related to sponsored reseach.

We expect research and development costs to remain flat or decrease modestly in 2023.

The decrease in research and development – licenses acquired of $14.9 million, or 96%, from the year ended December 31, 2021 as compared to the year ended December 31, 2022 is due primarily to $13.8 million expense recorded in 2021 for Journey's license, collaboration, and assignment agreement with Dr. Reddy's Laboratories, Ltd. for a potential rosacea treatment, referred to as the DFD-29 Agreement, as well as a related derivative warrant liability, and Mustang's $1.6 million of expense recorded in 2021 related to milestone payments on existing licenses and a $0.4 million upfront payment required by the Leiden University Medical Centre license, as compared to current research and development – licenses acquired expense of $0.7 million for the year ended December 31, 2022, comprised of $0.4 million in milestone payments on existing licenses at Mustang and a $0.3 million payment by Urica to expand the geographic regions covered by the existing license with Fuji for the development of dotinurad.

Selling, general and administrative expenses increased $26.8 million, or 31%, from the year ended December 31, 2021 to the year ended December 31, 2022. The following table shows selling, general and administrative spending for Fortress and by each partner company:

($ in thousands)	Year Ended December 31, 2022	2021	Change $	Change %
Selling, General & Administrative				
Stock-based compensation				
Fortress	$ 11,060	$ 8,897	$ 2,163	24 %
Partner Companies:				
Avenue	352	270	82	30 %
Checkpoint	2,036	2,453	(417)	(17)%
JMC	4,352	2,466	1,886	77 %
Mustang	700	1,030	(330)	(32)%
Other[2]	44	63	(19)	(20)%
Sub-total stock-based compensation expense	18,544	15,179	3,365	22 %
Other Selling, General & Administrative				
Fortress	15,859	17,165	(1,306)	(8)%
Partner Companies:				
Avenue	4,661	2,214	2,447	111 %
Checkpoint	5,746	4,553	1,193	26 %
JMC[1]	55,151	37,429	17,722	47 %
Mustang	10,040	7,836	2,204	28 %
Other[2]	3,655	2,467	1,188	48 %
Total Selling, General & Administrative Expense	**$ 113,656**	**$ 86,843**	**$ 26,813**	**31 %**

Note 1: Includes field sales force costs for the year ended December 31, 2022 and 2021 of $23.5 million and $16.0 million, respectively. During the course of 2022, JMC expanded their field sales force to accommodate their increased product portfolio.

Note 2: Includes the following subsidiaries: Aevitas, Baergic (though November 7, 2022), Cellvation, Cyprium, Helocyte, Oncogenuity and Urica.

The increase in stock-based compensation at Fortress, Avenue and Journey is due to new equity grants to key employees and consultants in 2022.

For the year ended December 31, 2022, the increase in selling, general and administrative expenses of $26.8 million or 31% is primarily attributable to increased expenses at Journey related to their increased salesforce as well as increased marketing expense related to Journey's expanded product portfolio, increased headcount and other supporting services related to being a public company, and increased legal costs associated with patent litigation. Mustang's increase is due to increased headcount costs, increased corporate and patent-related legal costs, as well as an increase in professional and consulting fees. The increase in selling, general and administrative costs at Checkpoint are attributable to increased legal and accounting fees.

We expect selling, general and administrative expenses to remain flat or decrease modestly in 2023.

For the year ended December 31, 2021, wire fraud related costs totaled approximately $9.5 million. These costs were attributable to funds erroneously wired to fraudulent accounts as a result of a sophisticated business email compromise fraud scheme. Any recovered proceeds will be recorded when considered probable.

Total other income (expense) changed $34.1 million, or 141%, from income of $24.2 million for the year ended December 31, 2021 to expense of $9.9 million for the year ended December 31, 2022, primarily due to the $39.3 million gain on the fair value of Caelum recognized in 2021, offset by the increase in change in fair value of warrant liabilities associated with warrants related to financings at Avenue and Checkpoint of $1.6 million, a decrease of $1.7 million in interest expense and financing fees due to non-recurring costs in 2021 related to Journey's convertible preferred share offering, and lower interest expense for the year ended December 31, 2022 associated with the Company's credit facility with Oaktree, as well as $1.3 million in grant income recognized by Mustang in the year ended December 31, 2022.

Net loss attributable to non-controlling interests increased $27.2 million, or 27% from the year ended December 31, 2021 to the year ended December 31, 2022. This increase reflects the partner companies' share of net loss. Net loss attributable to common stockholders increased $21.9 million or 27%, from a net loss of $64.7 million for the year ended December 31, 2021 to a net loss of $86.6 million for the year ended December 31, 2022.

Liquidity and Capital Resources

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

	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)

	For the Year Ended December 31, 2021					
($ in thousands)	Fortress[1]	Avenue	Checkpoint	JMC	Mustang	Total
Statement of cash flows data:						
Total cash (used in)/provided by:						
Operating activities	$ (30,636)	$ (3,750)	$ (26,306)	$ (2,181)	$ (53,667)	$ (116,540)
Investing activities	55,880	—	—	(10,000)	(5,366)	40,514
Financing activities	(19,519)	4,381	40,269	53,016	70,847	148,994
Net increase in cash and cash equivalents and restricted cash	$ 5,725	$ 631	$ 13,963	$ 40,835	$ 11,814	$ 72,968

Note 1: Includes Fortress and non-public subsidiaries.

	Year Ended December 31,		
($ in thousands)	2022	2021	Change
Statement of cash flows data:			
Total cash (used in)/provided by:			
Operating activities	$ (179,401)	$ (116,540)	$ (62,861)
Investing activities	(22,928)	40,514	(63,442)
Financing activities	75,319	148,994	(73,675)
Net increase in cash and cash equivalents and restricted cash	$ (127,010)	$ 72,968	$ (199,978)

Operating Activities

Net cash used in operating activities increased $62.9 million from the year ended December 31, 2021 to the year ended December 31, 2022. The increase is primarily due to the increase in net loss of $49.1 million for the year ended December 31, 2022 as compared to the year ended December 31, 2021, with the increases in cash used by accounts payable and accrued expenses of $34.2 million, accounts receivable of $6.1 million, deferred revenue of $4.5 million as compared to the year ended December 31, 2021 offset by the decrease in the fair value of the investment in Caelum for the year ended December 31, 2021 of $39.3 million.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2021 of $40.5 million decreased $63.4 million to net cash used by investing activities of $22.9 million for the year ended December 31, 2022. The change is primarily due to cash provided by the proceeds from the sale of Caelum of $56.9 million received in 2021 related to AstraZeneca's exercise of their purchase option, offset by Journey's purchase of the 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.

Financing Activities

Net cash provided by financing activities was $75.3 million for the year ended December 31, 2022, compared to $149.0 million of net cash provided by financing activities for the year ended December 31, 2021, a decrease of $73.7 million. The decrease is primarily due to the decrease of $94.4 million in proceeds from partner companies' at-the-market offerings, and the decrease of $17.0 million in proceeds from a partner company's sale of convertible preferred stock. Offsetting these decreases was the increase in proceeds from partner companies' long-term debt of $47.1 million, as well as the $10.5 million repayment of Fortress' Oaktree Note.

Sources of Liquidity

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, 2022, we had cash and cash equivalents of $178.3 million of which $51.8 million relates to Fortress and the private partner companies, primarily funded by Fortress, $12.1 million relates to Checkpoint, $75.7 million relates to Mustang, $32.0 million relates to JMC and $6.7 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 $2.7 million.

In July 2021, the Company filed a shelf registration statement on Form S-3 (File No. 333-258145), which was declared effective in July 2021 (the "2021 S-3"). As of December 31, 2022, no securities had been drawn down under the 2021 S-3.

In May 2020, the Company a filed shelf registration statement on Form S-3 (File No. 333-238327), which was declared effective in May 2020 (the "2020 S-3"). For the year ended December 31, 2022, the Company issued approximately 4.1 million shares of common stock at an average price of $1.50 per share for gross proceeds of $6.2 million. In connection with these sales, the Company paid aggregate fees of $0.2 million. Approximately $11.1 million of securities remain available for sale under the 2020 S-3 at December 31, 2022.

Subsequent to 2022, 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 16,642,894 shares of its common stock at a purchase price of $0.835 per share 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.

The amount of securities we are able to sell pursuant to the registration statement on Form S-3 is limited. See "Risk Factors."

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. At December 31, 2022, $150.0 million remains available under the Journey 2022 S-3.

In November 2020, Checkpoint filed a shelf registration statement on Form S-3 (File No. 333-251005) which was declared effective in December 2020 (the "Checkpoint 2020 S-3"). During the year ended December 31, 2022, Checkpoint issued a total of 532,816 shares of common stock under the Checkpoint 2020 S-3 for aggregate total gross proceeds of approximately $10.1 million at an average selling price of $18.99 per share.

In December 2022, Checkpoint closed on a 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. Each pre-funded warrant was exercisable 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 and associated common stock warrants, and $4.33249 per pre-funded warrant and associated common stock warrants. The pre-funded warrants were funded in full at closing except for a nominal exercise price of $0.0001 and became exercisable on the closing date of the offering and will terminate when such pre-funded warrants are exercised in full. The Series A warrants became exercisable immediately upon issuance and will expire five years following the issuance date and have an exercise price of $4.075 per share and the Series B warrants became exercisable immediately upon issuance and will expire eighteen months following the issuance date and have an exercise price of $4.075 per share. Checkpoint also issued placement agent warrants to purchase up to 104,046 shares of Checkpoint common stock with an exercise price of $5.406 per share. Net proceeds from the registered direct offering were $6.7 million after deducting commissions and other transaction costs. The shares and warrants were sold under the Checkpoint 2020 S-3.

In February 2023, Checkpoint closed on a registered direct offering ("February 2023 Direct Offering") with a single institutional investor for the issuance and sale of 1,180,000 shares of its common stock and 248,572 pre-funded warrants. Each pre-funded warrant is exercisable for one share of common stock. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 1,428,572 shares of common stock and Series B warrants to purchase up to 1,428,572 shares of common stock, at a purchase price of $5.25 per share of common stock and associated common stock warrants, and $4.2499 per pre-funded warrant and associated common stock warrants. Net proceeds from the February 2023 Direct Offering were $6.7 million after deducting commissions and other transaction costs.

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. As of December 31, 2022, there have been no sales of securities under the Mustang 2021 S-3. In October 2020, Mustang filed a shelf registration statement on Form S-3 (File No. 333-249657) which was declared effective in December 2020 (the "Mustang 2020 S-3"). Under the Mustang 2020 S-3, Mustang may sell up to a total of $100.0 million of its securities. During the year ended December 31, 2022, Mustang issued approximately 7.9 million shares of common stock at an average selling price of $0.84 per share under the Mustang 2020 S-3 for aggregate total gross proceeds of approximately $6.6 million. At December 31, 2022, approximately $8.0 million of the Mustang 2020 S-3 remains available for sales of securities.

In October 2022, Avenue announced the closing of an underwritten public offering of 3,636,365 common and pre-funded units. Each common unit consists of one share of common stock and one warrant to purchase one share of common stock, and each pre-funded unit consists of one pre-funded warrant to purchase one share of common stock and one warrant to purchase one share of common stock. Each share of common stock (or pre-funded warrant) was sold together with one warrant at a combined purchase price of $3.30 per common unit (or $3.2999 per pre-funded unit after reducing $0.0001 attributable to the exercise price of the pre-funded warrants). Avenue also simultaneously closed on the sale of an additional 545,454 warrants to purchase common stock, which were sold pursuant to a partial exercise of the underwriter's over-allotment option. Avenue received net proceeds of approximately $10.3 million at closing after deducting underwriting discounts and commissions and other expenses of the offering.

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. 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 and a purchase price of $0.125. The purchase price of each share is $1.55. The purchase price of each pre-funded warrant is $1.549 with an exercise price of $0.001. Avenue received approximately $2.6 million in net proceeds.

Debt

In December 2022, Urica commenced an offering of 8% Cumulative Convertible Class B Preferred Stock ("Urica Preferred Offering") in an aggregate maximum amount of $5.0 million. Urica issued an aggregate of 101,334 Class B Preferred shares at a price of $25.00 per share, for gross proceeds of $2.5 million. Following the payment of placement agent fees and other expenses of $0.3 million, Urica received $2.2 million in net proceeds.

In March 2022, Mustang announced completion of a $75 million long-term debt facility with Runway. Of the $75 million, $30 million was funded upon closing, and the additional $45 million available through the facility may be funded upon Mustang's achieving certain predetermined milestones. Proceeds from the facility will be used to support the ongoing clinical development of key investigational product candidates within Mustang's pipeline and for general working capital purposes.

