Risk Factors Comparison 2024-03-28 to 2023-03-31 Form: 10-K

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Risks Inherent in Drug Development ● Many of our product candidates are in early development stages and are subject to time and cost intensive regulation and clinical testing, which may result in the identification of safety or efficacy concerns. As a result, our product candidates may never be successfully developed or commercialized. ● Our competitors may develop treatments for our products' target indications, which could limit our product candidates' commercial opportunity and profitability. Risks Pertaining to the Need for and Impact of Existing and Additional Financing Activities ● We have a history of operating losses and expect such losses to continue in the future. ● We have funded our operations in part through the assumption of debt, and the applicable lending agreements may restrict our operations. Further, the occurrence of any default event under an applicable loan document could adversely affect our business. ● Our research and development (" R & D ") programs will require additional capital, which we may be unable to raise as needed and which may impede our R & D programs, commercialization efforts, or planned acquisitions. ● If we raise additional capital by issuing equity ~~or ,~~ equity-linked **securities or securities convertible into or exercisable for equity** securities, our existing stockholders will be diluted. Risks Pertaining to Our Existing Revenue Stream from Journey Medical Corporation (" Journey ") ● Our operating income derives primarily from the sale of our partner company Journey' s dermatology products, particularly Qbrexza, Accutane, Amzeeq, Zilxi, Targadox, ~~Ximino,~~ and Exelderm ~~,~~. Any issues relating to the manufacture, sale, utilization, or reimbursement of Journey' s products (including products liability claims) could significantly impact our operating results. ● A significant portion of Journey' s sales derive from products that are without patent protection and / or are or may become subject to third party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse effect on our operating income. ~~Four~~ **Three** of Journey' s marketed products, Qbrexza, Amzeeq ~~,~~ **and** Zilxi ~~and Ximino~~, as well as DFD- 29, a modified release oral minocycline for the treatment of rosacea licensed from Dr. Reddy' s Laboratories, currently have patent protection. Three of Journey' s marketed products, Accutane, Targadox, and Exelderm, do not have patent protection or otherwise are not eligible for patent protection. With respect to Journey products that are covered by valid claims of issued patents, such patents may be subject to invalidation, which would harm our operating income. ● Continued sales and coverage, including formulary inclusion without the need for a prior authorization or step edit therapy, of our products for commercial sale will depend in part on the availability of reimbursement from third- party **payors, including government** payors. Third- party payors are increasingly examining the medical necessity and cost- effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of current and newly approved therapeutics. Risks Pertaining to our Business Strategy, Structure and Organization ● We have entered, and will likely in the future enter, into certain collaborations or divestitures which may cause a reduction in our business' size and scope, market share and opportunities in certain markets, or our ability to compete in certain markets and therapeutic categories. ● We and our subsidiaries and partner companies have also entered into, and intend in the future to enter into, arrangements under which we and / or they have agreed to contingent dispositions of such companies and / or their assets. The failure to consummate any such transaction may impair the value of such companies and / or assets, and we may not be able to identify or execute alternative arrangements on favorable terms, if at all. The consummation of any such arrangements with respect to certain product candidates may also result in our eligibility to receive a lower portion of sales (if any) of resulting approved products than if we had developed and commercialized such products ourselves. ● Our growth and success depend on our acquiring or in- licensing products or product candidates and integrating such products into our businesses. ● We may act as guarantor and / or indemnitor of certain obligations of our subsidiaries and partner companies, which could require us to pay substantial amounts based on the actions or omissions of said entities. Risks Pertaining to Reliance on Third Parties ● We rely heavily on third parties for several aspects of our operations, including manufacturing and developing product candidates, conducting clinical trials, and producing commercial product supply. Such reliance on third ~~-~~parties reduces our ability to control every aspect of the drug development process and may hinder our ability to develop and commercialize our products in a cost- effective and timely manner. Risks Pertaining to Intellectual Property and Potential Disputes with Licensors Thereof ● If we are unable to obtain and maintain patent protection for our technologies and products, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technologies and products similar or identical to ours, and our ability to successfully commercialize our technologies and products may be impaired. ● We or our licensors may be subject to costly and time-consuming litigation for infringement of third- party intellectual property rights or to enforce our or our licensors' patents. ● Any dispute with our licensors may affect our ability to develop or commercialize our product candidates. Risks Pertaining to Generic Competition and Paragraph IV Litigation ● Generic drug companies may submit applications seeking approval to market generic versions of our products. ● In connection with these applications, generic drug companies may seek to challenge the validity and enforceability of our patents through litigation and / or with the United States Patent and Trademark Office (" PTO ") ~~, such as the Paragraph IV certification made by Perrigo pertaining to the patents covering Qbrexza, and subsequently, Amzeeq, and Zilxi, three products being commercialized by our partner company Journey~~ . Such challenges may subject us to costly and time- consuming litigation and / or PTO proceedings. ● As a result of the loss of any patent protection from such litigation or PTO proceedings, or the " at- risk " launch by a generic competitor of our products, our products could be sold at significantly lower prices, and we could lose a significant portion of product sales in a short period of time, which could adversely affect our business, financial condition, operating results and prospects. 5Risks Pertaining to the Commercialization of

Product Candidates ● If our ~~products~~ **product candidates, if approved,** are not broadly accepted by the healthcare community, the revenues from any such products are likely to be limited. ● We may not obtain the desired product labels or intended uses for product promotion, or favorable scheduling classifications desirable to successfully promote our products. ● Even if a product candidate is approved, it may be subject to various post- marketing requirements, including studies or clinical trials, the results of which could cause such products to later be withdrawn from the market. ● Any successful products liability claim related to any of our current or future product candidates may cause us to incur substantial liability and limit the commercialization of such products. Risks Pertaining to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries ● We operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations. General and Other Risks ● **We have previously failed to satisfy certain continued** ~~On October 31, 2022, we received a letter from the Listing~~ **listing rules** ~~Qualifications Staff~~ of The Nasdaq Stock Market LLC (" Nasdaq ") ~~indicating that the bid price of the Company' s common stock~~ , **and if we again** ~~par value $ 0. 001 per share~~ -- **are** ~~(unable to meet~~ the ~~" continued listing requirements, our~~ Common Stock ~~"), had closed below $ 1. 00 per share for 30 consecutive business days~~ and **Preferred** ~~, as a result, the Company is not in compliance with Nasdaq Listing Rule 5550 (a) (2), which sets forth the minimum bid price requirement for continued listing on The Nasdaq Capital Market. Our Common~~ Stock may be subject to delisting from The Nasdaq Capital Market if we are unable to regain compliance ~~which~~ **with such rules. The delisting of our Securities from the Nasdaq** may decrease the market liquidity and market price of our Common **Stock and Preferred** Stock. 6PART IItem 1. Business. OverviewFortress Biotech, Inc. (" Fortress " or the " Company ") is a biopharmaceutical company ~~dedicated to~~ **focused on** acquiring ~~, developing~~ and ~~commercializing pharmaceutical and biotechnology products and~~ **advancing assets to enhance long- term value for shareholders through** product ~~candidates~~ **revenue** , ~~which we do through~~ **equity holding and dividend and royalty revenue streams.** Fortress ~~itself and through partner companies and subsidiaries. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who work~~ **works** in concert with our extensive network of key opinion leaders to identify and evaluate promising products and product candidates for potential acquisition. We have executed arrangements in partnership with some of the world' s foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center **(" COH " or " City of Hope ")** , Fred Hutchinson Cancer Center, St. Jude Children' s Research Hospital (" St. Jude "), Dana- Farber Cancer Institute, Nationwide Children' s Hospital, Cincinnati Children' s Hospital Medical Center, Columbia University, the University of Pennsylvania, Mayo Foundation for Medical Education and Research (" Mayo Clinic "), AstraZeneca plc, and Dr. Reddy' s Laboratories, Ltd. Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and financial expertise to help the partners achieve their goals. Partner **and subsidiary** companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out- licensings, sales transactions, and public and private financings. To date, four partner companies are publicly- traded, and two have consummated strategic partnerships with industry leaders AstraZeneca plc as successor- in- interest to Alexion Pharmaceuticals, Inc. (" AstraZeneca ") and Sentynl Therapeutics, Inc. (" Sentynl "), respectively. ~~In October 2021, AstraZeneca purchased 100 % of our partner Caelum for approximately $ 150 million upfront and up to $ 350 million in contingent regulatory and sales milestone payments.~~ Our subsidiary and partner companies that are pursuing development and / or commercialization of biopharmaceutical products and product candidates are ~~Aevitas Therapeuties, Inc. (" Aevitas "),~~ Avenue Therapeutics, Inc. (Nasdaq: ATXI, " Avenue "), Baergic Bio, Inc. (" Baergic, " a subsidiary of Avenue), Cellvation, Inc. (" Cellvation "), Checkpoint Therapeutics, Inc. (Nasdaq: CKPT, " Checkpoint "), Cyprium Therapeutics, Inc. (" Cyprium "), Helocyte, Inc. (" Helocyte "), Journey Medical Corporation (Nasdaq: DERM, " Journey " or " JMC "), Mustang Bio, Inc. (Nasdaq: MBIO, " Mustang "), Oncogenuity, Inc. (" Oncogenuity ") and Urica Therapeutics, Inc. (" Urica ") **. Aevitas Therapeutics, Inc.** (~~formerly known~~ **" Aevitas ")** ~~as~~ **was** ~~UR- 1~~ **a consolidated subsidiary company until the sale of its primary asset to 4D Molecular** Therapeutics **in April 2023** ~~, Inc.)~~ . As used throughout this filing, the words " we ", " us " and " our " may refer to Fortress individually, to one or more of its subsidiaries and / or partner companies, or to all such entities as a group, as dictated by context. Generally, " subsidiary " refers to a private Fortress subsidiary, " partner company " refers to a public Fortress subsidiary, and " partner " refers to ~~entities~~ **an entity** with whom one of the foregoing parties has a significant business relationship, such as an exclusive license or an ongoing product- related payment obligation. The context in which any such term is used throughout this document, however, may dictate a different construal from the foregoing. Product Candidates and Other Intellectual ~~PropertyCommercialized ProductsThrough~~ **PropertyRevenue PortfolioThrough** our partner company Journey we actively market the following branded dermatology products **approved by the FDA for sale in the United States** : ● Qbrexza ® ~~: Qbrexza~~ (~~glycopyrronium 2. 4 %) is~~ a medicated cloth towelette for the treatment of primary axillary hyperhidrosis **); ●** ~~in adults and children 9 years and older.~~ Accutane ® ~~: Accutane~~ (~~isotretinoin) is~~ an oral ~~capsule~~ **isotretinoin drug** for the treatment of severe recalcitrant nodular acne ~~.~~ **); ●** Amzeeq ® ~~: Amzeeq~~ (minocycline ~~4 %~~) topical foam, ~~is~~ **4 % (a topical formulation of minocycline for** the ~~first~~ **treatment of inflammatory lesions of non- nodular moderate to severe acne vulgaris in adults** and ~~only~~ **children nine years and older); ● Zilxi ® (minocycline) topical foam, 1. 5 % (a** topical minocycline treatment for ~~the~~ inflammatory lesions of **rosacea** ~~non- nodular moderate to severe acne vulgaris~~ in adults ~~and children 9 years and older. 7Zilxi ®: Zilxi (minocycline 1. 5 %~~) **; 7 ●** ~~is a topical foam and the first and only topical minocycline treatment for inflammatory lesions of rosacea in adults. Ximino ®: Ximino (minocycline hydrochloride) is an oral minocycline drug for the treatment of moderate to severe acne.~~ Exelderm ® ~~: Exelderm~~ **Cream and Solution** (**a** ~~sulconazole nitrate) Cream and Solution are~~ broad- spectrum antifungal intended for topical use ~~.~~ **); ●** Targadox ® ~~: Targadox~~ (~~doxycycline hyclate) is~~ an oral doxycycline drug for adjunctive therapy for severe acne **); and ● Luxamend ® (a water- based emulsion formulated to provide an optimally moist healing environment for superficial wounds; minor cuts or scrapes; dermal ulcers; donor sites; first- and second- degree burns, including sunburns; and radiation dermatitis)** . Additionally, Journey

