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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2020

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.)**
2 Gansevoort Street, 9th Floor **New York, New York 10014** **(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 is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter: $173,878,853 based upon the closing sale price of our common stock of $2.68 on that date. Common stock held by each officer and director and by each person known to own in excess of 5% of outstanding shares of our common stock has been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status in not necessarily a conclusive determination for other purposes.

Class of Stock	**Outstanding Shares as of March 18, 2021**
Common Stock, $0.001 par value	94,907,448
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 2020 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

FORTRESS BIOTECH, INC.
ANNUAL REPORT ON FORM 10-K
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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Statements in this Annual Report on Form 10-K that are not descriptions of historical facts are forward-looking statements 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").

Risks Inherent in Drug Development

- Many of our and our partner companies' product candidates are in early development stages and are subject to time and cost intensive regulation and clinical testing. As a result, our product candidates may never be successfully developed or commercialized.
- Our competitors may develop treatments for our or our partner companies' 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 we expect such losses to continue in the future.
- We have funded our operations in part through the assumption of debt, which lending agreements may restrict our operations. Further, the occurrence of any default event under any 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 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 Ximino, Targadox and Exelderm. Any issues relating to the manufacture, sale, utilization, or reimbursement of Journey's products (including products liability claims) could significantly impact our operating results.
- The majority 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, could have a significant adverse effect on our operating income. 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.

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.
- Our growth and success depend on our acquiring or in-licensing products or product candidates and integrating such products into our business.
- We act as guarantor and/or indemnitor of certain obligations of our subsidiaries and affiliates, which could require us to pay substantial amounts based on the actions of said subsidiaries or affiliates.

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

Risks Pertaining to Generic Competition and Paragraph IV Litigation

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

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 at the Fortress level, at our majority-owned and majority-controlled subsidiaries and joint ventures, and at entities we founded and in which we maintain significant minority ownership positions. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who identify and evaluate promising products and product candidates for potential acquisition by new or existing partner companies. Through our partner companies, we have executed arrangements with some of the world's foremost universities, research institutes and pharmaceutical companies, including Fred Hutchinson Cancer Research 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, AstraZeneca plc, and City of Hope National Medical Center.

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 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, three partner companies are publicly traded, and three have consummated strategic partnerships with industry leaders Alexion Pharmaceuticals, Inc., Sentynl Therapeutics, Inc., and InvaGen Pharmaceuticals, Inc. (a subsidiary of Cipla Limited).

Several of our partner companies possess licenses to product candidate intellectual property, including Aevitas Therapeutics, Inc. ("Aevitas"), Avenue Therapeutics, Inc. ("Avenue"), Baergic Bio, Inc. ("Baergic"), Caelum Biosciences, Inc. ("Caelum"), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. ("Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Journey Medical Corporation ("Journey" or "JMC"), Mustang Bio, Inc. ("Mustang") and Oncogenuity, Inc. ("Oncogenuity").

The Company is a Delaware corporation incorporated in 2006. As used throughout this filing, the words "we", "us" and "our" may refer to Fortress individually or together with our affiliates and partners, as dictated by context.

Product Candidates and Other Intellectual Property

Commercialized Products

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

Ximino®: Ximino (minocycline hydrochloride) extended release capsule is a tetracycline-class drug indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris.

Targadox®: Targadox (doxycycline hyclate USP) 50mg tablets is a tetracycline-class drug indicated as adjunctive therapy for severe acne.

Exelderm®: Exelderm (sulconazole nitrate, USP) Cream and Solution are antifungal agents indicated for the treatment of tinea infection, such as ringworm and jock itch.

Ceracade®: Ceracade Skin Emulsion is a steroid-free, ceramide-dominant formulation used to treat dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatitis and radiation dermatitis.

Luxamend®: Luxamend Wound Cream is a water-based emulsion formulated for the dressing and management of superficial wounds, minor abrasions, dermal ulcers, donor sites, first- and second-degree burns, including sunburns, and radiation dermatitis.

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

Late Stage Product Candidates

Intravenous (IV) Tramadol

Our partner company Avenue, in collaboration with InvaGen Pharmaceuticals, Inc., is developing intravenous ("IV") Tramadol, for the treatment of post-operative acute pain. IV Tramadol may fill a gap in the acute pain market between IV acetaminophen/NSAIDs and conventional IV narcotics. Avenue announced in May 2018 that its first pivotal Phase 3 study had met its primary endpoint and all key secondary endpoints. In June 2019, Avenue announced that its second pivotal Phase 3 study had met its primary endpoint and all key secondary endpoints. In December 2019, Avenue submitted a new drug application ("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"). On October 12, 2020, Avenue announced that it had received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") regarding Avenue's NDA for IV Tramadol. In November 2020, Avenue attended a Type A Meeting with the FDA to discuss issues raised in the CRL. On February 12, 2021 Avenue resubmitted its NDA to the FDA for IV Tramadol. The NDA resubmission follows the receipt of official minutes from a Type A meeting with the FDA, which was conducted following receipt of Avenue's CRL. The NDA resubmission included revised language relating to the proposed product label and a report relating to terminal sterilization validation. On February 26, 2021, Avenue received an acknowledgement letter from the FDA that Avenue's resubmission of its NDA is a complete, class 1 response to the CRL, and a Prescription Drug User Fee Act goal date has been set for April 12, 2021.

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 recent genome-based ascertainment study. 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. CUTX-101 was also granted Rare Pediatric Disease Designation by the FDA for the treatment of Menkes disease and Fast Track Designation for classic Menkes disease in patients who have not demonstrated significant clinical progression. The European Medicines Agency "EMA" Committee for Orphan Medicinal Products also granted Orphan Drug Designation for CUTX-101. In August 2020 Cyprium reported positive top-line clinical efficacy results for CUTX-101. In December 2020 the FDA granted Breakthrough Therapy Designation to CUTX-101. Additional information on the Expanded Access study can be found on www.ClinicalTrials.gov using identifier NCT04074512. Cyprium intends to begin the rolling submission of a NDA to the FDA for CUTX-101 in the second half of 2021.

On February 24, 2021, Cyprium announced the execution of an asset purchase agreement with Sentynl Therapeutics, Inc. ("Sentynl"), a U.S.-based specialty pharmaceutical company owned by the Zydus Group. The asset purchase agreement commits Sentynl to an upfront cash payment to Cyprium of $8.0 million, which was paid upon execution of the agreement, and $12.0 million in future development and regulatory cash milestones through NDA approval, as well as potential sales milestones. Royalties on CUTX-101 net sales ranging from the mid-single digits up to the mid-twenties are also payable. Cyprium will retain development responsibility of CUTX-101 through approval of the NDA by the FDA, and Sentynl will be responsible for commercialization of CUTX-101 as well as progressing newborn screening activities. Continued development of CUTX-101 will be overseen by a Joint Steering Committee consisting of representatives from Cyprium and Sentynl. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.

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

Our partner company Mustang collaborates with St. Jude Children's Research Hospital ("St. Jude") in the development of a first-in-class *ex vivo* lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency ("XSCID"), also known as bubble boy disease. On August 2, 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. The acquisition of this license expands our pipeline into gene therapy, allowing us to leverage existing synergies for Mustang's Worcester, Massachusetts, cell-processing facility. 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). In April 2020, the EMA granted Advanced Therapy Medicinal Product ("ATMP") classification to MB-107. The FDA also previously granted Regenerative Medicine Advanced Therapy ("RMAT") designation to MB-107 in August 2019. In the third quarter of 2020, the FDA granted Rare Pediatric Disease Designation and Orphan Drug Designation to both MB-107 and MB-207.

In May 2020, Mustang submitted an Investigational New Product Drug Application ("IND") application with the FDA to initiate a registrational 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 CMC hold issues that Mustang satisfactorily addressed in a December 2020 submission to the Agency, and the CMC hold was removed in January 2021. Potential topline data from the trial are expected in the fourth quarter of 2022.

Mustang expects to file an IND in the second quarter of 2021 for a registrational multicenter Phase 2 clinical trial of MB-207 in previously transplanted XSCID patients. Potential topline data from this trial are expected in the first half of 2023.

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

Our partner company Checkpoint is currently evaluating its lead antibody product candidate, cosibelimab (formerly CK-301), an anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in a Phase 1 clinical trial in Checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts intended to support one or more Biologics License Application ("BLA") submissions. Additional information on the Phase 1 trial can be found on www.ClinicalTrials.gov using identifier NCT03212404. 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.

In September 2020, Checkpoint announced interim results from the registration-enabling Phase 1 clinical trial in metastatic cutaneous squamous cell carcinoma ("mCSCC") at the European Society for Medical Oncology ("ESMO") Virtual Congress 2020. Checkpoint expects top-line results from the trial in the second half of 2021.

In November 2020, Checkpoint announced updated results from the ongoing global, open-label, multicohort Phase 1 clinical trial including a cohort of patients with previously untreated high PD-L1 expressing advanced non-small cell lung cancer ("NSCLC").

CK-101 (EGFR inhibitor for EGFR mutation-positive NSCLC)

Checkpoint is also currently evaluating a lead small-molecule, targeted anti-cancer agent, CK-101, in a Phase 1 clinical trial for the treatment of patients with 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. The clinical trial is ongoing to identify the optimal dose to maximize therapeutic effect, following which a Phase 3 trial is planned in treatment-naïve EGFR mutation-positive NSCLC patients. Additional information on the Phase 1 trial can be found on www.ClinicalTrials.gov using identifier NCT02926768.

In November 2020, NeuPharma, Inc. commenced a Phase 3 clinical trial in China evaluating CK-101 in treatment-naïve locally advanced or metastatic NSCLC patients whose tumors have EGFR exon 19 deletion mutations. We intend to meet with the FDA to discuss the adequacy of the ongoing Phase 3 trial in China.

CAEL-101 (mAb for AL Amyloidosis)

Our partner company Caelum, in collaboration with Alexion Pharmaceuticals, Inc. ("Alexion"), 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. In a Phase 1a/1b study, CAEL-101 demonstrated improved organ function, including cardiac and renal function, in 27 patients with relapsed and refractory AL amyloidosis who had previously not had an organ response to standard of care therapy. These data support CAEL-101's potential to be a well-tolerated therapy that promotes amyloid resolution. In a Phase 2 dose escalation study, safety and tolerability of CAEL-101 supported the selection of the 1000 mg/m2 dose for the Phase 3 studies. CAEL-101 has received Orphan Drug Designation from the FDA as a therapy for patients with AL amyloidosis, and as a radio-imaging agent in AL amyloidosis.

In September 2020 Caelum initiated two Phase 3 studies of CAEL-101 for AL amyloidosis. Additional information on the Phase 3 trials, both of which are actively enrolling patients, can be found at www.ClinicalTrials.gov using identifiers NCT04512235 and NCT04504825.

In December 2020, AstraZeneca ("AZ") announced its intention to acquire Alexion, with the acquisition expected to close by the third quarter of 2021, as the acquisition is subject to approval by both AZ and Alexion shareholders, as well as certain regulatory approvals, share listing approvals, and other customary closing conditions. The acquisition of Alexion by AZ triggers the Change of Control clause in the Amended and Restated Development, Option and Stock Purchase Agreement entered into by and among Caelum, Alexion, the Company, and Caelum security holders, such that Alexion's purchase option expires on the date that is six months after the closing of any Change of Control.

Triplex (Vaccine for Cytomegalovirus)

Through our partner company 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 multiple other ongoing and planned studies, one involving vaccination of the stem cell transplant donor (followed by vaccination of the recipient) in higher risk patients. Helocyte will potentially initiate studies of Triplex for CMV control in recipients of kidney and liver transplant. Helocyte secured an exclusive, worldwide license to Triplex from City of Hope National Medical Center ("COH") in April of 2015.

CEVA101 (Cellular Therapeutic for Severe Traumatic Brain Injury)

Through our partner company, Cellvation, we are developing CEVA101, a cellular product comprised of autologous Bone Marrow-derived Mononuclear Cells ("BMMNCs") 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), see ClinicalTrials.gov Identifiers NCT01575470 and NCT0254722.

In a recently-completed, randomized, placebo-controlled, multi-center Phase 2 study of children with severe TBI, 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), see ClinicalTrials.gov Identifier NCT01851083). A randomized, placebo-controlled Phase 2 study of CEVA101 for the treatment of severe TBI in adults is ongoing (see ClinicalTrials.gov Identifier NCT02525432). In 2017, Cellvation secured RMAT designation for CEVA101 in the treatment of severe TBI. The RMAT designation is expected to facilitate expedited development and review of CEVA101. 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.

Early Stage Product Candidates

MB-102 (CD123 CAR T for BPDCN)

Our partner company Mustang collaborates with COH and Fred Hutchinson Cancer Research 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 the next generation of cancer care that may prove curative across tumor types that have proved resistant to standard pharmacological and biological treatments.

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

Mustang is currently investigating MB-102 as a target for adoptive cellular immunotherapy in BPDCN, since high CD123 expression is associated with enhanced malignant 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. CD123 is overexpressed in the vast majority of cases of AML and high-risk MDS 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). This is also the first clinical trial under a Mustang IND in which a patient was dosed with cells processed in Mustang's own manufacturing facility.

MB-101 (IL13Rα2 CAR T for Glioblastoma)

Mustang is also currently developing MB-101, an optimized CAR T product incorporating enhancements in CAR T design and T cell engineering to improve antitumor potency and T cell persistence. Having optimized dose, schedule, route of administration and T cell selection, a Phase 1 trial is currently underway at COH combining MB-101 with immune checkpoint inhibitors to treat patients with recurrent or refractory glioblastoma multiforme ("GBM"). Additional information on the trial can be found on www.ClinicalTrials.gov using identifier NCT04003649.

In December 2020, Mustang and COH announced the initiation of a Phase 1 trial of MB-101 to treat patients with leptomeningeal brain tumors (e.g. glioblastoma, ependymoma, or medulloblastoma) and additional information on the trial can be found on www.clinicaltrials.gov using identifier NCT04661384. In 2021, Mustang expects to initiate a trial of MB-101 in combination with MB-108, an oncolytic virus in-licensed from Nationwide Children's Hospital, with the goal of potentially enhancing efficacy in treating GBM.

GBM is the most common brain and central nervous system ("CNS") cancer, accounting for 45.2% 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 2020. 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 (2-3 cases per 100,000 persons per year in the US and EU), 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).

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 an 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 light chain amyloidosis ("AL"), 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-106 (CD20 CAR T for B-cell non-Hodgkin lymphoma)

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 non-Hodgkin lymphoma ("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. A CD20-targeted third-generation autologous CAR T cell therapy is being developed by our partner company Mustang in a collaboration with the Fred Hutchinson Cancer Research Center ("Fred Hutch").

More than 70,000 new cases of NHL are diagnosed each year in the United States, and more than 19,000 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. Innovative new treatments are therefore urgently needed.

Fred Hutch has an open IND for a Phase 1/2 clinical study to assess the anti-tumor activity and safety of administering CD20-directed CAR T cells (MB-106) to patients with relapsed or refractory B-cell NHL or chronic lymphocytic leukemia (Clinicaltrials.gov Identifier: NCT03277729). This IND was submitted on February 24, 2017, with Fred Hutch as the sponsor. The trial will also assess CAR T cell persistence and determine the potential immunogenicity of the cells, and Mustang together with Fred Hutch will determine a recommended Phase 2 dose.

In December 2020, at the 62nd American Society of Hematology Annual Meeting, Mustang and Fred Hutch announced interim data in patients with relapsed or refractory B-cell NHL from the ongoing Phase 1/2 clinical trial of MB-106. Following optimization of the cell processing, 9 patients – 7 with follicular lymphoma and 2 with mantle cell lymphoma – were treated at 4 different dose levels ranging from $1x10^5$ CAR T cells/kg to $3.3x10^6$ CAR T cells/kg. The overall response rate was 89% (8/9), and the complete response rate was 44% (4/9). One patient experienced a grade 1 episode of cytokine release syndrome, and no patients experienced immune effector cell-associated neurotoxicity syndrome. Mustang also plans to file an IND in the first quarter of 2021 to enable the initiation of a multicenter Phase 1/2 trial of MB-106.

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. Additional information on the Phase 1 trials can be found on www.ClinicalTrials.gov using identifiers NCT03389230 and NCT03696030.

MB-108 (HSV-1 Oncolytic Virus C134)

C134 is a next-generation oncolytic herpes simplex virus ("oHSV") 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 is currently in development at Mustang. 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. Additional information on the ongoing Phase 1 trial of MB-108 can be found on www.ClinicalTrials.gov using identifier NCT03657576. In 2021 Mustang intends to combine MB-108 with MB-101 to potentially enhance efficacy in treating GBM.

In October 2020 the Phase 1 trial of MB-108 was put on hold due to toxicity at the highest dose level, and UAB expects FDA clearance in the first half of 2021 in order to resume enrolling patients at a lower dose level. As a result of this clinical hold, as well as COVID-19 virus-related accrual delays in 2020, we expect that IND filing for the combination trial of MB-108 with MB-101 will be delayed until the fourth quarter of 2021.

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. Additional information on this trial can be found on www.ClinicalTrials.gov using 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. Mustang believes additional data could potentially be provided in the second half of 2021.

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

Through our majority-owned partner 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 will explore BAER-101 in a number of CNS disorders where patients are not adequately treated.

Preclinical Product Candidates

AAV-ATP7A Gene Therapy

Through our majority-owned partner Cyprium, we are developing adeno-associated virus ("AAV") gene therapy ("AAV-ATP7A"). In March 2017, Cyprium entered into a license agreement with *Eunice Kennedy Shriver* National Institute of Child Health and Human Development ("NICHD") 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 majority-owned partner 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. The lead target indications are Dry Age-related Macular Degeneration ("Dry AMD") and autoimmune disorders with high unmet need including atypical hemolytic uremic syndrome (also known as "aHUS") and paroxysmal nocturnal hemoglobinuria (also known as "PNH").

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 a collaboration with TGTX to develop CK-103 in the field of hematological malignancies. Checkpoint retains the right to develop and commercialize CK-103 in solid tumors.

CEVA-D and CEVA-102

In partnership with 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 ("WSS") to suppress tumor necrosis factor-a ("TNF-a") production by activated immune cells. CEVA-102 is the first cell product produced by CEVA-D, which we plan to develop for various indications, including the treatment of severe traumatic brain injury ("TBI") in adults and children.

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. GITR is a co-stimulatory molecule of the TNF receptor family and is expressed on activated T cells, B cells, natural killer ("NK") and regulatory T cells ("Treg"). Checkpoint is developing CK-302 for oncology indications where scientific literature supports the potential for an anti-GITR to be effective.

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 ("ADCC") 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"). Checkpoint is developing CK-303 for the treatment of patients with RCC in combination with an anti-PD-L1 and/or anti-GITR antibody as well as potentially other anti-tumor immune response potentiating compounds and/or targeted therapies.

ConVax (formerly Pentamer)

We and our partner Helocyte are also developing ConVax, a universal recombinant Modified Vaccinia Ankara viral vector vaccine designed to induce robust and durable humoral and cellular immune responses to cytomegalovirus ("CMV"). ConVax is currently undergoing nonclinical development.

ONCOlogues (Oligonucleotide Platform)

Our partner company Oncogenuity is developing a delivery platform that allows peptic nucleic acids ("PNAs") to enter cell membrane and nucleus, displace the targeted mutant DNA strand, and prevent mutant mRNA transcription. The platform has demonstrated in vitro proof-of-concept data in KRAS G12D models and 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 and our partners' 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 and our partners currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we and our partners 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 and our partners 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 and our partners' 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 and our partners. We and our partners 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, Vyne Therapeutics, Sol-Gel Technologies, Almirall, Verrica Pharmaceuticals, Cassiopea, MC2 Therapeutics, EPI Health, 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 PTO 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 and our partners 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 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 Institutional Review Board ("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, our partners, or related suppliers, will be able to fully comply with the CGMPs and other FDA regulatory requirements.

Post-Approval Requirements

Any pharmaceutical products for which we or our partners 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 ("BPCA"), 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 and our partners 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

As of December 31, 2020, we had 111 full-time employees at Fortress and our partner companies.

Executive Officers of Fortress

The following table sets forth certain information about our executive officers as of December 31, 2020.

Name	Age	Position
Lindsay A. Rosenwald, M.D.	65	Chairman of the Board of Directors, President and Chief Executive Officer
Robyn M. Hunter	59	Chief Financial Officer
George Avgerinos, Ph.D.	67	Senior Vice President, Biologics Operations
Michael S. Weiss	54	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. From November 2014 to August 2015, he served as interim President and Chief Executive Officer of Checkpoint Therapeutics, Inc. (Nasdaq: CKPT). Dr. Rosenwald currently serves as a member of the board of directors of Fortress partner companies Avenue Therapeutics, Inc. (Nasdaq: ATXI), Checkpoint Therapeutics, Inc. (Nasdaq: CKPT), and Mustang Bio, Inc. (Nasdaq: MBIO). From 1991 to 2008, Dr. Rosenwald served as the Chairman of Paramount BioCapital, Inc. He received his B.S. in finance from Pennsylvania State University and his M.D. from Temple University School of Medicine.

Robyn M. Hunter was appointed as the Company's Chief Financial Officer on June 26, 2017. Ms. Hunter has more than 30 years of financial and operational experience in an array of industries. Prior to serving as the Company's CFO, Ms. Hunter served as the Company's Vice President and Corporate Controller from June 2011 until June 2017, where she implemented financial and operational processes, procedures and policies to facilitate the Company's execution of its growth strategy. From January 2006 to May 2011, Ms. Hunter served as Senior Vice President and Chief Financial Officer of Schochet Associates. From August 2004 to January 2006, Ms. Hunter served as the Corporate Controller for Indevus Pharmaceuticals. From 1990 to 2004, Ms. Hunter held several positions from Accounting Manager to Vice President and Treasurer of The Stackpole Corporation. Ms. Hunter holds a Bachelor of Arts degree in Economics from Union College in Schenectady New York.

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 Therapeutics, Inc. (Nasdaq: CKPT) and Mustang Bio, Inc. (Nasdaq: MBIO). Mr. Weiss is currently the Executive Chairman of Mustang Bio, Inc. (where he served as interim CEO from March 2015 to April 2017) and the Chairman of the Board of Directors of Checkpoint Therapeutics, Inc. (where he served as interim CEO from August 2015 to October 2015). From March 2015 until February 2019, Mr. Weiss served on the board of Avenue Therapeutics, Inc. (Nasdaq: ATXI). Since December 2011, Mr. Weiss has served in multiple capacities at TG Therapeutics, Inc., 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 public may obtain these filings at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. 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.

Item 1A. Risk factors

Investing in our Common Stock, Series A Preferred Stock or any other type of equity or debt securities (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 partners and affiliates Checkpoint, Mustang, and Avenue 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 Checkpoint, Mustang or Avenue 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 partners and affiliates such that, if any of the negative outcomes associated with any such risk is experienced by one of our partners or affiliates, the value of Fortress' holdings in such partner or affiliate (if any) may decline.

Risks Inherent in Drug Development

Most of our or our partner companies' 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 Biologics License Application ("BLA") or New Drug Application ("NDA"). The approval process is uncertain, expensive, often spans many years, and can vary substantially based upon the type, complexity and novelty of the 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 would 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 a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching and maintaining agreements on acceptable terms with prospective clinical research organizations ("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 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 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 issues or any 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 Capital restricts our and certain of our partner companies' abilities to take certain actions.

At December 31, 2020, the total amount of debt outstanding, net of the debt discount was $51.7 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 a $60.0 million senior secured credit agreement with Oaktree Fund Administration, LLC and the lenders from time-to-time party thereto (collectively, "Oaktree"). The Oaktree credit agreement contains certain affirmative and negative covenants restricting our and certain of our partner companies' 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 credit 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 credit 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 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 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 continuing operations of approximately $103.0 million and $101.7 million for the years ended December 31, 2020 and 2019, respectively. At December 31, 2020, we had an accumulated deficit of approximately $482.8 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 partners and affiliates 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 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, 2020 and 2019 we incurred R&D expenses of approximately $61.3 million and $75.2 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 are 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, 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 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 dermatology products through our partner company Journey Medical Corporation. Any setback that may occur with respect to such products, in particular Ximino, Targadox and Exelderm, could significantly impair our operating results and/or reduce our revenue and the market prices of our Securities. Setbacks for such products could include, but are not necessarily limited to, problems with shipping, distribution, demand, manufacturing, product safety, marketing, government regulation or reimbursement, licenses and approvals, intellectual property rights, competition with existing or new products, physician or patient acceptance of the products, as well as higher than expected total rebates, returns or recalls.

Also, the majority 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 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 PTO proceedings, if a generic ompany 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.

Any disruptions to the capabilities, composition, size or existence of Journey's sales force may have a significant adverse impact on our existing revenue stream. If we are unable to establish and/or maintain sales and marketing capabilities or fail to enter into agreements with third parties to market, distribute and sell products that may be successfully developed in the future, we may be unable to effectively market and sell such products and generate product revenue.

Journey's sales force has been and is expected to continue to be an important contributor to its commercial success. Any disruptions to Journey's relationship with such sales force or the third-party contractor through which they are engaged could materially adversely affect Journey's product sales. Journey may from time-to-time acquire additional products with which its existing sales force has little familiarity (e.g., with respect to indications, product labels, dosages, formulations or delivery mechanisms), and there is no guarantee that Journey's sales force will have success in marketing such new products in the near-term or ever.

Apart from Journey, we do not currently have the infrastructure for the sales, marketing and distribution of any of our product candidates, and we must build and maintain such infrastructures or make arrangements with third parties to perform these functions in order to commercialize any products that we may successfully develop. The establishment and development of a sales force, either by us or our partners, or the establishment of a contract sales force, to market any products for which we may 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 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.

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 product 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. 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.

Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs and biological products apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Pricing Program;
- new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new regulatory pathway for the approval of biosimilar biological products, all of which will impact existing government healthcare programs and will result in the development of new programs; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court's prior decision. On December 14, 2018, a Texas federal district court judge issued a ruling declaring that the ACA in its entirety is unconstitutional. Upon appeal, the Fifth Circuit upheld the district court's ruling that the individual mandate is unconstitutional. However, the Fifth Circuit remanded the case back to the district court to conduct a more thorough assessment of the constitutionality of the entire ACA despite the individual mandate being unconstitutional. The Supreme Court agreed to hear the case on appeal from the Fifth Circuit on March 2, 2020 and held oral arguments on November 10, 2020. While this lawsuit has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome may have a significant impact on our business.

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.

The 116th Congress 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), marked up legislation intended to address various elements of the prescription drug supply chain. Proposals include a significant overhaul of the Medicare Part D benefit design, addressing patent "loopholes", and efforts to cap the increase in drug prices. The House Energy and Commerce Committee approved drug-related legislation intended to increase transparency of drug prices and also curb anti-competitive behavior in the pharmaceutical supply chain. In addition, the House Ways & Means Committee approved legislation intended to improve drug price transparency, including for drug manufacturers to justify certain price increases. The 117th Congress convened on January 3, 2021 and could reintroduce many of the bills targeting drug prices. 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 Senate Committee on Health, Education, Labor, and Pensions (HELP) advanced the Lower Health Care Costs Act of 2019. Among other things, the bill is intended to reduce costs in the United States health sector. The bill revises certain requirements to expedite the approval of generics and biosimilars. It also limits prices that pharmacy benefit managers may charge health insurers or enrollees for prescription drugs. Although this bill still needs to pass the full Senate and House of Representatives, it is worth noting the wide-ranging effects it could have on the health care sector.

On December 12, 2019, the House of Representatives passed broad legislation (H.R. 3, the *Elijah E. Cummings Lower Drug Costs Now Act*) that would, among other provisions, require HHS to negotiate drug prices and impose price caps and restructure the Medicare Part D benefit, imposing more financial responsibility on certain drug manufacturers. Failure by a manufacturer to reach an agreement with HHS on the negotiated price could result in significant penalties for prescription drug manufacturers. In addition, S. 2543, *the Prescription Drug Pricing Reduction Act* would also, among other provisions, restructure the Medicare Part D benefit, but it would not authorize direct negotiation by the federal government. 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 Trump Administration took several regulatory steps to redirect ACA implementation. The HHS finalized a Medicare hospital payment reduction for Part B drugs acquired through the 340B Drug Pricing Program.

Under the Trump Administration, HHS finalized several proposals aimed at lowering drug prices for Medicare beneficiaries and increasing price transparency. For example, the Trump Administration issued an interim final rule on November 27, 2020 implementing a "Most Favored Nation" payment model for Part B drugs that applies international reference pricing to determine reimbursement for certain drugs paid by Medicare Part B. The interim final rule was enjoined by federal courts prior to its implementation date of January 1, 2021, and the lawsuit is ongoing. In addition, HHS, in conjunction with the FDA, finalized four pharmaceutical importation pathways in September 2020: (1) regulations establishing importation of pharmaceuticals from Canada by wholesalers and pharmacists; (2) FDA guidance permitting manufacturers to import their own pharmaceuticals that were originally intended for marketing in other countries; (3) a request for proposals from private sector entities to import prescription drugs for personal use under existing statutory authority; and (4) a request for proposals from private sector entities to reimport insulin under existing statutory authority. Further, on November 11, 2020, the Trump Administration issued a final rule that changes the permissible structure of drug rebates and discounts between drug manufacturers and third-party payors (including pharmacy benefit managers that negotiate drug prices on behalf of such third-party payors). This final rule, often referred to as the "Rebate Rule," could have significant direct and indirect impacts on drug pricing in both government and commercial markets. With respect to price transparency, the Trump Administration promulgated regulations that require hospitals and third-party payors to disclose prices of items and services, which may impact negotiated rates in the commercial market.

On January 20, 2021, Joe Biden was inaugurated as the 46th president of the United States. As a presidential candidate, Mr. Biden indicated support for several policies aimed at lowering drug prices, including government price negotiation, drug importation, international reference pricing, and price increase controls. The incoming Biden Administration may continue, modify, or repeal many of the drug pricing policies proposed and finalized by the Trump Administration. While we cannot predict which policies the Biden Administration may support and enforce, the policies finalized in the months prior to the beginning of Mr. Biden's term, if continued, could significantly change the landscape in which the pharmaceutical market operates and significantly impact our ability to effectively market and sell our products.

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. 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 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.

In addition, governments may impose price controls, which may adversely affect our future profitability. In January 2020, President Trump signed into law the U.S.-Mexico-Canada (USMCA) trade deal into law. As enacted, there are no commitments with respect to biological product intellectual property rights or data protection, which may create an unfavorable environment across these three countries.

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 undergone, and are likely in the future to undergo, collaborations and/or divestitures with respect to certain of our assets and subsidiaries, some of which may be material and/or transformative, which could adversely affect

We have entered into several partnerships and/or contingent sales of our assets and subsidiaries, including an equity investment and contingent sale between Avenue and InvaGen, an equity investment and contingent option transaction between Caelum and Alexion Pharmaceuticals, Inc. and a development funding and contingent asset purchase between Cyprium and Sentynl Therapeutics, Inc. Each of these transactions has been time-consuming and has diverted management's attention. As a result of these 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. For example, in connection with execution of the Stock Purchase and Merger Agreement between Avenue and InvaGen, dated as of November 12, 2018 (the "Avenue SPMA"), we signed a Restrictive Covenant Agreement, which prohibits us from, directly or indirectly, engaging in the business of hospital administered pain management anywhere in the world other than Canada, Central America or South America for a period of five years after the earlier of the termination of the Avenue SPMA or consummation of the Merger Transaction (as defined in the Avenue SPMA).

In addition, in connection with any transaction involving a (contingent or non-contingent) sale of one of our assets or subsidiaries, we may surrender our ability to realize long-term value from such asset or subsidiary, in the form of foregone 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 subsidiary is granted FDA approval for commercialization following the execution of documentation governing the sale by us of such asset or subsidiary, the transferee of such asset or subsidiary 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 subsidiaries, 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.

As a result of certain developments and assertions by its partner, InvaGen, Avenue may not consummate the second closing of its merger.

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"), under which Avenue would be sold to InvaGen in a two-stage transaction. The first stage of the strategic transaction between InvaGen and Avenue 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. At the second stage closing, InvaGen would acquire the remaining shares of Avenue's common stock, pursuant to a reverse triangular merger with Avenue remaining as the surviving entity.

The second stage closing is subject to the satisfaction of certain closing conditions, including conditions pertaining to the FDA approval, labeling, scheduling and the absence of any Risk Evaluation and Mitigation Strategy or similar restrictions in effect with respect to IV Tramadol, as well as the expiration of any waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("HSR").

In October 2020, InvaGen communicated to Avenue that it believes a Material Adverse Effect (as defined in the Avenue SPMA) has occurred due to the impact of the COVID-19 pandemic on potential commercialization and projected sales of IV Tramadol, which means it is possible InvaGen could attempt to avoid its obligation to consummate the second stage closing under the Avenue SPMA, terminate the Avenue SPMA, and/or pursue monetary claims against Avenue and/or Fortress. Avenue disagrees with InvaGen's assertion that a Material Adverse Effect has occurred and has advised InvaGen of this position.

In February 2020, the U.S. Food and Drug Administration ("FDA") accepted the submission of Avenue's' New Drug Application ("NDA") for IV Tramadol for review and assigned a Prescription Drug User Fee Act ("PDUFA") date of October 10, 2020. In October 2020, Avenue announced that it had received a Complete Response Letter ("CRL") from the FDA regarding Avenue's NDA for IV Tramadol. The FDA held a Type A meeting with Avenue in November 2020 to discuss the issues outlined in the CRL. On February 12, 2021 Avenue resubmitted its NDA to the FDA for IV Tramadol. The NDA resubmission followed the receipt of the official minutes from Avenue's Type A meeting with the FDA. The NDA resubmission included revised language relating to the proposed product label and a report relating to terminal sterilization validation. On February 26, 2021, Avenue received an acknowledgement letter from the FDA that Avenue's resubmission of its NDA is a complete, class 1 response to the CRL, and a PDUFA goal date was set for April 12, 2021.