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.

In addition to the foregoing, based on the Company's current assessment, the Company does not expect any material impact on its long-term development timeline and its liquidity due to the worldwide spread of the COVID-19 virus. However, the Company is continuing to assess the effect on its operations by monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world.

Contractual Obligations

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

During the year ended December 31, 2022, Mustang entered into a new lease for office space commencing on July 1, 2022. The lease has a term of 7 years and 7 months, with rent obligations beginning on November 1, 2022. Base rent is $49,000 per month and increases to $56,000 per month during the term of the lease. The first 24 months of rent payments are abated, and the lease includes a $0.3 million tenant improvement allowance.

Recently Issued Accounting Pronouncements

See Note 2 of Notes to the Consolidated Financial Statements for a discussion of recent accounting standards and pronouncements.

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, 2022, 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, 2022. 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, 2022, our internal control over financial reporting was effective.

Changes in Internal Controls over Financial Reporting

Except for the remediation efforts described above taken to address the material weakness, 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

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2023 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2023 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2023 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2023 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2023 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 1, 2020 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 10 (file No. 000-54463) filed with the SEC on July 15, 2011).
3.2	First Certificate of Amendment of Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated May 20, 2011 (incorporated by reference to Exhibit 3.2 of the Registrant's Form 10 (file No. 000-54463) filed with SEC on July 15, 2011).
3.3	Second Certificate of Amendment of Amended and Restated Certificate of Incorporation, 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 of 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 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).
3.7	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated June 23, 2021, (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on June 23, 2020).
3.8	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc. dated July 8, 2022 (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on July 11, 2022).
3.9	Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.7 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on October 31, 2013.
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	Description of Securities of Fortress Biotech, Inc.*
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).#

Exhibit Number	Exhibit Title
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	Fortress Biotech, Inc. 2012 Employee Stock Purchase Plan (incorporated by reference to Annex A of the Registrant's Schedule 14A (file No. 001-35366) filed with the SEC on July 13, 2012). #
10.6	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). #
10.7	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).
10.8	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).#
10.9	Form of Coronado Biosciences, Inc. 2013 Stock Incentive Plan Award Agreement (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). #
10.10	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). #
10.11	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). #
10.13	Form of Common Stock Purchase Warrant in favor of National Securities Corporation (incorporated by reference to Exhibit 10.35 of the Registrant's Quarterly Report on Form 10-Q (file No. 001-35366) filed with the SEC on May 10, 2017).
10.14	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).
10.15	Fortress Biotech, Inc. Amended and Restated Long-Term Incentive Plan (incorporated by reference to Exhibit 10.39 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on June 12, 2017).
10.16	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).*
10.17	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 19, 2020).#

Exhibit Number	Exhibit Title
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 27, 2022).#
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	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).#
16.1	Letter from BDO USA, LLP to the Securities and Exchange Commission dated September 22, 2021 (incorporated by reference to Exhibit 16.1 of the Registrant's Current Report on Form 8-K (file No. 001-35366) filed with the SEC on September 24, 2021).
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.*
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

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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, 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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of accrued coupon liability

As discussed in Note 11 of the consolidated financial statements, the Company accrues for coupons on products for certain qualified commercially-insured parties. At December 31, 2022, the Company recorded $7,604 thousand in accrued coupon and rebates, which included the accrued coupon liability. 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 primarily based on historical company coupon redemption costs, cost per coupon claims, 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.

KPMG LLP

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

Short Hills, New Jersey
March 31, 2023

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

	December 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 178,266	$ 305,744
Accounts receivable, net	28,208	23,112
Inventory	14,159	9,862
Other receivables - related party	138	678
Prepaid expenses and other current assets	9,661	7,066
Total current assets	230,432	346,462
Property, plant and equipment, net	13,020	15,066
Operating lease right-of-use asset, net	19,991	19,005
Restricted cash	2,688	2,220
Intangible asset, net	27,197	12,552
Other assets	973	1,198
Total assets	**$ 294,301**	**$ 396,503**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 97,446	$ 90,660
Deferred revenue	728	2,611
Income taxes payable	722	345
Common stock warrant liabilities	13,869	—
Operating lease liabilities, short-term	2,447	2,104
Partner company convertible preferred shares, short-term, net	2,052	—
Partner company line of credit	2,948	812
Partner company installment payments - licenses, short-term, net	7,235	4,510
Other short-term liabilities	268	—
Total current liabilities	127,715	101,042
Notes payable, long-term, net	91,730	42,937
Operating lease liabilities, long-term	21,572	20,987
Partner company installment payments - licenses, long-term, net	1,412	3,627
Other long-term liabilities	1,847	2,033
Total liabilities	**244,276**	**170,626**
Commitments and contingencies (Note 15)		
Stockholders' equity		
Cumulative redeemable perpetual preferred stock, $0.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 110,494,245 shares issued and outstanding as of December 31, 2022; 170,000,000 shares authorized, 101,435,505 shares issued and outstanding as of December 31, 2021, respectively	110	101
Additional paid-in-capital	675,841	656,033
Accumulated deficit	(634,233)	(547,463)
Total stockholders' equity attributed to the Company	41,721	108,674
Non-controlling interests	8,304	117,203
Total stockholders' equity	50,025	225,877
Total liabilities and stockholders' equity	**$ 294,301**	**$ 396,503**

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,	
	2022	2021
Revenue		
Product revenue, net	$ 70,995	$ 63,134
Collaboration revenue	1,882	5,389
Revenue - related party	192	268
Other revenue	2,674	—
Net revenue	75,743	68,791
Operating expenses		
Cost of goods sold - product revenue	30,775	32,084
Research and development	134,199	113,240
Research and development - licenses acquired	677	15,625
Selling, general and administrative	113,656	86,843
Wire transfer fraud loss	—	9,540
Total operating expenses	279,307	257,332
Loss from operations	(203,564)	(188,541)
Other income (expense)		
Interest income	1,398	649
Interest expense and financing fee	(13,642)	(15,308)
Foreign exchange loss	(89)	—
Change in fair value of investments	—	39,294
Change in fair value of warrant liabilities	1,129	(447)
Grant income	1,304	—
Total other income (expense)	(9,900)	24,188
Loss before income tax expense	(213,464)	(164,353)
Income tax expense	449	473
Net loss	**(213,913)**	**(164,826)**
Net loss attributable to non-controlling interests	127,338	100,123
Net loss attributable to common stockholders	**$ (86,575)**	**$ (64,703)**
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.97)	$ (0.79)
Weighted average common shares outstanding - basic and diluted	88,874,519	81,700,220

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 amounts)	Series A Preferred Stock Shares		Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
Balance at December 31, 2020	**3,427,138**	**$ 3**	**94,877,492**	**$ 95**	**$ 583,000**	**$ (482,760)**	**$ 96,661**	**$ 196,999**
Stock-based compensation expense	—	—	—	—	19,486	—	—	19,486
Issuance of common stock related to equity plans	—	—	3,236,752	3	275	—	—	278
Issuance of common stock for at-the-market offering, net	—	—	3,067,446	3	9,082	—	—	9,085
Payment of Series A perpetual preferred stock dividends	—	—	—	—	(8,031)	—	—	(8,031)
Partner company's offering, net	—	—	—	—	34,996	—	—	34,996
Partner companies' at-the-market offering, net	—	—	—	—	110,887	—	—	110,887
Issuance of common stock under partner company's ESPP	—	—	—	—	309	—	—	309
Partner company's dividends declared and paid	—	—	—	—	(749)	—	—	(749)
Partner company's exercise of options for cash	—	—	—	—	7	—	—	7
Issuance of partner company's common shares for research and development expenses	—	—	—	—	176	—	—	176
Common shares issued for dividend on partner company's convertible preferred shares	—	—	253,815	—	820	—	—	820
Conversion of partner company convertible preferred shares	—	—	—	—	21,812	—	—	21,812
Conversion of partner company derivative warrant liabilities	—	—	—	—	4,628	—	—	4,628
Non-controlling interest in subsidiaries	—	—	—	—	(120,665)	—	120,665	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	(100,123)	(100,123)
Net loss attributable to common stockholders	—	—	—	—	—	(64,703)	—	(64,703)
Balance at December 31, 2021	**3,427,138**	**$ 3**	**101,435,505**	**$ 101**	**$ 656,033**	**$ (547,463)**	**$ 117,203**	**$ 225,877**
Stock-based compensation expense	—	—	—	—	22,987	—	—	22,987
Issuance of common stock related to equity plans	—	—	4,913,804	5	169	—	—	174
Issuance of common stock for at-the-market offering, net	—	—	4,144,936	4	6,049	—	—	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
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)
Issuance of common stock under partner company's ESPP	—	—	—	—	206	—	—	206
Partner company's dividends declared and paid	—	—	—	—	(749)	—	—	(749)
Partner company's redemption of preferred shares	—	—	—	—	(85)	—	—	(85)
Partner company's stock adjustment	—	—	—	—	(6)	—	—	(6)
Partner company's net settlement of shares withheld for taxes	—	—	—	—	(1,698)	—	—	(1,698)
Partner company stock adjustment	—	—	—	—	(23)	—	—	(23)
Partner company's warrants issued in conjunction with debt	—	—	—	—	384	—	—	384
Partner company's retained earning adjustment	—	—	—	—	195	(195)	—	—
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**	**110,494,245**	**$ 110**	**$ 675,841**	**$ (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, 2022	2021
Cash Flows from Operating Activities:		
Net loss	$ (213,913)	$ (164,826)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation expense	3,109	2,628
Loss on disposal of property and equipment	255	—
Bad debt expense	284	48
Amortization of debt discount	2,065	3,914
Accretion of partner company convertible preferred shares	—	2,845
Non-cash interest	770	781
Prepayment penalty of Oaktree Note	—	450
Amortization of product revenue license fee	4,277	2,474
Amortization of operating lease right-of-use assets	1,967	1,689
Stock-based compensation expense	22,987	19,486
Common shares issued for dividend on partner company's convertible preferred shares	—	820
Change in fair value of investment in Caelum	—	(39,294)
Change in fair value of partner companies' warrant liabilities	(1,129)	447
Research and development-licenses acquired, expense	642	15,625
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:		
Accounts receivable	(5,380)	768
Inventory	1,744	(8,458)
Other receivables - related party	540	66
Prepaid expenses and other current assets	(2,595)	(309)
Other assets	344	(185)
Accounts payable and accrued expenses	8,349	43,307
Deferred revenue	(1,883)	2,611
Income taxes payable	377	345
Lease liabilities	(2,025)	(1,856)
Other long-term liabilities	(186)	84
Net cash used in operating activities	(179,401)	(116,540)
Cash Flows from Investing Activities:		
Purchase of research and development licenses	(340)	(11,380)
Purchase of property and equipment	(2,715)	(4,566)
Proceeds from the sale of partner company's fixed assets	127	—
Purchase of intangible asset	—	(400)
Acquisition of Vyne products	(20,000)	—
Proceeds from sale of Caelum	—	56,860
Net cash used in investing activities	(22,928)	40,514

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,	
	2022	2021
Cash Flows from Financing Activities:		
Payment of Series A perpetual preferred stock dividends	$ (8,031)	$ (8,031)
Proceeds from issuance of common stock for at-the-market offering, net	6,053	9,085
Proceeds from issuance of common stock under ESPP	174	278
Proceeds from partner companies' ESPP	206	309
Partner company's dividends declared and paid	(749)	(749)
Proceeds from partner companies' sale of stock and warrants, net	17,835	35,367
Proceeds from partner companies' at-the-market offering, net	16,370	110,803
Proceeds from partner company convertible preferred shares, net	—	16,971
Proceeds from partner company's preferred stock offering, net	—	(13)
Proceeds from exercise of partner companies' equity grants	290	7
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 redemption of preferred shares	(85)	—
Payment of partner company's repurchase of stock	(1,105)	—
Payment of partner company's deferred financing cost	(119)	—
Payment of debt issuance costs associated with Oaktree Note	—	(95)
Repayment of Oaktree Note	—	(10,450)
Repayment of partner company installment payments - licenses	(5,000)	(5,300)
Proceeds from partner company convertible preferred shares	2,533	—
Payment of debt issuance costs associated with partner company convertible preferred shares	(597)	—
Proceeds from partner company long-term debt, net	47,112	—
Proceeds from partner's company line of credit	5,000	7,000
Repayment of partner company's line of credit	(2,864)	(6,188)
Net cash provided by financing activities	75,319	148,994
Net (decrease) increase in cash and cash equivalents and restricted cash	(127,010)	72,968
Cash and cash equivalents and restricted cash at beginning of period	307,964	234,996
Cash and cash equivalents and restricted cash at end of period	$ 180,954	$ 307,964
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 9,419	$ 6,918
Cash paid for tax	$ 858	$ 993
Supplemental disclosure of non-cash financing and investing activities:		
Settlement of restricted stock units into common stock	$ 5	$ 3
Unpaid fixed assets	$ —	$ 1,270
Conversion of partner company convertible preferred shares	$ —	$ 21,812
Conversion of partner company derivative warrant liabilities	$ —	$ 4,628
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	$ 214
Unpaid partner company's offering cost	$ 4	$ 371
Unpaid partner company's repurchase of stock	$ —	$ —
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	$ 90	$ 362
Partner company's warrants issued in conjunction with debt	$ 384	$ —
Unpaid research and development licenses acquired	$ 325	$ 250
Lease liabilities arising from obtaining right-of-use assets	$ 2,953	$ 207