sells ~~three~~ **two** authorized generic products: ● ~~minocycline hydrocholoride extended release capsules, launched in April 2020;~~ ● sulconazole nitrate cream and solution, ~~launched~~ **1 % antifungal agents indicated for the treatment of tinea cruris and tinea corporis caused by Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum, and Microsporum canis, * and for the treatment of tinea versicolor. * Efficacy for this organism** in ~~January 2020~~ **the organ system was studied in fewer than 10 infections. EXELDERM ® Cream is also indicated for the treatment of tinea pedis (athlete' s foot). Effectiveness of EXELDERM ® Solution has not been proven in tinea pedis** ; and ● doxycycline hyclate immediate release **50mg** tablets, ~~launched in May 2018~~ **indicated as adjunctive therapy for severe acne to reduce the development of drug- resistant bacteria as well as to maintain the effectiveness of doxycycline hyclate and other antibacterial drugs** . Late Stage Product CandidatesCosibelimab (~~Anti~~ **anti** - PD- L1 **antibody** ~~mAb for CSCC~~) Our partner company Checkpoint is currently ~~evaluating~~ **developing** its lead product candidate, cosibelimab, an anti- programmed death- ligand 1 (“ **anti-** PD- L1 ”) **monoclonal** antibody licensed from the Dana- Farber Cancer Institute, in ~~an ongoing global~~ **solid tumor indications. In 2017** , **Checkpoint commenced a** ~~open- label, multicohort~~ Phase 1 clinical trial in checkpoint therapy- naïve patients with selected recurrent or metastatic cancers **. In January 2022** , ~~including ongoing~~ **Checkpoint announced top- line results from a** ~~cohorts -~~ **cohort of this study with cosibelimab administered as a fixed dose of 800 mg every two weeks** in **patients with** ~~locally advanced and~~ metastatic cutaneous squamous cell carcinoma (“ ~~CSCC~~ **cSCC** ”) **. The cohort met its primary endpoint, with cosibelimab demonstrating a confirmed overall response (“ ORR ”) of 47. 4 % (95 % CI: 36. 0, 59. 1) based on independent central review of 78 patients enrolled in the metastatic cSCC cohort using RECIST 1. 1. In June 2022, Checkpoint announced interim results from another cohort of this study with cosibelimab administered as a fixed dose of 800 mg every two weeks in patients with locally advanced cSCC that are not candidates for curative surgery or radiation. Cosibelimab demonstrated a confirmed ORR of 54. 8 % (95 % CI: 36. 0, 72. 7) based on independent central review of 31 patients enrolled in the cohort. The design of the interim analysis incorporated feedback from the FDA and is** intended to **potentially** support **the** ~~one or more applications for marketing~~ approval **of cosibelimab in this indication. In July 2023, Checkpoint announced longer- term results for cosibelimab from its pivotal studies in locally advanced and metastatic cSCC. These results demonstrated a deepening of response over time, resulting in complete response rates of 26 % and 13 % in locally advanced and metastatic cSCC, respectively. Additionally, the confirmed ORR in metastatic cSCC increased to 50. 0 % based on independent central review. Furthermore, responses continue to remain durable over time with the median duration of response not yet reached in either group. Updated safety data across 247 patients enrolled and treated with cosibelimab in all cohorts of the ongoing study remain consistent with those previously reported** . Based on **these** ~~top- line and interim~~ results ~~in metastatic and locally advanced CSCC, respectively~~ , Checkpoint submitted a Biologics License Application (“ BLA ”) to the U. S. Food and Drug Administration (“ FDA ”) for **cosibelimab** ~~these indications~~ in January 2023 **. On December 15, 2023, the FDA issued a Complete Response Letter (“ CRL ”) for the cosibelimab BLA for the treatment of patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or radiation. The CRL only cited findings that arose during a multi- sponsor inspection of our third- party contract manufacturing organization as approvability issues to address in a resubmission. The CRL did not state any concerns about the clinical data package, safety, or labeling. Following resolution of the inspection issues at the third- party contract manufacturing organization raised in the CRL, a resubmission of the BLA is planned in 2024 to support the marketing approval of cosibelimab. 8Checkpoint also previously had a collaboration agreement with TG Therapeutics, Inc. (“ TGTX ”) whereby TGTX was granted the rights to develop and commercialize cosibelimab in the field of hematological malignancies, while Checkpoint retained the right to develop and commercialize these assets in solid tumors. Effective September 30, 2023, Checkpoint and TGTX agreed to mutually terminate these collaborations, with full rights reverting back to Checkpoint. DFD- 29 (modified release oral minocycline for the treatment of rosacea) Through our partner company Journey, in collaboration with Dr. Reddy’ s Laboratories, Ltd. (“ DRL ”), we are developing DFD- 29, a modified release oral minocycline being evaluated for the treatment of inflammatory lesions of rosacea. Under the DRL arrangement, Journey is responsible for the development of DFD- 29** , which **includes conducting two Phase 3 studies to assess the efficacy, safety and tolerability of DFD- 29 for the treatment of rosacea and the regulatory submission of a new drug** application ~~is~~ **under Section 505 (b) (2) of the FDCA. DRL provides development support including the monitoring of two Phase 3 clinical trials, which were initiated in the first quarter of 2022, and completed enrollment in January 2023. In July 2023, Journey announced positive topline data from our two DFD- 29 Phase 3 clinical trials for the treatment of papulopustular rosacea. The Phase 3 clinical trials achieved the co- primary and all secondary endpoints and subjects completed the 16- week treatment and the drug was well- tolerated. DFD- 29 demonstrated statistical superiority over both the standard of care, Oracea ® capsules, and placebo for Investigator’ s Global Assessment treatment success and the reduction in the total inflammatory lesion count in both studies. Journey** filed ~~and under review~~ **a New Drug Application (“ NDA ”)** with **the FDA for DFD- 29 on January 4, 2024, paying a $ 4. 0 million filing fee, and announced on March 18, 2024 that the FDA accepted the NDA and assigned** a Prescription Drug User Fee Act (“ PDUFA ”) goal date of ~~January 3~~ **November 4** , 2024. ~~Additional information on the Phase 1 trial can be found on ClinicalTrials. gov using identifier NCT03212404. The information contained on this website is not included in, or incorporated by reference into, this Annual Report on Form 10- K. In June 2022, Checkpoint announced interim results from a registration- enabling cohort of our multi- regional, Phase 1 clinical trial of cosibelimab in patients with locally advanced CSCC that are not candidates for curative surgery or radiation. Cosibelimab demonstrated a confirmed objective response rate (“ ORR ”) of 54. 8 % (95 % CI: 36. 0, 72. 7) based on independent central review of 31 patients enrolled in the cohort using Response Evaluation Criteria in Solid Tumors version 1. 1 (“ RECIST 1. 1 ”). In January 2022, Checkpoint announced top- line results from a registration- enabling cohort of our multi- regional, Phase 1 clinical trial of cosibelimab in patients with metastatic CSCC. The cohort met its primary endpoint, with cosibelimab demonstrating a confirmed ORR of 47. 4~~

~~% (95 % CI: 36. 0, 59. 1) based on independent central review of 78 patients enrolled in the metastatic CSCC cohort using RECIST 1. 1. Checkpoint also has a collaboration agreement with TG Therapeutics, Inc. (" TGTX ") whereby TGTX was granted the rights to develop and commercialize cosibelimab in the field of hematological malignancies, while Checkpoint retains the right to develop and commercialize these assets in solid tumors. In December 2021, Checkpoint announced the initiation of its' CONTERNO study, a multi- regional, open- label, multi- center, randomized Phase 3 trial of cosibelimab in combination with pemetrexed and platinum chemotherapy for the first- line treatment of patients with non- small cell lung cancer (" NSCLC "). The February 2022 invasion of Ukraine and the ensuing response disrupted our ability to conduct clinical trials in the region. The substantially longer enrollment period in other planned countries made the conduct of the CONTERNO study no longer viable. Accordingly, Checkpoint expects that the study will be wound down and closed by the end of the first quarter of 2023. 8CUTX~~ **CUTX** - 101 (~~Copper~~ **copper** ~~Histidinate~~ **histidinate** injection for Menkes ~~Disease~~ **disease**) Our partner company Cyprium ~~is currently~~ **was previously** developing CUTX- 101, a copper histidinate injection for the treatment of Menkes disease. Menkes disease is a rare X- linked pediatric disease caused by gene mutations of copper transporter ATP7A, which affects approximately 1 in 34, 810 live male births, and potentially as high as 1 in 8, 664 live male births, based on a recent genome- based ascertainment study. Menkes disease is characterized by distinctive clinical features, including sparse and depigmented hair (" kinky hair "), failure to thrive, connective tissue disorders and severe neurological symptoms such as seizures and hypotonia. Biochemically, Menkes patients may have low serum copper levels, as well as abnormal levels of catecholamine, but definitive diagnosis is typically made by sequencing of the ATP7A gene. There is no current FDA- approved treatment for Menkes disease. CUTX- 101, along with an AAV- ATP7A gene therapy that is ~~also~~ being developed by Cyprium, was granted Orphan Drug Designation by the FDA and the European Medicines Agency (" EMA ") Committee for Orphan Medicinal Products. CUTX- 101 was also granted Rare Pediatric Disease Designation by the FDA for the treatment of Menkes disease, Fast Track Designation for classic Menkes disease in patients who have not demonstrated significant clinical progression, and Breakthrough Therapy Designation. In August 2020, Cyprium reported positive top- line clinical efficacy results for CUTX- 101. The study demonstrated statistically significant improvement in overall survival for Menkes disease subjects who received early treatment (**"** ET **"**) with CUTX- 101, compared to an untreated historical control (**"** HC **"**) cohort, with a nearly 80 % reduction in the risk of death (Hazard Ratio = 0. 21, p < 0. 0001). Median survival for the ET cohort was 14. 8 years (177. 1 months) compared to 1. 3 years (15. 9 months) for the untreated HC cohort. **On February 24, 2021,** Cyprium **entered** ~~also continues to asses and enroll prospective patients~~ into **a development** ~~its Intermediate- Size Patient Population Expanded Access Protocol. Additional information on the Expanded Access study and requirements can be found on ClinicalTrials. gov using identifier NCT04074512. In February 2021, Cyprium announced the execution of an~~ **and** asset purchase agreement **(the " Sentynl APA ")** with Sentynl **Therapeutics** , a U. S.- based specialty pharmaceutical company owned by the Zydus Group. **Under the Sentynl APA, Sentynl provided certain development funding for the CUTX- 101 program, with Cyprium initially remaining in control of development of such program.** Pursuant to ~~the asset purchase agreement,~~ **a contractual right exercised by** Sentynl ~~paid~~ **in October 2023, however,** Cyprium **assigned the NDA** ~~an~~ **and** ~~upfront fee of~~ **certain other assets pertaining to the CUTX- 101 program to Sentynl and received** $ ~~8~~ **4** . ~~0~~ **5** million ~~upon execution,~~ **in connection with the closing of such transaction. Sentynl is now obligated to use commercially reasonable efforts to develop** and **commercialize CUTX- 101, including the funding of the same. Additionally,** Cyprium remains eligible to receive up to $ ~~12~~ **129** ~~. 0~~ million in **aggregate** ~~additional future~~ development ~~cash~~ **and sales** milestones **under the Agreement, and** ~~through New Drug Application (" NDA ") approval. Cyprium is also eligible to receive up to $ 255. 0 million in sales milestone payments (payable pursuant to five separate milestones). Royalties~~ **royalties** on ~~CUTX- 101~~ net sales ~~ranging from the mid- single digits up to the mid- twenties are also payable. All of the foregoing milestone and royalty payments are subject to 50 % diminution in the event Sentynl decides, at its option, to assume development control of CUTX- 101 during the 45- day period beginning on September 30, 2023. Under the asset purchase agreement, Cyprium retains development responsibility of CUTX- 101 (subject to the aforementioned right by Sentynl to assume development) and Sentynl will be responsible for commercialization~~ of CUTX- 101 as **follows: (i) 3 %** ~~well as progressing newborn screening activities. Continued development~~ of ~~CUTX- 101 is overseen by a Joint Steering Committee consisting~~ **annual net sales up to $ 75 million; (ii) 8. 75 %** of ~~representatives from Cyprium~~ **annual net sales between $ 75 million** and ~~Sentynl~~ **$ 100 million; and (iii) 12. 5 % of annual net sales in excess of $ 100 million** . Cyprium will ~~in any event~~ retain 100 % ownership over any FDA priority review voucher that may be issued ~~at~~ **if 9the** NDA ~~approval~~ for CUTX- 101 **is approved** . ~~In October~~ **The CUTX- 101 rolling NDA submission is ongoing and is expected to be completed by Sentynl in** ~~2021~~ **2024** ~~,~~ **.** Cyprium ~~announced positive results from~~ **previously enrolled patients into** an **Intermediate- Size** ~~efficacy and safety analysis of data integrated from two completed pivotal studies in patients~~ - **Patient Population Expanded Access Protocol which** ~~with Menkes disease treated with CUTX- 101, copper histidinate (CuHis). These data were presented as a virtual poster at the 2021 American Academy of Pediatrics National Conference & Exhibition. On December 7, 2021, Cyprium announced the initiation of a rolling submission of its NDA to the FDA for CUTX- 101 for the treatment of Menkes disease. Cyprium expects the rolling submission to complete in 2023. Cyprium~~ is **now administered** ~~currently in a dispute with its contract manufacturing organization (the " CMO "), regarding the CMO' s attempt to terminate a Master Services Agreement (together with related work orders, the " MSA ") between Cyprium and the CMO. Cyprium believes the CMO' s grounds for purporting to terminate the MSA are without merit and is currently availing itself of all appropriate legal remedies in efforts to ensure that the CMO abides~~ by **Sentynl Therapeutics** ~~its obligations under the MSA and / or to pursue monetary damages claims against the CMO~~ . **Additional information on** ~~To that end, Cyprium obtained a temporary restraining order in August 2022 and a preliminary injunction in September 2022 from a court in New York State;~~ the **Expanded Access study** ~~injunction invalidated the CMO' s attempted termination of the MSA~~ and **requirements can be found on ClinicalTrials** ~~prohibited the CMO from further attempts to terminate the MSA during the pendency of dispute resolution procedures, which are ongoing~~ . ~~9Intravenous (~~ **gov**