In connection with the resubmission of Avenue's NDA, InvaGen communicated to Avenue that it believes the proposed label for IV Tramadol under certain circumstances would constitute a Material Adverse Effect on the purported basis that the proposed label for IV Tramadol would make the product commercially unviable, and in addition that the indiciation that the FDA approves may fail to satisfy a condition precedent to InvaGen's obligation to consummate the second stage closing of the Avenue SPMA. Avenue has notified InvaGen that it disagrees with InvaGen's assertions. Nevertheless, InvaGen may seek to avoid its obligation to consummate the second stage closing under the Avenue SPMA, terminate the Avenue SPMA, and/or pursue monetary claims against Avenue and/or Fortress.

Over the past several months, Avenue has communicated with InvaGen relating to InvaGen's assertions. Nevertheless, InvaGen has communicated to Avenue its desire to consider all options on the proposed merger, including the option to not consummate the merger. This indicates that InvaGen may attempt to avoid its obligations under the Avenue SPMA to consummate the merger, terminate the Avenue SPMA, and/or pursue monetary claims against Avenue and/or Fortress. As a result, the possible timing and likelihood of the completion of the merger are uncertain, and, accordingly, there can be no assurance that such transaction will be completed on the expected terms, anticipated schedule, or at all. During the pendency of any dispute regarding these matters, Avenue may be, and so long as the Avenue SPMA remains in place Avenue will be, prohibited from engaging in a change-of-control transaction, selling its rights to IV Tramadol or effecting an equity or debt financing, in each case without the prior written consent of InvaGen.

If Avenue does not receive FDA approval for IV Tramadol by April 30, 2021, InvaGen will have the right to terminate the Avenue SPMA and will have no further obligations to consummate the second stage closing under the Avenue SPMA. In the event that InvaGen does not exercise its right to terminate the Avenue SPMA, certain restrictions relating to financings and strategic alternatives could exist through October 31, 2021, the time at which Avenue can terminate the Avenue SPMA. Regardless of whether the Avenue SPMA is terminated, InvaGen will retain certain rights pursuant to the Stockholder's Agreement between Avenue and InvaGen. These rights exist as long as InvaGen maintains at least 75% of the Avenue common shares acquired in the first stage closing. The following are some of the actions that shall not be taken by Avenue without the prior written consent of InvaGen:

- increase in authorized shares of Avenue's capital stock;
- any agreement or transaction that would adversely treat the holders of Avenue's common shares as compared to the holders of Avenue's Class A Preferred Shares;

- issuance of any shares of Avenue's capital stock or any securities convertible into, or other rights to acquire, shares of Avenue's capital stock (including options, warrants or bonds), except for issuances to Avenue's officers for services performed;
- any transfer or license of any asset for less than fair market value, as determined by a recognized independent valuation firm agreed upon by Avenue and Invagen; or
- entry into any transaction or agreement with any affiliate of Avenue's (including the Company or its Affiliates).

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 affiliated companies; we have also entered into certain arrangements with our subsidiaries and 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 affiliates.

We act, and are likely to continue acting, in as indemnitor of potential losses that may be experienced by one or more of our affiliated companies and/or their partners or investors. For instance, under that certain Indemnification Agreement, dated as of November 12, 2018 (the "Indemnification Agreement"), we indemnify InvaGen and its affiliates for losses they may sustain in connection with inaccuracies that may appear in the representations and warranties that Avenue made to InvaGen in the Avenue SPMA, as such representations and warranties were given as of the dates of signing and first closing, and as may be required to be given as of the second stage closing under the Avenue SPMA as well. The maximum amount of indemnification we may have to provide under the Indemnification Agreement is $35.0 million, and such obligation terminates upon the consummation of the Merger Transaction (as defined in the Avenue SPMA). In the event of payment by us of any such indemnification amount, we would be able to recoup such amounts (other than our pro rata share of the indemnification as a shareholder in Avenue) from the Merger Transaction proceeds, but if the Merger Transaction never occurs, we would have no means of recouping such previously-paid indemnification amounts. If we become obligated to pay all or a portion of such indemnification amounts (regardless of whether or not we are partially reimbursed out of the proceeds of the Merger Transaction), our business and the market value of our common stock and/or debt securities may be materially adversely impacted.

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 partners, affiliates, 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 partners, 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 may nonetheless arise. The existence and consequences of such potential 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, enter into joint ventures with or obtain a controlling interest in companies in the future, it could adversely affect our operating results and the value of our Securities, 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.

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 a 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 or pass any regulatory agency inspection 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, 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.

Certain of our partner companies, on whose successes we largely rely, are early-stage biopharmaceutical companies with limited operating histories. To date, we have engaged primarily in intellectual property acquisitions, and evaluative and R&D activities and have not generated any revenues from product sales (except through Journey). We have incurred significant net losses since our inception. As of December 31, 2020, we had an accumulated deficit of approximately $482.8 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 pre-market 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 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 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 good laboratory practice ("GLP") as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices ("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 by third parties that could ultimately prove to be inaccurate or unreliable.

As part of the strategy we implement to mitigate development risk, we seek to develop product candidates with well-studied mechanisms of action, and we intend to utilize biomarkers 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, we could make inaccurate assumptions and/or conclusions about our product candidates, and our research and development efforts could be compromised or called into question during the review of any marketing applications that we submit.

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.

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 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 or our partners 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 US Patent and Trademark Office ("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 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 has acquired an isotretinoin product and will begin 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 the Company 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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

We cannot predict the likelihood, nature or extent of how government regulation that may arise from future legislation or administrative or executive action taken by the U.S. presidential administration may impact our business and industry. In particular, the former U.S. President took several executive actions, specifically through rulemaking and guidance, that could impact the pharmaceutical business and industry. Shortly after taking office in January 2021, President Biden announced that his Administration would be freezing a number of the prior Administration's drug pricing reforms, while others remain subject to both executive orders or regulatory changes issued by the Department of Health and Human Services. A few of the major administrative actions include:

- On October 30, 2019, the Trump Administration issued an advanced notice of proposed rulemaking ("ANPRM") entitled, *International Pricing Index Model for Medicare Part B Drugs*. This ANPRM was intended to solicit feedback on a potential proposal to align United States drug prices in the Medicare Part B program with international prices. It also solicited public feedback on a policy that would allowing private-sector vendors to negotiate prices, take title to drugs, and improve competition for hospital and physician business. Although this is only a notice for a potential rule, it signals the Administration's desire to regulatorily influence the United States drug pricing system that could adversely affect the industry.

- On November 15, 2019, CMS issued a proposed rule entitled, *Transparency in Coverage* and finalized the *Calendar Year ("CY") 2020 Outpatient Prospective Payment System ("OPPS") & Ambulatory Surgical Center Price Transparency Requirements for Hospitals to Make Standard Charges Rule*. Together the rules would increase price transparency through health plans and in hospitals. The affects may influence consumer purchasing habits in the health care sector as a whole. Although the transparency provisions are not yet in effect and the hospital price transparency requirements are subject to litigation, there could be implications for the industry related to drug pricing if or when it is enacted.

- On November 18, 2019, CMS issued a proposed rule entitled, *Medicaid Fiscal Accountability Regulation ("MFAR")*. The proposed rule would significantly impact states' ability to finance their Medicaid programs. If finalized, the MFAR could force states to restructure their Medicaid financing that could disincentivize or change state prescription drug purchasing behavior that would adversely impact the industry.

- On December 18, 2019, the FDA issued a proposed rule entitled, *Importation of Prescription Drugs.* The proposed rule would allow the importation of certain prescription drugs from Canada. If finalized, states or other non-federal government entities would be able to submit importation program proposals to FDA for review and authorization. This proposed rule could also influence pricing practices in the United States.

- On January 30, 2020, CMS issued a state waiver option entitled, *Health Adult Opportunity ("HAO")*. The HAO would allow states to restructure benefits and coverage policies for their Medicaid programs. The HAO will provide states administrative flexibilities in exchange for a capped federal share. The cap on the federal share is commonly referred to as a "block grant." Importantly, the HAO allows states to set formularies that align with Essential Health Benefit requirements while still requiring manufacturers to participate in the Medicaid Rebate Program. Depending on utilization of the HAO by states, it could impact the industry – especially if states elect to use a formulary.

- On December 2, 2020, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule entitled, *Modernizing and Clarifying the Physician Self-Referral Regulations* and on the same day the HHS Office of Inspector General finalized a similar rule, entitled *Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary penalty Rules Regarding Beneficiary Inducements.* The rules are an effort to reform regulations dealing with anti-kickback and self-referral laws. These rules allow certain financial arrangements that would otherwise violate anti-kickback and self-referral laws for providers that are participating in value-based payment arrangements. The rule could impact drug purchasing behavior to ensure providers are within their budget and/or restructure existing payment structures between providers and manufacturers.

As with any change in the Executive Office, and particularly with respect to changes from a Republican Administration under former President Trump to a Democratic Administration under President Biden, we expect there to be significant changes to existing rules, regulations and policies, the enactment of new Executive Orders and other immediate or iterative political, legislative and administrative changes, affecting the pharmaceutical industry. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States, or based on similar governmental changes in other countries.

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 will play a primary role in the recommendation and prescription of any 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. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end of each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014; 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 Risks

Major public health issues, and specifically the pandemic caused by the coronavirus COVID-19 outbreak, could have an adverse effect on the clinical trials of our partner companies, and as a result, have an adverse impact on our financial condition and results of operations and other aspects of our business.

In December 2019, a novel strain of coronavirus which causes a disease referred to as COVID-19, was first detected in Wuhan, China, and has since spread worldwide. On March 11, 2020, the World Health Organization declared that the rapidly spreading COVID-19 outbreak had evolved into a pandemic. In response to the pandemic, many governments around the world are implementing a variety of control measures to reduce the spread of COVID-19, including travel restrictions and bans, instructions to residents to practice social distancing, quarantine advisories, shelter-in-place orders and required closures of non-essential businesses.

The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. The extent to which the COVID-19 pandemic impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the virus and the actions to contain it or treat its impact, among others.

Some factors from the COVID-19 outbreak that may delay or otherwise adversely affect our or our partner companies' clinical trial programs, as well as adversely impact our business generally, include:

- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical sites, and delays enrolling patients in our clinical trials or increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine, or not otherwise being able to complete study assessments, particularly for older patients or others with a higher risk of contracting COVID-19;

- missed study visits or study procedures which could lead to an abundance of protocol deviations that have the potential to interfere with the interpretability of trial results;

- impacts to clinical results, including an increased number of observed adverse events, as a result of participants enrolled in our clinical trials contracting COVID-19;

- diversion of healthcare resources, including clinical trial investigators and staff, away from the conduct of clinical trials to focus on pandemic concerns which could result in delays to our partner companies' clinical trials;

- limitations on travel, including limitations on domestic and international travel, and government-imposed quarantines or restrictions imposed by key third parties that could interrupt key trial activities, such as clinical trial site initiations and monitoring;

- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, or production slowdowns or stoppages;

- disruptions and delays caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home across the healthcare system; and

- disruptions in or delays to regulatory approvals, inspections, reviews or other regulatory activities, including review of NDAs and approvals of protocol changes or amendments to SPAs, as a result of the spread of COVID-19 affecting the operations of the FDA or other regulatory authorities.

The disruptions discussed above and other consequences of COVID-19 pandemic could result in missed study visits or study procedures in our clinical trials, which could lead to an abundance of protocol deviations that impact the interpretability of the trial results. A significant number of deviations may call into question whether the execution of a clinical trial was consistent with the protocol, which is of particular importance where study designs were agreed to as part of a Special Protocol Assessment (SPA). In extreme cases, significant deviations from the protocol may be considered a violation of a SPA and result in potential rescindment of a SPA agreement.

We and our partner companies currently rely on third parties for certain functions or services in support of our clinical trials and key areas of our operations. These third parties include contract research organizations (CROs), medical institutions and clinical investigators, contract manufacturing organizations, suppliers, and external business partners supporting our preparations for commercialization. If these third parties themselves are adversely impacted by restrictions resulting from the COVID-19 outbreak, we will likely experience delays and/or realize additional costs. As a result, our or our partner companies' efforts to obtain regulatory approvals for, and to commercialize, our or our partner companies' product candidates may be delayed or disrupted.

In addition, as a result of government directives on social distancing and to protect the health of our workforce, we have asked our office-based employees to work remotely and have restricted domestic and international travel indefinitely.

We restricted on-site staff to only those personnel and contractors who must perform essential activities that must be completed on-site. Third parties on which we rely may also increase their use of remote working arrangements in response to COVID-19. Our increased reliance on personnel working remotely may negatively impact productivity, including our ability to monitor clinical trials, prepare regulatory applications, and conduct data analysis, or disrupt, delay, or otherwise adversely impact our business. In addition, remote working could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors.

The ability of the Company's employees and consultants to work may be significantly impacted by the coronavirus.

The Company's employees and consultants are being affected by the COVID-19 pandemic. Substantially all of our office and management personnel are working remotely, and the Company may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the coronavirus. COVID-19 may also compromise the ability of independent contractors who perform consulting services for us to deliver services or deliverables in a satisfactory or timely manner. Further, our management team is focused on mitigating the adverse effects of the COVID-19 pandemic, which has required and will continue to require a large investment of time and resources, thereby diverting their attention from other priorities that existed prior to the outbreak of the pandemic. If these conditions worsen, or last for an extended period of time, the Company's ability to manage its business may be impaired, and operational risks, cybersecurity risks and other risks facing the Company even prior to the pandemic may be elevated.

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

Almost all of the 100.8 million outstanding shares of our Common Stock, inclusive of outstanding equity awards, as of December 31, 2020 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 statement on Form S-3, from time to time we may issue and sell shares of our Common Stock or Preferred Stock having an aggregate offering price of up to $26.7 million as of December 31, 2020. Any sale of a substantial number of shares of our Common Stock or our Preferred Stock could cause a drop in the trading price of our Common Stock or 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 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 partners 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 partners 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 our Common Stockholders 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. Back in March, Dr. Janet Woodcock, the Director of FDA's Center for Drug Evaluation and Research, temporarily stepped away from her role to focus on the therapeutic aspects of Operation Warp Speed, a major reorganization intended to better align FDA's activities with the national effort to develop COVID-19 countermeasures. Dr. Woodcock later named Acting Commissioner of FDA on January 20, 2021. These changes to leadership, enhanced focus on COVID-19 countermeasures, and the reorganization and rededication or critical resources, both at FDA and within similar governmental authorities across the world, are likely to 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

On October 3, 2014, we entered into a 15-year lease for approximately 23,000 square feet of office space at 2 Gansevoort Street, New York, NY 10014, at an average annual rent of $2.7 million. We took possession of this space, which serves as our principal executive offices, in December 2015, and took occupancy in April 2016. Total rent expense, over the full term of the lease for this space will approximate $40.7 million. In conjunction with the lease, we entered into Desk Space Agreements with two related parties: Opus Point Partners Management, LLC ("OPPM") and TGTX, to occupy 10% and 45%, respectively, of the office space that requires them to pay their share of the average annual rent of $0.3 million and $1.1 million, respectively. The total net rent expense to us is approximate $16.0 million over the lease term. These initial rent allocations will be adjusted periodically for each party based upon actual percentage of the office space occupied. As of 2020, only TGTX continues in a Desk Space Agreement with us, as OPPM dissolved in 2019. Additionally, we have reserved the right to execute desk space agreements with other third parties and those arrangements will also affect the cost of the lease actually borne by us.

In October 2015, we entered into a 5-year lease for approximately 6,100 square feet of office space in Waltham, MA at an average annual rent of approximately $0.2 million. We took occupancy of this space in January 2016. In December 2020, we amended our lease and entered into a new two-year extension of the same office space in Waltham, MA at an average annual rent of $0.2 million. The term of this amended lease commences on April 1, 2021 and will expire on March 31, 2023.

Journey

In June 2017, Journey extended its lease for 2,295 square feet of office space in Scottsdale, AZ by one year, at an average annual rent of approximately $55,000. Journey originally took occupancy of this space in November 2014. In August 2018, Journey amended their lease and entered into a new two-year extension for 3,681 square feet of office space in the same location in Scottsdale, AZ at an annual rate of approximately $0.1 million. The term of this amended lease commenced on December 1, 2018 and expired on November 30, 2020. In August 2020, Journey amended their lease and entered into a new 25-month extension of the same office space in Scottsdale, AZ at an average annual rent of $0.1 million. The term of this amended lease commenced on December 1, 2020 and will expire on December 31, 2022.

Mustang

On October 27, 2017, Mustang entered into a lease agreement with WCS - 377 Plantation Street, Inc., a Massachusetts nonprofit corporation. Pursuant to the terms of the lease agreement, we agreed to lease 27,043 square feet from the landlord, located at 377 Plantation Street in Worcester, MA (the "Facility"), through November 2026, subject to additional extensions at the Company's option. Base rent, net of abatements of $0.6 million over the lease term, totals approximately $3.6 million, on a triple-net basis.

The terms of the lease also require that we post an initial security deposit of $0.8 million, in the form of $0.5 million letter of credit and $0.3 million in cash, which increased to $1.3 million ($1.0 million letter of credit, $0.3 million in cash) on November 1, 2019. After the fifth lease year, the letter of credit obligation is subject to reduction.

The Facility began operations for the production of personalized CAR T and gene therapies in 2018.

Item 3. Legal Proceedings

In November 2020, a purported securities class action complaint was filed in the U.S. District Court for the Eastern District of New York, putatively on behalf of all shareholders who purchased or otherwise acquired Fortress securities between December 11, 2019 and October 9, 2020 (the "Class Period"), and who were allegedly damaged in connection therewith. The case is captioned *Cushman v. Fortress Biotech, Inc., et al.*, Case No. 1:20-cv-05767, and names as defendants the Company and two of our officers. The complaint alleges that, throughout the Class Period, the Company made false and/or misleading statements and/or failed to disclose various facts and circumstances with respect to a New Drug Application filed by Avenue Therapeutics, Inc., our partner company, regarding IV Tramadol, Avenue's lead product candidate. The complaint alleges violations of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and seeks damages as well as attorneys' fees, expert fees and other costs. The action is in the early stages of litigation, and the Company intends to vigorously contest the claims.

In addition, while not a legal proceeding, Avenue is aware of claims by Cipla and InvaGen that the conditions to the second closing of the Avenue merger cannot be met, something Avenue disagrees with, but may nevertheless lead to legal proceedings in the matter. *See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Late State Product Candidates – Intravenous (IV) Tramadol" on page [65].*

To our knowledge, there are no other 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.

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."

Issuer and Affiliate Purchases of our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock

Period	Total Number of Shares Purchased (Repurchased)	Average Price Paid per Share (or Unit)	Total Number of Shares Purchased (Repurchased) as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
March 1, 2020 - March 31, 2020	(5,000) [1]	$14.00	(5,000)	—
August 1, 2020 - August 31, 2020	69,167 [2]	$18.00	69,167	—

Note 1: Shares were purchased pursuant to the Company's share repurchase program of outstanding 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (Nasdaq: FBIOP) ("Preferred Stock"), announced on March 23, 2020.

Note 2: In connection with an underwritten offering of the Preferred Stock by the Company, 52,500 shares of Preferred Stock were purchased by Lindsay A. Rosenwald, M.D. and 16,667 shares of Preferred Stock were purchased by Malcolm Hoenlein on August 26, 2020, as reported on each director's Form 4 filed with the SEC on September 1, 2020.

Holders of Record

As of March 18, 2020, there were approximately 545 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.

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."

Item 6. Selected Consolidated Financial Data

Not applicable.

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.

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

We are a biopharmaceutical company dedicated to acquiring, developing and commercializing pharmaceutical and biotechnology products and product candidates, which we do at the Fortress level, at our majority-owned and majority-controlled subsidiaries and joint ventures, and at entities we founded and in which we maintain significant minority ownership positions. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who identify and evaluate promising products and product candidates for potential acquisition by new or existing partner companies. Through our 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 Research 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, and AstraZeneca plc.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, we leverage our business, scientific, regulatory, legal and finance expertise to help our partners achieve their goals. Our 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, three partner companies are publicly-traded, and two have consummated strategic partnerships with industry leaders Alexion Pharmaceuticals, Inc. and InvaGen Pharmaceuticals, Inc. (a subsidiary of Cipla Limited).

Recent Events

Marketed Dermatology Products

- In 2020, our marketed products generated net revenue of $44.5 million, compared to net revenue of $34.9 million in 2019.
- We currently have 42 sales representatives dedicated to the dermatology product portfolio.
- Our dermatology products are marketed by our partner company, Journey Medical Corporation ("Journey" or "JMC").

Late Stage Product Candidates

Intravenous (IV) Tramadol

- On November 12, 2018, Avenue entered into a Stock Purchase and Merger Agreement (the "Avenue SPMA") with InvaGen Pharmaceuticals Inc. ("InvaGen"), Madison Pharmaceuticals Inc. (the "Merger Sub"), and us under which Avenue would be sold to InvaGen in a two-stage transaction. The first stage of the strategic transaction between InvaGen and Avenue 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. At the second stage closing, InvaGen will acquire the remaining shares of Avenue's common stock, pursuant to a reverse triangular merger with Avenue remaining as the surviving entity. The second stage closing is subject to the satisfaction of certain closing conditions, including conditions pertaining to the FDA approval, labeling, scheduling and the absence of any Risk Evaluation and Mitigation Strategy or similar restrictions in effect with respect to IV Tramadol, as well as the expiration of any waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("HSR").
- In October 2020, InvaGen communicated to Avenue that it believes a Material Adverse Effect (as defined in the Avenue SPMA) has occurred due to the impact of the COVID-19 pandemic on potential commercialization and projected sales of IV Tramadol, which means it is possible InvaGen could attempt to avoid its obligation to consummate the second stage closing under the Avenue SPMA, terminate the Avenue SPMA, and/or pursue monetary claims against Avenue and/or Fortress. Avenue disagrees with InvaGen's assertion that a Material Adverse Effect has occurred and has advised InvaGen of this position.
- In February 2020, the U.S. Food and Drug Administration ("FDA") accepted the submission of Avenue's' New Drug Application ("NDA") for IV Tramadol for review and assigned a Prescription Drug User Fee Act ("PDUFA") date of October 10, 2020. In October 2020, Avenue announced that it had received a Complete Response Letter ("CRL") from the FDA regarding Avenue's NDA for IV Tramadol. The FDA held a Type A meeting with Avenue in November 2020 to discuss the issues outlined in the CRL. On February 12, 2021 Avenue resubmitted its NDA to the FDA for IV Tramadol. The NDA resubmission followed the receipt of the official minutes from Avenue's Type A meeting with the FDA. The NDA resubmission included revised language relating to the proposed product label and a report relating to terminal sterilization validation. On February 26, 2021, Avenue received an acknowledgement letter from the FDA that Avenue's resubmission of its NDA is a complete, class 1 response to the CRL, and a PDUFA goal date was set for April 12, 2021.
- In connection with the resubmission of Avenue's NDA, InvaGen communicated to Avenue that it believes the proposed label for IV Tramadol under certain circumstances would constitute a Material Adverse Effect on the purported basis that the proposed label for IV Tramadol would make the product commercially unviable, and in addition that the indiciation that the FDA approves may fail to satisfy a condition precedent to InvaGen's obligation to consummate the second stage closing of the Avenue SPMA. Avenue has notified InvaGen that it disagrees with InvaGen's assertions. Nevertheless, InvaGen may seek to avoid its obligation to consummate the second stage closing under the Avenue SPMA, terminate the Avenue SPMA, and/or pursue monetary claims against Avenue and/or Fortress.
- Over the past several months, Avenue has communicated with InvaGen relating to InvaGen's assertions. Nevertheless, InvaGen has communicated to Avenue its desire to consider all options on the proposed merger, including the option to not consummate the merger. This indicates that InvaGen may attempt to avoid its obligations under the Avenue SPMA to consummate the merger, terminate the Avenue SPMA, and/or pursue monetary claims against Avenue and/or Fortress. As a result, the possible timing and likelihood of the completion of the merger are uncertain, and, accordingly, there can be no assurance that such transaction will be completed on the expected terms, anticipated schedule, or at all. During the pendency of any dispute regarding these matters, Avenue may be, and so long as the Avenue SPMA remains in place Avenue will be, prohibited from engaging in a change-of-control transaction, selling its rights to IV Tramadol or effecting an equity or debt financing, in each case without the prior written consent of InvaGen.

- If Avenue does not receive FDA approval for IV Tramadol by April 30, 2021, InvaGen will have the right to terminate the Avenue SPMA and will have no further obligations to consummate the second stage closing under the Avenue SPMA. In the event that InvaGen does not exercise its right to terminate the Avenue SPMA, certain restrictions relating to financings and strategic alternatives could exist through October 31, 2021, the time at which Avenue can terminate the Avenue SPMA. Regardless of whether the Avenue SPMA is terminated, InvaGen will retain certain rights pursuant to the Stockholder's Agreement between Avenue and InvaGen. These rights exist as long as InvaGen maintains at least 75% of the Avenue common shares acquired in the first stage closing. The following are some of the actions that shall not be taken by Avenue without the prior written consent of InvaGen:
  - increase in authorized shares of Avenue's capital stock;
  - any agreement or transaction that would adversely treat the holders of Avenue's common shares as compared to the holders of Avenue's Class A Preferred Shares;
  - issuance of any shares of Avenue's capital stock or any securities convertible into, or other rights to acquire, shares of Avenue's capital stock (including options, warrants or bonds), except for issuances to Avenue's officers for services performed;
  - any transfer or license of any asset for less than fair market value, as determined by a recognized independent valuation firm agreed upon by Avenue and Invagen; or
  - entry into any transaction or agreement with any affiliate of Avenue's (including the Company or its Affiliates).

CUTX-101 (Copper Histidinate injection for Menkes Disease)

- In January 2020, our partner company Cyprium Therapeutics, Inc. ("Cyprium") announced that the FDA granted Rare Pediatric Disease Designation to Copper Histidinate, also referred to as CUTX-101, for the treatment of Menkes disease.
- In July 2020, the European Medicines Agency issued a positive opinion on the application for Orphan Drug Designation for CUTX-101. EMA Orphan Drug Designation provides companies with certain benefits and incentives, including clinical protocol assistance, differentiated evaluation procedures for Health Technology Assessments in certain countries, access to a centralized marketing authorization procedure valid in all EU member states, reduced regulatory fees and 10 years of market exclusivity. The FDA previously granted Orphan Drug and Fast Track Designations to CUTX-101 for the treatment of Menkes disease.
- In August 2020, Cyprium reported positive topline clinical efficacy results for CUTX-101. The study demonstrated statistically significant improvement in the primary endpoint of overall survival in Menkes disease patients who received early treatment with CUTX-101, compared to an untreated historical control, with a nearly 80% reduction in the risk of death (Hazard Ratio = 0.21, $p<0.0001$). Median survival for the early treatment cohort was 14.8 years (177.1 months) compared to 1.3 years (15.9 months) for the untreated historical control cohort.
- In December 2020, the FDA granted Breakthrough Therapy Designation to CUTX-101. Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. A Breakthrough Therapy Designation conveys all of the fast-track program features, more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers and eligibility for rolling review and priority review.

CAEL-101 (mAB for AL Amyloidosis)

- In March 2020, Caelum Biosciences, Inc. ("Caelum") began dosing patients in its Phase 2 dose selection clinical trial of CAEL-101, a light chain fibril-reactive monoclonal antibody for the treatment of AL amyloidosis. Subsequently upon completed dosing, the Phase 2 study met its primary objective, supporting the initiation of two parallel Phase 3 studies that will enroll approximately 370 AL amyloidosis patients.
- In September 2020, Caelum announced the initiation of two Phase 3 studies of CAEL-101 for AL amyloidosis. Both Phase 3 studies are actively enrolling patients.
- CAEL-101 is currently in development at Caelum Biosciences, Inc., a company founded by Fortress, in collaboration with Alexion Pharmaceuticals, Inc.
- In December 2020, AstraZeneca ("AZ") announced its intention to acquire Alexion, with the acquisition expected to close by the third quarter of 2021, as the acquisition is subject to approval by both AZ and Alexion shareholders, as well as certain regulatory approvals, share listing approvals, and other customary closing conditions. The acquisition of Alexion by AZ triggers the Change of Control clause in the Amended and Restated Development, Option and Stock Purchase Agreement entered into by and among Caelum, Alexion, the Company, and Caelum security holders, such that Alexion's purchase option expires on the date that is six months after the closing of any Change of Control.

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

- In April 2020, our partner company Mustang Bio, Inc. ("Mustang") announced that the European Medicines Agency ("EMA") granted Advanced Therapy Medicinal Product ("ATMP") classification to MB-107, a lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency ("XSCID"), also known as bubble boy disease.
- In May 2020, Mustang submitted an Investigational New Drug ("IND") application with the FDA to initiate a registrational multi-center 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 CMC hold issues that Mustang satisfactorily addressed in a December 2020 submission to the Agency, and the CMC hold was removed in January 2021. The trial is expected to enroll 10 patients who, together with 15 patients enrolled in the current multicenter trial led by St. Jude Children's Research Hospital, will be compared with 25 matched historical control patients who have undergone hematopoietic stem cell transplant ("HSCT"). The primary efficacy endpoint will be event-free survival. Mustang is targeting topline data from the trial in the second half of 2022.
- Mustang further expects to file an IND in the second quarter of 2021 for a registrational multi-center Phase 2 clinical trial of its lentiviral gene therapy in previously transplanted XSCID patients. This product is designated MB-207. Mustang anticipates enrolling 20 patients and is targeting topline data for this trial in the first half of 2023.
- In August 2020, Mustang announced that the FDA granted Rare Pediatric Disease Designations to MB-107, a lentiviral gene therapy for the treatment of XSCID in newly diagnosed infants, and MB-207.
- In September 2020, Mustang announced that the FDA granted Orphan Drug Designations to MB-107 for the treatment of XSCID in newly diagnosed infants and to MB-207.
- In October 2020, Mustang in-licensed LentiBOOST™ technology from SIRION Biotech GmbH for the development of MB-207.
- In November 2020, Mustang signed an agreement with Minaris Regenerative Medicine GmbH to enable technology transfer and GMP clinical manufacturing of the MB-107 lentiviral gene therapy program in Europe.
- Also in November 2020, Mustang announced that the European Commission issued a positive opinion on its application for Orphan Drug Designation for the MB-107 lentiviral gene therapy for the treatment of XSCID.

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

- In January 2020, our partner company Checkpoint Therapeutics, Inc. ("Checkpoint") announced confirmation of the registration path for cosibelimab in metastatic cutaneous squamous cell carcinoma ("mCSCC") and the FDA feedback supports the plan to submit a Biologics license application ("BLA") based on data from ongoing Phase 1 trial.
- In April 2020, Checkpoint announced the issuance of a composition of matter patent for cosibelimab by the USPTO providing protection through at least May 2038.
- In September 2020, positive interim results from the registration-enabling trial of cosibelimab in mCSCC were presented at the European Society for Medical Oncology Virtual Congress 2020. The e-poster presentation provided updated interim efficacy and safety results in mCSCC patients from the ongoing multicenter Phase 1 clinical trial. A 51.4% objective response rate and 13.5% complete response rate were observed. Median duration of response had not been reached yet, with 84.2% of responses ongoing and the longest response duration was 24 months (ongoing) at the time of analysis. Cosibelimab appeared to be safe and well-tolerated with a potentially favorable safety profile as compared to currently available anti-PD-1 therapies. Grade ≥3 treatment-related adverse events occurred in only 6 patients (5.3%). Checkpoint expects to report full topline results from the pivotal trial in the second half of 2021.
- In November 2020, Checkpoint announced the expansion of a long-term manufacturing partnership for cosibelimab with Samsung Biologics. Building upon an existing contract manufacturing agreement entered into in 2017, Samsung Biologics will provide additional commercial-scale drug substance manufacturing for cosibelimab.
- Also in November 2020, updated results from the previously untreated high PD-L1 expressing patients with advanced non-small cell lung cancer ("NSCLC") cohort of the Phase 1 clinical trial of cosibelimab were announced at the Society for Immunotherapy of Cancer 35th Anniversary Annual Meeting. A 44% objection response rate and 10.3 month median progression-free survival were observed. Cosibelimab appeared to be safe and well-tolerated with a potentially favorable safety profile as compared to currently available anti-PD-1 therapies. Grade ≥3 treatment-related adverse events occurred in only 6 patients (4.9%).

CK-101 (EGFR inhibitor for EGFR mutation-positive NSCLC)

- In November 2020, NeuPharma, Inc. commenced a Phase 3 clinical trial in China evaluating CK-101 in treatment-naïve locally advanced or metastatic NSCLC patients whose tumors have EGFR exon 19 deletion mutations. We intend to meet with the FDA to discuss the adequacy of the ongoing Phase 3 trial in China.

Early Stage Product Candidates

MB-102 (CD123-targeted CAR T cell therapy)

- In October 2020, Mustang announced that the first patient was dosed in a Mustang-sponsored, open-label, multicenter Phase 1/2 clinical trial to evaluate the safety and efficacy of MB-102 (CD123-targeted CAR T cell therapy) in patients with relapsed or refractory blastic plasmacytoid dendritic cell neoplasm ("BPDCN").

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

- In December 2020, Mustang announced that a Phase 1 single-center, two-arm clinical trial was initiated to establish the safety and feasibility of administering MB-101 to patients with leptomeningeal brain tumors (e.g., glioblastoma, ependymoma or medulloblastoma).

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

- In October 2020, Mustang announced that initial Phase 1 data on MB-105, a prostate stem cell antigen ("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 virtual 27th Annual Prostate Cancer Foundation Scientific Retreat. A 73-year-old male patient with PSCA-positive mCRPC was treated with MB-105 and lymphodepletion (a standard CAR T pre-conditioning regimen) after failing eight prior therapies. On day 28 of the patient's treatment, MB-105 demonstrated a 94% reduction in prostate-specific antigen, near complete reduction of measurable soft tissue metastasis by computerized tomography, and improvement in bone metastases by magnetic resonance imaging.