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 dedicated to acquiring, developing and commercializing pharmaceutical and biotechnology products and product candidates, which it does through Fortress itself and through partner companies and subsidiaries. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who work in concert with its extensive network of key opinion leaders to identify and evaluate promising products and product candidates for potential acquisition. The Company has executed such arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center, Fred Hutchinson Cancer Center, St. Jude Children's Research Hospital, 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, AstraZeneca plc and Dr. Reddy's Laboratories, Ltd.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and finance expertise to help the partners achieve their goals. Partner companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out-licensings, and public and private financings; to date, four partner companies are publicly-traded, and three have consummated strategic partnerships with industry leaders Alexion Pharmaceuticals, Inc. and InvaGen Pharmaceuticals, Inc. (a subsidiary of Cipla Limited) and Sentynl Therapeutics, Inc. ("Sentynl"), respectively. In October 2021, AstraZeneca plc ("AstraZeneca") (acquiror of Alexion) purchased 100% of the Company's partner Caelum Biosciences, Inc. ("Caelum") for approximately $150 million upfront and up to $350 million in contingent regulatory and sales milestone payments.

Several of the Company's partner companies possess licenses to product candidate intellectual property are Aevitas Therapeutics, Inc. ("Aevitas"), 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", formerly UR-1 Therapeutics, Inc).

Liquidity and Capital Resources

Since inception, the Company's operations have been financed primarily through the sale of equity and debt securities, from the sale of subsidiaries/partner companies, and the proceeds from the exercise of warrants and stock options. The Company has incurred losses from operations and negative cash flows from operating activities since inception and expects to continue to incur substantial losses for the next several years as it continues to fully develop and prepare regulatory filings and obtain regulatory approvals for its existing and new product candidates. The Company's current cash and cash equivalents are sufficient to fund operations for at least the next 12 months. However, the Company will need to raise additional funding through strategic relationships, public or private equity or debt financings, 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.

On October 31, 2022, we received a letter from the Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") indicating that the bid price of the Company's common stock, par value $0.001 per share (the "Common Stock"), had closed below $1.00 per share for 30 consecutive business days and, as a result, the Company is not in compliance with Nasdaq Listing Rule 5550(a)(2), which sets forth the minimum bid price requirement for continued listing on The Nasdaq Capital Market. Our Common Stock may be subject to delisting from The Nasdaq Capital Market if we are unable to regain compliance which may decrease the market liquidity and market price of our Common Stock.

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 accounting principles generally accepted in the United States of America ("GAAP"). The Company's consolidated financial statements include the accounts of the Company and the accounts of the Company's subsidiaries, listed above. All intercompany balances and transactions have been eliminated.

The accompanying consolidated financial statements include the accounts of the Company's subsidiaries. For consolidated entities where the Company owns less than 100% of the subsidiary, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations equal to the percentage of the economic or ownership interest retained in such entities by the respective non-controlling parties. The Company also consolidates subsidiaries in which it owns less than 50% of the subsidiary but maintains voting control. The Company continually assesses whether changes to existing relationships or future transactions may result in the consolidation or deconsolidation of partner companies.

Use of Estimates

The Company's consolidated financial statements include certain amounts that are based on management's best estimates and judgments. 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, useful lives assigned to long-lived assets and amortizable intangible assets, fair value of stock options and warrants, stock-based compensation, common stock issued to acquire licenses, investments, accrued expenses, provisions for income taxes and contingencies. Due to the uncertainty inherent in such estimates, actual results may differ from these estimates.

Revenue Recognition

The Company records and recognizes revenues 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 majority of coupon reserve accrual at the end of the period reflects coupons that have been redeemed for which the Company has been billed in addition to an accrual for expected redemptions for product in the distribution channel. The expected accrual reserve requires us to estimate the distribution channel inventory at period end, the expected redemption rates, and the cost per coupon claim that the Company expects to receive. The estimate of product remaining in the distribution channel is comprised of estimated inventory at the wholesaler as well as an estimate of inventory on the shelves 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, qualified government healthcare providers, qualified U.S. Department of Veterans Affairs hospitals, and 340B entities. 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. Because the price paid by the indirect customers and/or entities is lower than the price paid by the wholesaler, the Company provides a credit, called a chargeback, to the wholesaler for the difference between the contractual price with the indirect customers and their purchase price. 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.

Prompt-Pay Discounts – The Company provides for prompt pay discounts if payment is received within contractual payment term days, which generally ranges from 30 to 90 days. These discounts are recorded at the time of sale based on the customer's contracted rate and recorded as a reduction of revenue and a reduction to accounts receivables.

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 and its own 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 it's customers over time. The Company measures it's progress using an input method based on the effort expended or costs incurrd 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 Comapny recognizes each period. This approach requires the use of estimates and judgemenst. 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, 2022 and 2021, 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, 2022, 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. Credit risk in these securities is reduced as a result of the Company's investment policy to limit the amount invested in any single issuer and to only invest in securities of a high credit quality. 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.

In connection with Mustang's cell processing facility, Mustang incurred costs for the design and construction of the facility and the purchase of equipment; $1.0 million and $2.0 million are recorded in fixed assets – construction in process on the balance sheet at December 31, 2022 and 2021, respectively. Upon completion of the facility's construction, all costs associated with the buildout will be recorded as leasehold improvements and amortized over the shorter of the estimated useful lives or the term of the respective leases, upon the improvement being placed in service.

Intangible Assets

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.

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. The Company has not recorded any impairment losses on long-lived assets for the years ended December 31, 2022 and 2021.

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.

Restricted Cash

The Company records cash held in trust or pledged to secure certain debt obligations as restricted cash. 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 and an undertaking posted by Cyprium to secure potential damages in an injunctive proceeding. As of December 31, 2021, the Company had $2.2 million of restricted cash representing pledges to secure letters of credit in connection with certain office leases.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash from the consolidated balance sheets to the consolidated statements of cash flows for the years ended 2022 and 2021:

	December 31,	
	2022	2021
Cash and cash equivalents	$ 178,266	$ 305,744
Restricted cash	2,688	2,220
Total cash and cash equivalents and restricted cash	$ 180,954	$ 307,964

Inventories

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 $0.4 million and zero at December 31, 2022 and 2021, respectively.

Accounts Receivable, net

The Company's accounts receivable consists of amounts due from customers related to product sales and have standard payment terms. For certain customers, the accounts receivable for the customer is 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 $0.4 million and $0.1 million at December 31, 2022 and 2021, respectively.

Investments at Fair Value

The Company elects the fair value option for its long-term investments at fair value (see Note 6). The decision to elect the fair value option, which is irrevocable once elected, is determined on an instrument-by-instrument basis and applied to an entire instrument. The net gains or losses, if any, on an investment for which the fair value option has been elected are recognized as a change in fair value of investments on the Consolidated Statements of Operations.

The Company has various processes and controls in place to ensure that fair value is reasonably estimated. While the Company believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including intangible assets with finite useful lives, for impairment 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. The Company has not recorded any impairment losses on long-lived assets for the years ended December 31, 2022 and 2021.

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, it has been concluded that there are no significant uncertain tax positions requiring recognition in the Company's financial statements. The 2017 through 2019 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. There were no amounts accrued for penalties or interest as of or during the years ended December 31, 2022 and 2021. 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 net loss per share of common stock is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding during the reporting period. Diluted earnings per share is calculated by dividing net income by the weighted-average number of shares of common stock outstanding during the reporting period after giving effect to dilutive potential common shares for stock options and restricted stock units, determined using the treasury stock method.

Non-Controlling Interests

Non-controlling interests in consolidated entities represent the component of equity in consolidated entities held by third parties. Any change in ownership of a subsidiary while the controlling financial interest is retained is accounted for as an equity transaction between the controlling and non-controlling interests.

Comprehensive Loss

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

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20)* and *Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2023 for smaller reporting companies. Early adoption will be permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses*. The ASU sets forth a current expected credit loss model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. This ASU is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, with early adoption permitted. Recently, the FASB issued the final ASU to delay adoption for smaller reporting companies to calendar year 2023. The Company is currently assessing the impact of the adoption of this ASU on its consolidated financial statements.

3. Collaboration and Stock Purchase Agreements

Caelum

Agreement with AstraZeneca's Alexion

In January 2019, Caelum, a subsidiary of the Company at that time, entered into a Development, Option and Stock Purchase Agreement (as amended, the "DOSPA") and related documents by and among Caelum, AstraZeneca as successor-in-interest to Alexion Therapeutics, Inc., the Company and Caelum's other equity holders as parties thereto (such equity holders, including Fortress, the "Sellers"). Under the terms of the DOSPA, AstraZeneca obtained a minority interest in Caelum and a contingent exclusive option to acquire the remaining equity in Caelum.

On September 28, 2021 AstraZeneca notified Caelum of its intention to exercise its purchase option, and on October 5, 2021 AstraZeneca acquired 100% of the capital stock of Caelum. Fortress received 42.4% of the distribution of proceeds from the option exercise price of $150 million, approximately $56.9 million, which is net of the 10%, 24-month escrow holdback and other miscellaneous transaction expenses. The Sellers currently remain eligible to receive up to an additional $350 million in contingent regulatory and commercial milestone payments, of which Fortress is eligible to receive 42.4% or approximately $148.6 million.

Cyprium

Agreement with Sentynl

On February 24, 2021, Cyprium entered into a development and contingent asset purchase agreement with Sentynl. Pursuant to the terms of the agreement, Sentynl paid Cyprium an upfront fee of $8.0 million to complete the CUTX-101 development program for the treatment of Menkes disease, through the filing of Cyprium's New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"). Cyprium also remains eligible to receive up to an additional $12.0 million in development milestones, payable as follows: (i) $3.0 million upon acceptance by the FDA of the NDA for review; and (ii) $9.0 million upon FDA approval of the NDA and transfer of CUTX-101 to Sentynl. Cyprium would also be eligible to receive up to $255.0 million in additional sales milestone payments (payable pursuant to five separate milestones), as well as royaltieson CUTX-101 net sales ranging from mid-single digits up to the mid-twenties. All of the foregoing milestone and royalty payments are subject to 50% diminution in the event Sentynl decides, at its option, to assume development control of CUTX-101 during the 45-day period beginning on September 30, 2023. The Company will recognize revenue associated with these future milestones based upon achievement. At December 31, 2022, none of these future milestones was deemed probable.

Cyprium would retain 100% ownership over any FDA Priority Review Voucher that may be issued at NDA approval for CUTX-101.

The Company determined that this agreement falls within the scope of *ASC 606-10-15-3* and *ASC 808-10-15-5A Revenue from Collaborative Arrangements* ("ASC 808") and as such the Company will recognize revenue in connection with achievement of two future development milestone payments.

In connection with the $8.0 million upfront payment to Sentynl, the Company is recognizing revenue using an input method based upon the costs incurred to date in relation to the total estimated costs to complete the development activities. Accordingly, revenue is being recognized over the period in which the development activities are expected to occur. For the years ended December 31, 2022 and 2021, the Company recognized revenue of $1.9 million and $5.4 million, respectively.