using identifier NCT04074512. Information on clinicaltrials. gov does not constitute part of this Annual Report on Form 10- K. IV) TramadolOur partner company Avenue is developing **an** intravenous **formulation of** ~~Tramadol~~ **tramadol** (" IV ~~Tramadol~~ **tramadol** "), **a schedule IV opioid** for the treatment of post- operative acute pain. Avenue completed two Phase 3 efficacy studies in 2018 and 2019 and announced that both had met their primary endpoints and all key secondary endpoints. In December 2019, Avenue submitted an NDA for IV ~~Tramadol~~ **tramadol** to treat moderate to moderately severe postoperative pain pursuant to Section 505 (b) (2) of the Federal Food, Drug and Cosmetic Act (" FDCA "), and following a ~~Complete Response Letter (" CRL ")~~ received in October 2020, resubmitted the NDA in February 2021. ~~In August~~ **The FDA assigned a PDUFA goal date of April 12,** 2021 ~~Avenue~~ **for the resubmitted NDA for IV Tramadol. On June 14, 2021, we announced that we had received a second CRL. We** submitted a formal dispute resolution request (" FDRR ") ~~,~~ **with the Office** of ~~which~~ **Neuroscience of the FDA on July 27, 2021. On August 26, 2021,** we received ~~notice~~ **an Appeal Denied Letter from the Office** of ~~denial~~ **Neuroscience of the FDA** in ~~March~~ **response to the FDRR submitted on July 27, 2021. On August 31, 2021, we submitted a FDRR with the Office of New Drugs (" OND ") of the FDA. On October 21, 2021, we received a written response from the OND of the FDA stating that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR. In February** 2022 ~~after~~ **, Avenue held** an Advisory Committee meeting **with the FDA regarding IV tramadol. In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: " Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic** in ~~February~~ **an inpatient setting? " The results were 8 yes votes and 14 no votes. In March** 2022 ~~.~~ **,** Avenue **received an Appeal Denied Letter from** ~~then~~ **the Office of New Drugs in response to the formal dispute resolution request. In August 2022, Avenue** participated in a Type A Meeting with the FDA ~~in August 2022~~ **Division of Anesthesia** , ~~which resulted in~~ **Analgesia, and Addiction Products (" DAAAP ") regarding** a ~~collaborative discussion on~~ **briefing document submitted that presented a** study design ~~and a~~ **the Avenue believed would have the** potential ~~path forward~~ **to address the comments and deficiencies noted in the Letter** . **In January 2024,** Avenue ~~incorporated~~ **announced that they reached final agreement with** the FDA **on** ~~'s suggestions from~~ the **Phase 3 safety** ~~meeting minutes and submitted a detailed~~ study protocol ~~that could form~~ **and statistical analysis approach, including** the **primary endpoint** ~~basis for the submission of a complete response to the Second CRL~~ . ~~Avenue announced~~ **The final** ~~on~~ **non - inferiority** ~~March 8, 2023 that the Company would participate in a Type C meeting with the FDA on March 9, 2023 to discuss a proposed~~ study ~~protocol~~ **is designed** to assess the risk of **opioid- induced** respiratory depression related to opioid stacking on IV ~~Tramadol~~ **tramadol** ~~relative~~ **compared** to ~~an approved~~ **IV morphine. The study will randomize approximately 300 post bunionectomy patients to IV tramadol or IV morphine for pain relief administered during a 48- hour post- operative period. Of note, the same surgical model was used in a pivotal Phase 3 Trial. In the Phase 3 safety study to be conducted, patients will have access to IV hydromorphone, a Schedule II** opioid ~~analgesic and continues to evaluate next steps with regard to IV Tramadol. MB- 107 and MB- 207 (Ex vivo Lentiviral Therapy for X- linked Severe Combined Immunodeficiency (" XSCID ")) Our partner company Mustang collaborates with St. Jude in the development of a first- in- class ex vivo lentiviral gene therapy for the treatment of XSCID~~ , ~~also known~~ **for rescue of breakthrough pain. The primary endpoint is a composite of elements indicative of respiratory depression. Avenue plans to initiate the study** as **soon** ~~bubble boy disease. In August 2018, Mustang entered into an exclusive worldwide license agreement with St. Jude for the development of this therapy. XSCID is the most common form of severe combined immune deficiency. This gene therapy is currently in two Phase 1 / 2 clinical trials involving two different autologous cell products: a multicenter trial of the MB- 107 product in newly diagnosed infants sponsored by St. Jude (ClinicalTrials. gov Identifier: NCT01512888) and a single- center trial of the MB- 207 product in previously transplanted patients sponsored by the National Institutes of Health (" NIH ") (ClinicalTrials. gov Identifier: NCT01306019). MB- 107 (for newly diagnosed infants with XSCID) Interim Phase 1 / 2 data on treatment of newly diagnosed infants under the age of two with MB- 107 were updated at an oral presentation at the American Society of Gene & Cell Therapy 25th Annual Meeting in May 2022. All patients were alive with stable vector marking in all cell lineages, and no evidence of clonal expansion or malignant transformation was~~ - **as possible** ~~observed. In May 2020~~ , **subject** ~~Mustang submitted an Investigational New Product Drug Application (" IND ") application with the FDA to initiate a pivotal non- randomized multicenter Phase 2 clinical trial of MB- 107 in newly diagnosed infants with XSCID who are under the age of two~~ - **to having** . ~~In response,~~ the **necessary financing** ~~FDA identified Chemistry, Manufacturing and Controls (" CMC ") hold issues that Mustang satisfactorily addressed in a December 2020 submission to the Agency, and the CMC hold was removed in January 2021. MB- 107 has received Orphan Drug Designation and Rare Pediatric Disease, and Regenerative Medicine Advanced Therapy (" RMAT ") designations from the FDA. EMA has granted to MB- 107 Priority Medicines (" PRIME ") designation, Advanced Therapy Medicinal Product (" ATMP ") classification, and Orphan Drug Designation. MB- 207 (for previously transplanted patients with XSCID) The most recent peer- reviewed presentation of data from the MB- 207 trial at the NIH occurred at the 61st Annual Meeting of the American Society of Hematology in December 2019. With the exception of one patient who died of a pre- existing lung condition after full immune reconstitution, all patients were alive with stable vector marking in all cell lineages, and no evidence of clonal expansion or malignant transformation was observed. In February 2021, Mustang announced an encouraging clinical update from this trial, including consistent safety and efficacy data. Mustang filed an IND in the fourth quarter of 2021 for a pivotal non- randomized multicenter Phase 2 clinical trial of MB- 207 in previously transplanted XSCID patients. In January 2022, the FDA issued a hold, pending CMC clearance, on Mustang' s IND application. 10The FDA has granted MB- 207 Rare Pediatric Disease Designation and Orphan Drug Designation. The EMA has granted ATMP classification and Orphan Drug Designation to MB- 207~~ . Olafertinib (also known as CK- 101, EGFR inhibitor for EGFR mutation- positive NSCLC) Checkpoint is currently evaluating a lead small- molecule, targeted anti- cancer agent, olafertinib, as an oral, third- generation, irreversible kinase inhibitor against selective mutations of epidermal growth factor receptors (" EGFR ") for the potential treatment of adult patients with metastatic NSCLC, whose

tumors have EGFR exon 19 deletion mutations. Checkpoint believes that olafertinib has the potential to be effective in this population as a monotherapy or in combination with other anti- tumor immune response potentiating compounds. ~~Olafernitib~~ **Olafertinib** has FDA Orphan Drug Designation for the treatment of EGFR mutation- positive NSCLC. In September 2018, Checkpoint announced preliminary interim safety and efficacy data from the ongoing Phase 1 clinical trial. The data were presented in an oral presentation at the International Association for the Study of Lung Cancer (" IASLC ") 19th World Conference on Lung Cancer in Toronto. Additional information on the Phase 1 trial can be found on ClinicalTrials. gov using identifier NCT02926768. ~~In~~ **Information on clinicaltrials. gov does not constitute part of this Annual Report on Form 10- K. 10In** November 2020, NeuPharma, Inc. commenced a Phase 3 clinical trial in China evaluating olafertinib in treatment- naïve locally advanced or metastatic NSCLC patients whose tumors have EGFR exon 19 deletion mutations. ~~Checkpoint has met with the FDA to discuss the adequacy of the ongoing Phase 3 trial in China.~~ CAEL- 101 (~~Light Chain Fibril- reactive Monoclonal~~ **monoclonal** ~~Antibody~~ **antibody** for AL ~~Amyloidosis~~ **amyloidosis**) Our former subsidiary Caelum, in collaboration with AstraZeneca plc (" AstraZeneca "), is working to develop a novel, first- in- class monoclonal antibody called CAEL- 101 for the treatment of amyloid light chain (" AL ") amyloidosis. CAEL- 101 is designed to improve organ function by reducing or eliminating amyloid deposits in the tissues and organs of patients with AL amyloidosis. The antibody is designed to bind to insoluble light chain amyloid protein, including both kappa and lambda subtypes and received Orphan Drug Designation from the FDA as a therapy for patients with AL amyloidosis, and as a radio- imaging agent in AL amyloidosis. CAEL- 101 is currently in two Phase 3 trials for AL amyloidosis and additional information on those trials can be found at ClinicalTrials. gov using identifiers: NCT04512235 and NCT04504825. **Information on clinicaltrials. gov does not constitute part of this Annual Report on Form 10- K.** In October 2021, AstraZeneca acquired Caelum for an upfront payment of approximately $ 150 million paid to Caelum shareholders, of which approximately $ 56. 9 million was paid to Fortress, which was net of the ten percent ~~, 24- month~~ escrow holdback amount and other miscellaneous transaction expenses. The agreement also provides for additional potential payments to Caelum shareholders totaling up to $ 350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive 42. 4 % of all possible proceeds of the transaction, **including** ~~totaling up to~~ approximately $ ~~212~~ **148** million **to Fortress, with $ 31** . **8 million upon BLA approval.** ~~11Triplex~~ -- **Triplex** (~~Vaccine for Cytomegalovirus~~ **cytomegalovirus (CMV) vaccine**) Through our subsidiary Helocyte, we are developing Triplex, a universal recombinant Modified Vaccinia Ankara viral vector vaccine engineered to induce a rapid, robust and durable virus- specific T cell response to three immuno- dominant proteins (UL83 (pp65), UL123 (IE1), and UL122 (IE2)) linked to cytomegalovirus (" CMV ") complications in the transplant setting. In a Phase 1 study, Triplex was ~~found~~ **observed** to be safe, well- tolerated and highly immunogenic when administered to healthy volunteers at multiple dose levels (ClinicalTrials. gov Identifier: NCT01941056). In a Phase 2 trial, Triplex was observed to be safe, well- tolerated, highly immunogenic and **a** ~~efficacious in reducing~~ **reduction in** CMV events in allogeneic stem cell transplant recipients **was observed** (ClinicalTrials. gov Identifier: NCT02506933). Triplex is currently the subject of four, grant- funded trials in various clinical settings including: adults undergoing stem cell transplant; adults co- infected with CMV and **Anti- Human Immunodeficiency Virus (" HIV ")** ; and in combination with a CAR T cell therapy for adults with non- Hodgkin lymphoma (" NHL "). Helocyte secured an exclusive, worldwide license to Triplex from ~~City of Hope National Medical Center (" COH ")~~ in April 2015. Helocyte secured an exclusive, worldwide license to Triplex from ~~City of Hope National Medical Center (" COH ")~~ in April of 2015 **. Information on clinicaltrials. gov does not constitute part of this Annual Report on Form 10- K** . In December 2021, Helocyte announced that a Phase 2 double- blind, randomized, placebo- controlled clinical trial was initiated to evaluate the safety and efficacy of Triplex, a CMV vaccine, in eliciting a CMV- specific immune response and reducing CMV replication in people living with HIV. The trial is being conducted by the AIDS Clinical Trials Group and is funded by the National Institute of Allergy and Infectious Disease, part of the National Institutes of Health. In August 2022, Helocyte announced that Triplex ~~had~~ received a grant from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health that could provide over $ 20 million in non- dilutive funding. This competitive award will fund a multi- center, placebo- controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation. The company believes this data set could ultimately be used to support approval of Triplex in this setting ~~. The~~ **and the** trial is expected to commence in ~~2023~~ **2024** . ~~CEVA101~~ **Early and Mid- Stage Product CandidatesDotinurad** (~~Cellular Therapeutic~~ **urate transporter (URAT1) inhibitor** for **gout** ~~Severe Traumatic Brain Injury~~) Through ~~our subsidiary Cellvation, we are developing CEVA101, a cellular product comprised of autologous Bone Marrow- derived Mononuclear Cells currently being developed for the treatment of severe traumatic brain injury (" TBI ") in adults and children. In separate Phase 1 trials of adults and children with severe TBI, CEVA101 was observed to be safe, well- tolerated and efficacious (resulting in volumetric preservation versus time- matched controls, and in the case of children, reducing the Pediatric Intensity Level of Therapy or PILOT score, ClinicalTrials. gov Identifiers: NCT01575470 and NCT0254722). In a randomized, placebo- controlled, multi- center Phase 2 study of children with severe TBI completed in November 2020, CEVA101 was similarly observed to be safe, well- tolerated and efficacious (resulting in volumetric preservation and a reduction in the PILOT score of those receiving CEVA101 versus those receiving placebo), (ClinicalTrials. gov Identifier: NCT01851083). A randomized, placebo- controlled Phase 2 study of CEVA101 for the treatment of severe TBI in adults is ongoing (ClinicalTrials. gov Identifier: NCT02525432). Cellvation received RMAT designation for CEVA101 in the treatment of severe TBI. Cellvation secured an exclusive worldwide license to CEVA101 (as well as CEVA- D and CEVA102) from University of Texas Health Science Center at Houston in October of 2016. DFD- 29 (Modified Release Oral Minocycline for Inflammatory Lesions of Rosacea) Through our partner company Journey in collaboration with Dr. Reddy' s Laboratories, Ltd. (" DRL "), we are developing DFD- 29, a modified release oral minocycline being evaluated for the treatment of inflammatory lesions of rosacea. Under the DRL arrangement, Journey is responsible for the development of DFD- 29, which includes conducting two Phase 3 studies to assess the efficacy, safety and tolerability of DFD- 29 for the treatment of rosacea and the regulatory submission of a new drug application under Section 505**