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

- In February 2020, Mustang announced that the first subject treated with the optimized MB-106 (CD20-targeted, autologous CAR T cell therapy) manufacturing process, developed in collaboration between Mustang and the Fred Hutchinson Cancer Research Center, achieved a complete response at the lowest starting dose in an ongoing Phase 1/2 clinical trial. The trial is evaluating the safety and efficacy of MB-106 in subjects with relapsed or refractory B-cell non-Hodgkin lymphomas and chronic lymphocytic leukemia.
- In December 2020, Mustang announced positive interim Phase 1/2 data on MB-106 for patients with relapsed or refractory B-cell non-Hodgkin lymphomas, which were presented at the 62nd American Society of Hematology (ASH) Annual Meeting. Data presented showed a favorable safety profile and clinical activity, with an 89% overall response rate and 44% complete response rate in patients treated with the modified cell manufacturing process.

MB-108 (HSV-1 Oncolytic Virus C134)

- In October 2020, the Phase 1 trial of MB-108 was put on hold due to toxicity at the highest dose level. The University of Alabama at Birmingham, the clinical trial site for the Phase 1 trial, expects FDA clearance in the first half of 2021 in order to resume enrolling patients at a lower dose level.

ONCOlogues (proprietary platform technology using PNA oligonucleotides)

- In May 2020, Oncogenuity entered into an exclusive worldwide licensing agreement with Columbia University to develop novel oligonucleotides for the treatment of genetically driven cancers. The proprietary platform produces oligomers, known as "ONCOlogues," which are capable of binding gene sequences 1,000 times more effectively than complementary native DNA.
- ONCOlogues invade a DNA double helix and displace native mutated strands. This may prevent the mRNA that antisense binds to from ever being created. It is active higher upstream than traditional antisense approaches, as well as potentially more potent and broader in its utility.
- In addition, Oncugenuity is exploring the potential of the platform to treat novel coronaviruses, such as COVID-19.

General Corporate

- In February 2020, we closed an underwritten public offering of our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock for gross proceeds of $14.4 million.
- In May 2020, we closed an additional underwritten public offering of our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock for gross proceeds of $11.5 million.
- In June 2020, we announced the Company had been added to the Russell 3000 index.
- Also in June 2020, Mustang completed an underwritten public offering in which it sold its' common stock for gross proceeds of approximately $37.2 million.
- In August 2020, we closed an additional underwritten public offering of our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock for gross proceeds of $13.2 million and announced a $60 million loan agreement with funds managed by Oaktree Capital Management to refinance existing indebtedness.
- In September 2020, we closed a private offering of Cyprium's 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock for gross proceeds of $8.0 million.
- Also in September 2020, Checkpoint completed an underwritten public offering in which it sold its' common stock for gross proceeds of approximately $20.5 million.

Critical Accounting Policies and Use of Estimates

See Note 2 to the Consolidated Financial Statements.

Results of Operations

General

For the year ended December 31, 2020 we generated $45.6 million of net revenue $44.5 million relates to the sale of Journey branded and generic products and $1.1 million of revenue is in connection with Checkpoint's collaborative agreements with TGTX, a related party. At December 31, 2020, we had an accumulated deficit of $482.8 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 $14.6 million of costs of goods sold in connection with the sale of JMC branded and generic products for the year ended December 31, 2020.

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, 2020 and 2019, research and development expenses were approximately $61.3 million and $75.2 million, respectively. Additionally, during the years ended December 31, 2020 and 2019, we expensed approximately $2.8 million and $6.1 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, 2020 and 2019:

($ in thousands)	Year Ended December 31, 2020	Year Ended December 31, 2019	% of total 2020	% of total 2019
Research & Development				
Fortress	$ 1,725	$ 2,653	3 %	4 %
Partner Companies:				
Avenue	2,866	22,194	5 %	29 %
Checkpoint	11,734	16,815	19 %	22 %
Mustang	36,987	29,792	60 %	40 %
Other[1]	7,963	3,782	13 %	5 %
Total Research & Development Expense	**$ 61,275**	**$ 75,236**	**100 %**	**100 %**

Note 1: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and Tamid Bio, Inc. (a Fortress partner company that has since discontinued operations) ("Tamid").

Noncash, stock-based compensation expense included in research and development for the years ended December 31, 2020 and 2019, was $3.2 million and $2.8 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, 2020 and 2019, selling, general and administrative expenses were $61.2 million and $55.6 million, respectively. Stock based compensation expense included in selling, general and administrative expenses in 2020 and 2019 was $10.3 million and $10.4 million, respectively.

The table below provides a summary by entity of selling, general and administrative expenses for the years ended December 31, 2020 and 2019, respectively:

($ in thousands)	Year Ended December 31, 2020	Year Ended December 31, 2019	% of Total 2020	% of Total 2019
Selling, General & Administrative				
Fortress	$ 21,350	$ 18,320	35 %	33 %
Partner Companies:				
Avenue	2,347	3,071	4 %	6 %
Checkpoint	6,517	5,996	11 %	11 %
JMC[1]	22,100	19,421	36 %	35 %
Mustang	6,810	7,658	11 %	14 %
Other[2]	2,042	1,124	3 %	1 %
Total Selling, General & Administrative Expense	**$ 61,166**	**$ 55,590**	**100 %**	**100 %**

Note 1: Includes sales force costs for the year ended December 31, 2020 and 2019 of $10.4 million and $10.7 million, respectively.
Note 2: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and Tamid.

Comparison of Years Ended December 31, 2020 and 2019

($ in thousands)	Year Ended December 31, 2020	2019	Change $	Change %
Revenue				
Product revenue, net	$ 44,531	$ 34,921	$ 9,610	28 %
Revenue – related party	1,068	1,708	(640)	(37)%
Net revenue	45,599	36,629	8,970	24 %
Operating expenses				
Cost of goods sold – product revenue	14,594	10,532	4,062	39 %
Research and development	61,275	75,236	(13,961)	(19)%
Research and development – licenses acquired	2,834	6,090	(3,256)	(53)%
Selling, general and administrative	61,166	55,590	5,576	10 %
Total operating expenses	139,869	147,448	(7,579)	(5)%
Loss from operations	(94,270)	(110,819)	16,549	(15)%
Other income (expense)				
Interest income	1,518	2,559	(1,041)	(41)%
Interest expense and financing fee	(15,326)	(11,849)	(3,477)	29 %
Change in fair value of derivative liability	(1,189)	(27)	(1,162)	4304 %
Change in fair value of investment	6,418	—	6,418	100 %
Gain on deconsolidation of Caelum	—	18,476	(18,476)	(100)%
Total other (expense) income	(8,579)	9,159	(17,738)	(194)%
Income before income tax expense	(102,849)	(101,660)	(1,189)	1
Income tax expense	136	—	136	100
Net loss	**(102,985)**	**(101,660)**	(1,325)	1 **%**
Less: net loss attributable to non-controlling interest	56,459	61,700	(5,241)	(8)%
Net loss attributable to common stockholders	**$ (46,526)**	**$ (39,960)**	**$ (6,566)**	**16 %**

For the year ended December 31, 2020, $1.1 million of revenue – related party was in connection with Checkpoint's collaborative agreements with TGTX. The net increase in revenue of $9.0 million or 24% is due to the expansion of Journey's marketed products, as well as overall sales growth, which resulted in a product revenue increase of $9.6 million offset by a decrease in revenue from a related party of $0.6 million.

Cost of goods sold increased by $4.1 million or 39% due to the growth in Journey's product sales.

Research and development expenses decreased $14.0 million, or 19%, from the year ended December 31, 2019 to the year ended December 31, 2020. The following table shows research and development spending for Fortress and each partner company:

($ in thousands)	Year Ended December 31, 2020	2019	Change $	Change %
Research & Development				
Stock-based compensation				
Fortress	$ 808	$ 605	$ 203	34 %
Partner Companies:				
Avenue	274	616	(342)	(56)%
Checkpoint	617	707	(90)	(13)%
Mustang	1,437	874	563	64 %
Other[1]	36	9	27	300 %
Sub-total stock-based compensation expense	3,172	2,811	361	13 %
Other Research & Development				
Fortress	917	2,048	(1,131)	(55)%
Partner Companies:				
Avenue	2,592	21,578	(18,986)	(88)%
Checkpoint	11,117	16,108	(4,991)	(31)%
Mustang	35,550	28,918	6,632	23 %
Other[1]	7,927	3,773	4,154	110 %
Total Research & Development Expense	**$ 61,275**	**$ 75,236**	**$ (13,961)**	**(19)%**

Note 1: Includes the following partner company: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and Tamid.

The increase in stock-based compensation at both Fortress and Mustang is due to new equity grants to key employees and consultants in 2020, while the decrease in both Avenue and Checkpoint's stock-based compensation is due to the effect of fully vested equity grants to key employees and consultants.

The decrease in Fortress research and development spending is due to the lower research and development headcount in 2020 as compared to 2019. Avenue's decrease in research and development spending is attributable to the decrease in clinical trial costs associated with the completion of both the abdominoplasty study and the safety study in the first half of 2019 as well as the costs associated with an NDA submission in December 2019. Checkpoint's decrease in research and development spending is attributable to the decreased manufacturing costs for cosibelimab and clinical trial expense for CK-101. Mustang's increase in research and development spending is attributable to increased headcount, lentiviral manufacturing costs and sponsored research for several programs, including XSCID. The increase in "Other" is attributable to costs incurred by Cyprium as it prepares to file its rolling NDA submission for CUTX-101 in 2021 and Oncogenuity for its sponsored research costs related to the continued development of novel oligonucleotides for the treatment of genetically driven diseases.

Selling, general and administrative expenses increased $5.6 million, or 10%, from the year ended December 31, 2019 to the year ended December 31, 2020. The following table shows selling, general and administrative spending for Fortress and by each partner company:

($ in thousands)	Year Ended December 31, 2020	2019	Change $	Change %
Selling, General & Administrative				
Stock-based compensation				
Fortress	$ 5,976	$ 4,707	$ 1,269	27 %
Partner Companies:				
Avenue	436	1,223	(787)	(64)%
Checkpoint	2,163	2,414	(251)	(10)%
Mustang	1,550	1,790	(240)	(13)%
Other[2]	154	243	(89)	(37)%
Sub-total stock-based compensation expense	10,279	10,377	(98)	(1)%
Other Selling, General & Administrative				
Fortress	15,374	13,613	1,761	13 %
Partner Companies:				
Avenue	1,911	1,848	63	3 %
Checkpoint	4,354	3,582	772	22 %
JMC[1]	22,100	19,420	2,680	14 %
Mustang	5,260	5,868	(608)	(10)%
Other[2]	1,888	882	1,006	114 %
Total Selling, General & Administrative Expense	**$ 61,166**	**$ 55,590**	**$ 5,576**	**10 %**

Note 1: Includes sales force costs for the year ended December 31, 2020 and 2019 of $10.4 million and $10.7 million, respectively.

Note 2: Includes the following partner companies: Aevitas, Baergic, Cellvation, Cyprium, Helocyte, Oncogenuity and Tamid.

For the year ended December 31, 2020, the increase in selling, general and administrative expenses of $5.6 million or 10% is primarily attributable to increased headcount-related costs for Fortress and Checkpoint as well as an increase in JMC's sales and marketing costs due to the increased product portfolio and costs related to the launch of Ximino, an oral acne treatment. Mustang's decrease is due to less legal costs and less professional fees related to strategic marketing. The increase in "Other" is driven by the increase in professional fees incurred by Cyprium and Oncogenuity.

Total other income (expense) changed $17.7 million, or 194%, from income of $9.2 million for the year ended December 31, 2019 to expense of $8.6 million for the year ended December 31, 2020, primarily due to the $18.5 million gain on the deconsolidation of Caelum recognized in 2019 and an increase of $3.5 million in interest expense and financing fees due to the new credit facility transaction with Oaktree Fund Administration, LLC.

Net loss attributable to non-controlling interests decreased $5.2 million, or 8%, from the year ended December 31, 2019 to the year ended December 31, 2020. This decrease reflects the partner companies' share of net loss.

Liquidity and Capital Resources

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

	For the Year Ended December 31, 2020				
($ in thousands)	Fortress[1]	Avenue	Checkpoint	Mustang	Total
Statement of cash flows data:					
Total cash (used in)/provided by:					
Operating activities	$ (25,199)	$ (4,613)	$ (16,551)	$ (37,319)	$ (83,682)
Investing activities	(1,752)	(1,000)	—	(4,412)	(7,164)
Financing activities	63,042	—	31,246	78,122	172,410
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 36,091	$ (5,613)	$ 14,695	$ 36,391	$ 81,564

	For the Year Ended December 31, 2019				
($ in thousands)	Fortress[1]	Avenue	Checkpoint	Mustang	Total
Statement of cash flows data:					
Total cash (used in)/provided by:					
Operating activities	$ (13,748)	$ (26,259)	$ (21,373)	$ (33,581)	$ (94,961)
Investing activities	6,188	—	—	13,909	20,097
Financing activities	23,810	32,333	25,455	65,116	146,714
Net increase in cash and cash equivalents and restricted cash	$ 16,250	$ 6,074	$ 4,082	$ 45,444	$ 71,850

Note 1: Includes Fortress and non-public subsidiaries.

Operating Activities

Net cash used in operating activities decreased $11.3 million from the year ended December 31, 2019 to the year ended December 31, 2020. The decrease is primarily due to the decrease in gain from the deconsolidation of Caelum of $18.5 million recognized in 2019, offset by the increase in the fair value of investments of $6.4 million as well as the increase in net loss of $1.3 million for the year ended December 31, 2020.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2019 of $20.1 million decreased $27.3 million to net cash used in investing activities of $7.2 million for the year ended December 31, 2020. The change is primarily due to cash provided by discontinued investing activities of $13.1 million received in 2019 related to the sale of National, as well as the redemption of $22.6 million of certificates of deposit in 2019, offset by the purchase of $5.0 million of certificates of deposit, also in 2019. Cash used to purchase intangible assets decreased in 2020 by $1.2 million, cash used to purchase property and equipment and research and development licenses also decreased for the year ended December 31, 2020, by $0.4 million and $0.6 million, respectively.

Financing Activities

Net cash provided by financing activities was $172.4 million for the year ended December 31, 2020, compared to $146.7 million of net cash provided by financing activities for the year ended December 31, 2019, an increase of $25.7 million. The increase is primarily due to an increase of $33.0 million in net proceeds from the issuance of Series A preferred stock, $26.8 million increase in proceeds from the Company's at-the-market offering, $42.0 million increase in partner companys' at-the-market offering, and the $60 million gross proceeds from the Oaktree Note. Offsetting these financing activities was the decrease in proceeds from partner companies' sale of stock of $28.5 million, payment of partner company's Horizon Notes of $15.8 million, and repayment of $28.4 million of 2017 Subordinated Note Financing, $21.7 million of 2018 Venture Notes, $9.0 million of 2019 Notes, and $14.9 million for the payoff of the IDB Note.

We fund our operations through cash on hand, the sale of debt and third-party financings. At December 31, 2020, we had cash and cash equivalents of $233.4 million of which $78.8 million relates to Fortress, $40.8 million relates to Checkpoint, $97.8 million relates to Mustang, $3.1 million relates to Avenue, and $12.9 million relates to the remaining partner companies. Restricted cash of $1.6 million is comprised of: $0.6 million secures a letter of credit used as a security deposit for the New York, NY lease that became effective on October 3, 2014, $1.0 million secures the Worcester, Massachusetts lease signed by Mustang that became effective on October 27, 2017, and $0.1 million securing the Waltham, Massachusetts lease signed by Fortress that became effective in October 2015.

On June 28, 2019, Fortress entered into an At Market Issuance Sales Agreement ("2019 Common ATM"), with Cantor Fitzgerald & Co., Oppenheimer & Co., Inc., H.C. Wainwright & Co. Inc., Jones Trading Institutional Services LLC and B. Riley, as selling agents, governing potential sales of the Company's common stock. For the year ended December 31, 2020, the Company issued approximately 17.4 million shares of common stock for gross proceeds of $47.5 million at an average selling price of $2.73. Under the 2019 Common ATM, the Company pays the agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock, and in connection with these sales, with respect to the year ended December 31, 2020, Fortress paid aggregate fees of approximately $1.4 million.

On February 14, 2020, the Company announced the closing of an underwritten public offering, whereby it sold 625,000 shares of its 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (Nasdaq: FBIOP) (the "Preferred Stock"), (plus a 45-day option to purchase up to an additional 93,750 shares, which was exercised in February 2020) at a price of $20.00 per share for gross proceeds of approximately $14.4 million, before deducting underwriting discounts and commissions and offering expenses of approximately $1.3 million.

On May 29, 2020, the Company closed on an underwritten public offering whereby it sold 555,556 shares of its Preferred Stock, (plus a 45-day option to purchase up to an additional 83,333 shares, which was exercised in May 2020) at a price of $18.00 per share for gross proceeds of approximately $11.5 million, before deducting underwriting discounts and commissions and offering expenses of approximately $1.1 million.

On August 26, 2020, the Company closed on an underwritten public offering whereby it sold 666,666 shares of its Preferred Stock, (plus a 45-day option to purchase up to an additional 66,666 shares, which was exercised in August 2020) at a price of $18.00 per share for gross proceeds of approximately $13.2 million, before deducting underwriting discounts and commissions and offering expenses of approximately $1.1 million.

During the year ended December 31, 2020, Checkpoint sold a total of 5,104,234 shares of common stock under an At-the-Market Issuance Sales Agreement for aggregate total gross proceeds of approximately $12.8 million at an average selling price of $2.50 per share, resulting in net proceeds of approximately $12.4 million after deducting commissions and other transaction costs.

In September 2020, Checkpoint completed an underwritten public offering in which it sold 7,321,429 shares of its common stock at a price of $2.80 per share for gross proceeds of approximately $20.5 million. Total net proceeds from the offering were approximately $18.9 million, net of underwriting discounts and offering expenses of approximately $1.6 million. The shares were sold under the Checkpoint 2017 S-3.

From January 1, 2021 through March 5, 2021 Checkpoint issued approximately 3.2 million shares of common stock for gross proceeds of $12.3 million at an average selling price of $3.88 under the Checkpoint ATM.

During the year ended December 31, 2020, Mustang issued approximately 17.6 million shares of common stock at an average price of $3.40 per share for gross proceeds of $59.8 million under the Mustang ATM. In connection with these sales, Mustang paid aggregate fees of approximately $1.1 million for net proceeds of approximately $58.7 million.

On June 11, 2020, Mustang entered into an underwriting agreement (the "Mustang Underwriting Agreement") with Cantor Fitzgerald & Co., as representative of the underwriters named therein (each, an "Underwriter" and collectively with Cantor Fitzgerald & Co., the "Underwriters"). In connection with the Mustang Underwriting Agreement, Mustang issued 10,769,231 shares of common stock (plus a 30-day option to purchase up to an additional 1,615,384 shares of common stock, of which 686,373 were exercised) at a price of $3.25 per share for gross proceeds of approximately $37.2 million, before deducting underwriting discounts and commissions and offering expenses. In connection with the public offering, Mustang paid aggregate fees of approximately $2.4 million for net proceeds of approximately $34.8 million. The shares were sold under our S-3 registrations filed with the Securities and Exchange Commission.

From January 1, 2021 through March 18, 2021 Mustang issued approximately 10.6 million shares of common stock for gross proceeds of $44.9 million at an average selling price of $4.24 under the Mustang ATM.

In 2020, Fortress raised $0.3 million from the issuance of common shares in connection with the ESPP, compared to $0.1 million raised from the issuance of common shares in connection with the ESPP in 2019 .

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 (such as the stock purchase of Caelum by Alexion that would result from option exercise or the contingent merger of Avenue with InvaGen), 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.

Off-Balance Sheet Arrangements

We do not have any financings or other relationships with unconsolidated entities or other persons.

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, 2020, 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, 2020. 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, 2020, our internal control over financial reporting was effective.

Changes in Internal Controls over Financial Reporting.

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

Item 9B. Other Information

None.

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 2021 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 2021 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 2021 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 2021 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 2021 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits, 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 the Registrant.
3.2	First Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.
3.3	Second Amended and Restated Bylaws of the Registrant.
3.4	Second Certificate of Amendment of Amended and Restated Certificate of Incorporation, as amended.
3.5	Third Certificate of Amendment of Amended and Restated Certificate of Incorporation, as amended.
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc.
3.7	Certificate of Amendment to the Certificate of Designations of Rights and Preferences of the Fortress Biotech, Inc. 9.375% Series A Cumulative Preferred Stock under the Amended and Restated Certificate of Incorporation of Fortress Biotech, Inc.
4.1	Form of Common Stock Certificate.
4.2	Certificate of Designation of Rights and Preferences 9.375% Series A Perpetual Preferred Stock.
4.3	Description of Securities of Fortress Biotech, Inc.
10.2	Form of Stock Option Award Agreement. #
10.3	Amended and Restated Consulting Agreement, entered into as of January 1, 2019, by and between the Registrant and Eric Rowinsky.#
10.4	Form of Indemnification Agreement by and between the Registrant and its officers and directors.
10.5	Fortress Biotech, Inc. 2012 Employee Stock Purchase Plan. #
10.6	Restricted Stock Issuance Agreement, dated as of February 2, 2014, by and between the Registrant and Michael S. Weiss.#
10.7	Restricted Stock Issuance Agreement, dated as of December 19, 2013, by and between the Registrant and Michael S. Weiss.#
10.8	Restricted Stock Issuance Agreement, dated as of December 19, 2013, by and between the Registrant and Lindsay A. Rosenwald, M.D.#
10.9	Form of Coronado Biosciences, Inc. 2013 Stock Incentive Plan Award Agreement (2013 Stock Incentive Plan). #
10.10	Coronado Biosciences, Inc. Deferred Compensation Plan for Directors, dated March 12, 2015. #
10.11	Fortress Biotech, Inc. 2013 Stock Incentive Plan, as amended. #

Exhibit Number	Exhibit Title
10.12	Restricted Stock Unit Award Agreement between Fortress Biotech, Inc. and George Avgerinos effective July 15, 2015.#
10.13	Form of Common Stock Purchase Warrant in favor of National Securities Corporation.
10.14	Fortress Biotech, Inc. 2012 Employee Stock Purchase Plan, as amended.
10.15	Fortress Biotech, Inc. Amended and Restated Long-Term Incentive Plan.
10.16	Stock Purchase and Merger Agreement, dated as of November 12, 2018, by and between Avenue Therapeutics, Inc., InvaGen Pharmaceuticals Inc. and Madison Pharmaceuticals Inc.
10.17	Stockholders Agreement, dated as of November 12, 2018, by and between Fortress Biotech, Inc., Avenue Therapeutics, Inc., Dr. Lucy Lu, M.D. and InvaGen Pharmaceuticals Inc.
10.18	Credit Agreement, dated as of November 12, 2018, by and between Avenue Therapeutics, Inc. and InvaGen Pharmaceuticals Inc.
10.19	Guaranty, dated as of November 12, 2018, by and between Fortress Biotech, Inc. and InvaGen Pharmaceuticals Inc.
10.20	Voting and Support Agreement, dated as of November 12, 2018, by and between Fortress Biotech, Inc., Avenue Therapeutics, Inc., Dr. Lucy Lu, M.D. and InvaGen Pharmaceuticals Inc.
10.21	Waiver Agreement, dated as of November 12, 2018, by and between Fortress Biotech, Inc., Avenue Therapeutics, Inc. and InvaGen Pharmaceuticals Inc.
10.22	Restrictive Covenant Agreement, dated as of November 12, 2018, by and between Fortress Biotech, Inc. and InvaGen Pharmaceuticals Inc.
10.23	Indemnification Agreement, dated as of November 12, 2018, by and between Fortress Biotech, Inc. and InvaGen Pharmaceuticals Inc.
10.24	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.*
10.25	Amendment to the Fortress Biotech, Inc. 2013 Stock Incentive Plan.#
10.26	Credit Agreement entered into by and among Fortress Biotech, Inc. the lenders form time to time party thereto, and Oaktree Fund administration, LLC on August 27, 2020.
21.1	Subsidiaries of the Registrant.
23.1	Consent Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page of this Form 10-K).
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.*

Exhibit Number	Exhibit Title
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

Shareholders and Board of Directors
Fortress Biotech, Inc. and subsidiaries
New York, New York

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, 2020 and 2019, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved 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.

Accounting for Oaktree Note

As described in Note 2 and Note 10 to the consolidated financial statements, in August 2020, the Company entered into a $60.0 million senior secured credit agreement with Oaktree ("Note"). In connection with the Oaktree Note, the Company issued warrants to Oaktree and certain of its affiliates to purchase up to 1,749,450 shares of common stock (see Note 14)

with a relative fair value of $4.4 million. In accounting for the Oaktree Note, the Company analyzed the Note and warrants and their related features for the appropriate accounting of the arrangement, including assessment of potential embedded derivatives.

We identified the accounting for the Oaktree Note as a critical audit matter. The principal considerations that led us to determine this matter was a critical audit matter included the inherent complexity in assessing the accounting for the Note and related embedded derivatives. Auditing these elements required complex auditor judgment and an increased level of audit effort, including the need for specialized knowledge and skill in assessing these elements.

The procedures we performed to address this critical audit matter included:

- Evaluating management's accounting policies and practices including the appropriateness of management's evaluation of various terms and conditions in the debt agreement, and assessment of embedded derivatives.
- Inspecting the underlying agreements and testing management's evaluation and application of the relevant accounting guidance to the terms of the agreements.
- Utilizing personnel with specialized knowledge and skill with complex debt instruments to assist in assessing the analysis and accounting for the Note and its features including the warrants.

We have served as the Company's auditor since 2016.

/s/ BDO USA, LLP
Boston, Massachusetts
March 31, 2020

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 233,351	$ 136,858
Accounts receivable, net	19,349	13,539
Inventory	1,404	857
Other receivables - related party	744	865
Prepaid expenses and other current assets	6,723	4,133
Total current assets	261,571	156,252
Property and equipment, net	11,923	12,433
Operating lease right-of-use asset, net	20,487	21,480
Restricted cash	1,645	16,574
Long-term investment, at fair value	17,566	11,148
Intangible asset, net	14,629	7,377
Other assets	1,013	1,158
Total assets	**$ 328,834**	**$ 226,422**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 40,674	$ 35,451
Interest payable	—	1,042
Interest payable - related party	—	92
Income taxes payable	136	—
Notes payable, short-term	—	7,220
Operating lease liabilities, short-term	1,849	1,784
Derivative warrant liability	—	27
Partner company note payable, short-term	5,300	—
Total current liabilities	47,959	45,616
Notes payable, long-term (net of debt discount of $8,323 and $5,086 at December 31, 2020 and December 31, 2019, respectively)	51,677	77,436
Operating lease liabilities, long-term	22,891	23,712
Partner company note payable, long-term	7,359	4,990
Other long-term liabilities	1,949	2,136
Total liabilities	**131,835**	**153,890**
Commitments and contingencies		
Stockholders' equity		
Cumulative redeemable perpetual preferred stock, $.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 and 1,341,167 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively; liquidation value of $25.00 per share	3	1
Common stock, $.001 par value, 150,000,000 and 100,000,000 shares authorized, 94,877,492 and 74,027,425 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	95	74
Common stock issuable, 0 and 251,337 shares as of December 31, 2020 and December 31, 2019, respectively	—	500
Additional paid-in-capital	583,000	461,874
Accumulated deficit	(482,760)	(436,234)
Total stockholders' equity attributed to the Company	100,338	26,215
Non-controlling interests	96,661	46,317
Total stockholders' equity	196,999	72,532
Total liabilities and stockholders' equity	**$ 328,834**	**$ 226,422**

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,	
	2020	2019
Revenue		
Product revenue, net	$ 44,531	$ 34,921
Revenue - related party	1,068	1,708
Net revenue	45,599	36,629
Operating expenses		
Cost of goods sold - product revenue	14,594	10,532
Research and development	61,275	75,236
Research and development - licenses acquired	2,834	6,090
Selling, general and administrative	61,166	55,590
Total operating expenses	139,869	147,448
Loss from operations	(94,270)	(110,819)
Other income (expense)		
Interest income	1,518	2,559
Interest expense and financing fee	(15,326)	(11,849)
Change in fair value of derivative liability	(1,189)	(27)
Change in fair value of investments	6,418	—
Gain on deconsolidation of Caelum	—	18,476
Total other income (expense)	(8,579)	9,159
Loss before income tax expense	(102,849)	(101,660)
Income tax expense	136	—
Net loss	**(102,985)**	**(101,660)**
Less: net loss attributable to non-controlling interests	56,459	61,700
Net loss attributable to common stockholders	**$ (46,526)**	**$ (39,960)**
Net loss per common share - basic and diluted	$ (1.43)	$ (1.86)
Net loss per common share attributable to non - controlling interests - basic and diluted	$ (0.78)	$ (1.13)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.65)	$ (0.73)
Weighted average common shares outstanding - basic and diluted	72,005,181	54,711,838

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		Common Stock		Common Shares Issuable	Treasury Stock	Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares		Shares	Amount						
Balance at December 31, 2018	**1,000,000**	**$ 1**	**57,845,447**	**$ 58**	**$ 659**	**$ —**	**$ 397,408**	**$ (396,274)**	**$ 17,891**	**$ 19,743**
Stock-based compensation expense	—	—	—	—	—	—	13,188	—	—	13,188
Settlement of restricted stock units into common stock	—	—	1,905,367	2	—	—	(2)	—	—	—
Issuance of common stock under ESPP	—	—	98,007	—	—	—	123	—	—	123
Issuance of common stock for at-the-market offering, net	—	—	11,798,468	12	—	—	20,235	—	—	20,247
Issuance of Series A preferred stock for at-the-market offering, net	39,292	—	—	—	—	—	788	—	—	788
Issuance of Series A preferred stock for cash, net	301,875	—	—	—	—	—	5,307	—	—	5,307
Preferred A dividends declared and paid	—	—	—	—	—	—	(2,559)	—	—	(2,559)
Partner company's offering, net	—	—	—	—	—	—	78,607	—	—	78,607
Partner company's at-the-market offering, net	—	—	—	—	—	—	29,785	—	—	29,785
Issuance of partner company's common shares for license expenses	—	—	—	—	(164)	—	164	—	—	—
Issuance of partner company's common shares for research and development expenses	—	—	—	—	—	—	90	—	—	90
Issuance of partner company warrants in conjunction with Horizon Notes	—	—	—	—	—	—	888	—	—	888
Common shares issuable for 2017 Subordinated Note Financing interest expense	—	—	—	—	500	—	—	—	—	500
Common shares issued for 2017 Subordinated Note Financing interest expense	—	—	1,637,936	2	(495)	—	1,967	—	—	1,474
Common shares issuable for Opus interest expense	—	—	—	—	281	—	—	—	—	281
Common shares issued for Opus interest expense	—	—	345,375	—	(281)	—	662	—	—	381
Common shares issued for Opus debt	—	—	396,825	—	—	—	500	—	—	500
Non-controlling interest in subsidiaries	—	—	—	—	—	—	(85,277)	—	85,277	—
Deconsolidation of Caelum non-controlling interest	—	—	—	—	—	—	—	—	4,849	4,849
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	(61,700)	(61,700)
Net loss attributable to common stockholders	—	—	—	—	—	—	—	(39,960)	—	(39,960)
Balance at December 31, 2019	**1,341,167**	**$ 1**	**74,027,425**	**$ 74**	**$ 500**	**$ —**	**$ 461,874**	**$ (436,234)**	**$ 46,317**	**$ 72,532**

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		Common Stock		Common Shares Issuable	Treasury Stock	Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares		Shares	Amount						
Balance at December 31, 2019	**1,341,167**	**$ 1**	**74,027,425**	**$ 74**	**$ 500**	**$ —**	**$ 461,874**	**$ (436,234)**	**$ 46,317**	**$ 72,532**
Stock-based compensation expense	—	—	—	—	—	—	13,451	—	—	13,451
Issuance of common stock related to equity plans	—	—	2,335,808	2	—	—	16	—	—	18
Issuance of common stock under ESPP	—	—	122,786	—	—	—	253	—	—	253
Issuance of common stock for at-the-market offering, net	—	—	17,409,257	18	—	—	45,809	—	—	45,827
Preferred A dividends declared and paid	—	—	—	—	—	—	(6,515)	—	—	(6,515)
Repurchase of Series A preferred stock, net	(5,000)	—	—	—	—	(70)	(2)	—	—	(72)
Retirement of Series A preferred stock	—	—	—	—	—	70	(70)	—	—	—
Issuance of Series A preferred stock for cash, net	2,090,971	2	—	—	—	—	35,541	—	—	35,543
Partner company's offering, net	—	—	—	—	—	—	53,749	—	—	53,749
Partner companies' at-the-market offering, net	—	—	—	—	—	—	70,988	—	—	70,988
Partner company's preferred stock offering, net	—	—	—	—	—	—	7,074	—	—	7,074
Issuance of common stock under partner company's ESPP	—	—	—	—	—	—	349	—	—	349
Partner company's dividends declared and paid	—	—	—	—	—	—	(237)	—	—	(237)
Partner company's exercise of warrants for cash	—	—	—	—	—	—	13	—	—	13
Partner company's exercise of options for cash	—	—	—	—	—	—	13	—	—	13
Reclass partner company's warrants from liability to equity	—	—	—	—	—	—	1,216	—	—	1,216
Issuance of partner company's common shares for research and development expenses	—	—	—	—	—	—	46	—	—	46
Common shares issued for 2017 Subordinated Note Financing interest expense	—	—	982,216	1	(500)	—	1,816	—	—	1,317
Issuance of warrants in conjunction with Oaktree Note	—	—	—	—	—	—	4,419	—	—	4,419
Non-controlling interest in partner companies	—	—	—	—	—	—	(106,803)	—	106,803	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	(56,459)	(56,459)
Net loss attributable to common stockholders	—	—	—	—	—	—	—	(46,526)	—	(46,526)
Balance at December 31, 2020	**3,427,138**	**$ 3**	**94,877,492**	**$ 95**	**$ —**	**$ —**	**$ 583,000**	**$ (482,760)**	**$ 96,661**	**$ 196,999**