Avenue

Agreements with InvaGen

On November 12, 2018, Avenue entered into a Stock Purchase and Merger Agreement (the "Avenue SPMA") with InvaGen Pharmaceuticals Inc. ("InvaGen"), and Madison Pharmaceuticals Inc. (the "Merger Sub"), which contemplated: (i) the purchase by InvaGen of a 33.3% stake in Avenue and; (ii) the contingent sale of Avenue to InvaGen. The first stage stock purchase closed in February 2019: InvaGen acquired approximately 5.8 million shares of Avenue's common stock at $6.00 per share for total gross consideration of $35.0 million, representing a 33.3% stake in Avenue's capital stock on a fully diluted basis. Under a contingent second stage closing, InvaGen may have acquired the remaining shares of Avenue's capital stock (in some cases compulsorily and in some cases at InvaGen's option), pursuant to a reverse triangular merger with Avenue remaining as the surviving entity. On November 1, 2021, Avenue delivered InvaGen notice of termination of the Avenue SPMA, meaning that the second stage acquisition of Avenue by InvaGen pursuant to the Avenue SPMA is no longer possible. In July 2022 Avenue entered into a Share Repurchase Agreement with InvaGen (described below).

In connection with the closing by Avenue of an underwritten public offering (see Note 14) on October 11, 2022, Avenue consummated the transactions contemplated by the Share Repurchase Agreement with InvaGen, pursuant to which Avenue repurchased 100% of the shares in Avenue held by InvaGen (the "InvaGen Shares") for a purchase price of $3 million. In addition, under the Share Repurchase Agreement Avenue agreed to pay InvaGen an additional amount as a contingent fee, payable in the form of seven and a half percent (7.5%) of the proceeds of future financings, up to $4 million. In connection with the closing of the Share Repurchase Agreement, which occurred on October 31, 2022, all of the rights retained by InvaGen pursuant to the Stockholders Agreement entered into by and among Avenue, InvaGen and Fortress on November 12, 2018, were terminated.

4. Inventory

Inventory consisted of the following:

($ in thousands)	December 31, 2022	December 31, 2021
Raw materials	$ 6,454	$ 5,572
Work-in-process	395	—
Finished goods	7,739	4,290
Inventory reserve	(429)	—
Total inventories	$ 14,159	$ 9,862

5. Property and Equipment

Fortress' property and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	December 31, 2022	December 31, 2021
Computer equipment	3	$ 739	$ 739
Furniture and fixtures	5	1,387	1,387
Machinery & equipment	5	8,632	6,550
Leasehold improvements	2-15	13,175	13,175
Buildings	40	581	581
Construction in progress [1]	N/A	952	2,028
Total property and equipment		25,466	24,460
Less: Accumulated depreciation		(12,446)	(9,394)
Property, plant and equipment, net		$ 13,020	$ 15,066

Note 1: Relates to the Mustang cell processing facility.

Depreciation expenses of Fortress' property and equipment for the years ended December 31, 2022 and 2021 was $3.1 million and $2.6 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

Common Stock Warrant Liabilities

($ in thousands)	Warrants liabilities
Balance at December 31, 2020	$ —
Journey contingent payment liability	3,819
Journey placement agent warrant	362
Change in fair value of contingent payment liability	447
Satisfaction of partner company contingent payment	(4,628)
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

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 warrants and placement agent warrants. Net proceeds from the December 2022 Registered Direct Offering were $6.7 million after deducting commissions and other transaction costs (See Note 14).

The Company 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 of $7.9 million, determined by using the Black-Scholes model. As the total fair value of the common stock warrant liability exceeded the total net proceeds of $6.7 million, the Company recorded a loss of $1.2 million to loss on common stock warrant liabilities in the Consolidated Statements of Operations. Accordingly, there were no proceeds allocated to the common stock and pre-funded warrants issued as part of this transaction.

The Company revalued the December 2022 common warrants and placement agent warrants at December 31, 2022 using the Black-Scholes model. This resulted in an increase in common stock warrant liability of $3.3 million, with an offsetting loss recorded to loss on common stock warrant liabilities in the Statements of Operations.

($ 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

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 Series A Warrants	**December 16, 2022**	**December 31, 2022**
Exercise price	$ 4.08	$ 4.08
Volatility	89.5 %	89.4 %
Expected life	5.0	5.0
Risk-free rate	3.6 %	4.0 %
Dividend yield	—	—

Checkpoint Series B Warrants	**December 16, 2022**	**December 31, 2022**
Exercise price	$ 4.08	$ 4.08
Volatility	79.1 %	82.4 %
Expected life	1.5	1.5
Risk-free rate	4.2 %	4.7 %
Dividend yield	—	—

Checkpoint Placement Agent Warrants	December 16, 2022	December 31, 2022
Exercise price	$ 5.51	$ 5.41
Volatility	59.5 %	89.4 %
Expected life	5.0	5.0
Risk-free rate	3.6 %	4.0 %
Dividend yield	—	—

Avenue

On October 11, 2022, Avenue announced the closing of an underwritten public offering of 3,636,365 common and pre-funded units. Each common unit consists of one share of common stock and one warrant to purchase one share of common stock, and each pre-funded unit consists of one pre-funded warrant to purchase one share of common stock and one warrant to purchase one share of common stock. Each share of common stock (or pre-funded warrant) was sold together with one warrant at a combined purchase price of $3.30 per common unit (or $3.2999 per pre-funded unit after reducing $0.0001 attributable to the exercise price of the pre-funded warrants). Avenue also simultaneously closed on the sale of an additional 545,454 warrants to purchase common stock, which were sold pursuant to a partial exercise of the underwriter's over-allotment option. Avenue received net proceeds of approximately $10.3 million at closing after deducting underwriting discounts and commissions and other expenses of the offering.

The Company deemed the warrants to be classified as liabilities on the balance sheet as they contain terms for redemption of the underlying security that are outside its control. The warrants were recorded at the time of closing at a fair value of $8.3 million, determined by using the Monte Carlo simulation approach.

The Company revalued the warrants at December 31, 2022 using the Monte Carlo simulation approach. This resulted in a decrease in common stock warrant liability of $5.7 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

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:

	December 31 2022
Risk-free interest rate	4.02% - 4.14 %
Expected dividend yield	—
Expected term in years	4.8 - 5.0
Expected volatility	92.8% - 90.3 %

Urica

The fair value of Urica's contingently issuable placement agent warrants in connection with Urica's first close of their preferred offering in December 2022 (see Note 10), was measured using a Monte Carlo simulation valuation methodology. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Urica's warrant liability that are categorized within Level 3 of the fair value hierarchy was as follows:

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

At December 31, 2022 the value of the Urica's contingent payment warrant is $0.1 million, and was recorded on the consolidated balance sheet. No liability was recorded at December 31, 2021.

Caelum

Fair Value of Investment in Caelum

Upon AstraZeneca's notification of their intent to acquire Caelum in September 2021, the Company increased the carrying value of its investment in Caelum to 42.4% of the distribution of proceeds from the option exercise price of $150 million, or $56.9 million. Fortress received the funds at the acquisition close in October 2021. Prior to AstraZeneca's notification, the Company had valued its holdings in Caelum in accordance with ASC Topic 820, *Fair Value Measurements and Disclosures.*

Journey

Journey Placement Agent Warrant Liability

The fair value of Journey's contingently issuable Placement Agent Warrants in connection with Journey's preferred offering in March 2021 (see Note 10), was measured using a Monte Carlo simulation valuation methodology. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Journey's warrant liability that are categorized within Level 3 of the fair value hierarchy was as follows:

	December 31 2022
Risk-free interest rate	0.98 %
Expected dividend yield	—
Expected term in years	1.00
Expected volatility	0.50 %

Upon the closing of the Journey Initial Public Offering ("Journey IPO") (see note 14), Journey issued the Placement Agent Warrants to purchase 5% of the shares of Journey common stock into which the Journey Preferred Stock converted. The Placement Agent Warrants have a term of 5 years. At December 31, 2021, Journey issued 111,567 shares of Journey common stock related to the exercise of all of the Placement Agent Warrants.

Journey Contingent Payment Warrant

In connection with the Journey license, collaboration, and assignment agreement (the "DFD Agreement") to obtain the global rights for the development and commercialization of DFD-29 with Dr. Reddy's Laboratories, Ltd ("DRL") (see Note 7), Journey agreed to pay DRL additional consideration upon either an IPO of the Journey's common stock or an acquisition of Journey, the agreement further specifies that only one payment can be made. The contingent payment associated with an IPO of Journey's common stock is deemed to be achieved if upon the completion of an IPO Journey's market capitalization on a fully diluted basis is $150 million or greater at the close of business on the date of such Journey IPO. The payment due for the achievement of the IPO criteria is a follows: (a) issue to DRL a number of shares of Journey's common stock equal to $5.0 million as calculated using a fifteen (15) day volume weighted average price ("VWAP") of Journey's closing price, measured fifteen (15) days following the Journey IPO; or (b) make a cash payment to DRL equal to $5.0 million. Journey valued the contingent payment discussed above utilizing a Probability Weighted Expected Return Method (PWERM) model using a discount rate of 30% and expected term of 3 - 5 months.

As a result of Journey's IPO on November 16, 2021, Journey issued 545,131 unregistered shares of Journey common stock to DRL, calculated using a 15-day VWAP of $9.1721 per share.

7. Licenses Acquired

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. As such, for the years ended December 31, 2022 and 2021, the total purchase price of licenses acquired, totaling approximately $0.7 million and $15.6 million, respectively, was classified as research and development-licenses acquired in the Consolidated Statements of Operations.

For the years ended December 31, 2022 and 2021, the Company's research and development-licenses acquired are comprised of the following:

	Year Ended December 31,	
($ in thousands)	**2022**	**2021**
Partner companies:		
JMC	$ —	$ 13,819
Mustang	365	1,630
Urica	300	—
Other	12	176
Total	$ 677	$ 15,625

Journey

On June 29, 2021, Journey entered into a license, collaboration, and assignment agreement (the "DFD-29 Agreement") to obtain the global rights, except for DRL retained rights in the BRIC and CIS countries, for the development and commercialization of a late-stage development modified early release oral minocycline for the treatment of rosacea ("DFD-29") with Dr. Reddy's Laboratories, Ltd.("DRL"). Pursuant to the terms and conditions of the DFD-29 agreement, Journey paid $10.0 million. Additional contingent regulatory and commercial milestone payments totaling up to $158.0 million may also be payable. Royalties ranging from approximately 10% to approximately 15% are payable on net sales of the DFD-29 product.

The product candidates acquired by the Company require substantial completion of research and development, and regulatory and marketing approval efforts in order to reach technological feasibility. As such, the $10.0 million for the year ended December 31, 2021 for the purchase price of licenses acquired were classified as research and development-licenses acquired in the consolidated statement of operations.

The DFD-29 Agreement contained contingent consideration payable by Journey upon either an IPO of Journey's common stock or an acquisition of Journey. Journey recognized $3.8 million of expense classified as research and development-licenses acquired upon execution of the DFD-29 Agreement associated with the contingent consideration. In connection with the closing of Journey's IPO on November 16, 2021, Journey issued 545,131 shares of its common stock to DRL in a transaction exempt from registration under the Securities Act calculated using a 15-day volume weighted average price ("VWAP") of $9.1721 per share in full settlement of the contingent payment to DRL. The restrictions on the unregistered shares of common stock are governed by the terms set forth in the DFD-29 Agreement and applicable securities laws. See "Journey Contingent Payment Derivative" in Note 6 for further details.

Additionally, the Company is required to fund and oversee the Phase 3 clinical trials. Either party may terminate the agreement prior to NDA approval in the event of bankruptcy or a material breach that remains uncured beyond the applicable cure period. Additionally, DRL may terminate the agreement if the Company: i.) ceases development of the product for 6 consecutive months (except if such cessation is caused by DRL, applicable laws, or action/inaction of any third party beyond Company's control); ii.) files a patent challenge on any claim for a product patent or DRL background patent; or iii.) fails to initiate development of the product in the European Union ("EU") (such termination solely relates to the rights granted in EU) within 24 months after product regulatory approval or cause first commercial sale in at least one country in the EU within 72 months after product regulatory approval. From inception to date the Company has incurred approximately $13.0 million associated with the development of DFD-29.

Urica

In May 2021, Urica entered into an exclusive license agreement with Fuji Yakuhin Co. Ltd. ("Fuji") to develop Dotinurad in North America, Europe, and the UK. Dontinurad 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 amendment payment of $0.3 million, which was paid in December 2022.

Partner Companies

The Company's partner companies and subsidiaries have entered into various license agreements with other medical centers. These license agreements include upfront payments which are expensed and various developmental milestone payments due upon achievement of various milestones which in the aggregate are approximately $521.2 million, of which $348.2 million relates to Mustang agreements. The license agreements also have sales-based milestone payments that total approximately $378.4 million. The agreements also include royalty payments on any future sales.