~~(b) (2) of the FDCA. DRL provides development support including the monitoring of two Phase 3 clinical trials. Journey initiated the Phase 3 trials in the first quarter of 2022, and completed enrollment in January 2023. Top- line data is expected in the first half of 2023, with a potential NDA filing anticipated in the second half of 2023. 12Early Stage Product CandidatesDotinuradThrough~~ our partner company Urica, in May 2021, we acquired an exclusive license from Fuji Yakuhin Co. Ltd. (" Fuji ") to develop ~~Dotinurad~~ **dotinurad** in North America and Europe (with the exclusive licensed territory later expanded to include the Middle East and North Africa). Dotinurad is a potential best- in- class urate transporter (URAT1) inhibitor for gout and possibly other hyperuricemic indications. Dotinurad (URECE ® tablet) was approved in Japan in 2020 as a once- daily oral ~~therapy~~ **11therapy** for gout and hyperuricemia. Dotinurad was efficacious and well- tolerated in more than 500 Japanese patients treated for up to 58 weeks in Phase 3 clinical trials. **The clinical program supporting approval included over 1, 000 patients.** In ~~December~~ **June** ~~2022~~ **2023** , Urica announced **data from** the ~~expansion of our license to include additional territories in the Middle East and North Africa (" MENA ") and Turkey territories. Urica initiated a~~ Phase 1 clinical trial in ~~June~~ **healthy volunteers showed comparable pharmacokinetic, pharmacodynamic and safety profile between U. S. and Japanese healthy subjects. In the third quarter of** ~~2022~~ **2023** ~~to evaluate Dotinurad for the treatment of~~ **, Urica initiated a Phase 1b clinical trial in patients with** gout ~~; we anticipate topline~~ **and hyperuricemia in the U. S. to compare U. S. patients' response to dotinurad with** data **generated in Japan, and to assess drug- drug interactions, if any, with allopurinol. Urica expects to announce data from this trial** in the first half of ~~2023~~ **2024** . MB- 106 (CD20 **- targeted** CAR T **cell therapy) Mustang is currently developing MB- 106 in a collaboration with Fred Hutchinson Cancer Center (" Fred Hutch "), a CD20- targeted, 3rd generation autologous CAR T- cell therapy, for patients with relapsed** ~~for -~~ **or refractory** B- cell non- Hodgkin ~~lymphoma~~ **lymphomas** (" ~~B-~~NHL ") and chronic lymphocytic leukemia (" CLL ") ~~) CD20 is a B- cell lineage- specific phosphoprotein that is expressed in high, homogeneous density on the surface of more than 95 % of B- cell NHL. CD20 is stable on the cell surface with minimal shedding or internalization upon binding antibody and is present at only nanomolar levels as soluble antigen. It is well established as an effective immunotherapy target, with extensive studies demonstrating improved tumor responses and survival of B- NHL patients treated with rituximab and other anti- CD20 antibodies. MB- 106 is a CD20- targeted third- generation autologous CAR T cell therapy is being developed by our partner company Mustang in a collaboration with Fred Hutch. More than 80, 000 new cases of NHL are diagnosed each year in the United States, and over 20, 000 patients die of this group of diseases annually. Most forms of NHL including follicular lymphoma, mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytic lymphoma, and small lymphocytic lymphoma, which account collectively for ~ 45 % of all cases of NHL, are incurable with available therapies, except for allogenic hematopoietic stem cell transplant (" allo- SCT "). However, many NHL patients are not suitable candidates for allo- SCT, and this treatment is also limited by significant rates of morbidity and mortality due to graft- versus- host disease. Chronic lymphocytic leukemia / small lymphocytic lymphoma (" CLL / SLL ") is a mature B cell neoplasm characterized by a progressive accumulation of monoclonal B lymphocytes. CLL is considered to be identical (i. e., one disease with different manifestations) to NHL SLL. CLL is the most common leukemia in adults in Western countries, accounting for approximately 25 to 35 percent of all leukemias in the United States. It is estimated that over 18, 000 new cases of CLL / SLL will be diagnosed in the United States in 2023. Most patients will have a complete or partial response to initial therapy. However, conventional therapy for CLL is not curative and most patients experience relapse. In addition, many patients will require a change in therapy due to intolerance. Since patients with CLL are generally elderly with a median age older than 70 years, and due to the relatively benign course of the disease in the majority of patients, only selected patients are candidates for intensive treatments such as allo- SCT. Innovative new treatments with a favorable safety profile are therefore urgently needed for patients with relapsed and refractory disease~~ . Under their IND, Fred Hutch is currently conducting a Phase 1 / 2 clinical study to evaluate the anti- tumor activity and safety of administering CD20- directed third- generation CAR T cells incorporating both 4- 1BB and CD28 co- stimulatory signaling domains (MB- 106) to patients with relapsed or refractory B- NHL or CLL (ClinicalTrials. gov Identifier: NCT03277729). Secondary endpoints of this study include safety and toxicity, preliminary antitumor activity as measured by overall response rate and complete remission rate, progression- free survival, and overall survival. The study is also assessing CAR T cell persistence and the potential immunogenicity of the cells. Fred Hutch intends to enroll approximately 50 subjects on the study, which is being led by Principal Investigator Mazyar Shadman, M. D., M. P. H., Assistant Member of Fred Hutch' s Clinical Research Division. ~~13The~~ -- **The** Fred Hutch IND was amended in 2019 to incorporate an optimized manufacturing process that had been developed in collaboration with Mustang. In ~~October~~ **December** ~~2022~~ **2023** , Mustang **announced initial data from its ongoing multicenter, open- label, non- randomized Phase 1 / 2 clinical trial (Clinicaltrials. gov Identifier: NCT05360238) evaluating the safety and efficacy of MB- 106 CAR- T cell therapy at the 2023 American Society of Hematology (" ASH ") Annual Meeting. Initial data show that all patients responded clinically to treatment with MB- 106 (n = 9); 100 % overall response rate for patients with follicular lymphoma (" FL ") and Waldenstrom macroglobulinemia (" WM "). 100 % of patients with FL (n = 5) had a complete response; 1 very good partial response and 2 partial responses were observed in WM patients (n = 3); and the hairy cell leukemia variant (" HCL- v ") patient experienced stable disease, with prolonged, ongoing independence from blood transfusions. Complete responses were observed in patients previously** treated ~~the first~~ **with CD19- targeted CAR T- cell therapy. MB- 106 demonstrated a tolerable safety profile in** ~~patient~~ **patients** ~~in the Company~~ **with indolent NHL, with no occurrence of cytokine release syndrome (" CRS ") above grade 1 and no immune effector cell** ~~- sponsored~~ **associated neurotoxicity syndrome (" ICANS ") of any grade. Outpatient administration was allowed and found to be feasible. Information on clinicaltrials. gov does not constitute part of this Annual Report on Form 10- K. In June 2023, Mustang announced final results from the FL cohort of the Fred Hutch** Phase 1 / 2 clinical study **, and the data showed an ORR** of **95 %** ~~MB- 106 in patients with relapsed or refractory B cell NHL or CLL~~ (**n = 19 / 20** ~~Clinicaltrials. gov Identifier: NCT05360238~~) **and complete response rate** ~~. As of December 2022, Mustang dosed five patients at the starting dose level of~~

~~their respective protocol arms. The study is also being supported by a grant of approximately $ 2 million from the National Cancer Institute~~ (“ ~~NCI~~ **CR** ”) **of 80 % (n = 16 / 20). Ten patients were in remission for over one year, seven of whom were in remission for over two years. All cytokine release syndrome events were grade1 (n = 5 / 20) or grade 2 (n = 1 / 20) with no grade 3 or higher cytokine release syndrome (“ CRS ”) events. There was no occurrence of immune effector cell- associated neurotoxicity syndrome (“ ICANS ”) of any grade** . MB- 101 (IL13Rα2 CAR T Cell Program for Glioblastoma) Mustang is also currently developing MB- 101 for malignant brain tumors, including glioblastoma (“ GBM ”). MB- 101 is an optimized CAR T product targeting IL13Rα2 on the surface of the malignant cells and incorporates enhancements in CAR T design and T cell engineering to improve antitumor potency and T cell persistence. GBM is the most common brain and central nervous system (“ CNS ”) cancer, accounting for 49 % of malignant primary brain and CNS tumors, 54 % of all gliomas, and 16 % of all primary brain and CNS tumors. More than ~~13~~ **14** , ~~000~~ **490** new glioblastoma cases were predicted in the U. S. for ~~2022~~ **2023** . Malignant brain tumors are the most common cause of cancer- ~~related~~ **12related** deaths in adolescents and young adults aged 15- 39 and the most common cancer occurring among 15- 19 year- olds in the U. S. While GBM is a rare disease, it is quite lethal, with five- year survival rates historically under 10 %. Standard of care therapy consists of maximal surgical resection, radiation, and chemotherapy with temozolomide, which, while rarely curative, is shown to extend median overall survival from 4. 5 to 15 months. GBM remains difficult to treat due to the inherent resistance of the tumor to conventional therapies. Immunotherapy approaches targeting brain tumors offer promise over conventional treatments. IL13Rα2 is an attractive target for CAR T therapy, as it has limited expression in normal tissue but is over- expressed on the surface of greater than 50 % of GBM tumors. CAR T cells are designed to express membrane- tethered IL- 13 receptor ligand mutated at a single site (glutamic acid at position 13 to a tyrosine; E13Y) with high affinity for IL13Rα2 and reduced binding to IL13Rα1 in order to reduce healthy tissue targeting (Kahlon KS et al. Cancer Research. 2004; 64: 9160- 9166). Having optimized MB- 101 dose, schedule, route of administration and T cell selection in a completed Phase 1 trial, ongoing COH sponsored studies include: ● ~~1.~~ MB- 101 with or without nivolumab and ipilimumab in treating patients with recurrent or refractory glioblastoma (currently enrolling patients; ClinicalTrials. gov Identifier: NCT04003649); ~~2.~~ **and** ● MB- 101 in treating patients with recurrent or refractory glioblastoma with a substantial component of leptomeningeal disease (currently enrolling patients; ClinicalTrials. gov Identifier: NCT04661384) ~~;~~ **.** The final planned MB- 101 trial will be in combination with the HSV- 1 oncolytic virus (MB- 108) in treating patients with recurrent or refractory glioblastoma and anaplastic astrocytoma. The objective of this trial is to turn immunologically “ cold ” tumors “ hot ” with MB- 108 in order to potentially enhance the efficacy ~~the efficacy~~ of MB- 101, then infuse MB- 101 loco- regionally as was done in the Phase 1 single- agent MB- 101 trial. The combination of MB- 101 and MB- 108 is referred to as MB- 109. MB- 108 (HSV- 1 Oncolytic Virus C134 **for recurrent GBM**) MB- 108 is a next- generation oncolytic herpes simplex virus (“ oHSV ”) in development at Mustang that is conditionally replication competent; that is, it ~~can~~ **is designed to** replicate in tumor cells, but not in normal cells, thus killing the tumor cells directly through this process. It was in- licensed from Nationwide Children’ s Hospital, and the University of Alabama at Birmingham (“ UAB ”) is evaluating the safety of this oncolytic virus in patients with recurrent glioblastoma ~~multiforme~~ in an ongoing Phase 1 trial (ClinicalTrials. gov Identifier: NCT03657576) **. Information on clinicaltrials. gov does not constitute part of this Annual Report on Form 10- K** . The rationale for in- licensing MB- 108 was to potentially enhance the efficacy of MB- 101 by first turning immunologically “ cold ” malignant glioma tumors “ hot ” with MB- 108, then infusing MB- 101 loco- regionally, as was done in the phase 1 single- agent MB- 101 trial. This combination is to be referred to as MB- 109. ~~14MB~~ **MB** - ~~102~~ **109** (~~CD123~~ **MB- 101 (IL13Rα2- targeted** CAR T Cell **Therapy** ~~Program for BPDCN, AML and high- risk MDS~~) ~~Our partner company~~ **MB- 108 (HSV- 1 oncolytic virus))** Mustang ~~collaborates with COH~~ **is developing MB- 109, a combination approach of MB- 101** and ~~Fred Hutchinson Cancer Center~~ **MB- 108, as a potential treatment for IL13Rα2 relapsed or refractory glioblastoma** (“ **GBM** ~~Fred Hutch~~ ”) **and anaplastic astrocytoma** ~~in the development of proprietary, autologous, chimeric antigen receptor~~ (“ ~~CAR~~ **AA** ”) ~~engineered T- cell (“ CAR T ”) therapies~~ . **An attractive novel approach** ~~CAR T therapies use the patient’ s own T- cells~~ to **control glioblastoma** ~~engage and destroy specific tumors. The process involves selecting specific T- cell subtypes, genetically engineering them to express chimeric antigen receptors and placing them back in the patient where they recognize and destroy cancer cells. We believe that harnessing the body’ s own immune system to treat cancer~~ is ~~a promising approach to cancer care that may prove curative across tumor types that have proved resistant to standard pharmacological and biological treatments. MB- 102 is a CAR T directed against CD123, a subunit of the heterodimeric interleukin- 3- receptor (“ IL- 3R ”), which is widely expressed on human hematologic malignancies including blastic plasmacytoid dendritic cell neoplasm (“ BPDCN ”) and acute myeloid leukemia (“ AML ”). In addition, CD123 can be found on the surface of B cell acute lymphoblastic leukemia (“ B- ALL ”), hairy cell leukemia, myelodysplastic syndrome (“ MDS ”), chronic myeloid leukemia (“ CML ”) and Hodgkin lymphoma. Of these malignancies, Mustang is currently investigating CD123 as a target for~~ adoptive cellular immunotherapy **utilizing CAR T** ~~in BPDCN, since high CD123 expression is associated with enhanced cell proliferation, increased resistance of these~~ cells ~~to apoptosis, and poor clinical prognosis~~ . ~~Depending on the early results in this patient~~ **CAR T cells can be engineered to recognize very specific antigenically distinct tumor** ~~population~~ **populations** ~~, Mustang may broaden the inclusion criteria to include AML~~ and ~~high- risk MDS~~ **to migrate through the brain parenchyma to kill malignant cells. In addition, oncolytic viruses** (“ ~~hrMDS~~ **OVs** ”) **have been developed to effectively infect** ~~. CD123 is overexpressed in the vast majority of cases of AML~~ and ~~hrMDS and~~ **kill cancer cells** in ~~essentially all cases of BPDCN. In October 2020, Mustang announced~~ the **tumor,** ~~dosing of the first patient in a multicenter Phase 1 / 2 clinical trial of MB- 102 in patients with relapsed or refractory BPDCN (Clinicaltrials. gov Identifier: NCT04109482). MB- 104 (CS1 CAR T for Multiple Myeloma and Light Chain Amyloidosis) Another Mustang program is a CAR T directed against CS1 (also known~~ as **well** ~~CD319, CRACC and SLAMF7), which was identified~~ as ~~a natural killer (“ NK ”)~~ **modify the microenvironment to increase tumor immunogenicity and immune** cell ~~receptor regulating immune functions~~ **trafficking within the tumor** . **Due to these properties** ~~It is also expressed on B cells~~ , **OVs have been studied** ~~T cells, dendritic cells, NK- T cells, and monocytes. CS1 is~~