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

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

	For the Year Ended December 31,	
	2020	**2019**
Cash Flows from Operating Activities:		
Net loss	$ (102,985)	$ (101,660)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation expense	2,280	1,922
Bad debt expense	49	100
Amortization of debt discount	5,622	3,321
Non-cash interest	697	—
Amortization of product revenue license fee	1,420	1,174
Amortization of operating lease right-of-use assets	1,625	1,558
Stock-based compensation expense	13,451	13,188
Issuance of common stock for service	18	—
Issuance of partner company's common shares for research and development expenses	46	90
Common shares issuable for 2017 Subordinated Note Financing interest expense	—	500
Common shares issued for 2017 Subordinated Note Financing interest expense	1,317	1,474
Common shares issuable for 2019 Notes interest expense	—	281
Common shares issued for 2019 Notes interest expense	—	381
Change in fair value of derivative liability	1,189	27
Change in fair value of investment	(6,418)	—
Gain on deconsolidation of Caelum	—	(18,476)
Research and development-licenses acquired, expense	2,788	6,000
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:		
Accounts receivable	(5,859)	(8,141)
Inventory	(547)	(179)
Other receivables - related party	121	1,230
Prepaid expenses and other current assets	(2,590)	1,798
Other assets	145	(882)
Accounts payable and accrued expenses	6,522	2,095
Accounts payable and accrued expenses - related party	—	(149)
Interest payable	(1,042)	8
Interest payable - related party	(92)	(5)
Income taxes payable	136	—
Lease liabilities	(1,388)	(1,365)
Other long-term liabilities	(187)	749
Net cash used in operating activities	(83,682)	(94,961)
Cash Flows from Investing Activities:		
Purchase of research and development licenses	(4,038)	(4,650)
Purchase of property and equipment	(1,926)	(2,345)
Purchase of intangible asset	(1,200)	(2,400)
Purchase of short-term investment (certificates of deposit)	—	(5,000)
Redemption of short-term investment (certificates of deposit)	—	22,604
Deconsolidation of Caelum	—	(1,201)
Net cash provided by (used in) continuing investing activities	(7,164)	7,008
Net cash provided by discontinued investing activities	—	13,089
Net cash provided by (used in) investing activities	(7,164)	20,097

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

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

	For the Year Ended December 31,	
	2020	**2019**
Cash Flows from Financing Activities:		
Payment of Series A preferred stock dividends	$ (6,515)	$ (2,559)
Purchase of treasury stock	(70)	—
Payment of costs related to purchase of treasury stock	(2)	—
Proceeds from issuance of Series A preferred stock	39,075	6,038
Payment of costs related to issuance of Series A preferred stock	(3,535)	(578)
Proceeds from issuance of common stock for at-the-market offering	47,509	20,680
Payment of costs related to issuance of common stock for at-the-market offering	(1,658)	(427)
Proceeds from issuance of Series A preferred stock for at-the-market offering	—	812
Payment of costs related to issuance of Series A preferred stock for at-the-market offering	—	(24)
Proceeds from issuance of common stock under ESPP	253	123
Proceeds from partner companies' ESPP	349	—
Partner company’s dividends declared and paid	(237)	—
Proceeds from partner companies' sale of stock	57,729	86,180
Payment of costs related to partner companies' sale of stock	(4,049)	(6,671)
Proceeds from partner companies' at-the-market offering	72,570	30,526
Payment of costs related to partner companies' at-the-market offering	(1,498)	(741)
Proceeds from partner company's preferred stock offering	8,000	—
Payment of costs related to partner company's preferred stock offering	(913)	—
Proceeds from exercise of partner company’s warrants	13	—
Proceeds from exercise of partner company’s options	13	—
Payment of debt issuance costs associated with 2017 Subordinated Note Financing	(93)	(118)
Payment of debt issuance costs associated with 2018 Venture Notes	(58)	(134)
Proceeds from partner company's Horizon Notes	—	15,000
Payment of debt issuance costs associated with partner company's Horizon Notes	—	(1,393)
Proceeds from Oaktree Note	60,000	—
Payment of debt issuance costs associated with Oaktree Note	(4,302)	—
Repayment of 2017 Subordinated Note Financing	(28,356)	—
Repayment of 2018 Venture Notes	(21,707)	—
Repayment of 2019 Notes	(9,000)	—
Repayment of partner company's Horizon Notes	(15,750)	—
Repayment of IDB Note	(14,858)	—
Installment payment related to intangible asset	(500)	—
Net cash provided by financing activities	172,410	146,714
Net increase in cash and cash equivalents and restricted cash	81,564	71,850
Cash and cash equivalents and restricted cash at beginning of period	153,432	81,582
Cash and cash equivalents and restricted cash at end of period	$ 234,996	$ 153,432
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 8,204	$ 5,444
Cash paid for interest - related party	$ 617	$ 456

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,	
	2020	2019
Supplemental disclosure of non-cash financing and investing activities:		
Settlement of restricted stock units into common stock	$ 2	$ 2
Common shares issuable for license acquired	$ —	$ 164
Issuance of partner company warrants in conjunction with Horizon Notes	$ —	$ 888
Issuance of warrants in conjunction with Oaktree Note	$ 4,419	$ —
Common shares issued from 2017 Subordinated Note Financing interest expense	$ 500	$ —
Common shares issued for 2019 Notes	$ —	$ 500
Unpaid fixed assets	$ 31	$ 187
Partner company's unpaid intangible assets	$ 7,472	$ 4,734
Partner company's previous paid offering cost	$ —	$ 833
Reclass partner company's warrants from liability to equity	$ 1,216	$ —
Unpaid partner company’s offering cost	$ —	$ 69
Unpaid partner company’s at-the-market offering cost	$ 84	$ —
Unpaid partner company’s preferred stock offering cost	$ 13	$ —
Unpaid debt offering cost	$ 13	$ 26
Unpaid at-the-market offering cost	$ 30	$ 6
Unpaid Series A preferred stock offering cost	$ —	$ 153
Unpaid research and development licenses acquired	$ —	$ 1,350
Retirement of Series A preferred stock	$ 70	$ —

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 the Company does at the Fortress level, at its majority-owned and majority-controlled subsidiaries and joint ventures, and at entities the Company founded and in which it maintains significant minority ownership positions. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who identify and evaluate promising products and product candidates for potential acquisition by new or existing partner companies. Fortress through its partner companies 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 Research 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, and AstraZeneca plc.

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, three partner companies are publicly-traded, and two have consummated strategic partnerships with industry leaders Alexion Pharmaceuticals, Inc. and InvaGen Pharmaceuticals, Inc. (a subsidiary of Cipla Limited).

Several of our partner companies possess licenses to product candidate intellectual property, including Aevitas Therapeutics, Inc. ("Aevitas"), Avenue Therapeutics, Inc. ("Avenue"), Baergic Bio, Inc. ("Baergic"), Caelum Biosciences, Inc. ("Caelum"), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. ("Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Journey Medical Corporation ("Journey" or "JMC"), Mustang Bio, Inc. ("Mustang") and Oncogenuity, Inc. ("Oncogenuity").

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 partner companies, 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 company, grants or other arrangements to fully 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 plan and plans for expansion of its selling, general and administrative infrastructure will be curtailed. The Company 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. In addition to the foregoing, the Company does not expect any material impact on its development timelines, revenue levels and its liquidity due to the worldwide spread of COVID-19 (except as may be implicated by the Material Adverse Effect claimed by InvaGen in connection with their agreement with Avenue). However, the Company is continuing to assess the impact the spread of COVID-19 may have on its operations. Avenue will also continue to assess the alleged Material Adverse Effect claimed by InvaGen.

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, useful lives assigned to long-lived 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 recognizes revenue under Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The core principle of this revenue standard is that a company should recognize revenue to depict 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 following five steps are applied to achieve that core principle:

Step 1: Identify the contract with the customer
Step 2: Identify the performance obligations in the contract
Step 3: Determine the transaction price
Step 4: Allocate the transaction price to the performance obligations in the contract
Step 5: Recognize revenue when the company satisfies a performance obligation

In order to identify the performance obligations in a contract with a customer, a company must assess the promised goods or services in the contract and identify each promised good or service that is distinct. A performance obligation meets ASC 606's definition of a "distinct" good or service (or bundle of goods or services) if both of the following criteria are met:

The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct).

The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract).

If a good or service is not distinct, the good or service is combined with other promised goods or services until a bundle of goods or services is identified that is distinct.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The transaction price is allocated to each performance obligation on a relative standalone selling price basis. The transaction price allocated to each performance obligation is recognized when that performance obligation is satisfied, at a point in time or over time as appropriate.

The Company recognizes product revenue from sales of Ximino®, Targadox®, Exelderm®, Luxamend® and Ceracade®. The Company's performance obligation to deliver products is satisfied at the point in time that the goods are delivered to the customer, which is when the customer obtains title to and has the risks and rewards of ownership of the products.

The Company has variable consideration in the form of rights of return, coupons, and price protection to customers. The Company uses an expected value method to estimate variable consideration and whether the transaction price is constrained. Payment is due within months of when the customer is invoiced, with discounts for prompt payment. The Company recorded expense related to returns reserve of $1.3 million and $2.9 million for the years ended December 31, 2020 and December 31, 2019, respectively.

Because the Company's agreements for sales of product to its distributors can be cancelled early, prior to the termination date, they are deemed to have an expected duration of one year or less, and as such, the Company has elected the practical expedient in ASC 606-10-50-14(a) to not disclose information about its remaining performance obligations.

Discontinued Operations

Pursuant to the discontinued operations criteria set forth in ASC Subtopic 205-20-45, *Presentation of Financial Statements*, proceeds received from the Company's sale of its holdings in National Holding Corporation were classified as cash provided by discontinued investing activities in the Company's cash flow statement for the year ended December 31, 2019. See Note 3 for more information relating to the Company's discontinued operations.

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, 2020 and at December 31, 2019 consisted of cash and certificates of deposit in institutions in the United States. Balances at certain institutions have exceeded Federal Deposit Insurance Corporation insured limits and U.S. government agency securities.

Short-term Investments

The Company classifies its certificates of deposit as cash and cash equivalents or held to maturity in accordance with ASC 320, *Investments - Debt and Equity Securities*. The Company reassesses the appropriateness of the classification of its investments at the end of each reporting period.

At December 31, 2020, the Company had approximately $76.8 million and $15.0 million, respectively, in certificates of deposit, which the Company classified as cash and cash equivalents. There were no short term investments classified as held-to-maturity as of December 31, 2020.

Property and Equipment

Computer equipment, furniture & fixtures and machinery & 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; $0.5 million and $1.2 million are recorded in fixed assets – construction in process on the balance sheet at December 31, 2020 and 2019, 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.

Restricted Cash

The Company records cash held in trust or pledged to secure certain debt obligations as restricted cash. As of December 31, 2020, the Company had $1.6 million of restricted cash representing pledges to secure letters of credit in connection with certain office leases. As of December 31, 2019, the Company had $16.6 million of restricted cash collateralizing a note payable of $15.0 million and $1.6 million in certain 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 2020, and 2019:

($ in thousands)	December 31, 2020	2019
Cash and cash equivalents	$ 233,351	$ 136,858
Restricted cash	1,645	16,574
Total cash and cash equivalents and restricted cash	$ 234,996	$ 153,432

Inventories

Inventories comprise finished goods, which are valued at the lower of cost and net realizable value, on a first-in, first-out basis. The Company evaluates the carrying value of inventories on a regular basis, taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand.

Accounts Receivable, net

Accounts receivable consists of amounts due to the Company for product sales of JMC. The Company's accounts receivable reflects discounts for estimated early payment and for product estimated returns. Accounts receivable are stated at amounts due from customers, net of an allowance for doubtful accounts that are outstanding longer than the contractual payment terms are considered past due. The Company determines its allowance for doubtful accounts by considering a number of factors, including the length of time trade accounts receivable are past due and the customer's current ability to pay its obligation to the Company. The Company writes off accounts receivable when they become uncollectible. For the years ended December 31, 2020 and 2019 the allowance for doubtful accounts was approximately $0.1 million and $0.1 million, respectively.

The allowance for product estimated returns were $4.6 million and $5.4 million at December 31, 2020 and 2019, respectively, representing constrained revenue.

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.

Accounting for Warrants at Fair Value

The Company classifies as liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

The accounting treatment of derivative financial instruments requires that the Company record the warrants at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification.

The Company assessed the classification of warrants issuable in connection with 2018 Venture Notes and determined that the Cyprium Contingently Issuable Warrants met the criteria for liability classification. Accordingly, the Company classified the Cyprium Contingently Issuable Warrants as a liability at their fair value and adjusted the instruments to fair value at each balance sheet date until the warrants were issued. Any change in the fair value of the Cyprium Contingently Issuable Warrants is recognized as "change in the fair value of derivative liabilities" in the Consolidated Statements of Operations.

During the year ended December 31, 2020, Cyprium raised approximately $8.0 million in Cumulative Redeemable Perpetual Preferred Shares ("Cyprium Offering," see Note 14). The Cyprium Offering coupled with the repayment of the 2018 Venture Debt (see Note 10), triggered the issuance of the Cyprium Warrant, in that a price per share could be established. As such these events resulted in Cyprium recording the Cyprium Warrant as issued rather than contingently issuable.

Opus Credit Facility, with Detachable Warrants

The Company accounted for the Opus Credit Facility (see Note 10) with detachable warrants in accordance with ASC 470, *Debt*. The Company assessed the classification of its common stock purchase warrants as of the date of the transaction and determined that such instruments met the criteria for equity classification. The warrants were reported on the Consolidated Balance Sheets as a component of additional paid in capital within stockholders' equity.

The Company recorded the related issue costs and value ascribed to the warrants as a debt discount of the Opus Credit Facility. The discount was amortized utilizing the effective interest method over the term of the Opus Credit Facility. The unamortized discount, if any, upon repayment of the Opus Credit Facility would be expensed to interest expense. In accordance with ASC Subtopic 470-20, the Company determined the weighted average effective interest rate of the debt was approximately 16% at December 31, 2019. The Company also evaluated the Opus Credit Facility and warrants in accordance with the provisions of ASC 815, *Derivatives and Hedging*, including consideration of embedded derivatives requiring bifurcation.

As of December 31, 2019, Opus dissolved and distributed its assets among its Limited Partners. The dissolution did not impact any of the terms under the Opus Credit Facility. During the year ended December 31, 2020, the Company used certain proceeds from the Oaktree Note to pay off the $9.0 million balance previously outstanding under the Opus Credit Facility/2019 Notes (see Note 10).

Issuance of Debt and Equity

The Company issues complex financial instruments which include both equity and debt features. The Company analyzes 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.

The Company accounted for the Oaktree Note with detachable warrants in accordance with ASC 470, *Debt*. The Company assessed the classification of its common stock purchase warrants as of the date of the 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. The warrants were reported on the Consolidated Balance Sheets as a component of additional paid in capital within stockholders' equity.

The Company recorded the related issue costs and value ascribed to the warrants as a debt discount of the Oaktree Note. The discount was amortized utilizing the effective interest method over the term of the Oaktree Note. The unamortized discount, if any, upon repayment of the Oaktree Note would be expensed to interest expense. In accordance with ASC Subtopic 470-20, the Company determined the weighted average effective interest rate of the debt was approximately 15.13% at December 31, 2020. The Company also evaluated the Oaktree Note and warrants in accordance with the provisions of ASC 815, *Derivatives and Hedging*, including consideration of embedded derivatives requiring bifurcation.

Long-Lived Assets

Long-lived assets, primarily fixed assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. The Company will perform a periodic assessment of assets for impairment in the absence of such information or indicators. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. For long-lived assets to be held and used, the Company would recognize an impairment loss only if its carrying amount is not recoverable through its undiscounted cash flows and measures the impairment loss based on the difference between the carrying amount and estimated fair value. As of December 31, 2020 and 2019 there were no indicators of impairment.

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 during the period was reflected as research and development - licenses acquired on the Consolidated Statements of Operations for the years ended December 31, 2020 and 2019.

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

Effective January 1, 2019, 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 occurence.

For stock-based compensation awards to non-employees, prior to the adoption of ASU 2018-07 on January 1, 2019, the Company remeasured the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards were recognized as compensation expense in the period of change. Subsequent to the adoption of ASU 2018-07, the Company recognizes non-employees compensation costs over the requisite service period based on a measurement of fair value for each stock award at the time the award is granted.

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, 2020 and 2019. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

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.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820), - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company adopted ASU No. 2018-13 as of January 1, 2020. The adoption of this update did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *"Improvements to Nonemployee Share-Based Payment Accounting"*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU No. 2018-07 as of January 1, 2019. The adoption of this update did not have a material impact on the Company's consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The adoption of this ASU on January 1, 2019, did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted Topic 842 on January 1, 2019, using the optional transition method by recording a right of use asset of $23.0 million, a lease liability of $26.8 million and eliminated deferred rent of approximately $3.8 million; there was no effect on opening retained earnings, and the Company continues to account for leases in the prior period financial statements under ASC Topic 840. In adopting the new standard, the Company elected to apply the practical expedients regarding the identification of leases, lease classification, indirect costs, and the combination of lease and non-lease components.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *"Financial Instruments – Credit Losses"*. The ASU sets forth a "current expected credit loss" (CECL) 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.

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company adopted the new guidance in the first quarter of 2021 and the adoption of this guidance did not to have a material impact on the financial statements.

3. Discontinued Operations

On November 14, 2018, the Company announced that it had reached an agreement with NHC Holdings, LLC ("NHC") to sell all of its shares of National Holdings Corporation, a diversified independent brokerage company (together with its subsidiaries, herein referred to as "NHLD" or "National") for total consideration of $22.9 million. Pursuant to the terms of the agreement with NHC the sale of the shares was subject to two closings. The first closing occurred on November 14, 2018 in which the Company sold approximately 3.0 million of its shares in NHLD and received $9.8 million in proceeds. The second closing occurred on February 11, 2019 upon the receipt of FINRA approval of the sale in which the Company received $13.1 million in proceeds for the sale of its remaining 4.0 million shares of NHLD to NHC and two other minority holders. At December 31, 2019, the Company had no ownership interest in National.

The table below depicts the cash flows from the transaction for the year ended December 31, 2019:

($ in thousands)	For the Year Ended December 31, 2019
Investing activities	
Proceeds from sale of National	$ 13,089
Total cash provided by discontinued investing activities	$ 13,089

4. Collaboration and Stock Purchase Agreements

Caelum

Agreement with Alexion

In January 2019, Caelum, a subsidiary of the Company at that time, entered into a Development, Option and Stock Purchase Agreement (the "DOSPA") and related documents by and among Caelum, Alexion Therapeutics, Inc. ("Alexion"), the Company and Caelum security holders parties thereto (including Fortress, the "Sellers"). Under the terms of the agreement, Alexion purchased a 19.9% minority equity interest in Caelum for $30 million. Additionally, Alexion has agreed to make potential payments to Caelum upon the achievement of certain developmental milestones, in exchange for which Alexion obtained a contingent exclusive option to acquire the remaining equity in Caelum. The agreement also provides for potential additional payments, in the event Alexion exercises the purchase option, for up to $500 million, which includes an upfront option exercise payment and potential regulatory and commercial milestone payments. Alexion's 19.9% ownership does not participate in the potential additional payments.

The Company deconsolidated its holdings in Caelum immediately prior to the execution of the DOSPA. Following the DOSPA execution, the Company owns approximately 40% of the issued and outstanding capital stock of Caelum. The following table provides a summary of the assets and liabilities of Caelum impacted by the deconsolidation:

($ in thousands)	January 2019
ASSETS	
Current assets	
Cash and cash equivalents	$ 1,201
Prepaid expenses and other current assets	6
Total current assets	$ 1,207
LIABILITIES	
Current liabilities	
Accounts payable and accrued expenses	$ 2,246
Interest payable	198
Interest payable - related party	106
Note payable - related party	929
Note payable	9,914
Warrant liability	991
Total current liabilities	14,384
Net liability impacted by deconsolidation	**$ 13,177**

In connection with this transaction the Company recorded a gain resulting from the deconsolidation of Caelum on its consolidated financial statements for the year ended December 31, 2019:

($ in thousands)	Gain on deconsolidation of Caelum
Fair value of Caelum	$ 11,148
Net liabilities deconsolidated	13,177
Non-controlling interest share	(4,849)
Write off of MSA fees due Fortress	(1,000)
Gain on deconsolidation of Caelum	**$ 18,476**

In December 2019, following FDA feedback which resulted in the redesign and expansion of Caelum's planned clinical development program for CAEL-101, Caelum entered into an Amended and Restated DOSPA ("A&R DOSPA"), which amended the terms of the existing agreement with Alexion. The amendment modified the terms of Alexion's option to acquire the remaining equity in Caelum based on data from the expanded Phase II/III trials. The amendment also modified the development-related milestone events associated with the initial $30.0 million in contingent payments, provided for an additional $20.0 million in upfront funding, as well as funding of $60.0 million in exchange for an additional equity interest in Caelum at fair value upon achievement of a specific development-related milestone event.

On December 12, 2020, AstraZeneca ("AZ") announced its intention to acquire Alexion, with the acquisition expected to close by the third quarter of 2021, as the acquisition is subject to approval by both AZ and Alexion shareholders, as well as certain regulatory approvals, share listing approvals, and other customary closing conditions. The acquisition of Alexion by AZ triggers the Change of Control clause in the A&R DOSPA, such that Alexion's purchase option expires on the date that is six months after the closing of any Change of Control.

Avenue

Agreement 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"), under which Avenue would be sold to InvaGen in a two-stage transaction. The first stage of the strategic transaction between InvaGen and Avenue 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. At the second stage closing, InvaGen would acquire the remaining shares of Avenue's common stock, pursuant to a reverse triangular merger with Avenue remaining as the surviving entity. The second stage closing is subject to the satisfaction of certain closing conditions, including conditions pertaining to the FDA approval, labeling, scheduling and the absence of any Risk Evaluation and Mitigation Strategy or similar restrictions in effect with respect to IV Tramadol, as well as the expiration of any waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("HSR").

In October 2020, InvaGen communicated to Avenue that it believes a Material Adverse Effect (as defined in the Avenue SPMA) has occurred due to the impact of the COVID-19 pandemic on potential commercialization and projected sales of IV Tramadol, which means it is possible InvaGen could attempt to avoid its obligation to consummate the second stage closing under the Avenue SPMA, terminate the Avenue SPMA, and/or pursue monetary claims against Avenue and/or Fortress. Avenue disagrees with InvaGen's assertion that a Material Adverse Effect has occurred and has advised InvaGen of this position.

In February 2020, the U.S. Food and Drug Administration ("FDA") accepted the submission of Avenue's' New Drug Application ("NDA") for IV Tramadol for review and assigned a Prescription Drug User Fee Act ("PDUFA") date of October 10, 2020. In October 2020, Avenue announced that it had received a Complete Response Letter ("CRL") from the FDA regarding Avenue's NDA for IV Tramadol. The FDA held a Type A meeting with Avenue in November 2020 to discuss the issues outlined in the CRL. On February 12, 2021 Avenue resubmitted its NDA to the FDA for IV Tramadol. The NDA resubmission followed the receipt of the official minutes from Avenue's Type A meeting with the FDA. The NDA resubmission included revised language relating to the proposed product label and a report relating to terminal sterilization validation. On February 26, 2021, Avenue received an acknowledgement letter from the FDA that Avenue's resubmission of its NDA is a complete, class 1 response to the CRL, and a PDUFA goal date was set for April 12, 2021.

In connection with the resubmission of Avenue's NDA, InvaGen communicated to Avenue that it believes the proposed label for IV Tramadol under certain circumstances would constitute a Material Adverse Effect on the purported basis that the proposed label for IV Tramadol would make the product commercially unviable, and in addition that the indiciation that the FDA approves may fail to satisfy a condition precedent to InvaGen's obligation to consummate the second stage closing of the Avenue SPMA. Avenue has notified InvaGen that it disagrees with InvaGen's assertions. Nevertheless, InvaGen may seek to avoid its obligation to consummate the second stage closing under the Avenue SPMA, terminate the Avenue SPMA, and/or pursue monetary claims against Avenue and/or Fortress.

Over the past several months, Avenue has communicated with InvaGen relating to InvaGen's assertions. Nevertheless, InvaGen has communicated to Avenue its desire to consider all options on the proposed merger, including the option to not consummate the merger. This indicates that InvaGen may attempt to avoid its obligations under the Avenue SPMA to consummate the merger, terminate the Avenue SPMA, and/or pursue monetary claims against Avenue and/or Fortress. As a result, the possible timing and likelihood of the completion of the merger are uncertain, and, accordingly, there can be no assurance that such transaction will be completed on the expected terms, anticipated schedule, or at all. During the pendency of any dispute regarding these matters, Avenue may be, and so long as the Avenue SPMA remains in place Avenue will be, prohibited from engaging in a change-of-control transaction, selling its rights to IV Tramadol or effecting an equity or debt financing, in each case without the prior written consent of InvaGen.

Subject to the terms and conditions described in the Avenue SPMA, InvaGen may also provide interim financing to Avenue in an amount of up to $7.0 million during the time period between February 8, 2019 and the Merger Transaction. Any amounts drawn on the interim financing will be deducted from the aggregate consideration payable to Company stockholders by virtue of the Merger Transaction. There have been no amounts drawn upon this interim financing as of December 31, 2020.

Prior to the closing of the Merger Transaction, Avenue will enter into a Contingent Value Rights Agreement (the "CVR Agreement") with a trust company as rights agent, pursuant to which holders of common shares of Avenue, other than InvaGen (each, a "Holder"), will be entitled to receive on Contingent Value Right ("CVR") for each share held immediately prior to the Merger Transaction.

Each CVR represents the right of its holder to receive a contingent cash payment pursuant to the CVR Agreement upon the achievement of certain milestones. If, during the period commencing on the day following the closing of the Merger Transaction until December 31, 2028, IV Tramadol generates at least $325 million or more in Net Sales (as defined in the CVR Agreement) in a calendar year, each Holder shall be entitled to receive their pro rata share of (i) if the product generated less than $400 million in Net Sales during such calendar year, 10% of Gross Profit (as defined in the CVR Agreement), (ii) if the product generated between $400 million and $500 million in Net Sales during such calendar year, 12.5% of Gross Profit, or (iii) if the product generated more than $500 million in Net Sales during such calendar year, 15% of Gross Profit. Additionally, at any time beginning on January 1, 2029 that IV Tramadol has generated at least $1.5 billion in aggregate Net Sales, then with respect to each calendar year in which IV Tramadol generates $100 million or more in Net Sales, each Holder shall be entitled to receive their pro rata share of an amount equal to 20% of the Gross Profit generated by IV Tramadol. These additional payments will terminate on the earlier of December 31, 2036 and the date (which may be extended by up to 6 months) that any person has received approval from the FDA for an Abbreviated New Drug Application or an FDA AP-rated 505(b)(2) NDA using IV Tramadol.

5. Property and Equipment

Fortress' property and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	December 31, 2020	December 31, 2019
Computer equipment	3	$ 663	$ 648
Furniture and fixtures	5	1,199	1,162
Machinery & equipment	5	5,748	4,594
Leasehold improvements	2-15	10,580	9,358
Construction in progress [1]	N/A	499	1,157
Total property and equipment		18,689	16,919
Less: Accumulated depreciation		(6,766)	(4,486)
Property and equipment, net		$ 11,923	$ 12,433

Note 1: Relates to the Mustang cell processing facility.

Depreciation expenses of Fortress' property and equipment for the years ended December 31, 2020 and 2019 was $2.3 million and $1.9 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

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.

Fair Value of Caelum

The Company values its investment in Caelum in accordance with ASC Topic 820, *Fair Value Measurements and Disclosures*, and as of December 31, 2020, estimated the fair value to be $17.6 million based on a per share value of $2.43. As of December 31, 2020, the following inputs were utilized to derive the value: risk free rate of return of 0.36%, volatility of 70% and a discount for lack of marketability of 21.0% to 31.0% based on maturity dates of various scenerios. Further, the Company considered the impact of the acquisition of Alexion by AZ, which if consummated, will shorten the timeframe in which the option will be exercised in accordance with the A&R DOSPA.

As of December 31, 2019, the estimated fair value of the Company's investment in Caelum was $11.1 million based on a per share value of $1.54. As of December 31, 2019, the following inputs were utilized to derive the value: risk free rate of return of 1.6%, volatility of 70% and a discount for lack of marketability of 28.7%.

Caelum Warrant Liability

The fair value of Caelum's warrant liability, which was issued in connection with Caelum's convertible note, was written up to the full value of the liability prior to the conversion of the notes in January 2019 (see Note 10). The fair value 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 Caelum's warrant liabilities that are categorized within Level 3 of the fair value hierarchy as of January 2019 was as follows:

	January 2019
Risk-free interest rate	2.905% - 2.909 %
Expected dividend yield	— %
Expected term in years	3.84 - 3.96
Expected volatility	70 %

In connection with the DOSPA Caelum's convertible notes automatically converted into common shares of Caelum and the warrant liability payable to the placement agent in connection with the placement of the convertible notes was also issued (see Note 10).

($ in thousands)	Fair Value of Derivative Warrant Liability
Beginning balance at January 1, 2019	$ 991
Issuance of warrant due to conversion of note	(991)
Ending balance at December 31, 2019	$ —

Caelum Convertible Notes

Caelum's convertible debt was measured at fair value using the Monte Carlo simulation valuation methodology. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Caelum's convertible debt that is categorized within Level 3. As of December 31, 2018, conversion of the Caelum Convertible Notes was probable and as such the fair value approximated cost. The Caelum Convertible Notes were converted during 2019. As of January 2019 the following inputs were utilized to derive the notes' fair value:

	January 2019
Risk-free interest rate	2.302 %
Expected dividend yield	— %
Expected term in years	0.32
Expected volatility	67 %

($ in thousands)	Caelum Convertible Notes, at fair value
Beginning balance at January 1, 2019	$ 9,914
Change in fair value of convertible notes	(9,914)
Ending balance at December 31, 2019	$ —

Cyprium Warrant Liability

The fair value of the Cyprium Contingently Issuable Warrants in connection with the 2018 Venture Debt was determined by applying management's estimate of the probability of issuance of the Contingently Issuable Warrants together with an option-pricing model, with the following key assumptions:

	December 31,	
	2020	2019
Risk-free interest rate	0.69 %	1.92 %
Expected dividend yield	—	—
Expected term in years	10.0	10
Expected volatility	85 %	93 %
Probability of issuance of the warrant	100 %	5 %

($ in thousands)	Cyprium Contingently Issuable Warrant Liability
Beginning balance at January 1, 2019	$ —
Change in fair value	27
Ending balance at December 31, 2019	$ 27
Change in fair value	1,189
Reclass partner company's warrants from liability to equity	(1,216)
Ending balance at December 31, 2020	$ —

The following tables classify into the fair value hierarchy of Fortress' financial instruments, measured at fair value on a recurring basis on the Consolidated Balance Sheets as of December 31, 2020 and 2019:

	Fair Value Measurement as of December 31, 2020			
($ in thousands)	Level 1	Level 2	Level 3	Total
Assets				
Fair value of investment in Caelum	$ —	$ —	$ 17,566	$ 17,566
Total	$ —	$ —	$ 17,566	$ 17,566

($ in thousands)	Fair Value Measurement as of December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets				
Fair value of investment in Caelum	$ —	$ —	$ 11,148	$ 11,148
Total	$ —	$ —	$ 11,148	$ 11,148

($ in thousands)	Fair Value Measurement as of December 31, 2019			
	Level 1	Level 2	Level 3	Total
Liabilities				
Warrant liabilities	$ —	$ —	$ 27	$ 27
Total	$ —	$ —	$ 27	$ 27

The table below provides a roll forward of the changes in fair value of Level 3 financial instruments for the years ended December 31, 2020 and 2019:

($ in thousands)	Investment in Caelum	Warrant Liabilities	Total
Balance at December 31, 2019	$ 11,148	$ 27	$ 11,175
Change in fair value	—	1,189	1,189
Reclass partner company's warrants from liability to equity	—	(1,216)	(1,216)
Change in fair value of investments	6,418	—	6,418
Balance at December 31, 2020	$ 17,566	$ —	$ 17,566

($ in thousands)	Investment in Caelum	Caelum Convertible Notes	Warrants liabilities	Total
Balance at December 31, 2018	$ —	$ 9,914	$ 991	$ 10,905
Conversion of convertible notes	—	(9,914)	—	(9,914)
Issuance of warrant	—	—	(991)	(991)
Fair value of investment	11,148	—	—	11,148
Change in fair value of derivative liability	—	—	27	27
Balance at December 31, 2019	$ 11,148	$ —	$ 27	$ 11,175

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, 2020 and 2019, the total purchase price of licenses acquired, totaling approximately $2.8 million and $6.1 million, respectively, was classified as research and development-licenses acquired in the Consolidated Statements of Operations.

For the years ended December 31, 2020 and 2019, the Company's research and development-licenses acquired are comprised of the following:

($ in thousands)	For the Year Ended December 31, 2020	2019
Partner companies:		
Avenue	$ —	$ 1,000
Aevitas	62	—
Baergic	11	3,290
Cellvation	1	—
Helocyte	—	450
Mustang	2,489	1,350
Oncogenuity	271	—
Total	$ 2,834	$ 6,090

Aevitas

License Agreement with University of Massachusetts

On December 17, 2020, Aevitas entered into an exclusive license agreement (the "UMass license") with the University of Massachusetts to obtain an exclusive license to the University's intellectual property rights which relate to gene therapy for Factor H deficiency. For the year ended December 31, 2020, Aevitas recorded $0.1 million in connection with the execution of the UMass License.

Development milestone payments totaling approximately $1.0 million in the aggregate are due upon achievement of each milestone. Four net sales milestones totaling $4.0 million are due on licensed products as are high single digit royalties due on aggregate, annual, worldwide net sales of licensed products.