8. Sponsored Research and Clinical Trial Agreements

For the years ended December 31, 2022 and 2021, the Company recorded $7.0 million and $7.8 million, respectively, in research and development expenses in the Company's Consolidated Statement of Operations pursuant to the terms of various sponsored research and clinical trial agreements. The breakout of this expense by partner company is as follows:

($ in thousands)	For the Year Ended December 31, 2022	2021
Mustang	$ 6,989	$ 6,591
Aevitas	62	289
Cellvation	11	—
Checkpoint	17	—
Oncogenuity	(69)	965
Total	$ 7,011	$ 7,845

9. Intangibles

Journey

Agreement with Vyne Therapeutics Inc.

On January 12, 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 APA"), which was paid in January 2023. This expanded Journey's commercial portfolio to eight marketed branded dermatology products. Journey also acquired the associated inventory related to the products.

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

The following table summarizes the aggregate consideration transferred for the assets acquired by Journey in connection with the Vyne APA:

($ 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 is being accreted to the $5.0 million January 2023 cash payment over a one-year period through interest expense. The deferred cash payment had a carrying value of $5.0 million in the Company's consolidated balance sheets at December 31, 2022, and was paid to Vyne on January 12, 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.

On March 31, 2021, Journey executed an Asset Purchase Agreement (the "Qbrexza APA") with Dermira, Inc. a subsidiary of Eli Lilly and Company ("Dermira"). Pursuant to the terms of the agreement, Journey acquired global rights to Qbrexza® (glycoprronium), a prescription cloth towelette to treat primary axillary hyperhidrosis in patients nine years of age or older. Journey paid an upfront fee of $12.5 million to Dermira. In addition, Journey is obligated to pay Dermira up to $144 million in the aggregate upon the achievement of certain sales milestones. The royalty structure for the agreement is tiered with royalties for the first two years ranging 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.

Upon closing of the Qbrexza® purchase on May 13, 2021, Journey was substituted for Dermira as the plaintiff in U.S. patent litigation commenced by Dermira on October 21, 2020 in the U.S. District Court of Delaware (the "Patent Litigation") against Perrigo Pharma International DAC ("Perrigo") alleging infringement of certain patents covering Qbrexza® (the "Qbrexza® Patents"), which are included among the proprietary rights to Qbrexza®. The Patent Litigation was initiated following the submission by Perrigo, in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), of an Abbreviated New Drug Application ("ANDA"). The ANDA sought approval to market a generic version of Qbrexza® prior to the expiration of the Qbrexza® Patents and alleged that the Qbrexza® Patents were invalid. Perrigo was subject to a 30-month stay preventing it from selling a generic version, but that stay was set to expire on March 9, 2023. As of December 31, 2022, the Patent Litigation was settled by and between the parties and the case subsequently has been dismissed. Pursuant to the terms of the settlement agreement, Padagis is prohibited from launching its generic to Qbrexza, under its ANDA or otherwise, until August 15, 2030.

The purchase price of $12.5 million included the asset Qbrexza as well as finished goods and raw material inventory. Journey also has the obligation to accept any product returns related to sales made by Dermira. Journey allocated the upfront payment to inventory since the fair value of the inventory and Qbrexza rights exceeded the purchase price. The future contingent milestone payments, if achieved, will be recorded to intangible asset and amortized over the seven-year life of the asset commencing on the closing date.

The table below provides a summary of intangible assets as of December 31, 2022 and 2021, respectively:

($ in thousands)	Estimated Useful Lives (Years)	December 31, 2022	December 31, 2021
Intangible assets – product licenses	3 to 9	$ 37,925	$ 19,003
Accumulated amortization		(10,728)	(6,451)
Net intangible assets		$ 27,197	$ 12,552

Intangible asset activity for the years ended December 31, 2022 and 2021:

($ in thousands)	Intangible Assets, Net
Ending balance at December 31, 2020	$ 14,629
Additions:	
Exelderm milestone	397
Amortization expense	(2,474)
Bbalance at December 31, 2021	$ 12,552
VYNE Product Acquisition:	
Amzeeq®	15,162
Zilxi®	3,760
Amortization expense (recorded in cost of goods sold)	(4,277)
Ending balance at December 31, 2022	$ 27,197

The future amortization of these intangible assets is as follows:

($ in thousands)	Total Amortization
December 31, 2023	$ 4,277
December 31, 2024	4,277
December 31, 2025	4,277
December 31, 2026	3,064
Thereafter	7,360
Sub-total	$ 23,255
Asset not yet placed in service	3,942
Total	$ 27,197

10. Debt and Interest

Debt

Total debt consists of the following:

($ in thousands)	December 31, 2022	December 31, 2021	Interest rate	Maturity
Oaktree Note	$ 50,000	$ 60,450	11.00 %	August - 2025
EWB Term Loan	20,000	—	9.23 %	January - 2026
Runway Note	31,050	—	13.40 %	April - 2027
Less: Discount on notes payable	(9,320)	(7,063)		
Repayment of Oaktree Note	—	(10,450)		
Total notes payable	$ 91,730	$ 42,937		

Oaktree Note

On August 27, 2020 (the "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 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 amounts paid or prepaid may be reborrowed without Oaktree consent.

AstraZeneca's notification of its intent to acquire Caelum, received on September 28, 2021, is defined in the Oaktree Agreement as a monetization event and as such, triggered a $10 million prepayment and an applicable prepayment fee of $0.5 million. The prepayment fee of $0.5 million is included in interest expense for the year ended December 31, 2021. The Company paid the $10.5 million on October 12, 2021.

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, 2022.

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 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 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 1,749,450 shares of common stock of the Company (see Note 14) 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, 2022 and 2021, the Company amortized $1.5 million and $1.3 million, respectively, of debt discount associated with the Oaktree Note.

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

On January 12, 2022, Journey entered into a third amendment of the loan and security agreement with East West Bank ("EWB") (the "Amendment"), which increased the borrowing capacity of Journey's revolving line of credit to $10.0 million, $2.9 million of which was outstanding at December 31, 2022, and added a term loan not to exceed $20.0 million. Both the revolving line of credit and the term loan mature on January 12, 2026. In January 2022 and August 2022, Journey borrowed $15.0 million and $5.0 million, respectively, against the term loan. The term loan bears interest at a floating rate equal to 1.73% above the prime rate and are payable monthly. The term loan effective interest rate at December 31, 2022 is 9.64%. The term loan contains an interest-only payment period through January 12, 2024, with an extension through July 12, 2024, if certain covenants are met, after which the outstanding balance of each term loan is payable in equal monthly installments of principal, plus all accrued interest, through the term loan maturity date. Journey may prepay all or any part of the term loan without penalty or premium, but may not re-borrow any amount, once repaid. Any outstanding borrowing against the revolving line of credit bears interest at a floating rate equal to 0.70% above the prime rate. The Amendment includes customary financial covenants such as collateral ratios and minimum liquidity provisions. Journey was in compliance with all applicable financial covenants under the Amendment as of December 31, 2022. The remaining $7.1 million revolving line of credit is fully available to Journey without any restrictions, other than certain customary and ordinary closing conditions.

Journey accounted for the Amendment as a debt modification. The remaining unamortized debt issuance costs related to the original revolving facility together with any lender fees and direct third-party costs incurred in connection with the entry into the Amendment are considered associated with the new arrangement. The fees allocated to the revolving line are amortized over the new four-year term of the amended revolving facility. The fees allocated to the term loan are recorded as a debt discount and amortized to interest expense over the four-year term of the term loan under the effective interest method.

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

On March 4, 2022 (the "Closing Date"), Mustang entered into a $75.0 million long-term debt facility with Runway Growth Finance Corp. (the "Runway Note"). Under the Runway Note, $30.0 million of the $75.0 million loan was funded on the Closing Date, with the remaining $45.0 million fundable when Mustang achieves certain predetermined milestones.

The Runway Note matures on April 15, 2027 (the "Maturity Date"). Starting March 15, 2022, Mustang makes monthly payments of interest only until April 1, 2024 (the "Amortization Date"). The Amortization Date may be extended to April 1, 2025, if Mustang achieves certain predetermined milestones based on equity raises and the initiation of certain clinical trials. After that, Mustang will make monthly payments of interest and principal. If the Amortization Date is extended to April 1, 2025, the monthly payments will be recalculated in equal amounts according to the remaining number of payment dates through the Maturity Date. All unpaid outstanding principal and accrued and unpaid interest will be due and payable in full on the Maturity Date.

The Runway Note accrues interest at a variable annual rate equal to 8.75% plus the greater of (i) 0.50% and (ii) the three month LIBOR Rate for U.S. dollar deposits or a rate equivalent to the three month LIBOR (the "Applicable Rate"); provided that the Applicable Rate will not be less than 9.25%. On December 7, 2022, Mustang entered into the Runway First Amendment (the "Runway First Amendment") to the Runway Note by and between Mustang and Runway. The Runway First Amendment amended certain definitions and other provisions of the Runway Note to replace LIBOR-based benchmark rates applicable to loans outstanding under the Runway Note with SOFR-based rates, subject to adjustments as specified in the Runway First Amendment. At December 31, 2022 the floating interest rate was 13.40%.

Mustang has the option to prepay all of the outstanding Runway Note but not less. Prepayment would include outstanding principal, accrued interest, prepayment fee and final payment which is equal to the original principal amount of the Runway Note times 3.5% or $1.1 million and is accreted over the life of the Runway Note.

In addition, Mustang's Runway Note is secured by a lien on substantially all of Mustang's assets other than certain intellectual property assets and certain other excluded collateral, and it contains a minimum liquidity covenant and other covenants that include among other items: (i) limits on indebtedness, repurchase of stock from employees, officers and directors. Mustang was in compliance with all applicable covenants as of December 31, 2022.

The Runway Note contains customary events of default, in certain circumstances subject to customary cure periods. Following an event of default and any cure period, if applicable, Runway will have the right upon notice to accelerate all amounts outstanding under the Runway Note, in addition to other remedies available to the lenders as secured creditors of the Mustang.

Pursuant to the terms of the Runway Note, upon closing Mustang paid Runway an upfront commitment fee equal to 1% of the $30 million, or $0.3 million. In addition, Mustang paid a $75,000 deposit fee to Runway, together with other cash fees of $2.7 million directly to third parties involved in the transaction. Mustang also issued to Runway a warrant to purchase up to 748,036 of Mustang common shares with an exercise price of $0.8021 per share, pursuant to the terms of the Runway Note. In addition, the provisions of the warrant provide for additional warrants to be issued upon funding of the loan tranches.

The fair value of the warrant was determined utilizing a Black Scholes Model with the following assumptions: risk free rate of return 1.74%, volatility of 57.3%, 10-year life yielding a value of approximately $0.4 million at March 4, 2022. The fair value of the warrant was recorded in debt discount and will be amortized over the life of the note. For the year ended December 31, 2022, Mustang amortized approximately $0.5 million of debt discount associated with the Runway Note, which was included in interest expense in the consolidated statement of operations.

IDB Letters of Credit

The Company has letters of credit ("LOC") with IDB of approximately $2.7 million and $2.2 million as of December 31, 2022 and December 31, 2021, 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

On December 27, 2022, Urica consummated the first closing in a private offering 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 101,334 shares of Preferred Stock for gross proceeds of $2.5 million, before deducting underwriting discounts and commissions and offering expenses of approximately $0.3 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 Preferred Stock are payable quarterly in shares of Fortress common stock based upon a 7.5% discount to the average trading price over the 10-day period preceding the dividend payment date. Dividends will be recorded as interest expense and were immaterial in 2022.

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.

In February 2023, Urica completed two additional closings, raising a combined additional $0.9 million and paid placement agent fees of $0.1 million for net proceeds of $0.8 million.

Journey 8% Cumulative Convertible Class A Preferred Offering

In March 2021, Journey commenced an offering of 8% Cumulative Convertible Class A Preferred Stock ("Journey Preferred Offering") in an aggregate minimum amount of $12.5 million and an aggregate maximum amount of $30.0 million. The Journey Preferred Offering terminated on July 18, 2021. Journey issued an aggregate of 758,680 Class A Preferred shares at a price of $25.00 per share, for gross proceeds of $19.0 million. Following the payment of placement agent fees of $1.9 million, and other expenses of $0.1 million, Journey received $17.0 million of net proceeds.

The Journey Preferred Stock automatically converts into Journey's Common Stock upon a sale of Journey or a financing in an amount of at least $25.0 million within a year of the closing date of the Journey Preferred Offering (extendable by another six months at Journey's option) at a discount of 15% to the per share qualified stock price. On November 12, 2021 the Journey IPO was completed, resulting in the conversion of all of the Journey Preferred Stock into 2,231,346 shares of Journey common stock (see Note 14).