overexpressed in multiple myeloma (“ MM ”) and AL amyloidosis, which makes it a good target for immunotherapy. A humanized anti- CS1 antibody, elotuzumab (Empliciti ®), is approved in combination with other medications for the treatment **treatments to enhance the effectiveness** of adult patients with MM who have received prior therapies **immunotherapies** . Despite great advances **Preliminary anti- tumor activity has been observed** in treatment, MM remains **clinical studies administering the OV (MB- 108)** an **and** 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 **(MB- 101) as single agents; however, the combination has not yet been explored** . In **To determine if the combination of both therapies will result in a synergistic effect, investigators from COH developed** preclinical studies , they have demonstrated efficacy **in orthotopic GBM models in nude mice. Dr. Christine Brown from City** of **Hope presented** these **preclinical studies at the American 13Association for Cancer Research 2022 Annual Meeting. It was observed that co- treatment with MB- 108 OV and IL13Rα2- directed** CAR - T cells , both in vitro **gave no adverse events** and in vivo , **more notably, that pre- treatment** within -- **with MB** the context of clinically relevant models of MM and AL. COH is evaluating the safety of this CS1 - specific **108 re- shaped the tumor microenvironment by increasing immune cell infiltrates and enhanced the efficacy of sub- therapeutic doses of** CAR - T cell therapy in **delivered either intraventricularly or intratumorally. These preclinical studies aimed to provide** a Phase 1 trial **deeper understanding of this combination approach to support the potential benefit of a combination study that will evaluate an oHSV** (**MB- 108** ClinicalTrials. gov Identifier: NCT03710421) . Once COH has established a safe and effective dose for **IL13Rα2- directed CAR- T cells (** MB- 104 in this trial **101). In October 2023** , Mustang expects to file an **announced that the FDA had accepted the Investigational New Drug (“** IND for a multicenter Phase 1 / 2 trial for the treatment of patients with MM. 15MB- 103 (HER2 CAR T for GBM & Metastatic Breast Cancer to Brain) HER2 / neu (often shortened to “ HER2 ”) **application of MB- 109 for the treatment of recurrent GBM and high- grade astrocytoma. Mustang** is **currently planning** a growth- promoting protein on the outside of all breast cells. Breast cancer cells with higher than normal levels of HER2 are called HER2- positive (“ HER2 ”). These cancers tend to grow and spread faster than other breast cancers. Breast cancer is the most commonly diagnosed cancer in women, with over 42, 000 women in the United States expected to die from advanced metastatic disease in 2020. Approximately 20 % to 25 % of breast cancers overexpress HER2, which is an established therapeutic target of both monoclonal antibodies (“ mAbs ”) and receptor tyrosine kinase inhibitors. With the advent of effective mAbs directed against HER2, the median overall survival of patients with metastatic HER2 breast cancer has improved. However, management of metastatic disease in the CNS observed in up to 50 % of HER2 breast cancer patients continues to be a clinical challenge in large part due to the inability of mAbs to sufficiently cross the blood- brain barrier. Although small- molecule inhibitors of HER2 exist and have been clinically approved, their single- agent efficacy in the context of metastatic disease to the brain has been limited. While HER2- targeted therapy in combination with conventional agents has shown some promise for the treatment of patients with metastatic breast cancer, control of brain metastases remains a significant unmet clinical need, as most patients survive less than two years following CNS involvement. CAR- based T- cell immunotherapy is being actively investigated for the treatment of solid tumors, including HER2 cancers. Mustang’ s academic partners at COH have developed a second- generation HER2- specific CAR T- cell for the treatment of refractory / relapsed HER2 GBM, as well as for the treatment of brain and / or leptomeningeal metastases from HER2 cancers. COH’ s preclinical data demonstrate effective targeting of breast cancer brain metastases with intraventricular delivery of HER2- directed CAR T cells. COH is evaluating the safety of this HER2- specific CAR T cell therapy in two phase 1 trials that commenced in the fourth quarter of 2018 (ClinicalTrials. gov Identifiers: NCT03389230 and NCT03696030). MB- 105 (PSCA CAR T for Prostate & Pancreatic Cancers) Prostate stem- cell antigen (“ PSCA ”) is a glycosylphosphatidylinositol- anchored cell membrane glycoprotein. In addition to being highly expressed in the prostate it is also expressed in the bladder, placenta, colon, kidney, and stomach. Prostate cancer may be amenable to T cell- based immunotherapy since several tumor antigens, including PSCA, are widely over- expressed in metastatic disease. Mustang’ s academic partners at COH have developed a second- generation PSCA- specific CAR T cell therapy that has demonstrated robust in vitro and in vivo anti- tumor activity in patient- derived, clinically relevant, bone- metastatic prostate cancer xenograft models. COH is evaluating the safety of this PSCA- specific CAR T cell therapy in a Phase 1 trial treating patients with PSCA metastatic castration- resistant prostate cancer (ClinicalTrials. gov Identifier: NCT03873805). In October 2020, Mustang announced initial data from the Phase 1 clinical **study that will** 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 **investigate increasing doses of intratumorally administered** reported results from a highly refractory patient treated with MB- **108 followed** 105 who experienced a 94 percent reduction in prostate- specific antigen (PSA), near complete reduction of measurable soft tissue metastasis by **dual intratumoral** computerized tomography, and improvement in bone metastases by magnetic resonance imaging. Data presented in February 2022 indicate **intraventricular administration of MB- 101 to treat recurrent GBM and high- grade astrocytomas** that **express IL13Rα2 on the surface** PSCA- CAR T- cell therapy is feasible in patients with metastatic castration- resistant prostate cancer (“ mCRPC ”) with a dose- limiting toxicity of cystitis, and shows preliminary anti- tumor effect at a dose of 100M cells plus lymphodepletion . AJ201 (novel AR degrader and Nrf1 and Nrf2 activator **, androgen receptor degradation enhancer**) In February 2023, Avenue announced the license of intellectual property rights underlying AJ201 from AnnJi Pharmaceutical Co. Ltd. AJ201 is currently being studied in a Phase 1b / 2a multicenter, randomized, double- blind clinical trial at six clinical sites across the U. S. for the treatment of spinal and bulbar muscular atrophy (“ SBMA ”), also known as Kennedy’ s Disease (ClinicalTrials. gov Identifier: NCT05517603). **Enrollment was completed in January 2024, with topline data anticipated in the second quarter of 2024.** SBMA is a rare, inherited, X- linked genetic neuromuscular disease primarily affecting men and AJ201 was designed to modify SBMA through multiple mechanisms including degradation of the abnormal AR protein and by stimulating Nrf1 and Nrf2, which are involved in

protecting cells from oxidative stress which can lead to cell death. ~~16AJ201 --~~ **AJ201** has been granted Orphan Drug Designation by the FDA for the indications of SBMA, Huntington' s Disease, and Spinocerebellar Ataxia. **MB- 117 (Ex vivo Lentiviral Gene Therapy for Newly Diagnosed X- linked Severe Combined Immunodeficiency (" XSCID ")) and MB- 217 (Ex vivo Lentiviral Gene Therapy for Previously Transplanted XSCID) In partnership with St. Jude, Mustang' s XSCID gene therapy programs are being developed under an exclusive license to intellectual property underpinning potentially curative treatment for XSCID, a rare genetic immune system condition in which affected patients do not live beyond infancy without treatment. St. Jude' s first- in- class ex vivo lentiviral (" LV ") gene therapy has been utilized in two Phase 1 / 2 clinical trials involving two different autologous cell products produced via transduction of patients' hematopoietic stem cells using a predecessor LV vector. These cell products were designated MB- 107 and MB- 207, and the respective Phase 1 / 2 clinical trials were: a multicenter trial of the MB- 107 product in newly diagnosed infants sponsored by St. Jude (ClinicalTrials. gov Identifier: NCT01512888; referred to at St. Jude as LVXSCID- ND) and a single- center trial of the MB- 207 product in previously transplanted patients sponsored by the National Institutes of Health (" NIH ") (ClinicalTrials. gov Identifier: NCT01306019; referred to at the NIH as LVXSCID- OC). Going forward, this predecessor LV vector will be replaced by a modified LV vector which will be used to produce the MB- 117 and MB- 217 cell products. In 2024, following availability of the modified LV vector, we expect that St. Jude will initiate its Phase 1 trial to treat newly diagnosed infants with MB- 117 and that the NIH will initiate its Phase 1 trial to treat previously transplanted patients with MB- 217. MB- 110 (Ex Vivo Lentiviral Gene Therapy for RAG1 Severe Combined Immunodeficiency) Mustang is developing MB- 110, a first- in- class ex vivo treatment for recombinase- activating gene- 1 (" RAG1 ") Severe combined immunodeficiency (" SCID "), through an exclusive license and in partnership with Leiden University Medical Centre (" LUMC "). SCID due to complete recombinase- activating gene- 1 (RAG1) deficiency is a rare, genetic disorder due to null mutations in the RAG1 gene resulting in less than 1 % of wild type V (D) J recombination activity. Neonatal patients present with life- threatening, severe, recurrent infections by opportunistic fungal, viral and bacterial micro- organisms, as well as skin rashes, chronic diarrhea, failure to thrive and fever. Immunologic observations include profound T and B cell lymphopenia, low or absent serum immunoglobulins, and normal natural killer cell counts. As is the case with 14other types of SCID, RAG1- SCID is fatal in infancy unless immune reconstitution is achieved with hematopoietic stem cell transplantation (HSCT). MB- 110, which includes low- dose conditioning prior to reinfusion of the patients' own gene- modified blood stem cells, is currently being evaluated in a Phase 1 / 2 multicenter clinical trial in Europe. The ongoing clinical trial has enrolled its first patient, and additional clinical sites are expected to be added in the near future. The RAG1- SCID program has been granted Orphan Drug Designation by the European Medicines Agency.** BAER- 101 (~~novel~~ **GABAA** α2 / 3 ~~– subtype- selective GABA A~~ -positive allosteric modulator ~~(" PAM ")~~) Through Avenue' s subsidiary Baergic, we are developing BAER- 101, a high affinity, selective modulator of the gamma- aminobutyric acid (" GABA ") A, which is a receptor system with differential binding and modulatory properties dependent on the particular GABA A subtype. Baergic intends to explore BAER- 101 in a number of CNS disorders where patients are not adequately treated, including epilepsy and acute anxiety disorders **. In August 2023, Avenue reported preclinical data for BAER- 101 from an in vivo evaluation in SynapCell' s Genetic Absence Epilepsy Rate from the Strasbourg (" GAERS ") model of absence epilepsy. The GAERS model mimics behavioral, electrophysiological and pharmacological features of human absence seizures and has shown to be an early informative indicator of efficacy in anti- seizure drug development. In the model, BAER- 101 demonstrated full suppression of seizure activity with a minimal effective dose of 0. 3 mg / kg administered orally. In December 2023, Avenue presented the preclinical in vivo data evaluating BAER- 101 using the GAERS model of absence epilepsy at the American Epilepsy Society (AES) 2023 Annual Meeting** . Preclinical Product CandidatesMayo Clinic In Vivo CAR T Platform TechnologyIn August 2021, Mustang announced an exclusive license agreement with the Mayo Clinic for a novel technology to create in vivo CAR T cells that may be able to transform the administration of CAR T therapies and has the potential to be used as an off- the- shelf therapy. Preclinical proof- of- concept has been established, and the ongoing development of this technology ~~continues to take place at~~ **is continuing in partnership with the** Mayo Clinic. AAV- ATP7A Gene TherapyThrough our subsidiary Cyprium, we are developing adeno- associated virus (" AAV ") **- based** gene therapy (" AAV- ATP7A ") **for the treatment of Menkes disease** . Cyprium entered into a license agreement with Eunice Kennedy Shriver National Institute of Child Health and Human Development to acquire the global rights to develop and commercialize AAV- ATP7A gene therapy. AAV- ATP7A gene therapy has demonstrated the ability to rescue neurological phenotypes and improve survival when coadministered with copper histidinate injections in a mouse model of Menkes disease and has been granted Orphan Drug Designation by the FDA. **In March 2024, Cyprium announced a $ 4. 1 million grant from the National Institute of Neurological Disorders and Stroke (" NINDS ") of the NIH was awarded to the Research Institute at Nationwide Children' s Hospital and Principal Investigator, Stephen G. Kaler, M. D., M. P. H., to fund the completion of preclinical studies, manufacturing, and preparation of an IND application for a first- in- human clinical trial.** AVTS- 001 Gene ~~TherapyThrough our subsidiary~~ **TherapyIn April 2023, we announced the execution of an asset purchase agreement, pursuant to which 4D Molecular Therapeutics (" 4DMT ") acquired** Aevitas **' proprietary rights to its short- form human complement factor H (" sCFH ") asset for the treatment of complement- mediated diseases. Under the terms of the agreement** , ~~we~~ **Aevitas is eligible to receive cash payments from 4DMT totaling up to $ 140 million in potential late- stage development, regulatory and sales milestones. A range of single- digit royalties on net sales** are **also payable. 15Prior** ~~developing AVTS- 001, an AAV gene therapy~~ to **the agreement** ~~treat diseases associated~~ with **4DMT,** ~~a dysregulated complement system via AAV delivery of functional short Factor H.~~ Aevitas ~~has~~ licensed **the sCFH asset** ~~an engineered, fully functional shortened version of Factor H which can be packaged by AAV,~~ from the University of Pennsylvania **and** . ~~Aevitas~~ also ~~has a collaboration~~ **collaborated** with University of Massachusetts Medical to optimize AAV constructs. CK- 103 (BET Inhibitor) Checkpoint is currently developing