Avenue

License Agreement with Revogenex Ireland Ltd

In 2015, the Company purchased an exclusive license to IV Tramadol for the U.S. market from Revogenex, a privately held company in Dublin, Ireland, for an upfront fee of $3.0 million. The Company then assigned all of its right, title and interest to the exclusive license to Avenue. Under the terms of the license agreement assumed by Avenue, Revogenex is eligible to receive additional milestone payments upon the achievement of certain development milestones. As of December 31, 2020, one remaining development milestone of $3.0 million for approval of IV Tramadol by the FDA has not been achieved. In addition, royalty payments ranging from high single digit to low double digits are due on net sales of the approved product.

No expense was recorded in connection with this agreement in 2020. For the year ended December 31, 2019, Avenue recorded $1.0 million in connection with the filing of its NDA for IV Tramadol.

Baergic

AstraZeneca AB License Agreement

On December 17, 2019, Baergic entered into two license agreements: (i) a License Agreement (the "AZ License") with AstraZeneca AB ("AZ") to acquire an exclusive license to patent and related intellectual property rights pertaining to their proprietary compound Gamma-aminobutyric acid receptor A alpha 2 & 3 (GABAA α2,3) positive allosteric modulators (collectively, the "AZ IP"); and (ii) an Exclusive License Agreement (the "Cincinnati License") with Cincinnati Children's Hospital Medical Center ("Cincinnati") to acquire patent and related intellectual property rights pertaining to a GABA inhibitor program for neurological disorders (the "Cincinnati IP").

Pursuant to the terms of the AZ License, Baergic paid an upfront fee of $3.0 million and issued 2,492,192 common shares equal to 19.95% of Baergic to AZ as consideration for AZ License. In connection with the issuance of the shares, Baergic also provided AZ with anti-dilution protection up to $75 million. Baergic valued the stock grant to AZ utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.6%, weighted average cost of capital of 20.5%, and net of debt utilized, resulting in a value of $0.029 per share or $0.1 million on December 31, 2019.

Development milestone payments totaling approximately $75 million in the aggregate are due upon achievement of each milestone. Three net sales milestones totaling $130 million are due on licensed products as are high single digit royalties due on aggregate, annual, worldwide net sales of licensed products.

For the years ended December 31, 2020 and 2019, Baergic recorded expense of approximately $9,000 and nil, respectively, in connection with its licenses with AZ.

Cincinnati Children's License Agreement

Pursuant to the terms of the Cincinnati License, Baergic paid an upfront fee of $0.2 million as well as $30,000 for reimbursement of past patent expenses and issued 624,922 common shares equal to 5% of Baergic to Cincinnati as consideration for the license. In connection with the issuance of the shares, Baergic also provided Cincinnati with anti-dilution protection up to $15.0 million. Baergic valued the stock grant to Cincinnati utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.6%, weighted average cost of capital of 20.5%, and net of debt utilized, resulting in a value of $0.029 per share or $0.1 million on December 31, 2019.

Two development milestone payments of approximately $6.5 million are payable upon milestone achievements. Four net sales milestones totaling $21.0 million are due on licensed products as are low single digit royalties due on aggregate, annual, worldwide net sales of licensed products.

For the years ended December 31, 2020 and 2019, Baergic recorded expense of approximately $2,000 and nil, respectively, in connection with its Cincinnati License.

Cellvation

University of Texas Health Science Center at Houston License Agreement

In October 2016, Cellvation entered into a license agreement with the University of Texas Health Science Center at Houston ("University of Texas") for the treatment of traumatic brain injury using Autologous Bone Marrow Mononuclear Cells (the "Initial TBI License") for an upfront cash fee of approximately $0.3 million and the issuance of 500,000 common shares representing 5% of the outstanding shares of Cellvation. An additional 9 development milestones approximating $6.2 million are due in connection with the development of adult indications, and an additional 8 development milestones approximating $6.0 million are due in connection with the development of pediatric indications, as well as single digit royalty net sales and royalty milestones are due for the term of the contract. An additional minimum annual royalty ranging from $50,000 to $0.2 million is due, depending on the age of the license.

In addition, Cellvation entered into a secondary license with the University of Texas for a method and apparatus for conditioning cell populations for cell therapies (the "Second TBI License"). Cellvation paid an upfront fee of $50,000 in connection with the Second TBI License, and a minimum annual royalty of $0.1 million is payable beginning in the year after first commercial sale occurs (which minimum annual royalty is creditable against actual royalties paid under the Second TBI License). Additional payments of $0.3 million are due for the completion of certain development milestones and single digit royalties upon the achievement of net sales. In connection with the two University of Texas licenses, Cellvation granted each of two University of Texas researchers acting as consultants to Cellvation 500,000 shares of Cellvation common stock.

For the years ended December 31, 2020 and 2019, Cellvation recorded expense of approximately $1,000 and nil, respectively, in connection with its licenses with the University of Texas.

Checkpoint

Dana-Farber Cancer Institute License Agreement

In March 2015, Checkpoint entered into an exclusive license agreement with Dana-Farber Cancer Institute ("Dana-Farber") to develop a portfolio of fully human immuno-oncology targeted antibodies. The portfolio of antibodies licensed from Dana-Farber include antibodies targeting PD-L1, GITR and CAIX. Under the terms of the agreement, Checkpoint paid Dana-Farber an up-front licensing fee of $1.0 million in 2015 and, on May 11, 2015, granted Dana-Farber 500,000 shares of Checkpoint common stock, valued at $32,500 or $0.065 per share. The agreement included an anti-dilution clause that maintained Dana-Farber's ownership at 5% until such time that Checkpoint raised $10.0 million in cash in exchange for common shares. Pursuant to this provision, on September 30, 2015, Checkpoint granted to Dana-Farber an additional 136,830 shares of common stock valued at approximately $0.6 million and the anti-dilution clause thereafter expired. Dana-Farber is eligible to receive payments of up to an aggregate of approximately $21.5 million for each licensed product upon Checkpoint's successful achievement of certain clinical development, regulatory and first commercial sale milestones. In addition, Dana-Farber is eligible to receive up to an aggregate of $60.0 million upon Checkpoint's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales. Dana-Farber receives an annual license maintenance fee of $50,000, which is creditable against future milestone payments or royalties. The portfolio of antibodies licensed from Dana-Farber include antibodies targeting PD-L1, GITR and CAIX.

In connection with the license agreement with Dana-Farber, Checkpoint entered into a collaboration agreement with TGTX, which was amended and restated in June 2019, to develop and commercialize the anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies, while Checkpoint retains the right to develop and commercialize these antibodies in the field of solid tumors. Michael Weiss, Chairman of the Board of Directors of Checkpoint is also the Executive Chairman, President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the original agreement, TGTX paid Checkpoint $0.5 million, representing an upfront licensing fee. Upon the signing of the amended and restated collaboration agreement in June 2019, TGTX paid Checkpoint an additional $1.0 million upfront licensing fee. Checkpoint is eligible to receive substantive potential milestone payments for the anti-PD-L1 program of up to an aggregate of approximately $27.6 million upon TGTX's successful achievement of certain clinical development, regulatory and first commercial sale milestones. This is comprised of up to approximately $8.4 million upon TGTX's successful completion of clinical development milestones, and up to approximately $19.2 million upon regulatory filings and first commercial sales in specified territories. Checkpoint is also eligible to receive substantive potential milestone payments for the anti-GITR antibody program of up to an aggregate of approximately $21.5 million upon TGTX's successful achievement of certain clinical development, regulatory and first commercial sale milestones. This is comprised of up to approximately $7.0 million upon TGTX's successful completion of clinical development milestones, and up to approximately $14.5 million upon first commercial sales in specified territories. In addition, Checkpoint is eligible to receive up to an aggregate of $60.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales for both programs, in addition to royalty payments based on a tiered low double-digit percentage of net sales. Checkpoint also receives an annual license maintenance fee, which is creditable against future milestone payments or royalties. TGTX also pays Checkpoint for its out-of-pocket costs of material used by TGTX for their development activities. For the years ended December 31, 2020 and 2019, Checkpoint recognized approximately $1.0 million and $1.6 million, respectively, in revenue related to the collaboration agreement in the Consolidated Statements of Operations. The revenue for the year ended December 31, 2020 included a milestone of $925,000 upon the 12th patient dosed in a phase 1 clinical trial for the anti-PD-L1 antibody cosibelimab during March 2020.

Adimab, LLC Collaboration Agreement

In October 2015, Fortress entered into a collaboration agreement with Adimab to discover and optimize antibodies using their proprietary core technology platform. Under this agreement, Adimab optimized cosibelimab, Checkpoint's anti-PD-L1 antibody which it originally licensed from Dana-Farber. In January 2019, Fortress transferred the rights to the optimized antibody to Checkpoint, and Checkpoint entered into a collaboration agreement directly with Adimab on the same day. Under the terms of the agreement, Adimab is eligible to receive payments up to an aggregate of approximately $7.1 million upon the Checkpoint's successful achievement of certain clinical development and regulatory milestones, of which $4.8 million are due upon various filings for regulatory approvals to commercialize the product. In addition, Adimab is eligible to receive royalty payments based on a tiered low single digit percentage of net sales.

NeuPharma, Inc. License Agreement

In March 2015, the Company entered into an exclusive license agreement with NeuPharma, Inc. (“NeuPharma”) to develop and commercialize novel irreversible, 3rd generation epidermal growth factor receptor (“EGFR”) inhibitors including CK-101, on a worldwide basis (other than certain Asian countries). On the same date, the Company assigned all of its right and interest in the EGFR inhibitors to Checkpoint. Under the terms of the agreement, Checkpoint paid NeuPharma an up-front licensing fee of $1.0 million in 2015, and NeuPharma is eligible to receive payments of up to an aggregate of approximately $40.0 million upon Checkpoint’s successful achievement of certain clinical development and regulatory milestones in up to three indications, of which $22.5 million are due upon various regulatory approvals to commercialize the products. In addition, NeuPharma is eligible to receive payments of up to an aggregate of $40 million upon Checkpoint’s successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered mid to high-single digit percentage of net sales.

Jubilant Biosys Limited License Agreement

In May 2016, Checkpoint entered into a license agreement with Jubilant Biosys Limited (“Jubilant”), whereby Checkpoint obtained an exclusive, worldwide license (the “Jubilant License”) to Jubilant’s family of patents covering compounds that inhibit BRD4, a member of the BET domain for cancer treatment, including CK-103. Under the terms of the Jubilant License, Checkpoint paid Jubilant an up-front licensing fee of $2.0 million, and Jubilant is eligible to receive payments up to an aggregate of approximately $89.0 million upon Checkpoint’s successful achievement of certain preclinical, clinical development, and regulatory milestones, of which $59.5 million are due upon various regulatory approvals to commercialize the products. In addition, Jubilant is eligible to receive payments up to an aggregate of $89.0 million upon Checkpoint’s successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales.

In connection with the Jubilant License, Checkpoint entered into a sublicense agreement with TGTX (the “Sublicense Agreement”), a related party, to develop and commercialize the compounds licensed in the field of hematological malignancies, with Checkpoint retaining the right to develop and commercialize these compounds in the field of solid tumors. Under the terms of the Sublicense Agreement, TGTX paid Checkpoint $1.0 million, representing an upfront licensing fee, recorded as collaboration revenue – related party and Checkpoint is eligible to receive substantive potential milestone payments up to an aggregate of approximately $87.2 million upon TGTX’s successful achievement of clinical development and regulatory milestones. Such potential milestone payments may approximate $25.5 million upon TGTX’s successful completion of three clinical development milestones for two licensed products, and up to approximately $61.7 million upon the achievement of five regulatory approvals and first commercial sales in specified territories for two licensed products. In addition, Checkpoint is eligible to receive potential milestone payments up to an aggregate of $89.0 million upon TGTX’s successful achievement of three sales milestones based on aggregate net sales by TGTX, for two licensed products, in addition to royalty payments based on a mid-single digit percentage of net sales by TGTX. TGTX also pays Checkpoint for 50% of IND enabling costs and patent expenses. Checkpoint recognized $0.1 million and $0.1 million in revenue related to this arrangement during the year ended December 31, 2020 and 2019, respectively.

The collaborations with TGTX each contain single material performance obligations under Topic 606, which is the granting of a license that is functional intellectual property. Checkpoint's performance obligation was satisfied at the point in time when TGTX had the ability to use and benefit from the right to use the intellectual property. The performance obligations of the original agreements were satisfied prior to the adoption of Topic 606. The performance obligation of the amendment to the collaboration agreement was satisfied in June 2019.

The milestone payments are based on successful achievement of clinical development, regulatory, and sales milestones. Because these payments are contingent on the occurrence of a future event, they represent variable consideration and are constrained and included in the transaction price only when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The sales-based royalty payments are recognized as revenue when the subsequent sales occur. Checkpoint also receives variable consideration for certain research and development, out-of-pocket material costs and patent maintenance related activities that are dependent upon the Company's actual expenditures under the collaborations and are constrained and included in the transaction price only when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Revenue is recognized approximately when the amounts become due because it relates to an already satisfied performance obligation. For the year ended December 31, 2020, Checkpoint recognized the achievement of a clinical development milestone under its collaboration agreement with TGTX based upon their dosing of a 12th patient in a phase 1 clinical trial of cosibelimab. For the year ended December 31, 2019, Checkpoint did not receive any milestone or royalty payments.

Cyprium

License Agreement with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

In March 2017, Cyprium and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (“NICHD”), part of the National Institutes of Health (“NIH”), entered into a Cooperative Research and Development Agreement to advance the clinical development of Phase 3 candidate CUTX-101 (copper histidinate injection) for the treatment of Menkes disease. Cyprium and NICHD also entered into a worldwide, exclusive license agreement to develop and commercialize AAV-based ATP7A gene therapy for use in combination with CUTX-101 for the treatment of Menkes disease and related copper transport disorders. Cyprium made an upfront payment of $0.1 million to NICHD upon execution of the exclusive license. NICHD is eligible to receive payments of up to an aggregate of approximately $1.7 million upon Cyprium’s successful achievement of certain clinical development and regulatory milestones for each licensed product, in addition to $1 million upon first commercial sale of a product candidate. In addition, in the event Cyprium sells a Priority Review Voucher that it receives from the FDA in connection with the approval of one of its product candidates (a "PRV") to a third party, it is obligated to pay to NIH 20% of the proceeds that it receives from such third party with respect to the first PRV sold, and 15% of the proceeds with respect to the second PRV sold. In the alternative, in the event Cyprium redeems a PRV in connection with seeking priority review for one of its product candidates, Cyprium will be obligated to pay NIH $15 million. For the years ended December 31, 2020 and 2019, no expense was recorded in connection with this license.

Helocyte

License Agreement with the City of Hope

Helocyte entered into the original license agreement with City of Hope National Medical Center (“COH”) on March 31, 2015, to secure: (i) an exclusive worldwide license for two immunotherapies for Cytomegalovirus (“CMV”) control in the post-transplant setting (known as Triplex and PepVax). In consideration for the license and option, Helocyte made an upfront payment of $0.2 million. In March 2016, Helocyte entered into amended and restated license agreements for each of its PepVax and Triplex immunotherapies programs with its licensor COH. The amended and restated licenses expand the intellectual property and other rights granted to Helocyte by COH in the original license agreement without modifying the financial terms. In 2018, Helocyte discontinued the development of PepVax and terminated the related license and clinical trial agreements with COH.

If Helocyte successfully develops and commercializes Triplex, COH is eligible to receive up to $3.7 million related to three financial milestones, $7.5 million in development milestones for the remaining two development milestones and up to $26.0 million in three milestones related to net sales for each licensed product. To date Helocyte has completed a Phase 2 clinical trial program for Triplex.

In April 2015, Helocyte secured the exclusive worldwide rights to an immunotherapy for the prevention of congenital CMV: ConVax (formerly Pentamer) from COH for an upfront payment of $45,000. If Helocyte successfully develops and commercializes Pentamer, COH could receive up to $5.5 million for the achievement of four development milestones, $26.0 million for three sales milestones, single digit royalties based on net sales reduced by certain factors and a minimum annual royalty of $0.75 million per year following a first marketing approval. For the year ended December 31, 2020 and 2019, Helocyte recorded nil and nil respectively in research and development - licenses acquired on the Consolidated Statement of Operations in connection with this license.

License with the National Institute of Allergy and Infectious Disease (NIAD)

In December 2019, Helocyte entered into a non-exclusive license agreement with the National Institute of Allergy and Infectious Disease (a division of the National Institutes of Health ("NIAID")) for the use of certain material pertaining to one of its product candidates. Helocyte agreed to pay an upfront fee of $0.5 million, which is payable in three separate installments, as well as a minimum annual royalty of $55,000. Additional payments of up to $1,050,000 in the aggregate are due upon the achievement of four developmental milestones, and royalties in the low single digits are due on net sales of licensed products.

For the year ended December 31, 2020 and 2019, Helocyte recorded nil and $0.5 million, respectively, in research and development - licenses acquired on the Consolidated Statement of Operations in connection with this license.

Mustang

For the years ended December 31, 2020 and 2019 Mustang recorded the following expense in research and development – licenses acquired:

	For the Year Ended December 31,	
($ in thousands)	**2020**	**2019**
City of Hope National Medical Center		
CD123 (MB-102)[3]	$ 334	$ 250
IL13Rα2 (MB-101) [3]	334	—
HER2 (MB-103)[1]	500	—
CS1 (MB-104)	200	200
PSCA (MB-105)[3]	200	200
Spacer	334	—
Fred Hutch - CD20 (MB-106)[2]	300	—
Nationwide Children's Hospital - C134 (MB-108)	—	200
CSL Behring (Calimmune)	170	200
UCLA	—	300
SIRION LentiBOOST™	117	—
Total	$ 2,489	$ 1,350

License Agreement with City of Hope

In March 2015, Mustang entered into an exclusive license agreement with COH to acquire intellectual property rights pertaining to chimeric antigen receptor ("CAR") engineered T cell ("CAR T") technologies (the "COH License"). Pursuant to the COH License, Mustang paid COH an upfront fee of $2.0 million in April 2015 (included in *research and development-licenses acquired expenses* on the Consolidated Statement of Operations) and granted COH 1.0 million shares of Mustang's Class A Common Stock, representing 10% ownership of Mustang. Additional payments totaling $2.0 million are due upon the completion of two financial milestones, and payments totaling $14.5 million are due upon the completion of six development goals. Future mid-single digit royalty payments are due on net sales of licensed products, with a minimum annual royalty of $1.0 million.

In February 2017, the Company and COH amended and restated the COH License by entering into three separate amended and restated exclusive license agreements, one relating to CD123 (MB-102), one relating to IL13Rα2 (MB-101) and one relating to the Spacer technology, that amended the COH License in certain other respects, and collectively replace the COH License in its entirety. The total potential consideration payable to COH by the Company, in equity or cash, did not, in the aggregate, change materially from the COH License.

CD123 License with City of Hope (MB-102)

Pursuant to the CD123 License, Mustang and COH acknowledge that an upfront fee was paid under the COH License. In addition, an annual maintenance fee will continue to apply. COH is eligible to receive up to approximately $14.5 million in milestone payments upon and subject to the achievement of certain milestones. Royalty payments in the mid-single digits are due on net sales of licensed products. Mustang is obligated to pay COH a percentage of certain revenues received in connection with a sublicense in the mid-teens to mid-thirties, depending on the timing of the sublicense in the development of any product. In addition, equity grants made under the COH License were acknowledged, and the anti-dilution provisions of the COH License were carried forward. For the year ended December 31, 2020, Mustang expensed a non-refundable milestone payment of $0.3 million in connection with their public underwritten offerings. For the year ended December 31, 2019, Mustang expensed a non-refundable milestone payment of $0.3 million upon the twelfth patient dosed in a Phase 1 clinical study of CD123.

Nationwide Children's Hospital License Agreement (MB-108)

In February 2019, Mustang announced that it partnered and entered into an exclusive worldwide license agreement with Nationwide Children's Hospital ("Nationwide") to develop their C134 oncolytic virus (MB-108) for the treatment of glioblastoma multiforme ("GBM"). Mustang intends to combine MB-108 with MB-101 (IL13Rα2-specific CAR T) to potentially enhance efficacy in treating GBM. There were no expenses recorded in 2020 in connection with this license. For the year ended December 31, 2019, Mustang paid $0.2 million in consideration for the license to exclusive, worldwide rights to develop and commercialize products that incorporate data, know-how and/or patents related to MB-108 that were developed at Nationwide. Additional payments are due to Nationwide upon achievement of development and commercialization milestones totaling $152.8 million. Royalty payments in the low-single digits are due on net sales of licensed products.

CS1 License with City of Hope (MB-104)

On May 31, 2017, Mustang entered into an exclusive license agreement with the COH for the use of CS1-specific CAR T technology to be directed against multiple myeloma. Pursuant to the agreement, Mustang paid an upfront fee of $0.6 million on July 3, 2017, and owes an annual maintenance fee of $50,000, which began in 2019. Additional payments of up to $14.9 million are due upon and subject to the achievement of ten development milestones, and royalty payments in the mid-single digits are due on net sales of licensed products. During the year ended December 31, 2020, Mustang expensed a non-refundable milestone payment of $0.2 million in connection with this license for the issuance of the first patent related to the CS1 technology. During the year ended December 31, 2019, Mustang expensed a non-refundable milestone payment of $0.2 million upon the first patient dosed in a Phase 1 clinical study of the CS1 CAR T.

PSCA License with City of Hope (MB-105)

On May 31, 2017, Mustang entered into an exclusive license agreement with the COH for the use of prostate stem cell antigen ("PSCA") CAR T technology to be used in the treatment of prostate cancer. Pursuant to the agreement, Mustang paid an upfront fee of $0.3 million on July 3, 2017, and owes an annual maintenance fee of $50,000, which began in 2019. Additional payments of up to $14.9 million are due upon and subject to the achievement of ten development milestones, and royalty payments in the mid-single digits are due on net sales of licensed products. During the years ended December 31, 2020 and 2019, Mustang recorded an expense of $0.2 million and nil, respectively, in connection with the acquisition of this license.

CSL Behring (Calimmune) License (MB-107)

On August 23, 2019, Mustang entered into a non-exclusive license agreement with CSL Behring (Calimmune, Inc.) ("Calimmune License") for the Cytegrity™ stable producer cell line for the production of viral vector for Mustang's lentiviral gene therapy program for the treatment of XSCID. Mustang had previously licensed the XSCID gene therapy program from St. Jude in August 2018. Mustang paid $0.2 million in consideration for the Calimmune license. CSL Behring is eligible to receive additional payments totaling $1.2 million upon the achievement of three development and commercialization milestones. Royalty payments in the low-single digits are due on net sales of licensed products. Upon the execution of the Calimmune License, Mustang expensed a non-refundable milestone payment of $0.2 million and $0.2 million in the Consolidated Statement of Operations for the years ended December 31, 2020 and 2019, respectively.

University of California License

On March 17, 2017, Mustang entered into an exclusive license agreement with the Regents of the University of California ("UCLA License") to acquire intellectual property rights in patent applications related to the engineered anti-prostate stem cell antigen antibodies for cancer targeting and detection. Pursuant to the UCLA License, Mustang paid UCLA an upfront fee of $0.2 million on April 25, 2017. Annual maintenance fees also apply; additional payments are due upon achievement of certain development milestones totaling $14.3 million, and royalty payments in the mid-single digits are due on net sales of licensed products. In September 2019, COH commenced its Phase 1 clinical trial resulting in the achievement of a development milestone, and as a result Mustang recorded an expense of $0.3 million. There were no expenses recorded in 2020 in connection with this license.

HER2 License with City of Hope (MB-103)

On May 31, 2017, Mustang entered into an exclusive license agreement with the COH for the use of human epidermal growth factor receptor 2 ("HER2") CAR T technology ("HER2 Technology"), which will be applied in the treatment of glioblastoma multiforme. Pursuant to the agreement, Mustang paid an upfront fee of $0.6 million and owes an annual maintenance fee of $50,000, which began in 2019. Additional payments of up to $14.9 million are due upon and subject to the achievement of ten development milestones, and royalty payments in the mid-single digits are due on net sales of licensed products. During the year ended December 31, 2020, Mustang recorded a non-refundable milestone payment of $0.5 million in connection with the twelfth patient treated in the Phase 1 clinical study of HER2 CAR T technology at COH. For the year ended December 31, 2019, Mustang expensed a non-refundable milestone payment of $0.2 million upon the first patient dosed in the Phase 1 clinical study of HER2.

St. Jude Children's Research Hospital License (MB-107 and MB-207)

On August 2, 2018, Mustang entered into an exclusive worldwide license agreement with St. Jude for the development of a first-in-class *ex vivo* lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency ("XSCID"). Mustang paid $1.0 million in consideration for the exclusive license in addition to an annual maintenance fee of $0.1 million (which began in 2019). St. Jude is eligible to receive payments totaling $13.5 million upon the achievement of five development and commercialization milestones. Royalty payments in the mid-single digits are due on net sales of licensed products. During the years ended December 31, 2020 and 2019 Mustang did not record any expenses in connection with this license.

Manufacturing License with City of Hope

On January 3, 2018, Mustang entered into a non-exclusive license agreement with COH to acquire patent and licensed know-how rights related to developing, manufacturing, and commercializing licensed products. The Company paid $0.1 million in consideration for the licenses to the patent rights and the licensed know-how in addition to an annual maintenance fee. Royalty payments in the low-single digits are due on net sales of licensed products. During the years ended December 31, 2020 and 2019, respectively, Mustang recorded no expense in connection with the COH license.

IL13Rα2 License with City of Hope (MB-101)

Pursuant to the IL13Rα2 License, Mustang and COH acknowledge that an upfront fee was paid under the Original License. In addition, an annual maintenance fee will continue to apply. COH is eligible to receive up to approximately $14.5 million in milestone payments upon and subject to the achievement of certain milestones. Royalty payments in the mid-single digits are due on net sales of licensed products. Mustang is obligated to pay COH a percentage of certain revenues received in connection with a sublicense in the mid-teens to mid-thirties, depending on the timing of the sublicense in the development of any product. In addition, equity grants made under the Original License were acknowledged, and the anti-dilution provisions of the Original License were carried forward. For the year ended, December 31, 2020, Mustang expensed a non-refundable milestone payment of $0.3 million in connection with their public underwritten offerings. There was no expense recorded for the year ended December 31, 2019.

Spacer License with City of Hope

Pursuant to the Spacer License, Mustang and COH acknowledge that an upfront fee was paid under the Original License. In addition, an annual maintenance fee will continue to apply. No royalties are due if the Spacer technology is used in conjunction with a CD123 CAR or an IL13Rα2 CAR, and royalty payments in the low single digits are due on net sales of licensed products if the Spacer technology is used in conjunction with other intellectual property. Mustang is obligated to pay COH a percentage (in the mid-thirties) of certain revenues received in connection with a sublicense. In addition, equity grants made under the Original License were acknowledged, and the anti-dilution provisions of the Original License were carried forward. For the year ended December 31, 2020, Mustang expensed a non-refundable milestone payment of $0.3 million in connection with their public underwritten offerings. There was no expense recorded for the year ended December 31, 2019.

IV/ICV Agreement with City of Hope

On February 17, 2017, Mustang entered into an exclusive license agreement (the "IV/ICV Agreement") with COH to acquire intellectual property rights in patent applications related to the intraventricular and intracerebroventricular methods of delivering T cells that express CARs. Pursuant to the IV/ICV Agreement, Mustang paid COH an upfront fee of $0.1 million in March 2017. COH is eligible to receive up to approximately $0.1 million in milestone payments upon the achievement of a certain milestone as well as an annual maintenance fee. Royalty payments in the low-single digits are due on net sales of licensed products and services. During the years ended December 31, 2020 and 2019, Mustang recorded no expense in connection with the IV/ICV Agreement.

Fred Hutchinson Cancer Research Center License (MB-106)

On July 3, 2017, Mustang entered into an exclusive, worldwide licensing agreement with Fred Hutchinson Cancer Research Center ("Fred Hutch") for the use of a CAR T therapy related to autologous T cells engineered to express a CD20-specific chimeric antigen receptor ("CD20 Technology License"). Pursuant to the CD20 Technology License, Mustang paid Fred Hutch an upfront fee of $0.3 million and will owe an annual maintenance fee of $50,000 on each anniversary of the license until the achievement by Mustang of regulatory approval of a licensed product using CD20 Technology. Additional payments are due for the achievement of certain development milestones totaling $39.1 million and royalty payments in the mid-single digits are due on net sales of licensed products. During the years ended December 31, 2020 and 2019 Mustang recorded expenses totaling $0.3 million and nil, respectively, in connection with the CD20 Technology License.

Harvard College License

On November 20, 2017, Mustang entered into an exclusive, worldwide license agreement with President and Fellows of Harvard College (the "Harvard Agreement") for the use of gene editing, via the use of CRISPR/Cas9, to be used in enhancing the efficacy of chimeric antigen receptor T (CAR T) cell therapies for solid tumor indications and to generate universal off the shelf CAR T cell therapies for both liquid and solid tumor indications. Pursuant to the Harvard Agreement, Mustang paid Harvard College an upfront fee of $0.3 million and will owe an annual maintenance fee of $25,000 and $50,000 for calendar years 2018 and 2019, respectively, and $100,000 for each subsequent calendar year during the term of the agreement. Additional payments are due for the achievement of seven development milestones totaling $16.7 million and royalty payments in the low-single digits are due on the net sales of licensed products. During the years ended December 31, 2020 and 2019, Mustang recorded no expense in connection with the Harvard Agreement.

Mustang terminated the Harvard Agreement in January 2020.

SIRION Biotech GmbH - LentiBOOST™ (MB-207)

In October, 2020, Mustang announced a worldwide licensing agreement with SIRION Biotech ("SIRION") for the rights to SIRION's LentiBOOST™ technology for the development of MB-207, Mustang's lentiviral gene therapy for the treatment of previously transplanted patients with X-linked severe combined immunodeficiency (the "SIRION Technology License"). Pursuant to the SIRION Technology License, which requires payment in Euro, the Company paid SIRION a one-time upfront fee of $0.1 million (€0.1 million) during 2020. In addition, five future development milestone payments totaling up to approximately $5.6 million (€4.7 million) in the aggregate are due upon achievement of certain milestones. Additional milestone payments totaling up to $4.1 million (€3.5 million) in the aggregate are due in connection with the achievement of three commercial milestones and low- to mid-single digit royalties are due on aggregate cumulative worldwide net sales of licensed products.

For the year ended December 31, 2020, Mustang expensed an up-front payment of $0.1 million. There was no expense recorded for the year ended December 31, 2019.

Oncogenuity

Effective May 6, 2020, Oncogenuity entered into a license agreement with the Trustees of Columbia University in the City of New York ("Columbia") to develop novel oligonucleotides for the treatment of genetically driven cancers (the "Columbia License"). The proprietary platform produces oligomers, known as "ONCOlogues."

As consideration for the Columbia License, Oncogenuity paid an upfront fee of $0.3 million, and Fortress transferred to Columbia 1,000,000 shares of Oncogenuity common stock, representing 10.00% ownership of Oncogenuity. In connection with the share transfer, Oncogenuity also provided Columbia with limited anti-dilution protection. Oncogenuity valued the stock grant to Columbia utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 41.7%, weighted average cost of capital of 20.5%, and net of debt utilized, resulting in a value of $0.021 per share or $21,000 for the year ended December 31, 2020. Since a portion of the acquisition of the license was settled through the transfer of shares of Oncogenuity's common stock, this transaction fell within the scope of ASC Topic 718, *Compensation-Stock Compensation*, since equity was transferred in exchange for goods (the license). Specifically, Oncogenuity recorded the cost of the license as a non-employee share based payment, measured at the grant date fair value of the common stock. The common shares were equity-classified. The anti-dilution provision was concluded to represent a performance condition tied to a future liquidity event, which was not considered as probable to occur at December 31, 2020, because it was deemed outside of Oncogenuity's control.

Development milestone payments totaling up to approximately $18.0 million in the aggregate are due upon achievement of certain milestones in connection with the initial indication. Additional milestone payments totaling up to $15.3 million in the aggregate are due in connection with product development milestones for subsequent indications. A $15.0 million sales milestone is due upon the achievement of a licensed product sales threshold, and low- to mid-single digit royalties are due on aggregate cumulative worldwide net sales of licensed products.

For the year ended December 31, 2020, Oncogenuity recorded expense of $0.3 million in research and development - licenses acquired in the Company's Consolidated Statement of Operations.

Tamid

Licenses with the University of North Carolina

On November 30, 2017, Tamid entered into three exclusive AAV gene therapies licensing arrangements with the University of North Carolina at Chapel Hill ("UNC"). The preclinical product candidates acquired through these licenses target ocular manifestations of Mucopolysaccharidosis type 1 (MPS1), dysferlinopathies and corneal transplant rejections. The three therapies were developed in the lab of Matthew Hirsch, Ph.D., Assistant Professor, Ophthalmology at the UNC Gene Therapy center. In December 2019, Tamid discontinued the development of all three candidates and terminated the related licenses and clinical trial agreements with UNC. For the years ended December 31, 2020 and 2019, Tamid recorded no expense in connection with these licenses.

8. Sponsored Research and Clinical Trial Agreements

Aevitas

	For the Year Ended December 31,	
($ in thousands)	2020	2019
UMass - adeno-associated virus ("AAV")	$ 381	$ —
UPenn - AAV	567	1,067
Duke - AAV	—	66
Total	$ 948	$ 1,133

On January 25, 2018, Aevitas entered into a Sponsored Research Agreement with the University of Massachusetts ("UMass SRA") for certain continued research and development activities related to the development of adeno-associated virus ("AAV") gene therapies in complement-mediated diseases. The total amount to be funded by Aevitas under the UMass SRA is $0.8 million. Pursuant to the terms of the UMass SRA, Aevitas paid $0.8 million which was due upon execution. On May 31, 2020, a First Amendment to the UMass SRA was signed and the total amount to be funded was $0.7 million, including $0.4 million due within 30 days of execution. For the years ended December 31, 2020 and 2019, Aevitas recorded expense of approximately $0.4 million and nil, respectively, in connection with the UMass SRA. The expense was recorded in research and development expenses in the Company's Consolidated Statement of Operations.