The Company evaluated the terms of the Journey 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 Journey'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, until it converted into Journey common stock upon completion of the Journey IPO.

Dividends on the Journey Preferred Stock were paid quarterly 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 paid on the Journey Preferred Stock was recorded as interest expense on the consolidated statements of operations. For the year ended December 31, 2021, Journey issued 253,815 shares of common stock representing dividends paid of $0.8 million from issuance through conversion. As consideration for the foregoing, Journey issued to Fortress 81,985 shares of its common stock at the Journey IPO price of $10.00.

In connection with the Journey Preferred Offering, Journey issued upon the closing of the Journey IPO to the placement agent ("the Placement Agent Warrants") to purchase 5% of the shares of Journey common stock into which the Journey Preferred Stock converted. The Placement Agent Warrants have a term of 5 years. At December 31, 2021 Journey issued 111,567 shares of Journey common stock related to the conversion of all of the placement agent warrants.

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,					
	2022			2021		
($ in thousands)	*Interest*	*Fees*	Total	*Interest*	*Fees*	Total
LOC Fees	$ 54	$ —	$ 54	$ 51	$ —	$ 51
Oaktree Note[1]	5,561	1,532	7,093	6,897	1,342	8,239
Partner company convertible preferred shares	—	—	—	2,845	2,572	5,417
Partner company dividend payable	—	—	—	820	—	820
Partner company installment payments - licenses[2]	770	—	770	781	—	781
Partner company notes payable	4,021	533	4,554	—	—	—
Other	11	—	11	—	—	—
Total Interest Expense and Financing Fee	$ 10,417	$ 2,065	$ 12,482	$ 11,394	$ 3,914	$ 15,308

Note 1: Includes $0.5 million prepayment fee for the Oaktree Note included in interest expense in 2021.
Note 2: Imputed interest expense related to Ximino, Accutane, Anti-itch product license and Vyne product licenses (see Note 9).

11. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

($ in thousands)	December 31, 2022	December 31, 2021
Accounts payable	$ 57,244	$ 47,429
Accrued expenses:		
Professional fees	1,693	1,835
Salaries, bonus and related benefits	9,772	8,809
Research and development	7,390	7,932
Research and development - license maintenance fees	632	4,640
Research and development - milestones	4,600	850
Accrued royalties payable	2,627	3,833
Accrued coupon and rebates	7,604	10,603
Return reserve	3,689	3,240
Accrued interest	342	—
Other	1,853	1,489
Total accounts payable and accrued expenses	$ 97,446	$ 90,660

12. Non-Controlling Interests

Non-controlling interests in consolidated entities are as follows:

($ in thousands)	As of December 31, 2022 Non-controlling interests equity share	For the Year Ended December 31, 2022 Net loss attributable to non-controlling interests	As of December 31, 2022 Non-controlling interests in consolidated entities	Non-controlling ownership
Urica	$ (2,657)	$ (1,251)	$ (3,908)	40.2 %
Aevitas	(5,328)	(425)	(5,753)	45.2 %
Avenue [2]	5,409	(2,355)	3,054	89.9 %
Baergic[3]	113	(113)	—	— %
Cellvation	(1,689)	(102)	(1,791)	21.3 %
Checkpoint [1]	32,398	(48,406)	(16,008)	82.2 %
Coronado SO	(291)	—	(291)	13.0 %
Cyprium	(2,644)	(1,173)	(3,817)	29.0 %
Helocyte	(5,778)	(122)	(5,900)	17.9 %
JMC	19,887	(12,458)	7,429	43.7 %
Mustang [2]	98,461	(60,821)	37,640	81.3 %
Oncogenuity	(1,464)	(111)	(1,575)	27.4 %
Tamid	(775)	(1)	(776)	22.8 %
Total	$ 135,642	$ (127,338)	$ 8,304	

($ in thousands)	As of December 31, 2021 Non-controlling interests equity share	For the Year Ended December 31, 2021 Net loss attributable to non-controlling interests	As of December 31, 2021 Non-controlling interests in consolidated entities	Non-controlling ownership
Urica	$ (442)	(1,353)	$ (1,795)	34.5 %
Aevitas	(4,159)	(901)	(5,060)	45.9 %
Avenue [2]	5,739	(2,909)	2,830	82.0 %
Baergic	(2,047)	(39)	(2,086)	39.0 %
Cellvation	(1,413)	(131)	(1,544)	21.7 %
Checkpoint [1]	63,464	(39,226)	24,238	81.5 %
Coronado SO	(290)	—	(290)	13.0 %
Cyprium	(1,397)	(807)	(2,204)	29.8 %
Helocyte	(5,440)	(89)	(5,529)	18.3 %
JMC	23,150	(5,652)	17,498	41.6 %
Mustang [2]	141,527	(48,518)	93,009	82.7 %
Oncogenuity	(627)	(497)	(1,124)	24.9 %
Tamid	(739)	(1)	(740)	22.8 %
Total	$ 217,326	$ (100,123)	$ 117,203	

Note 1: Checkpoint is consolidated with Fortress' operations because Fortress maintains voting control through its ownership of Checkpoint's Class A Common Shares which provide super-majority voting rights.

Note 2: Avenue and Mustang are consolidated with Fortress' operations because Fortress maintains voting control through its ownership of Class A Preferred Shares which provide super-majority voting rights.

Note 3: Fortress' ownership in Baergic was transferred to Avenue as of November 7, 2022 (see Note 17).

13. Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of Common Stock outstanding during the period, without consideration for Common Stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of Common Stock and Common Stock equivalents outstanding for the period.

The following shares of potentially dilutive securities, weighted during the years ended December 31, 2022 and 2021 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,	
	2022	2021
Warrants to purchase Common Stock	3,495,870	4,528,196
Options to purchase Common Stock	724,757	832,134
Unvested Restricted Stock	18,375,001	16,363,068
Unvested Restricted Stock Units	39,125	180,848
Total	22,634,754	21,904,246

14. Stockholders' Equity

Common Stock

Fortress' Certificate of Incorporation, as amended, authorizes the Company to issue 200,000,000 shares of $0.001 par value Common Stock of which 110,494,245 shares of Common Stock are outstanding as of December 31, 2022. As of December 31, 2021, 170,000,000 shares were authorized and 101,435,505 shares of Common Stock were outstanding.

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.

Fully Paid and Nonassessable

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

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, 2022 and 2021, 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, 2022 and 2021, 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, 2022, 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, 2022, the Company had four equity compensation plans: the Fortress Biotech, Inc. 2007 Stock Incentive Plan (the "2007 Plan"), the Fortress Biotech, Inc. 2013 Stock Incentive Plan, as amended (the "2013 Plan"), the Fortress Biotech, Inc. 2012 Employee Stock Purchase Plan (the "ESPP") and the Fortress Biotech, Inc. Long Term Incentive Plan ("LTIP"). In 2007, the Company's Board of Directors adopted and stockholders approved the 2007 Plan authorizing the Company to grant up to 6,000,000 shares of Common Stock to eligible employees, directors, and consultants in the form of restricted stock, stock options and other types of grants. In 2013, the Company's Board of Directors adopted and stockholders approved the 2013 Plan authorizing the Company to grant up to 2,300,000 shares of Common Stock to eligible employees, directors, and consultants in the form of restricted stock, stock options and other types of grants. In 2015, the Company's Board of Directors and stockholders approved an increase of 7,700,000 shares for the 2013 Plan and in 2020 and 2022, the Company's Board of Directors and stockholders approved an increase of 3,000,000 shares each year, bringing the total number of shares approved under this plan to 16,000,000, with the aggregate total of authorized shares available for grants under the 2007 Plan and the 2013 Plan of up to 22,000,000 shares. An aggregate 21,110,948 shares have been granted under both the Company's 2007 and 2013 plans, net of cancellations, and 889,052 shares were available for issuance as of December 31, 2022.

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, 2022:

Partner Company	Stock Plan	Shares Authorized	Shares available at December 31, 2022
Aevitas	Aevitas Therapeutics, Inc. 2018 Long Term Incentive Plan	2,000,000	376,585
Avenue	Avenue Therapeutics, Inc. 2015 Stock Plan	266,666	122,489
Baergic	FBIO Acquisition Corp. III 2017 Incentive Plan	2,000,000	1,150,000
Cellvation	Cellvation Inc. 2016 Incentive Plan	2,000,000	300,000
Checkpoint	Checkpoint Therapeutics, Inc. Amended and Restated 2015 Stock Plan	3,000,000	2,238,798
Cyprium	Cyprium Therapeutics, Inc. 2017 Stock Plan	2,000,000	575,000
Helocyte	DiaVax Biosciences, Inc. 2015 Incentive Plan	2,000,000	341,667
Journey	Journey Medical Corporation 2015 Stock Plan	7,642,857	1,146,620
Mustang	Mustang Bio, Inc. 2016 Incentive Plan	11,000,000	4,462,870
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	589,315

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, 2022 and 2021

($ in thousands)	Year Ended December 31, 2022	2021
Employee and non-employee awards	$ 9,934	$ 8,603
Executive awards of Fortress Companies' stock	2,718	1,446
Partner Companies:		
Avenue	649	442
Checkpoint	2,924	3,137
Mustang	2,283	3,308
Journey	4,425	2,466
Other	54	84
Total stock-based compensation expense	$ 22,987	$ 19,486

For the years ended 2022 and 2021, $4.4 million and $4.3 million was included in research and development expenses, and $18.5 million and $15.2 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, 2020	1,053,490	$ 5.02	$ 647,482	2.63
Forfeited	(35,000)	4.33	—	—
Options vested and expected to vest at December 31, 2021	1,018,490	$ 5.04	$ 368,344	1.68
Granted	2,002,500	0.54	230,000	6.98
Expired	(370,000)	6.27	—	—
Options vested and expected to vest at December 31, 2022	2,650,990	$ 1.47	$ 230,000	5.64
Options vested and exercisable at December 31, 2022	650,990	$ 4.34	$ —	1.55

During the years ended December 31, 2022 and 2021, 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	2021
Risk-free interest rate	3.78 %	1.04 - 1.50 %
Expected dividend yield	—	—
Expected term in years	7.0	10.0
Expected volatility	78.48 %	100.65 - 102.71 %

As of December 31, 2022, the Company had $0.1 million of 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, 2022 and 2021 was $21.9 million and $19.5 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 2022, the Company granted 3.8 million restricted shares of its Common Stock to executives and directors of the Company and 1.6 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.

During 2021, the Company granted 2.3 million restricted shares of its Common Stock to executives and directors of the Company and 1.4 million restricted stock units to employees and non-employees of the Company. The fair value of the restricted stock awards issued during 2021 of $7.4 million and the fair value of the restricted stock unit awards issued during 2021 of $5.5 million were valued on the grant date using the Company's stock price as of the grant date. The 2021 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, 2020	15,507,504	$ 2.49
Restricted stock granted	2,330,678	3.17
Restricted stock vested	(374,825)	2.69
Restricted stock units granted	1,405,842	3.92
Restricted stock units forfeited	(96,750)	3.49
Restricted stock units vested	(712,449)	3.54
Unvested balance at December 31, 2021	18,060,000	$ 2.64
Restricted stock granted	3,755,972	1.87
Restricted stock vested	(1,755,637)	2.47
Restricted stock units granted	1,604,945	1.31
Restricted stock units forfeited	(232,500)	3.67
Restricted stock units vested	(882,753)	3.41
Unvested balance at December 31, 2022	20,550,027	$ 2.36

The total fair value of restricted stock units and awards that vested during the years ended December 31, 2022 and 2021 was $7.3 million and $3.5 million, respectively. As of December 31, 2022, the Company had unrecognized stock-based compensation expense related to all unvested restricted stock and restricted stock unit awards of $16.3 million and $1.5 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 2.4 years and 1.1 years, respectively. This amount does not include 0.1 million restricted stock units as of December 31, 2022 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, 2022 and 2021, certain non-employee directors elected to defer an aggregate of 330,000 and 230,000 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, 2022, 961,898 shares have been purchased and 38,102 shares are available for future sale under the Company's ESPP. The Company recognized share-based compensation expense of $0.1 million and $0.1 million for the years ended December 31, 2022 and 2021, 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, 2020	4,590,621	$ 3.17	$ 607,848	4.85
Expired	(60,000)	1.37	—	
Forfeited	(25,000)	3.00	—	
Outstanding as of December 31, 2021	4,505,621	$ 3.20	$ 68,800	3.93
Expired	(2,596,171)	3.26	—	
Outstanding as of December 31, 2022	1,909,450	$ 3.11	$ —	7.45
Exercisable as of December 31, 2022	1,774,450	$ 3.19	$ —	7.61

During 2020, in connection with the issuance of the Oaktree Note, the Company issued warrants to purchase 1,749,450 shares of common stock; in connection with a consulting agreement the Company issued warrants to purchase 100,000 shares of common stock. The relative fair value of the Oaktree warrants was recorded to debt discount and is being amortized over the term of the Oaktree Note (see Note 10). As of December 31, 2022, the Company had no unrecognized stock-based compensation expense related to warrants.