CK- 103, a novel, selective and potent small molecule inhibitor of bromodomain and extra- terminal (“ BET ”) bromodomains. Checkpoint plans to develop CK- 103 for the treatment of various advanced and metastatic solid tumor cancers, including, but not limited to, those associated with elevated c- Myc expression. Checkpoint entered into an exclusive license agreement with Jubilant Biosys Limited to develop and commercialize novel compounds that inhibit BET bromodomains on a worldwide basis. Checkpoint entered into a Sublicense Agreement with TGTX to develop and commercialize CK- 103 in the field of hematological malignancies. Checkpoint retains the right to develop and commercialize CK- 103 in solid tumors. Currently, Checkpoint has completed the required CMC, pharmacology and toxicology activities that it believes will support an IND application filing. ~~17CEVA --~~ **CEVA** - D and CEVA- 102 Through our subsidiary Cellvation, we are developing CEVA- D, a novel bioreactor device that **is designed to** ~~enhances --~~ **enhance** the anti- inflammatory potency of bone marrow- derived cells without genetic manipulation, using wall shear stress to suppress tumor necrosis factor- a (“ TNF- a ”) production by activated immune cells. CEVA- 102 is the first cell product produced by CEVA- D, and may be applicable for various indications, including the treatment of severe ~~TBI~~ **traumatic brain injury** . CK- 302 (Anti- GITR) CK- 302 is a fully human agonistic monoclonal antibody in development at Checkpoint that is designed to bind and trigger signaling in **Glucocorticoid- Induced TNFR- Related (“** GITR **”)** expressing cells. Scientific literature indicates GITR is a co- stimulatory molecule of the TNF receptor family and is expressed on activated T cells, B cells, NK and regulatory T cells. Checkpoint believes that an anti- GITR monoclonal antibody has the potential to be effective in one or more oncological indications as a monotherapy or in combination with an anti- PD- L1 antibody as well as other anti- tumor immune response potentiating compounds and targeted therapies. CK- 303 (Anti- CAIX) Also in development at Checkpoint is CK- 303, a fully human anti- carbonic anhydrase IX (“ CAIX ”) antibody designed to recognize CAIX expressing cells and kill them via antibody- dependent cell- mediated cytotoxicity and complement- dependent cytotoxicity (“ CDC ”). Scientific literature indicates that CAIX is a well characterized tumor associated antigen with expression almost exclusively limited to the cells of renal cell carcinoma (“ RCC ”). More than 85 % of RCC cases have been demonstrated to express high levels of CAIX expression. There is very limited expression of this antigen on healthy tissue which Checkpoint believes will limit reactivity of this antibody against healthy tissues. ONCOlogues (Oligonucleotide Platform) Our subsidiary Oncogenuity is developing a delivery platform that allows peptic nucleic acids to enter **a** cell membrane and nucleus, displace the targeted mutant DNA strand, and prevent mutant mRNA transcription. Oncogenuity is seeking to optimize lead candidates targeting genetically driven cancers, including KRAS G12D, and other genetic disorders. Intellectual Property GenerallyOur 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~~ **16We** also depend upon the skills, knowledge, experience and know- how of our management and research and development personnel, as well as that of our advisers, consultants and other contractors. To help protect our proprietary know- how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently ~~rely~~ **,** and will in the future **,** rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisers and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. ~~18CompetitionWe --~~ **CompetitionWe** operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than ~~us~~ **we do** . Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in research in direct competition with us. We also may compete with these organizations to recruit scientists and clinical development personnel. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors are pursuing the development and / or acquisition of pharmaceuticals, medical devices and over- the- counter (“ OTC ”) products that target the same diseases and conditions that we are targeting in biotechnology, biopharmaceutical, dermatological and other therapeutic areas. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions or decreased volume of sales, or both. Most new products that we introduce must compete with other products already on the market or products that are later developed by competitors. The principal methods of competition for our products include quality, efficacy, market acceptance, price, and marketing and promotional efforts, patient access programs and product insurance coverage reimbursement. The only pharmaceutical area in which we sell marketed products is dermatology, and the dermatology competitive landscape is highly fragmented, with a large number of mid- size and smaller companies competing in both the prescription sector and the OTC sector. Our competitors are pursuing the development and / or acquisition of pharmaceuticals, medical devices and OTC products that target the same diseases and conditions that we are targeting in dermatology. Competitive factors vary by product line and geographic area in which our products are sold. The principal methods of competition for our products include quality, efficacy, market acceptance, price, and marketing and promotional efforts. Branded products often must compete with therapeutically similar branded or generic products or with generic equivalents. Such competition frequently increases over time. For example, if competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products could be subject to progressive price reductions and / or decreased volume of sales. To successfully compete for business, we must often demonstrate that our products offer not

only medical benefits, but also cost advantages as compared with other forms of care. Accordingly, we face pressure to continually seek out technological innovations and to market our products effectively. Our major competitors **in dermatology** , including Galderma Laboratories, Almirall ~~, Novan Health~~ , Ortho- Dermatologics, Mayne Pharmaceuticals, Sun Pharma, Leo Pharma, and Arcutis Biotherapeutics, among others, vary depending on therapeutic and product category, dosage strength and drug- delivery systems, among other factors. Generic CompetitionOur partner company Journey faces increased competition from manufacturers of generic pharmaceutical products, who may submit applications to FDA seeking to market generic versions of Journey' s products. In connection with these applications, the generic drug companies may seek to challenge the validity and enforceability of our patents through litigation. When patents covering certain of our products (if applicable) expire or are successfully challenged through litigation or in **U. S. Patent and Trademark Office (“** USPTO **”)** proceedings, if a generic company launches a competing product " at risk, " or when the regulatory or licensed exclusivity for our products (if applicable) expires or is otherwise lost, we may face generic competition as a result. Generic versions are generally significantly less expensive than branded ~~versions~~ **17versions** , 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. ~~19Government~~ -- **Government** Regulation and Product ApprovalGovernment authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record- keeping, promotion, advertising, distribution, post- approval monitoring and reporting, marketing and export and import of products such as those we are developing. United States Pharmaceutical Product Development ProcessIn 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~~ **an** NDA or BLA for a new pharmaceutical product; ● satisfactory completion of an FDA pre- approval inspection of the manufacturing facility or facilities where the pharmaceutical product is produced to assess compliance with the FDA' s current Good Manufacturing Practices (“ cGMPs "), to assure that the facilities, methods and controls are adequate to preserve the pharmaceutical product' s identity, strength, quality and purity; ● potential FDA audit of the preclinical and clinical trial sites that generated the data in support of the NDA or BLA; and ● FDA review and approval of the NDA or BLA. The regulatory review and approval process is lengthy, expensive and uncertain. The process of seeking required approvals before we can market or sell a product, and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and we cannot guarantee that we will be able to obtain the appropriate marketing authorization for any product **candidate** . Before testing any compounds with potential therapeutic value in humans, the pharmaceutical product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the pharmaceutical product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or ~~literature~~ **18literature** 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. ~~20Clinical~~ -- **Clinical** trials involve the administration of the pharmaceutical product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by the sponsor. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA if conducted under a U. S. IND. Clinical trials must be conducted in accordance with GCP requirements. Further, each clinical trial must be reviewed and approved by an Institutional Review Board (“ IRB ") or ethics committee if conducted outside of the United States, at or servicing each institution at which the clinical trial will be conducted. An IRB or ethics committee is charged with protecting the welfare and rights of trial

participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB or ethics committee also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. We intend to use third- party clinical research organizations (“ CROs ”) to administer and conduct our planned clinical trials and will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols and to play a significant role in the subsequent collection and analysis of data from these trials. The failure by any of such third parties to meet expected timelines, adhere to our protocols or meet regulatory standards could adversely impact the subject product development program. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined: ● Phase 1. The pharmaceutical product is usually introduced into a small group of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life- threatening diseases, such as cancer treatments, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. ● Phase 2. The pharmaceutical product is evaluated in a larger, but still limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule. ● Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish safety and efficacy, the overall risk / benefit ratio of the product and provide an adequate basis for product labeling. Generally, it has been the FDA’ s position that Congress intended at least two adequate and well- controlled Phase 3 clinical trials for approval of an NDA or BLA or foreign authorities for approval of marketing applications. Post- approval studies, or Phase 4 clinical trials, may be required after initial receipt of marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA after it has been approved, and is on the market, as an ongoing condition of approval. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or, if used, its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB or ethics committee can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’ s or ethics committee’ s requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients. ~~Concurrent~~ **19Concurrent** 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. ~~21United~~ -- **United** States Review and Approval ProcessThe data and results generated from product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the pharmaceutical product, proposed labeling and other required information are submitted to the FDA as part of an NDA or BLA submission before the product can be marketed and sold. The review and approval process for an NDA or BLA is lengthy and difficult and the FDA may not approve an NDA or BLA if the applicable regulatory criteria are not satisfied or if the data and results in the submission are insufficient to support a finding of safety and efficacy, FDA may also require additional clinical data or other data and information to address deficiencies in an application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Even if a product receives regulatory approval, the approval may be significantly limited with respect to dosages, indications for use, or other label claims related to those disease states, conditions and patient populations for which the product is safe and effective and, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and are subject to periodic unannounced inspections by the FDA for compliance with cGMPs, which impose additional regulatory requirements upon us and our third- party manufacturers. We cannot be certain that we or our suppliers will be able to fully comply with the cGMPs or other FDA regulatory requirements. Post- Approval RequirementsAny pharmaceutical products for which we receive FDA approvals are subject to continuing postmarket regulation by the FDA, including, among other things, record- keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, standards for direct- to- consumer advertising, promoting pharmaceutical products for uses or in patient populations that are not described in the pharmaceutical product’ s approved labeling (known as “ off- label use ”), industry- sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, compliance and enforcement actions initiated by the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. The FDA also may require Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

Special FDA Expedited Review and Approval ProgramsThe FDA has various programs, including fast track

designation, accelerated approval, priority review and breakthrough therapy designation, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life- threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. To be eligible for fast track designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life- threatening disease or condition and based on preclinical or preliminary clinical data demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. 20The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. These six- and ten- month review periods are measured from the " filing " date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review. In addition, drugs studied for their safety and effectiveness in treating serious or life- threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well- controlled clinical trials establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post- marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint and under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, unless otherwise informed by the agency, pre- approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Moreover, a sponsor can request designation of a drug candidate as a " breakthrough therapy. " A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval and priority review. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. Additionally, under FDORA, a platform technology incorporated within or utilized by a drug or biological product is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a drug approved under an NDA; (2) preliminary evidence submitted by the sponsor of the approved or licensed drug, or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a drug that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original NDA for a drug that uses or incorporates the platform technology. Designated platform technology status does not ensure that a drug will be developed more quickly or receive FDA approval. Even if a product candidate or our platform qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, priority review, accelerated approval and breakthrough therapy designation, do not change the standards for approval and may not ultimately expedite the development or approval process. Section 505 (b) (2) Regulatory Approval Pathway Section 505 (b) (2) was added to the Act by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch- Waxman Amendments). Section 505 (b) (2) of the FDCA provides an alternate regulatory pathway for approval of a new 21drug by allowing the FDA to rely on data not developed by the applicant. Specifically, Section 505 (b) (2) permits the submission of an NDA where one or more of the investigations relied upon by the applicant for approval was not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and / or the FDA' s findings of safety and effectiveness for an approved drug already on the market. Approval or submission of a 505 (b) (2) application, like those for abbreviated new drugs, or ANDAs, may be delayed because of patent and / or exclusivity rights that apply to the previously approved drug. Under the 505 (b) (2) regulatory approval pathway, the applicant may reduce some of the burdens of developing a full clinical program by relying on investigations not conducted by the applicant and for which the applicant has not

obtained a right of reference, such as prior investigations involving the listed drug. In such cases, some clinical trials may not be required or may be otherwise limited. A 505 (b) (2) application may be submitted for a new chemical entity (NCE), when some part of the data necessary for approval is derived from studies not conducted by or for the applicant and when the applicant has not obtained a right of reference. Such data are typically derived from published studies, rather than FDA' s previous findings of safety and effectiveness of a previously approved drug. For changes to a previously approved drug however, an applicant may rely on the FDA' s finding of safety and effectiveness of the approved drug, coupled with information needed to support the change from the approved drug, such as new studies conducted by the applicant or published data. When based on an approved drug, the 505 (b) (2) drug may be approved for all of the indications permitted for the approved drug, as well as any other indication supported by additional data. Section 505 (b) (2) applications also may be entitled to marketing exclusivity if supported by appropriate data and information. As discussed in more detail below, three- year new data exclusivity may be granted to the 505 (b) (2) application if one or more clinical investigations conducted in support of the application, other than bioavailability / bioequivalence studies, were essential to the approval and conducted or sponsored by the applicant. Five years of marketing exclusivity may be granted if the application is for an NCE, and pediatric exclusivity is likewise available. Orange Book Listing and Paragraph IV CertificationFor NDA submissions, including 505 (b) (2) applications, applicants are required to list with the FDA certain patents with claims that cover the applicant' s product. Upon approval, each of the patents listed in the application is published in Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Any applicant who subsequently files an ANDA or a 505 (b) (2) application that references a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification. If an applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the holder of the NDA for the approved drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the ANDA or 505 (b) (2) application until the earlier of 30 months from the date of the lawsuit, the applicant' s successful defense of the suit, or expiration of the patent. Orphan DrugsUnder 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~~ **22limited** circumstances, for seven years. The FDA may approve a subsequent application from another person if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public' s need. If the FDA approves someone else' s application for the same drug that has orphan exclusivity, but for a different use, the competing drug could be prescribed by physicians outside its FDA approval for the orphan use, notwithstanding the existence of orphan exclusivity. A grant of an orphan designation is not a guarantee that a product will be approved. If a sponsor receives orphan drug exclusivity upon approval, there can be no assurance that the exclusivity will prevent another person from receiving approval for the same or a similar drug for the same or other uses. **U. S. Marketing Exclusivity and Patent Term Extensions Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, some of our U. S. patents may be eligible for limited patent term extension (" PTE ") under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a PTE of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, PTE cannot extend the remaining term of a patent beyond a total of 14 years from the product' s approval date. The PTE period is generally one- half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension. In the future, we intend to apply for PTE for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA. Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five- year period of non- patent marketing exclusivity within the U. S. to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505 (b) (2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non- infringement to one of the patents**

listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three- year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five- year and three- year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well- controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described below, may offer a seven- year period of marketing exclusivity, except in certain circumstances. ~~22Pediatric --~~ **Pediatric exclusivity is another type of regulatory market exclusivity in the U. S. which, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the active moiety and patent terms. This six month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA issued " Written Request " for such a trial, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining. Pediatric** InformationUnder 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~~ **23and** effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any product for an indication for which orphan designation has been granted. The Best Pharmaceuticals for Children Act provides BLA holders a six- month extension of any exclusivity- patent or non- patent- for a product if certain conditions are met. Conditions for exclusivity include the FDA' s determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within a specific time frame. **DEA RegulationThe Controlled Substances Act (CSA) imposes various registration, record- keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls, prescription and order form requirements and restrictions on prescription refills for certain kinds of pharmaceutical products. A principal factor for determining the particular requirements of the CSA applicable to a product, if any, is its actual or potential abuse profile, which is classified into a DEA schedule. A product may be listed as a Schedule I, II, III, IV or V controlled substance, with Schedule I presenting the highest perceived risk of abuse and Schedule V presenting the least. Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance and registration is specific to the particular location, activity and controlled substance schedule. The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II controlled substances and less stringent requirements for Schedules III, IV, and V. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings. In addition to federal scheduling, some drugs may be subject to state-controlled substance regulation and thus more extensive requirements than those determined by the DEA and FDA.** Other Healthcare Laws and Compliance RequirementsIn the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e. g., the Office of Inspector General), the United States Department of Justice **, the DEA** and individual United States Attorney offices within the Department of Justice, and state and local governments. ~~Pharmaceutical Coverage, Pricing~~ **We will also be subject to various federal** and ~~ReimbursementIn the United States~~ **state laws targeting fraud** and ~~markets~~ **abuse** in **the healthcare industry. These laws may impact, among** other ~~countries~~ **things** , **our proposed** sales ~~of any products for~~ **, marketing and educational programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in** which we ~~receive regulatory approval for commercial sale will depend in part on~~ **conduct our business. The laws that may affect our ability to operate include: ● The federal Anti- Kickback Statute, which prohibits, among** ~~the~~ **other** ~~availability of reimbursement~~ **things, persons** from ~~third- party payors~~ **knowingly and willfully soliciting** , ~~including~~ **receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or 24reward, or in return for, either (1) the referral of an individual to a person for furnishing any item or service for which payment is available under a federal health care program, or (2) the purchase, lease, order or recommendation thereof of any good, facility, service or item for which payment is available under a federal health care program; ● The False Claims Act and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or**

causing to be presented, false or fraudulent claims for payment from the federal government **or making or using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; ● The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program, obtaining money or property of the** health ~~administrative authorities, managed~~ care ~~providers~~ **benefit program through false representations or knowingly and willingly falsifying** , ~~private~~ **concealing or covering up a material fact, making false statements or using or making any false or fraudulent document in connection with the delivery of, or payment for,** health ~~insurers and other organizations. Third- party payors are~~ **care benefits or** ~~increasingly examining the medical necessity and cost- effectiveness of medical products and~~ services **; ● HIPAA** , ~~in addition to their safety and efficacy, and, accordingly, significant uncertainty exists~~ as ~~to~~ **amended by** the **Health Information Technology** ~~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~~ **for Economic** ~~state healthcare legislation~~ and **Clinical Health Act, or HITECH, and its implementing** regulations, ~~including~~ **which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; ● The provision under** the Affordable Care Act (" ACA ") **commonly referred to as the Sunshine Act, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and group purchasing organizations; applicable manufacturers are also required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse- midwives; and ● State law equivalents of each of the above federal laws, such as the Anti- Kickback Statute and False Claims Act, and state laws concerning security and privacy of health care information, which may differ in substance and application from state- to- state thereby complicating compliance efforts. The ACA broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti- Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U. S. C. Section 1320a- 7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti- Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. Pharmaceutical Coverage, Pricing and ReimbursementIn the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third- party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third- party payors are increasingly examining the medical necessity and cost- effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third- party reimbursement may not be available for any products for which we obtain regulatory approval to enable us to realize an appropriate return on our investment in research and product development. We are unable to predict the future course of federal or state healthcare legislation and regulations, including the ACA** . The ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the payments received for any approved drug. Any ~~reduction~~ **25reduction** 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~~ **in** the **future** ~~2020 election and subsequent change of Administration~~ . International RegulationIn 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. ~~23Employees~~ -- **Employees** and Human Capital Management As of December 31, ~~2022~~ **2023** , we had ~~187~~ **186** full- time employees at Fortress and our subsidiaries and partner companies. **None of our** ~~Journey relies on professional employer~~ **employees** ~~organizations and staffing organizations for the employment of its~~ - **is represented by a labor union** ~~field sales force, which totaled 74 at December 31, 2022~~ . We have retained a number of expert advisors and consultants who help navigate us through different aspects of our business. We consider our relations with our employees to be good and have not experienced any work stoppages, slowdowns or other serious labor problems that have materially impeded our business operations. Our human capital management objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our new and existing employees. The principal purpose of our equity incentive plan is to attract, retain, and motivate selected employees, consultants, and directors through the granting of share- based compensation awards and cash- based bonus awards. Executive Officers of FortressThe following table sets forth certain information about our executive officers as of December 31, ~~2022~~ **2023** . Name Age PositionLindsay A. Rosenwald, M. D. ~~67~~ **68** Chairman of the

Board of Directors, President and Chief Executive OfficerDavid Jin ~~32~~ **34** Chief Financial ~~OfficerGeorge~~ **Officer and Head of Corporate DevelopmentGeorge** Avgerinos, Ph. D. ~~69~~ **70** Senior Vice President, Biologics OperationsMichael S. Weiss ~~56~~ **57** Executive Vice Chairman **,** Strategic DevelopmentLindsay A. Rosenwald, M. D. has served as a member of the Company' s Board of Directors since October 2009 and as Chairman, President and Chief Executive Officer of the Company since December 2013. Dr. Rosenwald also currently serves as a member of the board of directors of Fortress partner companies Avenue (Nasdaq: ATXI), Checkpoint (Nasdaq: CKPT), Mustang (Nasdaq: MBIO) and Journey (Nasdaq: DERM **). Additionally, Dr. Rosenwald serves as a member of the board of directors of each of Fortress' private subsidiaries (and has so served in each case since company inception**). From 1991 to 2008, Dr. Rosenwald served as the Chairman of Paramount BioCapital, Inc. Over the past 30 years, Dr. Rosenwald has acted as a biotechnology entrepreneur and has been involved in the founding, recapitalization and sale of numerous public and private biotechnology and life science companies. He received his B. S. in finance from Pennsylvania State University and his M. D. from Temple University School of Medicine. David Jin has served as our Chief Financial Officer since August 2022 and as Head of Corporate Development since May 2020. He also serves as Interim Chief Financial Officer and Chief Operating Officer of Avenue. Previously, he was on the investment team in the Private Equity & Real Assets group at Barings, Director of Corporate Development at Sorrento Therapeutics, Vice President of Healthcare Investment Banking at FBR & Co., and was in the management consulting group at IMS Health (now IQVIA). He holds a B. S. in Industrial Engineering & Management Sciences with a double- major in Mathematical Methods in the Social Sciences from Northwestern University. ~~George~~ **26George** 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. ~~24Michael~~ -- **Michael** S. Weiss has served as our Executive Vice Chairman, Strategic Development since February 2014. He currently serves as a member of the board of directors of several of our partner companies, including Checkpoint (Nasdaq: CKPT) and Mustang (Nasdaq: MBIO). Mr. Weiss is currently the Executive Chairman of Mustang Bio, Inc. and the Chairman of the Board of Directors of Checkpoint. From March 2015 until February 2019, Mr. Weiss served on the board of Avenue (Nasdaq: ATXI). Since December 2011, Mr. Weiss has served in multiple capacities at TG Therapeutics, Inc. (Nasdaq: TGTX), a related party, and is currently its Executive Chairman, Chief Executive Officer and President. In 1999, Mr. Weiss founded Access Oncology, which was later acquired by Keryx Biopharmaceuticals (Nasdaq: KERX) in 2004. Following the merger, Mr. Weiss remained as CEO of Keryx. He began his professional career as a lawyer with Cravath, Swaine & Moore LLP. Mr. Weiss earned his B. S. in Finance from The University of Albany and his J. D. from Columbia Law School. Available InformationWe and certain of our affiliates file annual reports on Form 10- K, quarterly reports on Form 10- Q, current reports on Form 8- K, proxy and information statements and amendments to reports filed or furnished pursuant to Sections 13 (a), 14 and 15 (d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The SEC also maintains a website at http: / / www. sec. gov that contains reports, proxy and information statements and other information regarding our Company and other companies that file materials with the SEC electronically. Copies of our and certain of our affiliates' reports on Form 10- K, Forms 10- Q and Forms 8- K may be obtained, free of charge, electronically through our website at www. fortressbiotech. com. Our website also includes announcements of investor conferences and events, information on our business strategies and results, corporate governance information, and other news and announcements that investors might find useful or interesting. The information contained on our website is not included in, or incorporated by reference into, this Annual Report on Form 10- K. ~~Item~~ **27Item** 1A. Risk FactorsInvesting in our Common Stock, our 9. 375 % Series A Cumulative Redeemable Perpetual Preferred Stock $ 0. 001 par value (the " Series A Preferred Stock ") or any other type of equity or debt securities we may issue from time to time (together, our " Securities ") involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10- K including the consolidated financial statements and the related notes, as well as the risks, uncertainties and other information set forth in the reports and other materials filed or furnished by our partner companies Avenue, Checkpoint, Journey and Mustang with the SEC, before deciding to invest in our Securities. If any of the following risks or the risks included in the public filings of Avenue, Checkpoint, Journey or Mustang were to materialize, our business, financial condition, results of operations, and future growth prospects could be materially and adversely affected. In that event, the market price of our Securities could decline, and you could lose part of or all of your investment in our Securities. In addition, you should be aware that the below stated risks should be read as being applicable to our subsidiaries and partner companies such that, if any of the negative outcomes associated with any such risk is experienced by one of our subsidiaries or partner companies, the value of Fortress' holdings in such entity may decline. As used throughout this filing, the words " we ", " us " and " our " may refer to Fortress individually, to one or more subsidiaries and / or partner companies, or to all such entities as a group, as dictated by context. Risks Inherent in Drug DevelopmentMost of our product candidates are in the early stages of development and may not be successfully developed or commercialized, and the product candidates that do advance into clinical trials may not receive regulatory approval. Most of our existing product candidates remain in the early stages of development and will require substantial further capital expenditures, development, testing and regulatory approvals prior to commercialization. The development and regulatory

approval processes **can** take ~~several~~ **many** years, and it is unlikely that our product candidates, even if successfully developed and approved by the FDA and / or foreign equivalent regulatory bodies, would be commercially available for several years. Only a small percentage of drugs under development successfully obtain regulatory approval and are successfully commercialized. Accordingly, even if we are able to obtain the requisite financing to fund development programs, we cannot be sure that any of our product candidates will be successfully developed or commercialized, which could result in the failure of our business and a loss of your investment. ~~25Pharmaceutical~~ -- **Pharmaceutical** development has inherent risks. Before we may seek regulatory approval for the commercial sale of any of our ~~products~~ **product candidates**, we will be required to demonstrate, through well- controlled clinical trials, that our product candidates are effective and have a favorable benefit- risk profile for their target indications. Success in early clinical trials is not necessarily indicative of success in later stage clinical trials, during which product candidates may fail to demonstrate sufficient safety or efficacy, despite having progressed through initial clinical testing, which may cause significant setbacks. Further, we may need to conduct additional clinical trials that are not currently anticipated. As a result, product candidates that we advance into clinical trials may never receive regulatory approval. Even if any of our product candidates are approved, regulatory authorities may approve any such product candidates for fewer or more limited indications than we request, may place limitations on our ability to commercialize products at the intended price points, may grant approval contingent on the product' s performance in costly post- marketing clinical trials, or may approve a label that does not include the claims necessary or desirable for the successful commercialization of that product candidate. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of the product. In addition, the Drug Enforcement Agency (" DEA "), or foreign equivalent, may schedule one or more of our product candidates under the Controlled Substances Act, or its foreign equivalent, which could impede such product' s commercial viability. Any of these scenarios could impact the commercial prospects for one or more of our current or future product candidates. The extensive regulation to which our product candidates are subject may be costly and time consuming, cause anticipated delays, and / or prevent the receipt of the required approvals for commercialization. The research and clinical development, testing, manufacturing, labeling, storage, record- keeping, advertising, promotion, import, export, marketing and distribution of any product candidate, including our product candidates, is subject to ~~extensive~~ **28extensive** regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market a product candidate until the FDA approves such product candidate' s BLA or NDA. The approval process is uncertain, expensive, often spans many years, and can vary substantially based upon the type, complexity and novelty of the ~~products~~ **product candidates** involved. In addition to significant and expansive clinical testing requirements, our ability to obtain marketing approval for product candidates depends on the results of required non- clinical testing, including the characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our manufacturing processes, testing procedures or equipment and facilities are inadequate to support approval. Further, the FDA has substantial discretion in the pharmaceutical approval process and may change approval policies or interpretations of regulations at any time, which could delay, limit or preclude a product candidate' s approval. The FDA and other regulatory agencies may delay, limit or refuse approval of a product candidate for many reasons, including, but not limited to: ● disagreement with the trial design or implementation of our clinical trials, including proper use of clinical trial methods and methods of data analysis; ● an inability to establish sufficient data and information to demonstrate that a product candidate is safe and / or effective for an indication; ● the FDA' s rejection of clinical data from trials conducted by individual investigators or in countries where the standard of care is potentially different from that of the United States; ● the FDA' s determination that clinical trial results do not meet the statistical significance levels required for approval; ● a disagreement by the applicable regulator regarding the interpretation of preclinical study or trial data; ● determination by the FDA that our manufacturing processes or facilities or those of third- party manufacturers with which we or our collaborators contract for clinical supplies or plan to contract for commercial supplies, do not satisfactorily comply with cGMPs; ~~or26~~ **or** ● a change to the FDA' s approval policies or interpretation of regulations rendering our clinical data, product characteristics, or benefit- risk profile insufficient or unfavorable for approval. Foreign approval procedures vary by country and may, in addition to the aforementioned risks, involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, rapid drug and biological development during the COVID- 19 pandemic has raised questions about the safety and efficacy of certain marketed pharmaceuticals and may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals may prevent us from commercializing our product candidates. Delays in the commencement of our clinical trials, or suspensions or terminations of such trials, could result in increased costs and / or delay our ability to pursue regulatory approvals. The commencement or resumption of clinical trials can be delayed for a variety of reasons, including, but not necessarily limited to, delays in: ● obtaining regulatory approval to commence or resume a clinical trial; ● identifying, recruiting and training suitable clinical investigators; **29** ● reaching and maintaining agreements on acceptable terms with CROs and trial sites, the terms of which may be subject to extensive negotiation and modification from time to time and may vary significantly among different CROs and trial sites; ● obtaining sufficient quantities of a product candidate for use in clinical trials; ● obtaining IRB or ethics committee approval to conduct a clinical trial at a prospective site; ● developing and validating companion diagnostics on a timely basis, if required; ● adding new clinical sites once a trial has begun; ● the death, disability, departure or other change to the principal investigator or other staff overseeing the clinical trial at a given site; ● identifying, recruiting and enrolling patients to participate in a clinical trial; or ● retaining patients who participate in a clinical trial and replacing those who may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process, personal issues, or other reasons. Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for product candidates. In addition, many of the factors that cause, or lead to,