On July 24, 2018, Aevitas entered into a Sponsored Research Agreement with the Trustees of the University of Pennsylvania ("UPenn SRA") for certain continued research and development activities related to the development of AAV gene therapies in complement-mediated diseases. The total amount to be funded by Aevitas under the UPenn SRA is $2.0 million. Pursuant to the terms of the UPenn SRA, Aevitas paid $0.3 million which was due upon execution. For the years ended December 31, 2020 and 2019, Aevitas recorded expense of approximately $0.6 million and $1.1 million, respectively, in connection with the UPenn SRA. The expense was recorded in research and development expenses in the Company's Consolidated Statement of Operations.

On September 1, 2019, Aevitas entered into a Sponsored Research Arrangement ("SRA") with Duke University School of Medicine ("Duke"). For the years ended December 31, 2020 and 2019, Aevitas recorded approximately nil and $0.1 million, respectively, for the purpose of conducting a study to identify a dose range for AAV8 vectors in Dry Age-related Macular Degeneration ("Dry AMD") in research and development expense on the Consolidated Statement of Operations.

Cellvation

In October 2016, Cellvation entered research funding agreement with the University of Texas in connection with the license for a method and apparatus for conditioning cell populations for cell therapies. In connection with this agreement Cellvation agreed to fund $0.8 million of research quarterly through March 31, 2018. The agreement was revised effective May 1, 2017, with quarterly payments extended through December 31, 2018. For the years ended December 31, 2020 and 2019, Cellvation recorded an expense of nil and $0.1 million, respectively, representing amounts due under this arrangement.

Mustang

For the years ended December 31, 2020 and 2019 Mustang recorded the following expense in research and development for sponsored research and clinical trial agreements:

	For the Year Ended December 31,	
($ in thousands)	**2020**	**2019**
City of Hope National Medical Center	$ 500	$ 2,000
CD123 (MB-102)	433	1,202
IL13Rα2 (MB-101)	530	876
Manufacturing	—	457
CS1 (MB-104)	885	—
HER2 (MB-103)	1,519	—
PSCA (MB-105)	204	—
Beth Israel Deaconess Medical Center - CRISPR	—	69
St. Jude Children's Research Hospital - XSCID (MB-107)	1,842	777
Fred Hutchinson Cancer Research Center - CD20 (MB-106)	1,804	762
Total	$ 7,717	$ 6,143

City of Hope Sponsored Research Agreement

In March 2015, in connection with Mustang's license with COH for the development of CAR T, Mustang entered into a Sponsored Research Agreement in which Mustang will fund continued research in the amount of $2.0 million per year, payable in four equal annual installments, until 2020. The research covered under this arrangement is for IL13Rα2 (MB-101), CD123 (MB-102) and the Spacer technology. For the years ended December 31, 2020 and 2019, Mustang incurred expense of $0.5 million and $2.0 million, respectively and recorded as research and development expense in the Company's Consolidated Statement of Operations.

CD123 (MB-102) Clinical Research Support Agreement

On February 17, 2017, Mustang entered into a Clinical Research Support Agreement for CD123. Pursuant to the terms of this agreement, Mustang made an upfront payment of approximately $20,000 and will contribute an additional $0.1 million per patient in connection with the on-going investigator-initiated study. Further, Mustang agreed to fund approximately $0.2 million over three years pertaining to the clinical development of CD123. For the years ended December 31, 2020 and 2019, Mustang recorded approximately $0.4 million and $1.2 million, respectively, in research and development expenses in the Company's Consolidated Statements of Operations.

CS1(MB-104) Clinical Research Support Agreement

In June 2020, Mustang entered into a clinical research and support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: "Phase I Study to Evaluate Cellular Immunotherapy Using Memory-Enriched T Cells Lentivirally Transduced to Express a CS1-Targeting, Hinge-Optimized, 41BB-Costimulatory Chimeric Antigen Receptor and a Truncated EGFR Following Lymphodepleting Chemotherapy in Adult Patients with CS1+ Multiple Myeloma." The CAR T being studied under this protocol has been designated by Mustang as MB-104. Under the terms of the agreement Mustang will reimburse COH for costs associated with this trial not to exceed $2.4 million. The agreement will expire upon the delivery of the final study report or earlier. During the year ended December 31, 2020, Mustang recorded approximately $0.9 million in research and development expenses in the Company's Consolidated Statement of Operations pursuant to this agreement.

IL13Rα2 (MB-101) Clinical Research Support Agreements

On February 17, 2017, Mustang entered into a Clinical Research Support Agreement for IL13Rα2 (the "IL13Rα2 GBM CRA"). Pursuant to the terms of this agreement Mustang made an upfront payment of approximately $9,300 and will contribute an additional $0.1 million per patient in connection with the on-going investigator-initiated study. Further, Mustang agreed to fund approximately $0.2 million over three years pertaining to the clinical development of IL13Rα2.

In October 2020, Mustang entered into a Clinical Research Support Agreement for the IL13Rα2 directed CAR T program for adult patients with Leptomeningeal Glioblastoma, Ependymoma or Medulloblastoma (the "IL13Rα2 Leptomeningeal CRA"). Pursuant to the terms of the IL13Rα2 Leptomeningeal CRA, Mustang made an upfront payment of $29,375 and will contribute an additional $0.1 million per patient in connection with the on-going investigator-initiated study. Further, the Company agreed to fund approximately $0.2 million annually pertaining to the clinical development of IL13Rα2.

For the years ended December 31, 2020 and 2019, Mustang recorded approximately $0.5 million and $0.9 million, respectively, in research and development expenses under the IL13Rα2 CRAs in the Company's Consolidated Statement of Operations.

HER2 (MB-103) Clinical Research Support Agreement

In September 2020, Mustang entered into a clinical research support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: "Phase I Study of Cellular Immunotherapy using Memory-Enriched T Cells Lentivirally Transduced to Express a HER2-Specific, Hinge-Optimized, 41BB-Costimulatory Chimeric Receptor and a Truncated CD19 for Patients with Recurrent/Refractory Malignant Glioma." The CAR T being studied under this protocol has been designated as MB-103. Under the terms of the agreement Mustang will pay COH $29,375 upon execution and will reimburse COH for costs associated with this trial not to exceed $3.0 million. The agreement will expire upon the delivery of a final study report or earlier. For the year ended December 31, 2020, Mustang recorded $1.5 million in research and development expenses in the Company's Consolidated Statement of Operations pursuant to this agreement.

PSCA (MB-105) Clinical Research Support Agreement

In October 2020, Mustang entered into a clinical research support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: "A Phase 1b study to evaluate PSCA-specific chimeric antigen receptor (CAR)-T cells for patients with metastatic castration resistant prostate cancer." The CAR T being studied under this protocol has been designated as MB-105. Under the terms of the agreement Mustang will pay COH $33,000 upon execution and will reimburse COH for costs associated with this trial not to exceed $2.3 million. The agreement will expire upon the delivery of a final study report or earlier. For the year ended December 31, 2020, Mustang recorded $0.2 million in research and development expenses in the Company's Consolidated Statement of Operations pursuant to this agreement.

City of Hope Sponsored Research Agreement - Manufacturing

On January 3, 2018, Mustang entered into a Sponsored Research Agreement ("SRA") with COH to optimize and develop CAR T cell processing procedures. Pursuant to the SRA, Mustang funded continued research in the amount of $0.9 million for the program, with an initial term of two (2) years. The SRA expired in January 2020. For the years ended December 31, 2020 and 2019, Mustang recorded approximately nil and $0.5 million, respectively, in research and development expenses in the Company's Consolidated Statements of Operations.

CRISPR Sponsored Research Agreement with Beth Israel Deaconess Medical Center, Inc.

On November 28, 2017, Mustang entered into a Sponsored Research Agreement with Beth Israel Deaconess Medical Center Inc. ("BIDMC") to perform research relating to gene editing, via the use of CRISPR/Cas9, to be used in enhancing the efficacy of CAR T cell therapies for solid tumor indications and to generate universal off the shelf CAR T cell therapies for both liquid and solid tumor indications. Mustang agreed to fund approximately $0.8 million over a three-year period. Mustang recorded nil and $0.1 million in 2020 and 2019, respectively, related to this agreement in research and development expenses in the Company's Consolidated Statements of Operations. In January 2019, Mustang terminated the SRA with BIDMC due to the departure of key personnel from BIDMC.

CD20 (MB-106) Clinical Trial Agreement with Fred Hutch

On July 3, 2017, in conjunction with the CD20 Technology License from Fred Hutch, Mustang entered into an investigator-initiated clinical trial agreement ("CD20 CTA") to provide partial funding for a Phase 1/2 clinical trial at Fred Hutch evaluating the safety and efficacy of the CD20 Technology in patients with relapsed or refractory B-cell non-Hodgkin lymphomas. In connection with the CD20 CTA, Mustang agreed to fund up to $5.3 million of costs associated with the clinical trial, which commenced during the fourth quarter of 2017. In November 2020, the CD20 CTA was amended to include additional funding of approximately $0.8 million for the treatment of five patients with chronic lymphocytic leukemia. For the years ended December 31, 2020 and 2019 Mustang recorded $1.8 million and $0.6 million of expense, respectively, related to this agreement in research and development expenses in the Company's Consolidated Statements of Operations.

CD20 (MB-106) Sponsored Research Agreement – Manufacturing with Fred Hutch

On March 17, 2018, Mustang entered into a Sponsored Research Agreement ("SRA") with Fred Hutch related to developing and optimizing processes and systems associated with CD20 cell processing. Pursuant to the SRA, Mustang funded research in the amount of $0.6 million during the term of the SRA, which expired in March 2019. For the years ended December 31, 2020 and 2019, Mustang recorded expense of nil and $0.2 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement.

XSCID (MB-107) Data Transfer Agreement with St. Jude

In June 2020, Mustang entered into a Data Transfer Agreement with St. Jude under which Mustang will reimburse St. Jude for costs associated with St. Jude's clinical trial for the treatment of infants with XSCID. Pursuant to the terms of this agreement and for the year ended December 31, 2020, Mustang paid an upfront fee of $1.1 million, which was recorded in research and development expenses in the Company's Consolidated Statement of Operations. Mustang will continue to reimburse St. Jude for costs incurred in connection with this trial.

MB-107 (XSCID) Non-Interventional Services Agreement with Children's CGMP

In December 2019, Mustang entered into a Non-Interventional Services Agreement with Children's CGMP, LLC ("Children's"), an affiliate of St. Jude Children's Research Hospital, pursuant to which Children's provides lentiviral vector for non-clinical XSCID research purposes, as well as related advisory services. Mustang agreed to fund approximately $0.8 million upon execution of the agreement, which was recorded in research and development expenses for the year ended December 31, 2019 in the Company's Consolidated Statement of Operations.

Oncogenuity

Columbia Sponsored Research Agreement

Pursuant to the terms of the Columbia License, Oncogenuity will make semi-annual research payments to Columbia over a five year period ending in November 2024; such payments not to exceed $4.8 million. For the year ended December 31, 2020, Oncogenuity recorded expense of $0.5 million in research and development in the Company's Consolidated Statements of Operations. No expense was recorded in 2019.

University of Oxford Sponsorship Agreement

On December 16, 2020 Oncogenuity entered into an agreement with The Chancellor Masters and Scholars of the University of Oxford ("Oxford"). Under the terms of the agreement Oxford will engage in preclinical development of antisense oligonulcleotides as a therapy in certain indications. In connection with the agreement Oncogenuity agreed to fund research for approximately 18 months for up to of $0.6 million (£0.4 million). Oncogenuity made an up-front payment of $0.1 million (£0.1 million) in January 2021.

Tamid

On November 30, 2017, in connection with its three separate license agreements with UNC, Tamid entered into a Sponsored Research Agreement with UNC ("UNC SRA") for certain continued research and development activities related to Nanodysferlin for treatment of Dysferlinopathy, and AAV-HLA-G for corneal transplant rejection. Total amount to be funded by Tamid under the UNC SRA is $2.3 million over a term of three years. Pursuant to the terms of the UNC SRA, Tamid paid $0.8 million which was due upon execution. For the years ended December 31, 2020 and 2019, Tamid recorded expense of nil and nil respectively in connection with the UNC SRA. The expense was recorded in research and development expenses in the Company's Consolidated Statements of Operations. Effective December 2019, Tamid returned the license to UNC and ceased to incur costs associated with the development of products under this license.

9. Intangibles

On December 18, 2020, Journey entered an Asset Purchase Agreement with a third party (the "Anti-itch Product Agreement") for a topical product that is indicated to treat scabies and skin itch conditions ("Anti-itch Product"). Pursuant to the terms and conditions of the Anti-itch Product Agreement, Journey agreed to pay $4.0 million, comprised of a non-refundable deposit of $0.2 million upon the execution of the term sheet, a cash upfront payment of $1.8 million on January 1, 2021 and additional future payments of $0.5 million on April 1, 2021, $0.5 million on July 1, 2021, and $1.0 million on January 1, 2022. There are no subsequent milestone payments or royalties beyond the aforementioned payments. Commercial launch of this product is expected in the third quarter of 2021.

The Company, in accordance with ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, determined the purchase of the Anti-itch Product did not constitute the purchase of a business, and therefore recorded the purchase price of the Anti-itch Product as an asset, to be amortized over the life of the product, which is deemed to be three years.

On July 29, 2020, Journey entered into a License and Supply Agreement with a third party to acquire intellectual property rights to an oral acne product that is indicated for the treatment of severe acne (the "Isotretinoin Agreement"). Pursuant to the terms and conditions of the Isotretinoin Agreement, Journey agreed to pay $5.0 million, comprised of an upfront payment of $1.0 million paid upon execution with remaining payments due as follows: $0.5 million upon achievement of a regulatory approval milestone and $0.5 million upon the delivery of the first order and $3.0 million due in $1.0 million installments, on the 18-month anniversary, the 24-month anniversary and the 36-month anniversary of execution of the Isotretinoin Agreement. Three additional milestone payments totaling $17.0 million are contingent upon the achievement of certain net sales milestones. Royalties in the low-double digits based on net sales, subject to specified reductions are also due. Commercial launch of this product is expected in the second quarter of 2021.

The Company, in accordance with ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, determined the purchase of the Isotretinoin Agreement did not constitute the purchase of a business, and therefore recorded the purchase price of the Isotretinoin Agreement as an asset, to be amortized over the life of the product, which is deemed to be five years.

On July 22, 2019 Journey purchased Ximino®, a minocycline hydrochloride used to treat acne from a third party. Pursuant to the terms and conditions of the Asset Purchase Agreement ("APA"), total consideration for the APA is $9.4 million, comprised of an upfront payment of $2.4 million payable within 60 days after execution on September 22, 2019. The remaining four payments totaling $7.0 million are due in consecutive years commencing on the second anniversary of execution of the APA. In addition, Journey is obligated to pay royalties in the mid-single digits based on net sales of Ximino, subject to specified reductions.

The Company, in accordance with ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, determined the purchase of Ximino did not constitute the purchase of a business, and therefore recorded the purchase price of Ximino as an asset, to be amortized over the life of the product, which is deemed to be seven years. In addition, the Company determined pursuant to ASC 450, *Contingencies,* that royalty payments in connection with the APA will be recorded when they become payable with a corresponding charge to cost of goods sold.

In accordance with the terms of the APA Journey will incur interest expense in the event of payment default. As such per ASC 835-30 *Interest-Imputed Interest,* Journey recorded an initial discount for imputed interest of $2.3 million. As of December 31, 2019, Journey recorded an intangible asset related to this transaction of $7.1 million which was recorded on the Consolidated Balance Sheet of Fortress.

On August 31, 2018, JMC entered into an agreement with a third party to acquire the exclusive rights to Exelderm®, a topical antifungal available in a cream and solution. This acquisition was recorded as an intangible asset and expense will be recognized over the expected life of Exelderm® of 3 years. JMC commenced the sale of Exelderm® in September 2018 and accordingly commenced the amortization of this cost.

In January 2016, JMC entered into a licensing agreement with a third party to distribute its prescription wound cream Luxamend ® and paid an upfront fee of $50,000. Additionally, in January 2016, JMC entered into a licensing agreement with a third party to distribute its prescription emollient Ceracade ® for the treatment of various types of dermatitis and paid an upfront fee of $0.3 million. JMC commenced the sale of both of these products during the year ended December 31, 2016 and accordingly commenced the amortization of these costs over their respective three year estimated useful life.

In March 2015, JMC entered into a license and supply agreement to acquire the rights to distribute Targadox® a dermatological product for the treatment of acne. JMC made an upfront payment of $1.3 million. Further payments will be made based on a revenue sharing arrangement. JMC received FDA approval for the manufacturing of this product in July 2016 and commenced sales of this product in October 2016.

The table below provides a summary of intangible assets as of December 31, 2020 and 2019, respectively:

($ in thousands)	Estimated Useful Lives (Years)	December 31, 2020	December 31, 2019
Total Intangible assets – asset purchases	3 to 7	$ 18,606	$ 9,934
Accumulated amortization		(3,977)	(2,557)
Net intangible assets		$ 14,629	$ 7,377

The table below provides a summary for the years ended December 31, 2020 and 2019, of recognized expense related to product licenses, which was recorded in costs of goods sold on the Consolidated Statement of Operations (see Note 19):

($ in thousands)	Intangible Assets, Net
Beginning balance at December 31, 2018	$ 1,417
Additions:	
Purchase of Ximino[1]	7,134
Amortization expense	(1,174)
Beginning balance at December 31, 2019	7,377
Additions:	
Isotretinoin Agreement[2]	4,727
Anti-itch product license acquisition[3]	3,945
Amortization expense	(1,420)
Ending balance at December 31, 2020	$ 14,629

Note 1: Includes an upfront payment of $2.4 million and four payments totaling $7.0 million due in consecutive years commencing on the second anniversary of the execution of the APA. Such payments were discounted by $2.3 million as a result of the long-term nature of such payments.

Note 2: Includes an upfront payment of $1.0 million and a milestone payment of $0.5 million in 2020 and three payments totaling $3.5 million due at various points between 2021 through 2023. Such payments were discounted by $0.3 million as a result of the long-term nature of such payments. As of December 31, 2020, this asset has not yet been placed in service, therefore no amortization expense was recognized on this asset for the year ended December 31, 2020. Journey expects the asset to be placed in service in the first half of 2021. Once the asset is placed in service Journey will amortize the asset over five years, which represents its expected useful life.

Note 3: Includes an upfront payment of $0.2 million and three payments totaling $2.8 million in 2021 and $1.0 million in 2022. Such payments were discounted by $0.1 million as a result of the long-term nature of such payments. As of December 31, 2020, this asset has not yet been placed in service, therefore no amortization expense was recognized on this asset for the year ended December 31, 2020. The Company expects to launch this asset in Q3 2021. Once the asset is placed in service Journey will amortize the asset over three years, which represents its expected useful life.

The future amortization of these intangible assets is as follows:

($ in thousands)	Ximino®	Exelderm®	Total Amortization
Year Ended December 31, 2021	$ 1,019	$ 267	$ 1,286
Year Ended December 31, 2022	1,019	—	1,019
Year Ended December 31, 2023	1,019	—	1,019
Year Ended December 31, 2024	1,019	—	1,019
Year Ended December 31, 2025	1,019	—	1,019
Thereafter	595	—	595
Sub-total	5,690	267	5,957
Intangible assets not yet placed in service	—	—	8,672
Total	$ 5,690	$ 267	$ 14,629

10. Debt and Interest

Debt

Total debt consists of the following:

($ in thousands)	December 31, 2020	2019	Interest rate	Maturity
IDB Note	$ —	$ 14,929	2.25 %	Aug - 2021
2017 Subordinated Note Financing[3]	—	3,254	8.00 %	March - 2022
2017 Subordinated Note Financing[3]	—	13,893	8.00 %	May - 2022
2017 Subordinated Note Financing[3]	—	1,820	8.00 %	June - 2022
2017 Subordinated Note Financing[3]	—	3,018	8.00 %	August - 2022
2017 Subordinated Note Financing[3]	—	6,371	8.00 %	September - 2022
2018 Venture Notes[4]	—	6,517	8.00 %	August - 2021
2018 Venture Notes[4]	—	15,190	8.00 %	September - 2021
2019 Notes[1]	—	9,000	12.00 %	September - 2021
Mustang Horizon Notes[2]	—	15,750	9.00 %	October - 2022
Oaktree Note	60,000	—	11.00 %	August - 2025
Total notes payable	60,000	89,742		
Less: Discount on notes payable	8,323	5,086		
Total notes payable	$ 51,677	$ 84,656		

Note 1: Formerly the Opus Credit Facility (see Note 17).
Note 2: Interest rate is 9.0% plus one-month LIBOR Rate in excess of 2.5%; at December 31, 2019, $1.2 million is included in Notes payable, short-term on the Consolidated Balance Sheet.
Note 3: As a result of a one year maturity date extension, the interest rate of 9.0% takes effect in year 4 of the note.
Note 4: At December 31, 2019, $6.0 million is included in Notes payable, short-term on the Consolidated Balance Sheet.

Oaktree Note

On August 27, 2020 (the "Closing Date"), Fortress, as borrower, entered into a $60.0 million senior secured credit agreement (the "Oaktree Agreement") with Oaktree. The Company borrowed the full $60.0 million in connection with the terms of the Oaktree Note on the Closing Date and used the bulk of the proceeds to repay its outstanding debt to other lenders (2017 Subordinated Notes, 2018 Venture Notes and 2019 Notes (previously the "Opus Credit Facility")).

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.

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, 2020.

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 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 (plus Caelum) 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 asets 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.

In connection with the Oaktree Note, the Company 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.

As of December 31, 2020, 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. These costs will be amortized over the term of the Oaktree Note.

IDB Note

On February 13, 2014, the Company executed a promissory note in favor of IDB in the amount of $15.0 million (the "IDB Note"). The Company borrowed $14.0 million against this note and used it to repay its prior loan from Hercules Technology Growth Capital, Inc. The Company could request revolving advances under the IDB Note in a minimum amount of $0.1 million (or the remaining amount of the undrawn balance under the IDB Note if such amount were less than $0.1 million). All amounts advanced under the IDB Note were due in full at the earlier of: (i) August 1, 2020, as extended or (ii) on the IDB's election following the occurrence and continuation of an event of default. The unpaid principal amount of each advance shall bear interest at a rate per annum equal to the rate payable on the Company's money market account plus a margin of 150 basis points. The interest rate at December 31, 2019 was 2.25%. The IDB Note contains various representations and warranties customary for financings of this type.

The obligations of the Company under the IDB Note were collateralized by a security interest in, a general lien upon, and a right of set-off against the Company's money market account of $15.0 million, which was recorded as restricted cash in the Company's Consolidated Balance Sheets, pursuant to the Assignment and Pledge of Money Market Account, dated as of February 13, 2014 (the "Pledge Agreement"). Pursuant to the Pledge Agreement, the Bank may, after the occurrence and continuation of an event of default under the IDB Note, recover from the money market account all amounts outstanding under the IDB Note. The Pledge Agreement contained various representations, warranties, and covenants customary for pledge agreements of this type.

The Company could default on the IDB Note if, among other things, it failed to pay outstanding principal or interest when due. Following the occurrence of an event of default under the IDB Note, the Bank may: (i) declare the entire outstanding principal balance of the IDB Note, together with all accrued interest and other sums due under the IDB Note, to be immediately due and payable; (ii) exercise its right of setoff against any money, funds, credits or other property of any nature in possession of, under control or custody of, or on deposit with IDB; (iii) terminate the commitments of IDB; and (iv) liquidate the money market account to reduce the Company's obligations to IDB.

On September 18, 2017, the maturity on the IDB Note was extended to August 1, 2020. In January 2020, the maturity on the IDB Note was extended to August 1, 2021. The Company applied the 10% cash flow test pursuant to ASC 470 to calculate the difference between the present value of the amended IDB Note's cash flows and the present value of the original remaining cash flow and concluded that the results didn't exceed the 10% factor, the debt modification is not considered substantially different and therefore did not apply extinguishment accounting, rather it accounted for the modification on a prospective basis pursuant to ASC 470. The Company only paid interest on the IDB Note through maturity.

During August 2020, the Company repaid the IDB Note utilizing the cash collateral securing the IDB Note, which was classified as restricted cash on the Company's Consolidated Balance Sheet.

At December 31, 2020 and 2019, the Company had approximately nil and $14.9 million, respectively, outstanding under its promissory note with IDB.

2019 Notes (formerly the Opus Credit Facility)

On September 14, 2016, Fortress entered into a Credit Facility Agreement (the "Opus Credit Facility") with Opus Point Healthcare Innovations Fund, LP ("OPHIF"). Since Fortress's Chairman, President and Chief Executive Officer (Lindsay A. Rosenwald) and Fortress's Executive Vice President, Strategic Development (Michael S. Weiss), are Co-Portfolio Managers and Partners of Opus Point Partners Management, LLC ("Opus"), an affiliate of OPHIF, all of the disinterested directors of Fortress's board of directors approved the terms of the Credit Facility Agreement and accompanying Pledge and Security Agreement and forms of Note and Warrant (collectively, the "Financing Documents").

Pursuant to the Opus Credit Facility, Fortress was eligible to borrow up to a maximum aggregate amount of $25.0 million from OPHIF and any other lender that joins the Credit Facility Agreement from time to time (OPHIF and each subsequent lender, a "Lender") under one or more convertible secured promissory notes (each a "Note") from September 14, 2016 until September 1, 2017 (the "Commitment Period"). All amounts borrowed under the Credit Facility Agreement were required to be paid in full by September 14, 2018 (the "Maturity Date"), however Fortress had the right to prepay the Notes at any time without penalty.

Pursuant to the Opus Credit Facility and form of Note, each Note will bear interest at 12% per annum and interest will be paid quarterly in arrears commencing on December 1, 2016 and on the first business day of each September, December, March and June thereafter until the Maturity Date. Upon the occurrence and continuance of an event of default (as specified in Credit Facility Agreement and form of Note), each Note will bear interest at 14% and be payable on demand. The Lenders may elect to convert the principal and interest of the Notes at any time into shares of Fortress's common stock ("Common Stock") at a conversion price of $10.00 per share. All Notes are secured by shares of capital stock currently held by Fortress in certain Fortress Companies as set forth in the Pledge and Security Agreement entered into between Fortress, its wholly owned subsidiary, FBIO Acquisition, Inc., and OPHIF (as collateral agent on behalf of all the Lenders) on September 14, 2016 (the "Pledge and Security Agreement").

Fortress may terminate the Opus Credit Facility upon notice to the Lenders and payment of all outstanding obligations under the Credit Facility Agreement. Notwithstanding any early termination of the Credit Facility Agreement, within 15 days after termination of the Commitment Period, Fortress will issue each Lender warrants (each a "Warrant") pursuant to the terms of the Credit Facility Agreement and form of Warrant to purchase their pro rata share of (a) 1,500,000 shares of Common Stock; and (b) that number of shares of Common Stock equal to the product of (i) 1,000,000, times (ii) the principal amount of all Notes divided by 25,000,000. The Warrants will have a five-year term and will be exercisable at a price of $3.00 per share.

On March 12, 2018, the Company and OPHIF amended and restated the Opus Credit Facility (the "A&R Opus Credit Facility"). The A&R Opus Credit Facility extended the maturity date of the notes issued under the Opus Credit Facility from September 14, 2018 by one year to September 14, 2019. In September 2019 the A&R Opus Credit Facility was amended to extend the maturity of the notes under the Opus Credit Facility from September 14, 2019 to September 14, 2021. The A&R Opus Credit Facility also permits the Company to make portions of interest and principal repayments in the form of shares of the Company's common stock and/or in common stock of the Company's publicly traded subsidiaries, subject to certain conditions. Fortress retains the ability to prepay the Notes at any time without penalty. The notes payable under the A&R Opus Credit Facility continue to bear interest at 12% per annum. The A&R Opus Credit Facility was accounted for as a debt modification for the year ended December 31, 2018.

On July 18, 2019, Fortress issued 396,825 common shares of Fortress at $1.26 per share to Dr. Rosenwald. The shares were issued as a prepayment by Fortress of $500,000 of debt owed to Dr. Rosenwald that was held in the name of OPHIF. The prepayment was made in the form of Fortress common stock, measured at the closing price on July 18, 2019, under that certain A&R Opus Credit Facility.

Effective December 31, 2019, OPHIF dissolved and distributed it assets among its limited partners. Following the distribution, the $9.0 million facility comprised of separate notes (collectively, the "2019 Notes") held by DAK Capital Inc. ($3.8 million); Fortress' Chairman, President and Chief Executive Officer Lindsay A. Rosenwald, M.D. ($0.3 million); Fortress's Executive Vice President, Strategic Development Michael S. Weiss ($2.0 million); and various entities and individuals affiliated with Dr. Rosenwald and Mr. Weiss ($2.9 million). The terms of the 2019 Notes did not change in connection with such reallocations.

In August, 2020, the Company used certain proceeds from the Oaktree Note to pay off the $9.0 million balance previously outstanding under the 2019 Notes. As of December 31, 2020 and 2019, nil and $9.0 million, respectively, was outstanding under the 2019 Notes.

IDB Letters of Credit

The Company has several letters of credit ("LOC") with IDB securing rent deposits for lease facilities totaling approximately $1.6 million. The 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.

2017 Subordinated Note Financing

On March 31, 2017, the Company entered into Note Purchase Agreements (the "Purchase Agreements") with NAM Biotech Fund II, LLC I ("NAM Biotech Fund") and NAM Special Situations Fund I QP, LLC ("NAM Special Situations Fund"), both of which are accredited investors, and sold subordinated promissory notes (the "Notes") of the Company (the "2017 Subordinated Note Financing") in the aggregate principal amount of $3.25 million. The Notes bear interest at the rate of 8% per annum; additionally, the Notes accrue paid-in-kind interest at the rate of 7% per annum, which will be paid quarterly in shares of the Company's common stock and/or shares of common stock of one of the Company's subsidiaries that are publicly traded, in accordance with the terms of the Notes. Each Note is due on the third anniversary of its issuance, provided that the Company may extend the maturity date for two one-year periods in its sole discretion. The 2017 Subordinated Note Financing is for a maximum of $40.0 million (which the Company may, in its sole discretion, increase to $50.0 million).

National Securities Corporation ("NSC"), a subsidiary of National and a related party, (see Note 17), pursuant to a Placement Agency Agreement entered into between the Company, NAM Biotech Fund and NSC (the "NAM Placement Agency Agreement") and a Placement Agency Agreement entered into between the Company, NAM Special Situations Fund and NSC (together with the NAM Placement Agency Agreement, the "Placement Agency Agreements") acts as placement agent in the 2017 Subordinated Note Financing. Pursuant to the terms of the Placement Agency Agreements, NSC receives (in addition to reimbursement of certain expenses) an aggregate cash fee equal to 10% of the aggregate sales price of the Notes sold in the 2017 Subordinated Note Financing to NAM Biotech Fund and NAM Special Situations Fund. The Placement Agent also receives warrants equal to 10% of the aggregate principal amount of the Notes sold in the 2017 Subordinated Note Financing divided by the closing share price of the Company's common stock on the date of closing (the "Placement Agent Warrants"). The Placement Agent Warrants are exercisable immediately at such closing share price for a period of five years. The Placement Agent will have a right of first offer for a period of 12 months for any proposed issuance of the Company's capital stock in a private financing, subject to certain exceptions, and will also have the right to participate as an investor in subsequent financings.

On March 31, 2017, the Company held its first closing of the 2017 Subordinated Note Financing and received gross proceeds of $3.2 million. NSC received a cash fee of approximately $0.3 million and warrant to purchase 87,946 shares of the Company's common stock at an exercise price of per share $3.70.

On May 1, 2017, the Company held a second closing of the 2017 Subordinated Note Financing and received gross proceeds of $8.6 million, before expenses. NSC received a placement agent fee of approximately $0.9 million in the second closing and warrants to purchase 234,438 shares of the Company's common stock at an exercise price of $3.65 per share.

On May 31, 2017, the Company held a third closing of the 2017 Subordinated Note Financing and received gross proceeds of $5.3 million, before expenses. NSC received a placement agent fee of approximately $0.5 million in the third closing and warrants to purchase 147,806 shares of the Company's common stock at an exercise price of $3.61 per share.

On June 30, 2017, the Company held a fourth closing of the 2017 Subordinated Note Financing and received gross proceeds of $1.8 million, before expenses. NSC received a placement agent fee of approximately $0.2 million in the fourth closing and warrants to purchase 38,315 shares of the Company's common stock at an exercise price of $4.75 per share.

On August 31, 2017, the Company held a fifth closing of the 2017 Subordinated Note Financing and received gross proceeds of $3.0 million, before expenses. NSC received a placement agent fee of approximately $0.3 million in the fifth closing and warrants to purchase 63,526 shares of the Company's common stock at an exercise price of $4.75 per share.

On September 30, 2017, the Company held a sixth closing of the 2017 Subordinated Note Financing and received gross proceeds of $6.4 million, before expenses. NSC received a placement agent fee of approximately $0.6 million in the sixth closing and warrants to purchase 144,149 shares of the Company's common stock at an exercise price of $4.42 per share.

In August, 2020, the Company used certain proceeds from the Oaktree Note to pay off the $28.4 million balance previously outstanding under the 2017 Subordinated Note Financing. As of December 31, 2020 and 2019, nil and $28.4 million, respectively, was outstanding under the 2017 Subordinated Note Financing.

2018 Venture Notes

During the year ended December 31, 2018, the Company closed a private placement of promissory notes for an aggregate of $21.7 million (the "2018 Venture Notes") through NSC. The Company intends to use the proceeds from the 2018 Venture Notes to acquire and license medical technologies and products through existing or recently formed Company subsidiaries. The Company may also use the proceeds to finance its subsidiaries. The notes mature 36 months from issuance, provided that during the first 24 months the Company may extend the maturity date by six months. No principal amount will be due for the first 24 months (or the first 30 months if the maturity date is extended). Thereafter, the note will be repaid at the rate of 1/12 of the principal amount per month for a period of 12 months. Interest on the note is 8% payable quarterly during the first 24 months (or the first 30 months if the note is extended) and monthly during the last 12 months.