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, 2022 and 2021, the Compensation Committee granted 1,102,986 and 1,030,339 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 and were granted in recognition of their performance in 2021 and 2020. The shares will vest in full once both of the following conditions are met: (i) the Company's market capitalization has increased by a minimum of $100.0 million, and (ii) the employee is either in the service of the Company as an employee or as a Board member (or both) on the tenth anniversary of the LTIP, or the eligible employee has had an involuntary separation from service (as defined in the LTIP). The Company's repurchase option on such shares will also lapse upon the occurrence of a corporate transaction (as defined in the LTIP) if the eligible employee is in service on the date of the corporate transaction. The fair value of each grant on the grant date was approximately $2.8 million for the January 1, 2022 grant and $3.3 million for the January 1, 2021 grant. For the year ended December 31, 2022 and 2021, the Company recorded stock compensation expense of approximately $5.3 million and $3.8 million, respectively related to the LTIP grants on the Consolidated Statements of Operations.

Capital Raises

2021 Shelf

On July 23, 2021, the Company filed a shelf registration statement 333-255185 on Form S-3, which was declared effective on July 30, 2021 (the "2021 Shelf"). No securities have been drawn down under the 2021 Shelf.

Common Stock At the Market Offering and 2020 Shelf

On July 23, 2021, the Company filed shelf registration statement 333-258145 on Form S-3, which was declared effective on July 30, 2021 (the "2021 Shelf"). No securities have been drawn down under the 2021 Shelf.

On May 18, 2020, the Company filed a shelf registration statement on Form S-3 (File No. 333-238327), which was declared effective on May 26, 2020 (the "2020 Shelf"). In connection with the 2020 Shelf, the Company entered into an At Market Issuance Sales Agreement ("2020 Common ATM"), governing potential sales of the Company's common stock. ATM activity since June 1, 2020 were made under the 2020 Shelf. For the year ended December 31, 2022, the Company issued approximately 4.1 million shares of common stock at an average price of $1.50 per share for gross proceeds of $6.2 million. In connection with these sales, the Company paid aggregate fees of $0.2 million. Approximately $11.1 million of securities remain available for sale under the 2020 Shelf at December 31, 2022.

For the year ended December 31, 2021, the Company issued approximately 3.1 million shares of common stock at an average price of $3.05 per share for gross proceeds of $9.4 million. In connection with these sales, the Company paid aggregate fees of $0.3 million.

Journey

On December 30, 2022, Journey filed a shelf registration statement on Form S-3 (File No. 333-269079), which was declared effective by the Securities and Exchange Commission ("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 (the "Journey 2022 Shelf"). At December 31, 2022, $150.0 million remains available under the Journey 2022 Shelf. In connection with the Journey 2022 shelf, Journey has entered into an At-the-Market Issuance Sales Agreement (the "Sales Agreement") with B. Riley Securities, Inc. ("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.

Journey's common stock began trading on the Nasdaq Capital Market on November 12, 2021 under the ticker symbol "DERM." On November 16, 2021, Journey completed an initial public offering (the "Journey IPO") whereby it sold 3,520,000 shares of its common stock at a price of $10.00 per share for net proceeds of $30.6 million, after deducting underwriting discounts and other offering costs of $4.6 million.

Checkpoint

In November 2020, Checkpoint filed a shelf registration statement on Form S-3 (the "Checkpoint 2020 S-3"), which was declared effective in December 2020. Under the Checkpoint 2020 S-3, Checkpoint may sell up to a total of $100 million of its securities. In connection with the Checkpoint 2020 S-3, Checkpoint entered into an At-the-Market Issuance Sales Agreement (the "Checkpoint 2020 ATM") with certain agents relating to the sale of shares of Checkpoint's common stock. Under the Checkpoint 2020 ATM, Checkpoint will pay the sales agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of Checkpoint's common stock.

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.

During the year ended December 31, 2021, Checkpoint sold a total of 1,189,999 shares of common stock under the Checkpoint 2020 ATM for aggregate total gross proceeds of approximately $41.3 million at an average selling price of $34.69 per share, resulting in net proceeds of approximately $40.3 million after deducting 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. Each pre-funded warrant was exercisable 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 and associated common stock warrants, and $4.33249 per pre-funded warrant and associated common stock warrants. The pre-funded warrants were 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 Series A warrants are exercisable immediately upon issuance and will expire five years following the issuance date and have an exercise price of $4.075 per share and the Series B warrants are exercisable immediately upon issuance and will expire eighteen months following the issuance date and have an exercise price of $4.075 per share. Net proceeds from the registered direct offering were $6.7 million after deducting commissions and other transaction costs. As the total fair value of the resulting warrant liability exceeded the total net proceeds of $6.7 million, Checkpoint recorded a loss of $1.2 million to loss on common stock warrant liabilities in the Consolidated Statements of Operations. Accordingly, there were no proceeds allocated to the common stock and pre-funded warrants issued as part of this transaction (See Note 6).

As of December 31, 2022, approximately $22.3 million of the shelf remains available for sale under the Checkpoint 2020 S-3.

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 56,671 shares and 29,749 shares to Fortress for the year ended December 31, 2022 and 2021, respectively.

Mustang

On April 23, 2021, Mustang filed a shelf registration statement No. 333-255476 on Form S-3 (the "Mustang 2021 S-3"), which was declared effective on May 24, 2021. Under the Mustang 2021 S-3, Mustang may sell up to a total of $200 million of its securities. As of December 31, 2022, $200 million of the Mustang 2021 S-3 remained available for sales of securities.

On October 23, 2020, Mustang filed a shelf registration statement No. 333-249657 on Form S-3 (the "2020 Mustang S-3"), which was declared effective in December 2020. Under the 2020 Mustang S-3, Mustang may sell up to a total of $100.0 million of its securities. As of December 31, 2022, approximately $8.0 million of the 2020 S-3 remains available for sales of securities.

During the year ended December 31, 2022, Mustang issued approximately 7.9 million shares of common stock at an average price of $0.84 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.

During the year ended December 31, 2021, Mustang issued approximately 19.4 million shares of common stock at an average price of $3.70 per share for gross proceeds of $71.9 million under the ATM Agreement. In connection with these sales, the Company paid aggregate fees of approximately $1.3 million for net proceeds of approximately $70.6 million.

Pursuant to the terms of the Second Amended and Restated Founders Agreement, Mustang issued to Fortress 2.5% of the aggregate number of shares of Mustang common stock issued in the offerings noted above. Accordingly, Mustang issued 196,952 shares of common stock to Fortress for the year ended December 31, 2022 and issued 576,157 common shares to Fortress for the year ended December 31, 2021.

Avenue

On October 11, 2022, Avenue announced the closing of an underwritten public offering of 3,636,365 common and pre-funded units. Each common unit consists of one share of common stock and one warrant to purchase one share of common stock, and each pre-funded unit consists of one pre-funded warrant to purchase one share of common stock and one warrant to purchase one share of common stock. Each share of common stock (or pre-funded warrant) was sold together with one warrant at a combined purchase price of $3.30 per common unit (or $3.2999 per pre-funded unit after reducing $0.0001 attributable to the exercise price of the pre-funded warrants). Avenue also simultaneously closed on the sale of an additional 545,454 warrants to purchase common stock, which were sold pursuant to a partial exercise of the underwriter's over-allotment option. Avenue received net proceeds of approximately $10.3 million at closing after deducting underwriting discounts and commissions and other expenses of the offering. This transaction, along with Avenue's repurchase of 100% of the Avenue shares held by InvaGen for a purchase price of $3.0 million, and the closing of the Share Repurchase Agreement between Avenue and InvaGen in October 2022 (see Note 3), resulted in the November 2022 consummation of the Contribution Agreement between Fortress and Avenue (see Note 17).

In November 2021, Avenue, pursuant to an underwritten public offering, sold 2,238,805 shares of its common stock at a price of $1.34 per share for gross proceeds of approximately $3.0 million. After deducting underwriting discounts and commissions and other expenses, net proceeds to Avenue from this underwritten public offering were $2.6 million.

In December 2021, Avenue, pursuant to an underwritten public offering, sold 1,910,100 shares of its common stock at a price of $1.07 per share for gross proceeds of approximately $2.0 million. After deducting underwriting discounts and commissions and other expenses, net proceeds to Avenue from this underwritten public offering were $1.8 million.

Urica

In December 2022, Urica commenced an offering of 8% Cumulative Convertible Class B Preferred Stock. Urica issued an aggregate of 101,334 Class B Preferred shares at a price of $25.00 per share, for gross proceeds of $2.5 million. Following the payment of placement agent fees and other expenses of $0.3 million, Urica received $2.2 million in net proceeds (see Note 21). The Company determined liability classification is appropriate and as such, this instrument was accounted for as a liability (see Note 10) at December 31, 2022.

15. 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, 2022, the Company had operating lease liabilities of $24.0 million and right of use assets of $20.0 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, 2022 and 2021 was $2.0 million and $2.1 million, respectively. The components of lease cost are as follows:

	Year Ended December 31,	
($ in thousands)	2022	2021
Operating lease cost	$ 3,524	$ 3,253
Shared lease costs	(2,127)	(1,835)
Variable lease cost	648	727
Total lease expense	$ 2,045	$ 2,145

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

	Year Ended December 31,	
($ in thousands)	2022	2021
Operating cash flows from operating leases	$ (3,473)	$ (3,366)
Right-of-use assets exchanged for new operating lease liabilities	$ 2,953	$ 207
Weighted-average remaining lease term – operating leases (years)	4.7	5.2
Weighted-average discount rate – operating leases	6.6 %	6.3 %

($ in thousands)	Future Lease Liability
Year Ended December 31, 2023	$ 3,550
Year Ended December 31, 2024	3,665
Year Ended December 31, 2025	4,134
Year Ended December 31, 2026	3,879
Year Ended December 31, 2027	3,572
Other	12,486
Total operating lease liabilities	31,286
Less: present value discount	(7,267)
Net operating lease liabilities, short-term and long-term	$ 24,019

License Agreements

The Company has undertaken to make contingent 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.

16. 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, 2022 and 2021, the Company paid a matching contribution of $1.1 million and $0.8 million, respectively.

17. 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 10.5% and 10.3% of the Company's issued and outstanding Common Stock as of December 31, 2022 and 2021, respectively. The Company's Executive Vice Chairman, Strategic Development individually owns approximately 11.2% and 11.1% of the Company's issued and outstanding Common Stock at December 31, 2022 and 2021, respectively.

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, 2022 and 2021, respectively.

Shared Services Agreement with Journey

On November 12, 2021, Journey and the Company entered into an arrangement to share the cost of certain legal, finance, regulatory, and research and development employees. The Company's Executive Chairman and Chief Executive Officer is the Executive Chairman of Journey. Under the terms of the Agreement, Journey will reimburse 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. For the year ended December 31, 2021, the Company's employees have provided services to Journey totaling approximately $0.6 million. Upon completion of Journey's initial public offering in November 2021 (see Note 14) $0.5 million was converted into 52,438 shares of Journey common stock at the initial public offering price of $10.00 per share.

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, 2022 and 2021, the Company had paid $2.7 million and $2.7 million in rent, respectively, and invoiced TGTX approximately $1.9 million and $1.6 million respectively, for their prorated share of the rent base. At December 31, 2022, there were no amounts due from TGTX related to this arrangement.

As of July 1, 2018, TGTX employees began to occupy desks in the Waltham, MA office under the Desk Share Agreement. TGTX began to pay their share of the rent based on actual percentage of the office space occupied on a month by month basis. For the years ended December 31, 2022 and 2021, the Company had paid approximately $0.2 million and $0.2 million in rent for the Waltham, MA office, and invoiced TGTX approximately $0.1 million and $0.1 million, respectively.

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.

Journey Promissory Note

On September 30, 2021, the Company increased the Journey promissory note by $9.5 million in response to a cyber incident that occurred at Journey and resulted in $9.5 million of fraudulent payments. The $9.5 million contribution was approved by the boards of directors of both the Company and Journey, and ensured that Journey's accounts payable function continued to operate smoothly. This contribution, along with the $5.2 million already outstanding under the Journey Promissory Note, converted into 1,476,044 shares of Journey common stock upon completion of Journey's initial public offering in November 2021 (see Note 14) at the initial public offering price of $10.00 per share. The amounts associated with the Journey Promissory Note are eliminated in the consolidated balance sheets.

Avenue Share Contribution Agreement

In November 2022, Fortress completed a Share Contribution Agreement with Avenue to contribute its' shares in Baergic, which is developing BAER-101, a novel α2/3–subtype-selective GABA A positive allosteric modulator ("PAM"), to Avenue. As a result, Baergic became a majority-controlled and owned subsidiary company of Avenue. Under the Contribution Agreement, Fortress also agreed to assign to Avenue certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement and Management Services Agreement.

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
Aevitas	July 28, 2017	2.5 %	Common Stock
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, 2022 and 2021 ($ in thousands):

Partner company	PIK Dividend Date	Year Ended December 31, 2022	Year Ended December 31, 2021
Aevitas	July 28	$ 23	$ 22
Avenue	January 1	268	—
Baergic[1]	December 17	—	10
Cellvation	October 31	10	9
Checkpoint	January 1	1,885	6,598
Cyprium	January 1	422	1,304
Helocyte	January 1	90	141
Mustang	January 1	1,109	4,212
Oncogenuity	May 8	8	5
Urica	November 25	51	26
Fortress		(3,866)	(12,327)
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):

Partner Company/Subsidiary	Effective Date	Year Ended December 31, 2022	2021
Aevitas	July 28, 2017	$ 500	$ 500
Avenue[1]	February 17, 2015	83	—
Baergic[2]	March 9, 2017	417	500
Cellvation	October 31, 2016	500	500
Checkpoint	March 17, 2015	500	500
Cyprium	March 13, 2017	500	500
Helocyte	March 20, 2015	500	500
Mustang	March 13, 2015	1,000	500
Oncogenuity	February 10, 2017	500	500
Urica	November 7, 2017	500	500
Fortress		(5,000)	(4,500)
Consolidated (Income)/Expense		$ —	$ —

Note 1: Fees under the MSA were not due or accrued during the pendency of agreements formerly in place between Avenue and InvaGen (now terminated).

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 MSA previously between Fortress and Baergic, such that Baergic's annual MSA fee 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.

18. 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)	For the years ended December 31, 2022	2021
Current		
Federal	$ —	$ —
State	449	473
Deferred		
Federal	—	—
State	—	—
Total	$ 449	$ 473

For the years ended December 31, 2022 and 2021, income tax expense was $0.4 million and $0.5 million, respectively, resulting in an effective income tax rate of 0% and 0%. The income tax expense in 2022 is primarily due to the recording of uncertain tax positions and state income taxes.

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 $318.0 million against its net deferred tax assets. Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

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

	As of December 31,	
($ in thousands)	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 198,250	$ 180,994
Amortization of license fees	30,151	31,556
Amortization of in-process R&D	334	384
Stock compensation	13,754	13,560
Lease liability	7,011	6,965
Accruals and reserves	3,402	2,265
Tax credits	33,501	23,239
Startup costs	42	49
Unrealized gain/loss on investments	406	420
Section 174 R&D expenditure capitalization	34,170	—
State taxes	192	215
Business interest limitation	2,359	7
Reserve on Sales Return, Discount and Bad Debt	2,286	1,883
Total deferred tax assets	325,858	261,537
Less: valuation allowance	(317,959)	(251,052)
Net deferred tax assets	$ 7,899	$ 10,485
Deferred tax liabilities:		
Section 483 imputed interest	$ (92)	$ —
Debt issuance costs	(347)	—
Right of use asset	(5,835)	(5,732)
Basis in subsidiary	(1,625)	(4,753)
Total deferred tax assets, net	$ —	$ —

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

	For the Year Ended December 31,	
	2022	2021
Percentage of pre-tax income:		
U.S. federal statutory income tax rate	21.00 %	21.00 %
State taxes, net of federal benefit	7.00 %	10.00 %
Credits	4.00 %	4.00 %
Non-deductible items	(1.00)%	(3.00)%
Provision to return	2.00 %	— %
Stock based compensation shortfall	(1.00)%	(1.00)%
Change in state rate	(2.00)%	1.00 %
Intercompany elimination adjustments	— %	— %
Change in valuation allowance	(31.00)%	(29.00)%
Change in subsidiary basis	— %	(2.00)%
Other	1.00 %	(1.00)%
Effective income tax rate	— %	— %

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, 2022 and 2021. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2022 and 2021. The valuation allowance increased by a net $67.0 million during the current year.

The Company has incurred net operating losses ("NOLs") since inception. At December 31, 2021, the Company had federal NOLs of $680.1 million, which will begin to expire in the year 2032, state NOLs of $838.1 million, which will begin to expire in 2023, and federal income tax credits of $30.3 million and state income tax credits of $4.0 million, which will begin to expire in 2028. Approximately $476.7 million of the federal NOLs and $10.8 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. 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 had an immaterial amount of accrued interest and penalties at December 31, 2022 and 2021. The NOLs from tax years 2006 through 2021 remain open to examination (and adjustment) by the Internal Revenue Service and state tax authorities. In addition, Federal tax years ending December 31, 2019, 2020 and 2021 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.

19. 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, 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 income	(2,048)	(7,852)	(9,900)
Income tax expense	—	(449)	(449)
Segment loss	$ (29,600)	$ (184,313)	$ (213,913)

Year Ended December 31, 2021	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net revenue	$ 63,134	$ 5,657	$ 68,791
Cost of goods - product revenue	(32,084)	—	(32,084)
Research and development	(16,558)	(112,307)	(128,865)
Selling, general and administrative	(39,895)	(46,948)	(86,843)
Wire transfer fraud loss	(9,540)	—	(9,540)
Other expense	(7,479)	31,667	24,188
Income tax expense	—	(473)	(473)
Segment income (loss)	$ (42,422)	$ (122,404)	$ (164,826)

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

($ 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

($ in thousands) December 31, 2021	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Total Assets
Intangible assets, net	$ 12,552	$ —	$ 12,552
Tangible assets	84,732	299,219	383,951
Total segment assets	$ 97,284	$ 299,219	$ 396,503

20. 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 17).

The table below summarizes the Company's revenue for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Revenue		
Qbrexza®	$ 26,715	$ 17,056
Accutane®	18,373	10,053
Amzeeq®	7,242	—
Targadox®	7,972	22,378
Ximino®	4,957	8,247
Zilxi®	2,273	—
Exelderm®	3,463	5,363
Other branded revenue	—	37
Collaboration revenue	1,882	5,389
Revenue – related party	192	268
Other revenue[1]	2,674	—
Net revenue	$ 75,743	$ 68,791

Note 1: 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® Wipes 2.5% (Qbrexza®), as well as $0.2 million in royalties from Maruho on sales of Rapifort® Wipes 2.5% in Japan.

Significant Customers

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

At December 31, 2022, two of Journey's customers accounted for more than 10% of its total accounts receivable balance at 16.3% and 12.9%. As of December 31, 2021, one of the Company's Dermatology Products customers accounted for 12% of its total accounts receivable balance.

21. Subsequent Events

Avenue Therapeutics Private Offering

On January 27, 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. 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 and a purchase price of $0.125. The purchase price of each share is $1.55. The purchase price of each pre-funded warrant is $1.5499 with an exercise price of $0.0001. Avenue received $2.8 million in net proceeds.

Avenue License Agreement

In March 2023, Avenue announced that it had entered into an exclusive license agreement with AnnJi Pharmaceutical Co., a Taiwanese clinical-stage drug company, for AJ201, a first-in-class clinical asset currently in a Phase 1b/2a study in the U.S. for the treatment of spinal and bulbar muscular atrophy, also known as Kennedy's Disease. Under the license agreement, in exchange for exclusive rights to the intellectual property underlying the AJ201 product candidate, Avenue will pay an initial cash license fee of $3.0 million, of which $2.0 million is payable within 60 days and $1.0 million payable within 180 days after the effective date of the License Agreement.

Checkpoint Therapeutics Registered Direct Offering

In February 2023, Checkpoint closed on a registered direct offering ("February 2023 Direct Offering") with a single institutional investor for the issuance and sale of 1,180,000 shares of its common stock and 248,572 pre-funded warrants. Each pre-funded warrant is exercisable for one share of common stock. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 1,428,572 shares of common stock and Series B warrants to purchase up to 1,428,572 shares of common stock, at a purchase price of $5.25 per share of common stock and associated common stock warrants, and $4.2499 per pre-funded warrant and associated common stock warrants. Net proceeds from the February 2023 Direct Offering were $6.7 million after deducting commissions and other transaction costs.

Checkpoint BLA Submission and Acceptance

Checkpoint submitted a BLA to FDA in January 2023, for Cosibelimab as a Treatment for Patients with Metastatic or Locally Advanced Cutaneous Squamous Cell Carcinoma. In March 2023 the FDA accepted this submission and set a Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024.

Fortress 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 16,642,894 shares of its common stock at a purchase price of $0.835 per share and secured approximately $13.3 million in net proceeds after deducting estimated offering expenses.

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

Urica Preferred Offering

In February 2023, Urica completed two additional closings of the Urica Preferred Offering, whereby it sold 34,160 Class B Preferred shares at a price of $25.00 per share, for net proceeds of $0.8 million, after deducting placement agent fees of $0.1 million.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Fortress Biotech, Inc.

March 31, 2023

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 31, 2023
/s/ David Jin David Jin	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	March 31, 2023
/s/ Eric K. Rowinsky, M.D. Eric K. Rowinsky, M.D.	Vice Chairman of the Board of Directors	March 31, 2023
/s/ Michael S. Weiss Michael S. Weiss	Executive Vice Chairman, Strategic Development and Director	March 31, 2023
/s/ Jimmie Harvey, Jr., M.D. Jimmie Harvey, Jr., M.D.	Director	March 31, 2023
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director	March 31, 2023
/s/ Dov Klein Dov Klein	Director	March 31, 2023
/s/ J. Jay Lobell J. Jay Lobell	Director	March 31, 2023
/s/ Kevin L. Lorenz, J.D. Kevin Lorenz	Director	March 31, 2023
/s/ Lucy Lu, M.D. Lucy Lu, M.D.	Director	March 31, 2023

Exhibit 4.3

DESCRIPTION OF SECURITIES

When used herein, the terms "we," "our," "the Company," and "us" refer to Fortress Biotech, Inc.

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 series of preferred stock being offered by us will be described in the applicable prospectus supplement or similar offering documentation 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 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.

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, 2022, there were 1,749,450 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 1,749,450 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 is $3.20 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, 2022, there were 100,000 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 100,000 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) 25,000 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 $2.50 for ten (10) consecutive trading days;

(ii) 25,000 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 $4.00 for ten (10) consecutive trading days;

(iii) 25,000 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 $6.00 for ten (10) consecutive trading days; and

(iv) 25,000 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 $10.00 for ten (10) consecutive trading days;

Exercise Price

The exercise price of the Common Stock purchasable upon exercise of the Consulting Warrants is $2.16 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.

EXHIBIT 21.1

SUBSIDIARIES OF FORTRESS BIOTECH, INC.

Subsidiaries of Fortress Biotech, Inc. at December 31, 2022, 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. 333-255185, 333-258145, 333-249983, 333-238327, and 333-269687) on Form S-3 and (Nos. 333-184616, 333-194588, 333-206645, 333-221485, 333-233195, 333-249985, and 333-267977) on Form S-8 of our report dated March 31, 2023, with respect to the consolidated financial statements of Fortress Biotech, Inc.

Short Hills, NJ

March 31, 2023

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, 2022 of Fortress Biotech, Inc. (the "Registrant");

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

(4) The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

(d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

(5) The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of Registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Dated: March 31, 2023

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

EXHIBIT 31.2

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

I, David Jin, certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 of Fortress Biotech, Inc. (the "Registrant");

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

(4) The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

(d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

(5) The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of Registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Dated: March 31, 2023

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

EXHIBIT 32.1

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

In connection with the Annual Report on Form 10-K of Fortress Biotech, Inc. (the "Company") for the period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lindsay A. Rosenwald, M.D., Chairman, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Dated: March 31, 2023

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

EXHIBIT 32.2

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

In connection with the Annual Report on Form 10-K of Fortress Biotech, Inc. (the "Company") for the period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Jin, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Dated: March 31, 2023

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