NSC acted as the sole placement agent for the 2018 Venture Notes. The Company paid NSC a fee of $1.7 million during the three months ended March 31, 2018 in connection with its placement of the 2018 Venture Notes.

The 2018 Venture Notes allows the Company to transfer a portion of the proceeds from the 2018 Venture Notes to a Fortress subsidiary upon the completion by such subsidiary of an initial public offering in which it raises sufficient equity capital so that it has cash equal to five times the amount of the portion of the proceeds of the 2018 Venture Notes so transferred (the “SubCo Funding Threshold”).

Through December 31, 2019, the Company had transferred $3.8 million to Aevitas, $1.6 million to Tamid, $2.2 Million to Cyprium and $2.0 million to Cellvation. Notwithstanding such transfers, the Company continued to hold such debt balances as liabilities on its own balance sheet on a consolidated basis, until such time as the SubCo Funding Threshold is met with respect to a particular subsidiary.

In connection with this transfer NSC received warrants to purchase each such subsidiary’s stock equal to 25% of that subsidiary’s proceeds of the 2018 Venture Notes divided by the lowest price at which the subsidiary sells its equity in its first third party equity financing. The warrants issued have a term of 10 years and an exercise price equal to the par value of the Fortress subsidiary’s common stock. As of December 31, 2019, the warrants were contingently issuable as neither an initial public offering nor a third-party financing had occurred at any such subsidiary.

In August, 2020, the Company used certain proceeds from the Oaktree Note to pay off the $21.7 million balance previously outstanding under the 2018 Venture Notes. As of December 31, 2020 and 2019, nil and $21.7 million, respectively, was outstanding under the 2018 Venture Notes.

Mustang Horizon Notes

On March 29, 2019 (the "Closing Date"), Mustang entered into a $20.0 million Loan Agreement with Horizon Technology Finance Corporation ("Horizon"), herein referred to as the "Mustang Horizon Notes". In accordance with the Loan Agreement, $15.0 million of the $20.0 million loan was funded on the Closing Date, with the remaining $5.0 million fundable upon Mustang achieving certain predetermined milestones.

Each advance under the Mustang Horizon Notes will mature 42 months from the first day of the month following the funding of the advance. The first three advances will mature on October 1, 2022 (the "Loan Maturity Date"). Each advance accrues interest at a per annum rate of interest equal to 9.00% plus the amount by which the one-month LIBOR Rate, as reported in the Wall Street Journal, exceeds 2.50%. The Loan Agreement provides for interest-only payments commencing May 1, 2019, through and including October 1, 2020. The interest-only period may be extended to April 1, 2021, if the Company satisfies the Interest Only Extension Milestone (as defined in the Loan Agreement). Thereafter, commencing May 1, 2021, amortization payments will be payable monthly in eighteen installments of principal and interest. At its option, upon ten business days' prior written notice to Horizon, the Company may prepay all or any portion greater than or equal to $500,000 of each of the outstanding advances by paying the entire principal balance (or portion thereof) and all accrued and unpaid interest, subject to a prepayment charge of 4.0% of the then outstanding principal balance of each advance if such advance is prepaid on or before the Loan Amortization Date (as defined in the Loan Agreement), 3% if such advance is prepaid after the Loan Amortization Date applicable to such Loan, but on or prior to twelve months following the Loan Amortization Date, and 2% thereafter. In addition, a final payment equal to $250,000 for each advance (i.e., $750,000 in aggregate with respect to the initial $15.0 million) is due on the maturity date or other date of payment in full. Amounts outstanding during an event of default shall be payable on demand and shall accrue interest at an additional rate of 5.0% per annum of the past due amount outstanding.

Each advance of the loan is secured by a lien on substantially all of the assets of Mustang, other than Intellectual Property and Excluded Collateral (in each case as defined in the Loan Agreement), and contains customary covenants and representations, including a liquidity covenant, financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries.

The events of default under the Loan Agreement include, among other things, without limitation, and subject to customary grace periods, (1) Mustang's failure to make any payments of principal or interest under the Loan Agreement, promissory notes or other loan documents, (2) the Mustang's breach or default in the performance of any covenant under the Loan Agreement, (3) the occurrence of a material adverse change, (4) Mustang making a false or misleading representation or warranty in any material respect, (5) the Mustang's insolvency or bankruptcy, (6) certain attachments or judgments on the Mustang's assets, (7) the occurrence of any material default under certain agreements or obligations of Mustang involving indebtedness in excess of $250,000, or (8) failing to maintain certain minimum monthly cash balances which range from approximately $8 to $13 million over the term of the loan ($13.0 million as of December 31, 2019). If an event of default occurs, Horizon is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

The Loan Agreement also contains warrant coverage of 5% of the total amount funded. Four warrants (the "Warrants") were issued by Mustang to Horizon to purchase a combined 288,184 shares of Mustang's common stock with an exercise price of $3.47 and a fair value of $0.9 million. The Warrants are exercisable for ten years from the date of issuance. Horizon may exercise the Warrant either by (a) cash or check or (b) through a net issuance conversion. The shares of the Company's common stock will, upon request by Horizon, be registered and freely tradable following a period of six months after issuance.

Mustang paid Horizon an initial commitment fee of $0.2 million and reimbursed Horizon for $30,000 of legal fees in connection with the Loan Agreement. Mustang incurred approximately $1.2 million of legal and other direct costs in connection with the Loan Agreement.

All fees, warrants and costs paid to Horizon and all direct costs incurred by Mustang are recognized as a debt discount to the funded loans and are amortized to interest expense using the effective interest method over the term of the Loan Agreement.

On September 30, 2020, Mustang repaid the amount outstanding under the Horizon Notes in full, which was comprised of $15.0 million face value of the outstanding notes, $0.1 million in accrued and unpaid interest, a $0.8 million final payment fee and prepayment penalties of $0.6 million.

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,					
	2020			2019		
($ in thousands)	*Interest*	*Fees*	Total	*Interest*	*Fees*	Total
IDB Note	$ 246	$ —	$ 246	$ 356	$ -	$ 356
2017 Subordinated Note Financing[1]	2,870	1,890	4,760	4,220	1,381	5,601
2019 Notes	710	—	710	1,113	336	1,449
2018 Venture Notes[1]	1,253	1,000	2,253	1,737	639	2,376
LOC Fees	34	—	34	60	—	60
Mustang Horizon Notes[1,3]	1,585	2,321	3,906	1,042	710	1,752
Oaktree Note[1]	2,311	411	2,722	—	—	—
Note Payable[2]	697	—	697	—	255	255
Other	(2)	—	(2)	—	—	—
Total Interest Expense and Financing Fee	$ 9,704	$ 5,622	$ 15,326	$ 8,528	$ 3,321	$ 11,849

Note 1:For the year ended December 31, 2020, includes $1.2 million expense of unamortized debt discount fees for the 2017 Subordinated Note Financing, $0.3 million for the 2018 Venture Notes and $1.8 million for the Mustang Horizon Notes.
Note 2: Imputed interest expense related to Ximino purchase (see Note 9).
Note 3: Includes $0.6 million of prepayment penalties included in interest expense for the Mustang Horizon Notes.

11. Accrued Liabilities and other Long-Term Liabilities

Accrued expenses and other long-term liabilities consisted of the following:

($ in thousands)	December 31, 2020	2019
Accrued expenses:		
Professional fees	$ 1,236	$ 1,153
Salaries, bonus and related benefits	6,701	6,683
Research and development	5,007	4,215
Research and development - manufacturing	518	1,017
Research and development - license maintenance fees	461	361
Research and development - milestones	600	—
Accrued royalties payable	2,682	2,320
Accrued coupon funding expense	10,869	8,391
Other	1,188	1,259
Total accrued expenses	$ 29,262	$ 25,399
Other long-term liabilities:		
Deferred rent and long-term lease abandonment charge[1]	$ 1,949	$ 2,136
Partner company note payable, long-term		
Ximino agreement[2]	3,622	4,990
Isotretinoin agreement[3]	2,792	—
Anti-itch product agreement[4]	945	—
Total other long-term liabilities and partner company note payable, long-term	$ 9,308	$ 7,126

Note 1: Balance consists of deferred charges related to build-out of the New York facility

Note 2: As of December 31, 2019, Journey recorded a note payable, net of an imputed interest discount of $2.3 million, of $4.7 million in connection with its acquisition of Ximino, see Note 9. The imputed interest discount was calculating utilizing an 11.96% effective interest rate based upon a non-investment grade “CCC” rate over a five-year period. Amortization of interest discount was $0.6 million and $0.3 million for the years ended December 31, 2020 and 2019, respectively. At December 31, 2020, $2.0 million was classified as Partner company note payable, short-term on the Company’s Consolidated Balance Sheet.

Note 3: As of December 31, 2020, Journey recorded a note payable, net of an imputed interest discount of $0.3 million, of $3.7 million in connection with its acquisition of the Isotretinoin agreement, see Note 9. The imputed interest discount was calculated utilizing a 4.00% effective rate, which represents the market rate for an asset-backed three year loan, secured by receivables. Amortization of interest discount was $0.1 million for the year ended December 31, 2020. At December 31, 2020, $0.5 million of note payable was classified as Partner company note payable, short-term on the Company’s Consolidated Balance Sheet.

Note 4: As of December 31, 2020, Journey recorded a note payable, net of an imputed interest discount of $0.1 million, of $3.7 million in connection with its acquisition of an anti-itch product, see Note 9. The imputed interest discount was calculated utilizing a 4.25% effective rate, which represents the market rate for an asset-backed three year loan, secured by receivables. Amortization of interest discount was negligible for the year ended December 31, 2020. As of December 31, 2020, $2.8 million of note payable was classified as Partner company note payable, short-term on the Company’s Consolidated Balance Sheet.

12. Non-Controlling Interests

Non-controlling interests in consolidated entities are as follows:

($ in thousands)	As of December 31, 2020 NCI equity share	For the year ended December 31, 2020 Net loss attributable to non-controlling interests	As of December 31, 2020 Non-controlling interests in consolidated entities	Non-controlling ownership
Acquisition Corp VIII	$ (7)	$ (27)	$ (34)	10.0 %
Aevitas	(2,370)	(823)	(3,193)	39.0 %
Avenue [2]	5,800	(3,974)	1,826	77.4 %
Baergic	(1,662)	(97)	(1,759)	39.5 %
Cellvation	(1,089)	(182)	(1,271)	22.1 %
Checkpoint [1]	41,704	(13,265)	28,439	80.4 %
Coronado SO	(290)	—	(290)	13.0 %
Cyprium	567	(1,478)	(911)	30.5 %
Helocyte	(4,986)	(259)	(5,245)	18.8 %
JMC	138	491	629	7.1 %
Mustang [2]	116,060	(36,429)	79,631	80.9 %
Oncogenuity	(82)	(376)	(458)	25.3 %
Tamid	(663)	(40)	(703)	22.8 %
Total	$ 153,120	$ (56,459)	$ 96,661	

($ in thousands)	As of December 31, 2019 NCI equity share	For the year ended December 31, 2019 Net loss attributable to non-controlling interests	As of December 31, 2019 Non-controlling interests in consolidated entities	Non-controlling ownership
Aevitas	$ (1,249)	$ (694)	$ (1,943)	35.8 %
Avenue [2]	24,269	(19,011)	5,258	77.3 %
Baergic	23	(1,162)	(1,139)	33.0 %
Cellvation	(732)	(158)	(890)	20.6 %
Checkpoint [1]	29,389	(14,687)	14,702	78.0 %
Coronado SO	(290)	—	(290)	13.0 %
Cyprium	(320)	(99)	(419)	10.6 %
Helocyte	(4,322)	(402)	(4,724)	19.3 %
JMC	(211)	325	114	6.9 %
Mustang [2]	62,025	(25,727)	36,298	70.3 %
Tamid	(565)	(85)	(650)	22.8 %
Total	$ 108,017	$ (61,700)	$ 46,317	

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 Preferred Class A Shares which provide super-majority voting rights.

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, 2020 and 2019 have been excluded from the computations of diluted weighted average shares outstanding as the effect of including such securities would be antidilutive:

	Year Ended December 31,	
	2020	2019
Warrants to purchase Common Stock	3,419,812	2,729,186
Options to purchase Common Stock	1,103,643	1,179,680
Convertible preferred stock	—	1,038,251
Unvested Restricted Stock	14,302,004	12,625,144
Unvested Restricted Stock Units	391,336	721,478
Total	19,216,795	18,293,739

14. Stockholders' Equity

Common Stock

At the Company's 2020 Annual Meeting of Stockholders held on June 17, 2020, its stockholders approved an amendment to its certificate of incorporation to increase the number of authorized shares of common stock available to issue by 50,000,000 to 150,000,000 with a par value of $0.001 per share. The amendment was filed with the Secretary of State of the State of Delaware on June 18, 2020. 94,877,492 and 74,027,425 shares of common stock are outstanding at December 31, 2020 and 2019, respectively.

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

Voting Rights

Each holder of Common Stock is entitled to one vote per share of Common Stock held on all matters submitted to a vote of the stockholders,f 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 Preferred Stock

On October 26, 2017, the Company designated 5,000,000 shares of $0.001 par value preferred stock as Series A Preferred Stock. As of December 31, 2020, and 2019, 3,427,138 and 1,341,167 shares, respectively, 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 $6.5 million and $2.6 million of dividends in Additional Paid in Capital on the Consolidated Balance Sheets as of December 31, 2020 and 2019, 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.

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, 2020, 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, the Company's Board of Directors and stockholders approved an increase of 3,000,000 shares bringing the total number of shares approved under this plan to 13,000,000, with the aggregate total of authorized shares available for grants under the 2007 Plan and the 2013 Plan of up to 19,000,000 shares. An aggregate 14,721,911 shares were granted under both the Company's 2007 and 2013 plans, net of cancellations, and 4,278,089 shares were available for issuance as of December 31, 2020.

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, 2020:

Partner Company	Stock Plan	Shares Authorized	Shares available at December 31, 2020
Aevitas	Aevitas Therapeutics, Inc. 2018 Long Term Incentive Plan	2,000,000	1,602,000
Avenue	Avenue Therapeutics, Inc. 2015 Stock Plan	2,000,000	229,436
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	9,000,000	4,288,465
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	3,642,857	34,000
Mustang	Mustang Bio, Inc. 2016 Incentive Plan	5,000,000	1,180,085
Oncogenuity, Inc.	FBIO Acquisition Corp. VII 2017 Incentive Plan	2,000,000	1,600,000
Tamid	FBIO Acquisition Corp. V 2017 Incentive Plan	2,000,000	1,600,000

The purpose of the Company's and partner company's 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, 2020 and 2019

($ in thousands)	Year Ended December 31, 2020	2019
Employee awards	$ 4,991	$ 3,666
Executive awards of Fortress Companies' stock	1,504	1,428
Non-employee awards	159	121
Warrants	130	97
Partner Companies:		
Avenue	710	1,839
Checkpoint	2,780	3,121
Mustang	2,987	2,664
Other	190	252
Total stock-based compensation expense	$ 13,451	$ 13,188

For the years ended 2020 and 2019, $3.2 million and $2.8 million was included in research and development expenses, and $10.3 million and $10.4 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:

	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, 2018	1,285,501	$ 3.75	$ —	2.93
Granted	125,000	1.18	173,750	
Options vested and expected to vest at December 31, 2019	1,410,501	$ 4.30	$ 684,752	2.33
Exercised	(100,000)	1.18	—	—
Forfeited	(257,011)	2.57	—	—
Options vested and expected to vest at December 31, 2020	1,053,490	$ 5.02	$ 647,482	2.63

During the years ended December 31, 2020 and 2019, there were no exercises of stock options.

As of December 31, 2020, the Company had no unrecognized stock-based compensation expense related to options.

Restricted Stock

Stock-based compensation expense from restricted stock awards and restricted stock units for the years ended December 31, 2020 and 2019 was $12.5 million and $11.5 million, respectively.

During 2020, the Company granted 1.9 million restricted shares of its Common Stock to executives and directors of the Company and 0.6 million restricted stock units to employees and non-employees of the Company. The fair value of the restricted stock awards issued during 2020 of $4.8 million and the fair value of the restricted stock unit awards issued during 2020 of $2.4 million were estimated on the grant date using the Company's stock price as of the grant date. The 2020 restricted stock awards and restricted stock unit awards vest upon both the passage of time as well as meeting certain performance criteria. 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 milstone will be achieved.

During 2019, the Company granted 1.5 million restricted shares of its Common Stock to executives and directors of the Company and 0.3 million restricted stock units to employees and non-employees of the Company. The fair value of the restricted stock awards issued during 2019 of $1.4 million and the fair value of the restricted stock unit awards issued during 2019 of $0.4 million were estimated on the grant date using the Company's stock price as of the grant date. The 2019 restricted stock awards and restricted stock unit awards vest upon both the passage of time as well as meeting certain performance criteria. 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 milstone will be achieved.

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, 2018	12,645,982	$ 2.72
Restricted stock granted	1,546,408	0.88
Restricted stock vested	(220,000)	3.16
Restricted stock units granted	290,000	1.49
Restricted stock units forfeited	(135,416)	3.91
Restricted stock units vested	(358,960)	3.61
Unvested balance at December 31, 2019	13,768,014	$ 2.46
Restricted stock granted	1,873,072	2.57
Restricted stock vested	(230,000)	2.78
Restricted stock units granted	630,126	3.82
Restricted stock units forfeited	(148,750)	3.30
Restricted stock units vested	(384,958)	3.49
Unvested balance at December 31, 2020	15,507,504	$ 2.49

The total fair value of restricted stock units and awards that vested during the years ended December 31, 2020 and 2019 was $2.0 million and $2.0 million, respectively. As of December 31, 2020, the Company had unrecognized stock-based compensation expense related to all unvested restricted stock and restricted stock unit awards of $12.6 million and $3.1 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 4.1 years and 2.8 years, respectively. This amount does not include 0.1 million restricted stock units as of December 31, 2020 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, 2020 and 2019, certain non-employee directors elected to defer an aggregate of 230,000 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, 2020, 577,301 shares have been purchased and 422,699 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, 2020 and 2019, 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, 2018	2,754,189	$ 3.28	$ —	3.49
Granted	60,000	1.92	39,000	—
Forfeited	(73,009)	5.65	—	—
Outstanding as of December 31, 2019	2,741,180	$ 3.19	$ 111,000	2.73
Granted	1,849,450	3.14	101,000	—
Forfeited	(9)	3.00	2	—
Outstanding as of December 31, 2020	4,590,621	$ 3.17	$ 607,848	4.85
Exercisable as of December 31, 2020	4,430,621	$ 3.21	$ 452,848	4.80

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 will be amortized over the term of the Oaktree Note (see Note 10). As of December 31, 2020, 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, 2020 and 2019, the Compensation Committee granted 801,536 and 648,204 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 2019 and 2018. The shares are subject to repurchase by the Company until both of the following conditions are met: (i) the Company's market capitalization increases 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 $2.1 million for the 2020 grant and $0.6 million for the 2019 grant. For the year ended December 31, 2020 and 2019, the Company recorded stock compensation expense of approximately $2.5 million and $1.4 million, respectively related to the LTIP grants on the Consolidated Statements of Operations.

Capital Raise

2019 Common Stock At the Market Offering

On June 28, 2019, the Company entered into an At Market Issuance Sales Agreement ("2019 Common ATM"), with Cantor Fitzgerald & Co., Oppenheimer & Co., Inc., H.C. Wainwright & Co. Inc., Jones Trading Institutional Services LLC and B. Riley, as selling agents, governing potential sales of the Company's common stock. For the years ended December 31, 2020 and 2019, the Company issued approximately 17.4 million and 3.8 million shares of common stock, respectively, for gross proceeds of $47.5 million and $5.6 million, respectively, at an average selling price of $2.73 and $1.49, respectively. Under the 2019 Common ATM, the Company pays the agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock, and in connection with these sales, with respect to the years ended December 31, 2020 and 2019, the Company paid aggregate fees of approximately $1.4 million and $0.2 million, respectively.

Common Stock At the Market Offering

On August 17, 2016, the Company entered into an Amended and Restated At Market Issuance Sales Agreement, or Sales Agreement, with MLV & Co. LLC, or MLV, and FBR Capital Markets & Co., or FBR ("ATM"). On August 18, 2016, the Company filed a Registration Statement on Form S-3, which became effective on December 1, 2016 and permits the Company to issue and sell shares of its common stock having an aggregate offering price of up to $53.0 million from time to time through MLV and FBR, as sales agents under the Sales Agreement. The Sales Agreement terminated on August 17, 2019.

Pursuant to the terms of the ATM, for the year ended December 31, 2019, the Company issued approximately 8.0 million shares of common stock, respectively, at an average price of $1.88 per share for gross proceeds of $15.1 million. In connection with these sales, the Company paid aggregate fees of approximately $0.3 million, respectively.

2019 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock Offering

In November 2019, the Company completed an underwritten public offering of 262,500 shares of its 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock, (Nasdaq: FBIOP) (the "Preferred Stock"), (plus a 45-day option to purchase up to an additional 39,375 shares, which was exercised in November, 2019) at a price of $20 per share for gross proceeds of approximately $6.0 million, before deducting underwriting discounts and commissions and offering expenses.

On February 14, 2020, the Company announced the closing of an underwritten public offering, whereby it sold 625,000 shares of its Preferred Stock, (plus a 45-day option to purchase up to an additional 93,750 shares, which was exercised in February 2020) at a price of $20.00 per share for gross proceeds of approximately $14.4 million, before deducting underwriting discounts and commissions and offering expenses of approximately $1.3 million.

On May 29, 2020, the Company closed on an underwritten public offering whereby it sold 555,556 shares of its Preferred Stock, (plus a 45-day option to purchase up to an additional 83,333 shares, which was exercised in May 2020) at a price of $18.00 per share for gross proceeds of approximately $11.5 million, before deducting underwriting discounts and commissions and offering expenses of approximately $1.1 million.

On August 26, 2020, the Company closed on an underwritten public offering whereby it sold 666,666 shares of its Preferred Stock, (plus a 45-day option to purchase up to an additional 66,666 shares, which was exercised in August 2020) at a price of $18.00 per share for gross proceeds of approximately $13.2 million, before deducting underwriting discounts and commissions and offering expenses of approximately $1.1 million.

2018 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock At the Market Offering

On April 5, 2018, the Company entered into an At Market Sales Agreement (the "2018 Preferred ATM"), with B. Riley, National Securities Corporation, LifeSci Capital LLC, Maxim Group LLC and Noble Capital Markets, Inc. as selling agents, governing the issuance of the Company's 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock ("Perpetual Preferred Stock"). For the year ended December 31, 2019, the Company issued 39,292 shares of Perpetual Preferred Stock for gross proceeds $0.8 million at an average selling price of $20.67. No shares of Perpetual Preferred Stock were issued in 2018. Under the 2018 Preferred ATM, the Company pays the agents a commission rate of up to 7.0% of the gross proceeds from the sale of any shares of Perpetual Preferred Stock, and in connection with these sales, with respect to the year ended December 31, 2019, the Company paid aggregate fees of approximately $24,000.

The above-mentioned shares of Perpetual Preferred Stock were sold under the 2016 Shelf. The 2016 Shelf expired on December 1, 2019.

2019 Shelf

The 2019 offerings of both common stock and preferred stock were sold under the Company's shelf registration statement on Form S-3 originally filed on July 6, 2018 and declared effective July 23, 2019 (the "2019 Shelf"). The shares of common stock were sold under the Company's shelf registration statement on Form S-3 originally filed on July 6, 2018 and declared effective July 23, 2019 (the "2019 Shelf") through May 27, 2020.

2020 Shelf

On May 18, 2020, the Company filed a new shelf registration statement on Form S-3, 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"), with Cantor Fitzgerald & Co., Oppenheimer & Co., Inc., H.C. Wainwright & Co. Inc., B. Riley and Dawson James Securities, Inc., as selling agents, governing potential sales of the Company's common stock. ATM sales commencing on June 1, 2020 were made under the 2020 Shelf as were Perpetual Preferred Offerings. Approximately $26.7 million of securities remain available for sale under the 2020 Shelf at December 31, 2020.

Cyprium 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock Offering

On August 28, 2020, Cyprium closed on an underwritten public offering whereby it sold 255,400 shares of its 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock ("Cyprium Perpetual Preferred Stock" or "Cyprium PPS"), plus an overallotment of an additional 64,600 shares, which was exercised on September 18, 2020, at a price of $25.00 per share for gross proceeds of $8.0 million, before deducting underwriting discounts and commissions and offering expenses of approximately $0.9 million (the "Cyprium Offering").

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

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

Cyprium paid an initial dividend of $49,883 ($0.19531 per share) to shareholders of record on September 30, 2020. Cyprium paid $0.2 million in dividends for the year ended December 31, 2020.

Checkpoint Therapeutics, Inc.

In November 2017, the Checkpoint filed a shelf registration statement on Form S-3 (No. 333-221493) (the "Checkpoint 2017 S-3"), which was declared effective in December 2017. Under the Checkpoint S-3, Checkpoint may sell up to a total of $100 million of its securities. In connection with the Checkpoint S-3, Checkpoint entered into an At-the-Market Issuance Sales Agreement (the "Checkpoint 2017 ATM") with Cantor Fitzgerald & Co., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock. Under the Checkpoint 2017 ATM, Checkpoint pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. The Checkpoint 2017 S-3 expired in December 2020.

During the year ended December 31, 2020, Checkpoint sold a total of 5,104,234 shares of common stock under the Checkpoint ATM for aggregate total gross proceeds of approximately $12.8 million at an average selling price of $2.50 per share, resulting in net proceeds of approximately $12.4 million after deducting commissions and other transaction costs.

During the year ended December 31, 2019, Checkpoint sold a total of 2,273,189 shares of common stock under the Checkpoint ATM for aggregate total gross proceeds of approximately $8.0 million at an average selling price of $3.52 per share, resulting in net proceeds of approximately $7.8 million after deducting commissions and other transaction costs.

In September 2020, Checkpoint completed an underwritten public offering in which it sold 7,321,429 shares of its common stock at a price of $2.80 per share for gross proceeds of approximately $20.5 million. Total net proceeds from the offering were approximately $18.9 million, net of underwriting discounts and offering expenses of approximately $1.6 million. The shares were sold under the Checkpoint 2017 S-3.

In November 2019, Checkpoint completed an underwritten public offering of 15,400,000 shares of its common stock at a price of $1.27 per share for gross proceeds of approximately $19.6 million. Total net proceeds from the offering were approximately $17.6 million, net of underwriting discounts and offering expenses of approximately $2.0 million. The shares were sold under the Checkpoint 2017 S-3.

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 S-3, Checkpoint entered into an ATM (the "Checkpoint 2020 ATM") with Cantor Fitzgerald & Co., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each an “Agent” and collectively, the “Agents”), relating to the sale of shares of common stock. Under the ATM, Checkpoint pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

As of December 31, 2020, approximately $83.6 million of the shelf remains available for sale under the Checkpoint 2020 S-3.

Mustang Bio, Inc.

On July 13, 2018, Mustang filed a shelf registration statement No. 333-226175 on Form S-3 , as amended on July 20, 2018 (the "2018 Mustang S-3"), which was declared effective in August 2018. Under the 2018 Mustang S-3, Mustang may sell up to a total of $75.0 million of its securities. In connection with the 2018 Mustang S-3, Mustang entered into an At-the-Market Issuance Sales Agreement (the "Mustang ATM") with B. Riley Securities, Inc. (Formerly B. Riley FBR, Inc.), Cantor Fitzgerald & Co., National Securities Corporation, and Oppenheimer & Co. Inc. (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock. Under the Mustang ATM, Mustang pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

During the year ended December 31, 2020, Mustang issued approximately 17.6 million shares of common stock at an average price of $3.40 per share for gross proceeds of $59.8 million under the Mustang ATM. In connection with these sales, Mustang paid aggregate fees of approximately $1.1 million for net proceeds of approximately $58.7 million.

During the year ended December 31, 2019, Mustang issued approximately 3.5 million shares of common stock at an average price of $6.42 per share for gross proceeds of $22.5 million under the Mustang ATM. In connection with these sales, Mustang paid aggregate fees of approximately $0.5 million for net proceeds of approximately $22.0 million.

On June 11, 2020, Mustang entered into an underwriting agreement (the “Mustang Underwriting Agreement”) with Cantor Fitzgerald & Co., as representative of the underwriters named therein (each, an “Underwriter” and collectively with Cantor Fitzgerald & Co., the “Underwriters”). In connection with the Mustang Underwriting Agreement, Mustang issued 10,769,231 shares of common stock (plus a 30-day option to purchase up to an additional 1,615,384 shares of common stock, of which 686,373 were exercised) at a price of $3.25 per share for gross proceeds of approximately $37.2 million, before deducting underwriting discounts and commissions and offering expenses. In connection with the public offering, Mustang paid aggregate fees of approximately $2.4 million for net proceeds of approximately $34.8 million. The shares were sold under the Mustang S-3 registrations filed with the Securities and Exchange Commission. The offering closed on June 15, 2020, and the over-allotment closed on June 25, 2020.

In April 2019, Mustang completed an underwritten public offering of 6,875,000 shares of its common stock, (plus a 30-day option to purchase up to an additional 1,031,250 shares of common stock, which was exercised in May 2019) at a price of $4.00 per share for gross proceeds of approximately $31.6 million, before deducting underwriting discounts and commissions and offering expenses. The shares were sold under the 2018 Mustang S-3. Mustang paid aggregate fees of approximately $2.1 million and received approximately $29.5 million of net proceeds.

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 on December 4, 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, 2020, approximately $85.7 million of the 2020 Mustang S-3 remains available for sales of securities.

On August 16, 2019, Mustang filed a shelf registration statement No. 333-233350 on Form S-3 (the "2019 Mustang S-3"), which was declared effective on September 30, 2019. Under the 2019 Mustang S-3, Mustang may sell up to a total of $75.0 million of its securities. As of December 31, 2020, the 2019 S-3 is no longer available for sales of securities.

15. Commitments and Contingencies

Leases

On October 3, 2014, the Company entered into a 15-year lease for office space at 2 Gansevoort Street, New York, NY 10014, at an average annual rent of $2.5 million. The Company took possession of this space, which serves as its principal executive offices, in December 2015, and took occupancy in April 2016. Total rent expense, over the full term of the lease for this space will approximate $40.7 million. In conjunction with the lease, the Company entered into Desk Space Agreements with two related parties: OPPM and TGTX, to occupy 10% and 45%, respectively, of the office space that requires them to pay their share of the average annual rent of $0.3 million and $1.1 million, respectively. The total net rent expense will approximate $16.0 million over the lease term. These initial rent allocations will be adjusted periodically for each party based upon actual percentage of the office space occupied. Additionally, the Company has reserved the right to execute desk space agreements with other third parties and those arrangements will also affect the cost of the lease actually borne by us.

In October 2015, the Company entered into a 5-year lease for approximately 6,100 square feet of office space in Waltham, MA at an average annual rent of approximately $0.2 million. The Company took occupancy of this space in January 2016. In December 2020, we amended our lease and entered into a new two-year extension of the same office space in Waltham, MA at an average annual rent of $0.2 million. The term of this amended lease commences on April 1, 2021 and will expire on March 31, 2023.

Journey

In June 2017, Journey extended its lease for 2,295 square feet of office space in Scottsdale, AZ by one year, at an average annual rent of approximately $55,000. Journey originally took occupancy of this space in November 2014. In August 2018, Journey amended their lease and entered into a new two-year extension for 3,681 square feet of office space in the same location in Scottsdale, AZ at an annual rate of approximately $94,000. The term of this amended lease commenced on December 1, 2018 and will expire on November 30, 2020. In August 2020, Journey amended their lease and entered into a new 25-month extension of the same office space in Scottsdale, AZ at an average annual rent of $0.1 million. The term of this amended lease commenced on December 1, 2020 and will expire on December 31, 2022.

Mustang

On October 27, 2017, Mustang entered into a lease agreement with WCS - 377 Plantation Street, Inc., a Massachusetts nonprofit corporation ("Landlord"). Pursuant to the terms of the lease agreement, Mustang agreed to lease 27,043 square feet from the Landlord, located at 377 Plantation Street in Worcester, MA (the "Facility"), through November 2026, subject to additional extensions at Mustang's option. Base rent, net of abatements of $0.6 million over the lease term, totals approximately $3.6 million, on a triple-net basis.

The terms of the lease also require that Mustang post an initial security deposit of $0.8 million, in the form of $0.5 million letter of credit and $0.3 million in cash, which increased to $1.3 million ($1.0 million letter of credit, $0.3 million in cash) on November 1, 2019. After the fifth lease year, the letter of credit obligation is subject to reduction.

The Facility began operations for the production of personalized CAR T and gene therapies in 2018.

The Company leases copiers under agreements classified as operating leases that expire on various dates through 2024.

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, 2020, the Company had operating lease liabilities of $24.7 million and right of use assets of $20.5 million, which were included in the Consolidated Balance Sheet.

During the years ended December 31, 2020 and 2019, the Company recorded $3.2 million and $3.2 million, respectively, as lease expense to current period operations.

	Year Ended December 31,	
($ in thousands)	**2020**	**2019**
Lease Cost		
Operating lease cost	$ 3,246	$ 3,199
Shared lease costs	(1,873)	(1,876)
Variable lease cost	593	801
Total lease expense	$ 1,966	$ 2,124

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

($ in thousands)	Year Ended December 31, 2020	2019
Operating cash flows from operating leases	$ (2,958)	$ (3,001)
Right-of-use assets exchanged for new operating lease liabilities	634	—
Weighted-average remaining lease term – operating leases (years)	5.7	6.3
Weighted-average discount rate – operating leases	6.3 %	6.2 %

($ in thousands)	Future Lease Liability
Year Ended December 31, 2021	$ 3,353
Year Ended December 31, 2022	3,461
Year Ended December 31, 2023	3,233
Year Ended December 31, 2024	3,193
Year Ended December 31, 2025	3,244
Other	17,028
Total operating lease liabilities	33,512
Less: present value discount	(8,772)
Net operating lease liabilities, short-term and long-term	$ 24,740

The Company recognizes rent expense on a straight-line basis over the non-cancellable lease term. Rent expense for the years ended December 31, 2020 and 2019 was $2.0 million and $2.1 million, respectively.

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. Pursuant to agreements with clinical trial sites, the Company provides indemnification to such sites in certain conditions.

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.

In November 2020, a purported securities class action complaint was filed in the U.S. District Court for the Eastern District of New York, putatively on behalf of all shareholders who purchased or otherwise acquired Fortress securities between December 11, 2019 and October 9, 2020 (the "Class Period"), and who were allegedly damaged in connection therewith. The case is captioned *Cushman v. Fortress Biotech, Inc., et al.*, Case No. 1:20-cv-05767, and names as defendants the Company and two of our officers. The complaint alleges that, throughout the Class Period, the Company made false and/or misleading statements and/or failed to disclose various facts and circumstances with respect to a New Drug Application filed by Avenue Therapeutics, Inc., our partner company, regarding IV Tramadol, Avenue's lead product candidate. The complaint alleges violations of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and seeks damages as well as attorneys' fees, expert fees and other costs. The action is in the early stages of litigation, and the Company intends to vigorously contest the claims.

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, 2020 and 2019, the Company paid a matching contribution of $0.5 million and $0.4 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 9.9% and 11.6% of the Company's issued and outstanding Common Stock as of December 31, 2020 and 2019, respectively. The Company's Executive Vice Chairman, Strategic Development individually owns approximately 10.8% and 12.7% of the Company's issued and outstanding Common Stock at December 31, 2020 and 2019, 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 $0.6 million and $0.5 million, and received payments of $0.5 million and $0.5 million for the years ended December 31, 2020 and 2019, respectively.

Desk Share Agreements with TGTX and OPPM

In September 2014, the Company entered into Desk Share Agreements with TGTX and Opus Point Partners Management, LLC ("OPPM") to occupy 40% and 20% of the New York, NY office space that requires TGTX and OPPM to pay their share of the average annual rent. These initial rent allocations will be adjusted periodically for each party based upon actual percentage of the office space occupied. Additionally, the Company has reserved the right to execute desk share agreements with other third parties and those arrangements will also affect the cost of the lease actually borne by the Company. Each initial Desk Share Agreement has a term of five years. The Company took possession of the New York, NY office space in December 2015, commenced build out of the space shortly thereafter and took occupancy of the space in April 2016. The Desk Share Agreement was amended in May 2016, adjusting the initial allocations to 45% for TGTX and 10% for OPPM. The Desk Share Agreement was amended again in 2020, adjusting the rent allocations to 65% for TGTX and 0% for OPPM.

In connection with the Company's Desk Space Agreements for the New York, NY office space, for the years ended December 31, 2020 and 2019, the Company had paid $2.6 million and $2.6 million in rent, respectively, and invoiced TGTX and OPPM approximately $1.6 million and $1.3 million and nil and $0.2 million respectively, for their prorated share of the rent base. At December 31, 2020, the amount due related to this arrangement from TGTX and OPPM approximated nil and $0.4 million, respectively.

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, 2020 and 2019, the Company had paid approximately $0.3 million and $0.2 million in rent for the Waltham, MA office, and invoiced TGTX approximately $0.1 million and $0.1 million, respectively.

As of December 31, 2020 and 2019, the Company had paid a total of $2.9 million and $2.8 million, respectively, in rent under the Desk Share Agreements for both the New York, NY office and the Waltham, MA office combined, and invoiced TGTX approximately $1.7 million and $1.4 million, respectively, for their prorated share of the rents.

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.

2019 Notes (formerly the Opus Credit Facility)

On September 14, 2016, the Company and Opus Point Health Innovations Fund ("OPHIF") entered into a Credit Facility Agreement (the "Opus Credit Facility"). Fortress's Chairman, President and Chief Executive Officer (Lindsay A. Rosenwald) and Fortress's Executive Vice President, Strategic Development (Michael Weiss), are Co-Portfolio Managers and Partners of OPPM, an affiliate of OPHIF. As such, all of the disinterested directors of Fortress's board of directors approved the terms of the Opus Credit Facility and related agreements.

On March 12, 2018, the Company and OPHIF amended and restated the Opus Credit Facility (the "A&R Opus Credit Facility"). The A&R Opus Credit Facility extended the maturity date of the notes issued under the Opus Credit Facility from September 14, 2018 by one year to September 14, 2019. On September 13, 2019, the Company and OPHIF extended the maturity dates of the notes from September 14, 2019 by two years to September 14, 2021. Fortress retained the ability to prepay the Notes at any time without penalty. The notes payable under the A&R Opus Credit Facility bear interest at 12% per annum.

Effective December 31, 2019, OPHIF dissolved and distributed it assets among its limited partners. Following the distribution, the $9.0 million facility comprised of separate notes (collectively, the "2019 Notes") held by DAK Capital Inc. ($3.8 million); Fortress' Chairman, President and Chief Executive Officer Lindsay A. Rosenwald, M.D. ($0.3 million); Fortress's Executive Vice President, Strategic Development Michael S. Weiss ($2.0 million); and various entities and individuals affiliated with Dr. Rosenwald and Mr. Weiss ($2.9 million). The terms of the 2019 Notes did not change in connection with such reallocations.

During the year ended December 31, 2020, the Company used certain proceeds from the Oaktree Note to pay off the $9.0 million balance previously outstanding under the 2019 Notes. For the year ended December 31, 2020, in connection with the 2019 Notes pay off, the Company paid $0.5 million in interest on the portion of the 2019 Notes held by the Company's Chairman, President and Chief Executive Officer and the Company's Executive Vice President, Strategic Development.

2018 Venture Notes

For the year ended December 31, 2018, the Company raised approximately $21.7 million in promissory notes. National Securities Corporation ("NSC"), a wholly owned subsidiary of National, and a related party as a result of the Company's ownership of National, acted as the sole placement agent for the 2018 Venture Notes. In November 2018, the Company announced that it had an agreement to sell its majority holding in National, the sale was completed in February of 2019, see Note 3. During the year ended December 31, 2020, the Company used certain proceeds from the Oaktree Note to pay off the $21.7 million balance previously outstanding under the 2018 Venture Notes.

2017 Subordinated Note Financing

On March 17, 2017, the Company and NSC entered into placement agency agreements with NAM Biotech Fund and NAM Special Situation Fund in connection with the sale of subordinated promissory notes (see Note 10). Pursuant to the terms of the agreements, NSC received a placement agent fee in cash of 10% of the debt raised and warrants equal to 10% of the aggregate principal amount of debt raised divided by the closing share price of the Company's common stock on the date of closing.

For the year ended December 31, 2017, NSC earned a placement agent fee of $2.8 million and a Placement Agent Warrant to purchase 716,180 shares of the Company's common stock, all of which are outstanding, with exercise prices ranging from $3.61 to $4.75. During the year ended December 31, 2020, the Company used certain proceeds from the Oaktree Note to pay off the $28.4 million balance previously outstanding under the 2017 Subordinated Note Financing.

Avenue Credit Facility Agreement

On June 12, 2020, Avenue, the Company and InvaGen entered into a Facility Agreement ("Avenue Facility Agreement"), under which, beginning on October 1, 2020, Avenue may borrow up to $2.0 million collectively from the Company and InvaGen, subject to certain conditions set forth therein. The Company's commitment amount is $0.8 million, and InvaGen's is $1.2 million, and a 7% per annum interest rate applies (payable on the last day of each fiscal quarter). Repayment of the loan is due upon the earliest to occur of: (i) the Second Stage Closing Date, as defined in the Avenue SPMA; (ii) April 29, 2021; and (iii) the date that is 30 days following the termination of the Avenue SPMA. As of December 31, 2020, there have been no amounts drawn by Avenue on the Avenue Facility Agreement.

Founders Agreement and Management Services Agreement

The Company has entered into Founders Agreements with each of the Fortress partner companies 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 and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, the Company will loan each such partner company 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 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, 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'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 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 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 that has a Founders Agreement with the Company.

As additional consideration under the Founders Agreement, each partner company 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, payable within five (5) business days of the closing of any equity or debt financing for each partner company 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'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'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 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%).

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' certificates of incorporation.

Fortress Partner Company	Effective Date [1]	PIK Dividend as a % of fully diluted outstanding capitalization	Class of Stock Issued
Helocyte	March 20, 2015	2.5 %	Common Stock
Avenue	February 17, 2015	0.0 %[2]	Common Stock
Mustang	March 13, 2015	2.5 %	Common Stock
Checkpoint	March 17, 2015	0.0 %[3]	Common Stock
Cellvation	October 31, 2016	2.5 %	Common Stock
Caelum	January 1, 2017	0.0 %[4]	Common Stock
Baergic	December 17, 2019[5]	2.5 %	Common Stock
Cyprium	March 13, 2017	2.5 %	Common Stock
Aevitas	July 28, 2017	2.5 %	Common Stock
Oncogenuity	April 22, 2020 [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 will not be paid or accrued.

Note 3: 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 4: Effective January 31, 2019 the Caelum Founders Agreement and MSA with Fortress were terminated in conjunction with the execution of the DOSPA between Caelum and Alexion (See Note 4).

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' certificates of incorporation for the years ended December 31, 2020 and 2019 ($ in thousands):

Partner company	PIK Dividend Date	Year Ended December 31, 2020[1]	Year Ended December 31, 2019
Aevitas	January 1	$ 11	$ 6
Caelum[2]	January 1	—	—
Cellvation	January 1	7	7
Checkpoint	January 1	4,617	2,510
Cyprium	January 1	711	5
Helocyte	January 1	138	131
Mustang	January 1	7,577	4,923
Tamid	January 1	—	7
Fortress		(13,061)	(7,589)
Total		$ —	$ —

Note 1: Includes 2021 PIK dividend accrued for the year ended December 31, 2020, as Type 1 subsequent event.
Note 2: Pursuant to the terms of the Amended and Restated Mutual Conditional Termination Agreement between Fortress and Caelum, the Founders Agreement dated January 1, 2017 was terminated upon signing of the DOSPA with Alexion on January 30, 2019.

Management Services Agreements

The Company has entered into Management Services Agreements (the "MSAs") with certain of its partner companies. Pursuant to each MSA, the Company's management and personnel provide advisory, consulting and strategic services to each partner company 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 partner company's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of each such partner company with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). Each such partner company 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 partner companies are not obligated to take or act upon any advice rendered from Fortress, and the Company shall not be liable to any such partner company for its actions or inactions based upon the Company's advice. The Company and its affiliates, including all members of Fortress' Board of Directors, have been contractually exempted from fiduciary duties to each such partner company relating to corporate opportunities.

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

		Year Ended December 31,	
Fortress partner company	**Effective Date**	**2020**	**2019**
Helocyte	March 20, 2015	$ 500	$ 500
Avenue [1]	February 17, 2015	—	—
Mustang	March 13, 2015	500	500
Checkpoint	March 17, 2015	500	500
Cellvation	October 31, 2016	500	500
Baergic	March 9, 2017	500	500
Cyprium	March 13, 2017	500	500
Aevitas	July 28, 2017	500	500
Tamid[2]	November 30, 2017	—	500
Oncogenuity[3]	February 10, 2017	500	—
Fortress - MSA Income		(4,000)	(4,000)
Consolidated (Income)/Expense		$ —	$ —

Note 1: Pursuant to the terms of the agreement between Avenue and InvaGen Pharmaceuticals, Inc. during the term of the Avenue SPMA fees under the MSA will not be due or accrued.
Note 2: In December 2019, Tamid discontinued development and terminated its' licenses and clinical trial agreements with UNC.
Note 3: Oncogenuity license was purchased in the year ended December 31, 2020.

Fees and Stock Grants Received by Fortress

Fees recorded in connection with the Company's agreements with its subsidiaries 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 (benefit) are as follows:

	For the Year Ended December 31,	
($ in thousands)	**2020**	**2019**
Current		
Federal	$ —	$ —
State	136	—
Deferred		
Federal	—	—
State	—	—
Total	$ 136	$ —

For the years ended December 31, 2020 and 2019, income tax expense was $0.1 million and nil, respectively, resulting in an effective income tax rate of 0.13% and 0%. The increase in income tax expense in 2020 is due to additional state tax return filings.

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 $203.9 million against its net deferred tax assets. Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

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

($ in thousands)	As of December 31, 2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 152,295	$ 125,657
Amortization of license fees	20,628	17,077
Amortization of in-process R&D	415	449
Stock compensation	14,732	13,280
Lease liability	7,306	7,454
Accruals and reserves	1,570	1,810
Tax credits	16,326	12,716
Startup costs	54	58
Unrealized gain/loss on investments	1,075	716
State taxes	41	—
Reserve on Sales Return, Discount and Bad Debt	1,455	—
Total deferred tax assets	215,897	179,217
Less: valuation allowance	(203,930)	(168,223)
Net deferred tax assets	$ 11,967	$ 10,994
Deferred tax liabilities:		
Right of use asset	$ (6,050)	$ (6,280)
Fair Value adjustment on investment in Caelum	(4,804)	(2,879)
Basis in subsidiary	(1,113)	(1,835)
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, 2020	2019
Percentage of pre-tax income:		
U.S. federal statutory income tax rate	21 %	21 %
State taxes, net of federal benefit	11 %	12 %
Credits	4 %	3 %
Non-deductible items	(1)%	— %
Provision to return	1 %	1 %
Stock based compensation shortfall	(1)%	(1)%
Change in state rate	— %	3 %
Deconsolidation of Caelum	— %	(3)%
Change in valuation allowance	(35)%	(36)%
Change in subsidiary basis	1 %	(1)%
Other	(1)%	1 %
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 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, 2020 and 2019. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2020 and 2019. The valuation allowance increased by a net $35.7 million during the current year.

The Company has incurred net operating losses ("NOLs") since inception. At December 31, 2020, the Company had federal NOLs of $525.7 million, which will begin to expire in the year 2026, state NOLs of $648.2 million, which will begin to expire in 2022, and federal income tax credits of $15.4 million and state income tax credits of $1.2 million, which will begin to expire in 2028. Approximately $284.8 million of the federal NOLs and $4.5 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 limiatations on its use of pre-change NOLs and income tax credits carryforwards to offset future tax liabilities. The Company is currently evaluating the impact of Section 382 on its 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.

As of December 31, 2020, th Company had no unrecognized tax benefits and does not anticipate any significant change to the unrecognized tax benefit balance. The Company would classify interest and penalties related to uncertain tax positions as income tax expense, if applicable. There was no interest expense or penalties related to unrecognized tax benefits recorded through December 31, 2020. The NOLs from tax years 2008 through 2019 remain open to examination (and adjustment) by the Internal Revenue Service and state taxing authorities. In addition, federal tax years ending December 31, 2017, 2018 and 2019 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.

In January 2019, in connection with the Alexion DOSPA, the Company ceased to consolidate Caelum (see Note 4). As a result of the deconsolidation of Caelum, the Company has eliminated Caelum's deferred tax assets and the valuation allowance for a net tax expense charge or benefit of zero for the year ended December 31, 2019.

Coronavirus Aid, Relief and Economic Security Act ("CARES Act")

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods and modifications to the net interest deduction limitations. The CARES Act did not have a material impact on the Company's income tax provision for 2020. The Company will continue to evaluate the impact of the CARES Act on its financial position, results of operations and cash flows.

On December 27, 2020, the President of the United States signed the Consolidated Appropriations Act, 2021 ("Consolidated Appropriations Act") into law. The Consolidated Appropriations Act is intended to enhance and expand certain provisions of the CARES Act, allows for the deductions of expenses related to the Paycheck Protection Program funds received by companies, and provides an update to meals and entertainment expensing for 2021. The Consolidated Appropriations Act did not have a material impact to the Company's income tax provision for 2020.

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:

($ in thousands) Year Ended December 31, 2020	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net revenue	$ 44,531	$ 1,068	$ 45,599
Direct cost of goods	(14,594)	—	(14,594)
Sales and marketing costs	(17,384)	—	(17,384)
Research and development	—	(64,109)	(64,109)
General and administrative	(4,716)	(39,066)	(43,782)
Other expense	(697)	(7,882)	(8,579)
Income tax expense	(96)	(40)	(136)
Segment income (loss)	$ 7,044	$ (110,029)	$ (102,985)
Segment assets			
Intangible assets, net	14,629	—	14,629
Tangible assets	30,843	283,362	314,205
Total segment assets	$ 45,472	$ 283,362	$ 328,834

($ in thousands) Year Ended December 31, 2019	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net revenue	$ 34,921	$ 1,708	$ 36,629
Direct cost of goods	(10,532)	—	(10,532)
Sales and marketing costs	(17,120)	—	(17,120)
Research and development	—	(81,326)	(81,326)
General and administrative	(2,556)	(35,914)	(38,470)
Other income	—	9,159	9,159
Segment income (loss)	$ 4,713	$ (106,373)	$ (101,660)
Segment assets			
Intangible assets, net	7,377	—	7,377
Tangible assets	19,946	199,099	219,045
Total segment assets	$ 27,323	$ 199,099	$ 226,422

20. Revenues from Contracts and Significant Customers

Disaggregation of Total Revenues

The Company has five marketed products, Targadox®, Ximino®, Exelderm®, Luxamend® and Ceracade®. Substantially all of the Company's product revenues are recorded in the U.S. Substantially all of the Company's collaboration revenues are from its collaboration with TGTX.

The table below summarizes the Company's revenue for the years ended December 31, 2020 and 2019:

($ in thousands)	Year Ended December 31, 2020	2019
Revenue		
Product revenue, net	$ 44,531	$ 34,921
Revenue – related party	1,068	1,708
Net revenue	$ 45,599	$ 36,629

Significant Customers

For the year ended December 31, 2020, none of the Company's Dermatology Products customers accounted for more than 10.0% of its total gross product revenue.

For the year ended December 31, 2019, two of the Company's Dermatology Products customers each accounted for more than 10.0% of its total gross product revenue, accounting for approximately 50% and 10%, respectively. The revenue from these customers is captured in the product revenue, net line item within the Consolidated Statements of Operations.

At December 31, 2020, one of the Company's Dermatology Products customers accounted for 12% of its total accounts receivable balance.

At December 31, 2019, two of the Company's Dermatology Products customers accounted for more than 10% of its total accounts receivable balance at 21% and 18%, respectively.

Included in Product revenue, net, for the years ended December 31, 2020 and 2019 was $1.4 million and nil, respectively, of revenue that was constrained in a prior period.

Revenue – related party represents collaboration revenue from TGTX in connection with Checkpoint.

21. Subsequent Events

Cyprium

On February 24, 2021, Cyprium announced the execution of an asset purchase agreement with Sentynl Therapeutics, Inc. ("Sentynl"), a U.S.-based specialty pharmaceutical company owned by the Zydus Group. The asset purchase agreement commits Sentynl to an upfront cash payment to Cyprium of $8.0 million for development, a $3.0 million cash milestone payment at NDA acceptance, the purchase price of $9.0 million, as well as potential sales milestones totaling $255.0 million. Royalties on CUTX-101 net sales range from the mid-single digits up to the mid-twenties are also payable. Cyprium will retain development responsibility of CUTX-101 through approval of the NDA by the FDA, and Sentynl will be responsible for commercialization of CUTX-101 as well as progressing newborn screening activities. Continued development of CUTX-101 will be overseen by a Joint Steering Committee consisting of representatives from Cyprium and Sentynl. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.

Avenue

On February 12, 2021, Avenue resubmitted its NDA to the FDA for IV Tramadol. The NDA for IV Tramadol was resubmitted following the receipt of official minutes from a Type A meeting with the FDA, which was conducted following a CRL issued by the FDA in October 2020. The resubmission included revised language relating to the proposed product label and a report relating to terminal sterilization validation. On February 26, 2021, Avenue received an acknowledgement letter from the FDA that Avenue's resubmission of its NDA is a complete, class 1 response to the CRL, and a Prescription Drug User Fee Act goal date has been set for April 12, 2021.

Journey

8% Cumulative Convertible Class A Preferred Offering

In March 2021, our partner company Journey is conducting an offering to accredited investors of 8% Cumulative Convertible Class A Preferred Stock in an aggregate minimum amount of $12.5 million and an aggregate maximum amount of $30.0 million, which may be increased if Journey and the placement agent agree to do so. Dividends on the Journey preferred stock will be paid quarterly in shares of the Company's common based upon a 7.5% discount to the average trading price over the 10-day period preceding the dividend payment date. The approximate number of shares issuable as a dividend per quarter, based upon the Company's common stock price as of March 26, 2021, would be 72,849 shares if the minimum amount is raised and 174,838 if the maximum amount is raised.

In addition, if the Journey preferred stock has not been converted into Journey common stock upon a sale of Journey or a financing of Journey in an amount of at least $25.0 million within a year of the closing (extendable by another six months at Journey's option), the Journey preferred stock will be exchanged for shares of the Company's common stock, also based upon a 7.5% discount to the average Company common stock trading price over the 10-day period preceding such exchange. The approximate number of the Company's common shares issuable upon such exchange would be approximately 3.4 million shares if the minimum amount is sold and 8.1 million if the maximum amount is sold, in each case based upon the Company's common stock price as of March 26, 2021. The Company will be obligated to file one or more registration statements covering the issuance of shares that result from such dividends/exchange. As consideration for the foregoing Journey will issue to the Company additional shares of Journey common stock, debt securities, or a combination of the foregoing. From the initial closing on March 31, 2021, the Company raised gross proceeds of $12.5 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, 2021

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

POWER OF ATTORNEY

We, the undersigned directors and/or executive officers of Fortress Biotech, Inc., hereby severally constitute and appoint Lindsay A. Rosenwald, M.D., acting singly, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing necessary or appropriate to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that said attorney-in-fact and agent, or his substitute, may lawfully do or cause to be done by virtue hereof.

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, 2021
/s/ Robyn M. Hunter Robyn M. Hunter	Chief Financial Officer (*Principal Financial Officer*)	March 31, 2021
/s/ Eric K. Rowinsky, M.D. Eric K. Rowinsky, M.D.	Vice Chairman of the Board of Directors	March 31, 2021
/s/ Michael S. Weiss Michael S. Weiss	Executive Vice Chairman, Strategic Development and Director	March 31, 2021
/s/ Jimmie Harvey, Jr., M.D. Jimmie Harvey, Jr., M.D.	Director	March 31, 2021
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director	March 31, 2021
/s/ Dov Klein Dov Klein	Director	March 31, 2021
/s/ J. Jay Lobell J. Jay Lobell	Director	March 31, 2021
/s/ Kevin L. Lorenz, J.D. Kevin Lorenz	Director	March 31, 2021

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 100,000,000 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 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

We may issue warrants to purchase shares of our Common Stock and/or preferred stock in one or more series together with other securities or separately, as described in each applicable prospectus supplement or similar offering documentation.

The prospectus supplement or similar offering documentation relating to any warrants we offer will include specific terms relating to the offering. These terms will include some or all of the following:

- the title of the warrants;
- the aggregate number of warrants offered;
- the designation, number and terms of the shares of Common Stock purchasable upon exercise of the warrants and procedures by which those numbers may be adjusted;
- the exercise price of the warrants;
- the dates or periods during which the warrants are exercisable;
- the designation and terms of any securities with which the warrants are issued;
- if the warrants are issued as a unit with another security, the date on and after which the warrants and the other security will be separately transferable;

- if the exercise price is not payable in U.S. dollars, the foreign currency, currency unit or composite currency in which the exercise price is denominated;
- any minimum or maximum amount of warrants that may be exercised at any one time;
- any terms relating to the modification of the warrants;
- any terms, procedures and limitations relating to the transferability, exchange or exercise of the warrants; and
- any other specific terms of the warrants.

DESCRIPTION OF DEBT SECURITIES

We may offer debt securities which may be senior, subordinated or junior subordinated and may be convertible. Unless otherwise specified in the applicable prospectus supplement or similar offering documentation, our debt securities will be issued in one or more series under an indenture to be entered into between us and a trustee. We will issue the debt securities under an indenture to be entered into between us and the trustee identified in the applicable prospectus supplement or similar offering documentation. The terms of the debt securities will include those stated in the indenture and those made part of the indenture by reference to the Trust Indenture Act of 1939, as in effect on the date of the indenture. We have filed a copy of the form of indenture as an exhibit to this annual report on Form 10-K. The indenture will be subject to and governed by the terms of the Trust Indenture Act of 1939.

The following description briefly sets forth certain general terms and provisions of the debt securities that we may offer. The particular terms of the debt securities and the extent, if any, to which general provisions may apply to the debt securities, will be described in the related prospectus supplement or similar offering documentation. Accordingly, for a description of the terms of a particular issue of debt securities, reference must be made to both the related prospectus supplement or similar offering documentation and to the following description.

The aggregate principal amount of debt securities that may be issued under the indenture is unlimited. The debt securities may be issued in one or more series as may be authorized from time to time pursuant to a supplemental indenture entered into between us and the trustee or an order delivered by us to the trustee. For each series of debt securities we offer, a prospectus supplement or similar offering documentation will describe the following terms and conditions of the series of debt securities that we are offering, to the extent applicable:

- title and aggregate principal amount;
- whether the debt securities will be senior, subordinated or junior subordinated;
- applicable subordination provisions, if any;
- provisions regarding whether the debt securities will be convertible or exchangeable into other securities or property of the Company or any other person;
- percentage or percentages of principal amount at which the debt securities will be issued;
- maturity date(s);
- interest rate(s) or the method for determining the interest rate(s);
- whether interest on the debt securities will be payable in cash or additional debt securities of the same series;
- dates on which interest will accrue or the method for determining dates on which interest will accrue and dates on which interest will be payable;
- whether the amount of payment of principal of, premium, if any, or interest on the debt securities may be determined with reference to an index, formula or other method;
- redemption, repurchase or early repayment provisions, including our obligation or right to redeem, purchase or repay debt securities under a sinking fund, amortization or analogous provision;

- if other than the debt securities' principal amount, the portion of the principal amount of the debt securities that will be payable upon declaration of acceleration of the maturity;
- authorized denominations;
- form;
- amount of discount or premium, if any, with which the debt securities will be issued, including whether the debt securities will be issued as "original issue discount" securities;
- the place or places where the principal of, premium, if any, and interest on the debt securities will be payable;
- where the debt securities may be presented for registration of transfer, exchange or conversion;
- the place or places where notices and demands to or upon the Company in respect of the debt securities may be made;
- whether the debt securities will be issued in whole or in part in the form of one or more global securities;
- if the debt securities will be issued in whole or in part in the form of a book-entry security, the depository or its nominee with respect to the debt securities and the circumstances under which the book-entry security may be registered for transfer or exchange or authenticated and delivered in the name of a person other than the depository or its nominee;
- whether a temporary security is to be issued with respect to such series and whether any interest payable prior to the issuance of definitive securities of the series will be credited to the account of the persons entitled thereto;
- the terms upon which beneficial interests in a temporary global security may be exchanged in whole or in part for beneficial interests in a definitive global security or for individual definitive securities;
- the guarantors, if any, of the debt securities, and the extent of the guarantees and any additions or changes to permit or facilitate guarantees of such debt securities;
- any covenants applicable to the particular debt securities being issued;
- any defaults and events of default applicable to the debt securities, including the remedies available in connection therewith;
- currency, currencies or currency units in which the purchase price for, the principal of and any premium and any interest on, such debt securities will be payable;
- time period within which, the manner in which and the terms and conditions upon which the Company or the purchaser of the debt securities can select the payment currency;
- securities exchange(s) on which the debt securities will be listed, if any;
- whether any underwriter(s) will act as market maker(s) for the debt securities;
- extent to which a secondary market for the debt securities is expected to develop;
- provisions relating to defeasance;
- provisions relating to satisfaction and discharge of the indenture;
- any restrictions or conditions on the transferability of the debt securities;
- provisions relating to the modification of the indenture both with and without the consent of holders of debt securities issued under the indenture;
- any addition or change in the provisions related to compensation and reimbursement of the trustee;

- provisions, if any, granting special rights to holders upon the occurrence of specified events;
- whether the debt securities will be secured or unsecured, and, if secured, the terms upon which the debt securities will be secured and any other additions or changes relating to such security; and
- any other terms of the debt securities that are not inconsistent with the provisions of the Trust Indenture Act (but may modify, amend, supplement or delete any of the terms of the indenture with respect to such series of debt securities).

General

One or more series of debt securities may be sold as "original issue discount" securities. These debt securities would be sold at a substantial discount below their stated principal amount, bearing no interest or interest at a rate which at the time of issuance is below market rates. One or more series of debt securities may be variable rate debt securities that may be exchanged for fixed rate debt securities.

United States federal income tax consequences and special considerations, if any, applicable to any such series will be described in the applicable prospectus supplement or similar offering documentation.

Debt securities may be issued where the amount of principal and/or interest payable is determined by reference to one or more currency exchange rates, commodity prices, equity indices or other factors. Holders of such debt securities may receive a principal amount or a payment of interest that is greater than or less than the amount of principal or interest otherwise payable on such dates, depending upon the value of the applicable currencies, commodities, equity indices or other factors. Information as to the methods for determining the amount of principal or interest, if any, payable on any date, the currencies, commodities, equity indices or other factors to which the amount payable on such date is linked and certain additional United States federal income tax considerations will be set forth in the applicable prospectus supplement or similar offering documentation.

The term "debt securities" includes debt securities denominated in U.S. dollars or, if specified in the applicable prospectus supplement or similar offering documentation, in any other freely transferable currency or units based on or relating to foreign currencies.

We expect most debt securities to be issued in fully registered form without coupons and in denominations of $1,000 and any integral multiples thereof. Subject to the limitations provided in the indenture and in the prospectus supplement or similar offering documentation, debt securities that are issued in registered form may be transferred or exchanged at the principal corporate trust office of the trustee, without the payment of any service charge, other than any tax or other governmental charge payable in connection therewith.

Global Securities

The debt securities of a series may be issued in whole or in part in the form of one or more global securities that will be deposited with, or on behalf of, a depositary identified in the prospectus supplement or similar offering documentation. Global securities will be issued in registered form and in either temporary or definitive form. Unless and until it is exchanged in whole or in part for the individual debt securities, a global security may not be transferred except as a whole by the depositary for such global security to a nominee of such depositary or by a nominee of such depositary to such depositary or another nominee of such depositary or by such depositary or any such nominee to a successor of such depositary or a nominee of such successor. The specific terms of the depositary arrangement with respect to any debt securities of a series and the rights of and limitations upon owners of beneficial interests in a global security will be described in the applicable prospectus supplement or similar offering documentation.

Governing Law

The indenture and the debt securities shall be construed in accordance with and governed by the laws of the State of New York.

DESCRIPTION OF UNITS

We may issue, in one more series, units comprised of shares of our Common Stock, Series A Preferred Stock or preferred stock, warrants to purchase Common Stock, Series A Preferred Stock or preferred stock, debt securities or any combination of those securities. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We may evidence units by unit certificates that we issue under a separate agreement. We may issue the units under a unit agreement between us and one or more unit agents. If we elect to enter into a unit agreement with a unit agent, the unit agent will act solely as our agent in connection with the units and will not assume any obligation or relationship of agency or trust for or with any registered holders of units or beneficial owners of units. We will indicate the name and address and other information regarding the unit agent in the applicable prospectus supplement or similar offering documentation relating to a particular series of units if we elect to use a unit agent.

We will describe in the applicable prospectus supplement or similar offering documentation the terms of the series of units being offered, including:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement that differ from those described herein; and
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

The other provisions regarding our Common Stock, Series A Preferred Stock, preferred stock, warrants and debt securities as described in this section will apply to each unit to the extent such unit consists of shares of our Common Stock, preferred stock, warrants and/or debt securities.

EXHIBIT 21.1

SUBSIDIARIES OF FORTRESS BIOTECH, INC.

Subsidiaries of Fortress Biotech, Inc. at December 31, 2020, with jurisdiction of incorporation or formation:

- Aevitas Therapeutics, Inc. (Delaware)
- Avenue Therapeutics, Inc. (Delaware)
- Baergic Bio, Inc. (Delaware)
- Caelum Biosciences, Inc. (Delaware), formerly FBIO Acquisition Corp. II
- Cellvation, Inc. (Delaware), formerly FBIO Acquisition Corp. I
- Checkpoint Therapeutics, Inc. (Delaware)
- Cyprium Therapeutics, Inc. (Delaware)
- Helocyte, Inc. (Delaware), formerly DiaVax Biosciences, Inc.
- Hepla Sciences, Inc. (Delaware), formerly FBIO Acquisition Corp. IV
- Journey Medical Corporation (Delaware)
- Mustang Bio, Inc. (Delaware)
- Oncogenuity, Inc. (Delaware), formerly FBIO Acquisition Corp. VI
- CB Securities Corporation (Massachusetts)
- Coronado SO Co. (Delaware)
- Escala Therapeutics, Inc., formerly Altamira Biosciences, Inc. (Delaware)
- FBIO Acquisition Corps. VI – XIV (Delaware)
- Fortress Biotech, China, Inc.
- Innmune Limited (United Kingdom)
- Tamid Bio, Inc. (Delaware)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Fortress Biotech, Inc.
New York, New York

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-238327) and Form S-8 (Nos. 333-184616, 333-194588, 333-20664, 333-221458, 333-233195 and 333-249985) of Fortress Biotech, Inc. of our report dated March 31, 2021 relating to the consolidated financial statements, which appears in this Annual Report on Form 10-K.

/s/ BDO USA, LLP

Boston, Massachusetts
March 31, 2021

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, 2020 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 the 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, 2021

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, Robyn M. Hunter certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2020 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 the 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, 2021

By: /s/ Robyn M. Hunter
Robyn M. Hunter
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, 2020, 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 as of, and for, the periods presented in the Report.

Dated: March 31, 2021

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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robyn M. Hunter, 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 as of, and for, the periods presented in the Report.

Dated: March 31, 2021

By: /s/ Robyn M. Hunter
Robyn M. Hunter
Chief Financial Officer
(Principal Financial Officer)