a delay in the commencement of clinical trials may also ultimately lead to the termination of a given development program or the denial of regulatory approval of a product candidate. If any of our product candidates causes unacceptable adverse safety events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product, preventing us from generating revenue from such products' sale. Alternatively, even if a product candidate is approved for marketing, future adverse events could lead to the withdrawal of such product from the market. ~~27Suspensions~~ -- **Suspensions** or delays in the completion of clinical testing could result in increased costs and / or delay or prevent our ability to complete development of that product **candidate** or generate product revenues. Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements and on a timely basis. Further, a clinical trial may be modified, suspended or terminated by us, an IRB, an ethics committee or a data safety monitoring committee overseeing the clinical trial, any clinical trial site with respect to that site, or the FDA or other regulatory authorities, due to a number of factors, including, but not necessarily limited to: ● failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; ● inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; ● stopping rules contained in the protocol; ● unforeseen safety or chemistry, manufacturing and control issues, or other determination that the clinical trial presents unacceptable health risks; and ● lack of adequate funding to continue the clinical trial. ~~Regulatory~~ **30Regulatory** 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; ~~28~~ ● 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~~ **31trials** , even if not ultimately attributable to our product candidates, and the resulting publicity, could lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that do obtain approval and / or a decrease in demand for any such product candidates. Concern about environmental spread of our products, whether real or anticipated, may also hinder the commercialization of our products. The **making, use, sale, importation, exportation and distribution of controlled substances are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies. Controlled substances are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Controlled substances are regulated under the Federal Controlled Substances Act of 1970 (" CSA ") and regulations of the DEA. IV tramadol, under development by our partner company Avenue, will be subject to these regulations. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse and no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II**

substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Various states also independently regulate controlled substances. Though state- controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law. For any of our products classified as controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in clinical trials for our product candidates and the ability to produce and distribute our products in the volume needed to both meet commercial demand and build inventory to mitigate possible supply disruptions. Regulations associated with controlled substances govern manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product candidates including controlled substances. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our product candidates that are classified as controlled substances, which would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline. The FDA limits regulatory approval for our product candidates to those specific indications and conditions for which clinical safety and efficacy have been demonstrated. Any regulatory approval is limited to the indications for use and related treatment of those specific diseases set forth in the approval for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain ~~FDA~~ **32FDA** approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected. While physicians may prescribe drugs for uses that are not described in the product' s label or that differ from those tested in clinical studies and approved by the regulatory authorities (" off label uses "), our ability to promote the products is limited to those indications that are specifically approved by the FDA. Such off- label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U. S. generally do not regulate the practice of medicine or behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies regarding the promotion of off- label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to compliance or enforcement actions, including Warning Letters **or Untitled Letters** , by, these authorities. In addition, our failure to follow FDA laws, regulations and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, request a recall, institute fines, or could result in disgorgement of money, operating restrictions, corrective advertising, injunctions or criminal prosecution, any of which could harm our business. **If the FDA does not conclude that a product candidate satisfies the requirements for the Section 505 (b) (2) regulatory approval pathway, or if the requirements for such product candidate under Section 505 (b) (2) are not as we expect, the approval pathway for the product candidate will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act, added Section 505 (b) (2) to the FDCA. Section 505 (b) (2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505 (b) (2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA' s prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505 (b) (2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505 (b) (2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are**

allowed to pursue the Section 505 (b) (2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization in a timely manner, or at all. In addition, notwithstanding the approval of a number of products by the FDA under Section 505 (b) (2) over the last few years, certain brand- name pharmaceutical companies and others have objected to the FDA' s interpretation of Section 505 (b) (2). If the FDA' s interpretation of Section 505 (b) (2) is successfully challenged, the FDA may change its Section 505 (b) (2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505 (b) (2). In addition, the pharmaceutical industry is highly competitive, and Section 505 (b) (2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505 (b) (2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505 (b) (2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval. 33Moreover, even if our product candidates are approved under Section 505 (b) (2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the products. ~~29Risks --~~ **Risks** Pertaining to the Need for and Impact of Existing and Additional Financing ActivitiesWe have historically financed a significant portion of our growth and operations in part through the assumption of debt. Should an event of default occur under any applicable loan documents, our business would be materially adversely affected. Further, our current credit arrangement with Oaktree restricts our and certain of our subsidiaries' and partner companies' abilities to take certain actions. At December 31, ~~2022~~ **2023** , the total amount of debt outstanding, net of the debt discount, was $ ~~91~~ **60** . ~~7~~ **9** million. If we default on our obligations, the holders of our debt may declare the outstanding amounts immediately payable together with accrued interest, and / or take possession of any pledged collateral. If an event of default occurs, we may be unable to cure it within the applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment and we may be unable to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. In addition, current or future debt obligations may limit our ability to finance future operations, satisfy capital needs, or to engage in, expand or pursue our business activities. Such restrictions may also prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding debt, which may not be desirable or possible. On August 27, 2020, we entered into ~~the~~ **a** $ 60 million senior secured credit agreement (the " Oaktree Agreement " and the debt thereunder, the " Oaktree Note ") with Oaktree Fund Administration, LLC and the lenders from time- to- time party thereto (collectively, " Oaktree "). **At December 31, 2023 the amount outstanding under the Oaktree Agreement was $ 50 million.** The Oaktree Agreement contains certain affirmative and negative covenants restricting our and certain of our subsidiaries' abilities to take certain actions, especially as pertains indebtedness, liens, investments, affiliate transactions, acquisitions, mergers, dispositions, prepayment of other indebtedness, dividends and other distributions (subject in each case to exceptions). The Oaktree Agreement also contains financial covenants obligating us to maintain a minimum liquidity amount and a minimum amount of revenue, in both cases subject to exceptions. The breach of any such provisions (even, potentially, in an immaterial manner) could result in an event of default under the Oaktree Agreement, the announcement and impact of which could have a negative impact on the trading prices of our securities. The restrictions imposed by such provisions may also inhibit our and certain of our subsidiaries and partner companies' ability to enter into certain transactions or arrangements that management otherwise believes would be in our or such partner companies' best interests, such as dispositions that would result in cash inflows to Fortress and / or our subsidiaries and partner companies, or acquisitions or financings that would promote future growth. We have a history of operating losses that is expected to continue, and we are unable to predict the extent of future losses, whether we will be able to sustain current revenues or whether we will ever achieve or sustain profitability. We continue to generate operating losses in all periods including losses from operations of approximately $ **142. 3 million and $** 203. 6 ~~million and $ 188. 5~~ million for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. At December 31, ~~2022~~ **2023** , we had an accumulated deficit of approximately $ ~~634~~ **694** . ~~2~~ **9** million. We expect to make substantial expenditures and incur increasing operating costs and interest expense in the future, and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates and finance investments in certain of our existing and new subsidiaries in accordance with our growth strategy. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if: ● one or more of our development- stage product candidates is approved for commercial sale and we decide to commercialize such product (s) ourselves, due to the need to establish the necessary commercial infrastructure to launch and commercialize this product ~~candidate~~ without substantial delays, including hiring sales and marketing personnel ~~and~~ **34and** 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; ~~30~~ ● there are any delays in completing our clinical trials or the development of any of our product candidates; ● we execute other collaborative, licensing or similar arrangements, depending on the timing of payments we may make or receive under these arrangements; ● there are variations in the level of expenses related to our future development programs; ● we become involved

in any product liability or intellectual property infringement lawsuits; and ● there are any regulatory developments affecting our competitors' product candidates. Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage products, and we do not know when, or if, we will generate any revenue from such development- stage products. Our ability to generate revenue from such development- stage products depends on a number of factors, including, but not limited to, our ability to: ● obtain regulatory approval for one or more of our product candidates, or any future product candidate that we may license or acquire in the future; ● manufacture commercial quantities of one or more of our product candidates or any future product candidate, if approved, at acceptable cost levels; and ● develop a commercial organization and the supporting infrastructure required to successfully market and sell one or more of our product candidates or any future product candidate, if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations **, which would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline** . A decline in the value of our company could also cause you to lose all or part of your investment. To fund our operations and service our debt securities, which may be deemed to include our Series A Preferred Stock, we will be required to generate a significant amount of cash. Our ability to generate cash depends on a number of factors, some of which are beyond our control, and any failure to meet our debt obligations would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Common Stock and / or Series A Preferred Stock to decline. Prevailing economic conditions and financial, business and other factors, many of which are beyond our control, may affect our ability to make payments on our debt. If we do not generate sufficient cash flow to satisfy our debt obligations, we may have to undertake alternative financing plans, such as refinancing or restructuring our debt, selling assets, reducing or delaying capital investments or seeking to raise additional capital. Alternatively, as we have done in the past, we may also elect to refinance certain of our debt, for example, to extend maturities. Our ability to restructure or refinance our debt will depend on the capital markets and our financial condition at such time. If we are unable to access the capital markets, whether because of the condition of those capital markets or our own financial condition or reputation within such capital markets, we may be unable to refinance our debt. In addition, any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. Our inability to generate sufficient cash flow to satisfy our debt obligations or to refinance our obligations on commercially ~~reasonable~~ **35reasonable** 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~~ **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. ~~31Our~~ -- **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~~ **trading** prices of our ~~securities~~ **Securities** . If additional funds are required to support our operations and such funds cannot be obtained on favorable terms, we may not be able to develop products, which will adversely impact our growth strategy. Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, **2023 and** 2022 ~~and 2021~~ , we incurred R & D expenses of approximately $ **101. 7 million and $** 134 ~~. 2 million and $ 113~~ . 2 million, respectively. We expect to continue to spend significant amounts on our growth strategy. We believe that our current cash and cash equivalents will enable us to continue to fund operations in the normal course of business for at least the next 12 months from the filing of this **Annual Report on Form** 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 **. Under current SEC regulations, if at the time we file our Annual Report on Form 10- K our public float is less than $ 75 million, and for so long as our public float remains less than $ 75 million, the amount we can raise through primary public offerings of securities in any twelve- month period using shelf registration statements is limited to an aggregate of one- third of our public float, which is referred to as the " baby shelf rules. " SEC regulations permit us to use the highest closing sales price of our common stock (or the average of the last bid and last ask prices of our common stock) on any day within 60 days of sales under the registration statement to calculate our public float. As of the date of this Form 10- K, our public float was less than $ 75 million. As a result, for sales following the date of this Form 10- K, and until we again have a public float with a value in exceeds of $ 75 million, if ever, we only have the capacity to sell shares up to one- third of our public float under shelf registration statements in any twelve- month period. If our public float decreases, the amount of**

securities we may sell under our Form S- 3 shelf registration statements will also decrease . Our ability to obtain additional funding when needed, changes to our operating plans, our existing and anticipated working capital needs, the acceleration or modification of our planned R & D activities, expenditures, acquisitions and growth strategy, increased expenses or other events may affect our need for additional capital in the future and require us to seek additional funding sooner or on different terms than anticipated. In addition, if we are unable to raise additional capital when needed, we might have to delay, curtail or eliminate one or more of our R & D programs and commercialization efforts and potentially change our growth strategy **, which would have a material adverse effect on our business, financial 36condition, cash flows and results of operations and could cause the market value of our Securities to decline** . The terms of our existing debt arrangements, including that with Oaktree, have and will continue to inhibit our and our subsidiaries' abilities to raise capital. We may be unable to generate returns for our investors if our partner companies and subsidiaries, several of which have limited or no operating history, have no commercialized revenue generating products or, if not yet profitable, cannot obtain additional third- party financing. As part of our growth strategy, we have made and will likely continue to make substantial financial and operational commitments in our subsidiaries, which often have limited or no operating history, have no commercialized revenue generating products, and require additional third- party financing to fund product and services development or acquisitions. Our business depends in large part on the ability of one or more of our subsidiaries and / or partner companies to innovate, in- license, develop or acquire successful biopharmaceutical products and / or acquire companies in increasingly competitive and highly regulated markets. If certain of our subsidiaries and / or partner companies do not successfully obtain additional third- party financing to commercialize products, or are not acquired in change- of- control transactions that result in cash distributions, as applicable, the value of our businesses and our ownership stakes in our partner companies may be materially adversely affected **, which would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline** . ~~32Raising --~~ **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~~ **other Securities** that ~~is~~ **are** convertible into **or exercisable for shares of** Common Stock), the share ownership of existing stockholders will be diluted. We have also entered into financing arrangements to raise capital for our subsidiaries under which ~~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~~ **impose** covenants that restrict our operations, including ~~limitations on~~ **by limiting** our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain financial commitments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing or sublicensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Risks Pertaining to Our Existing Revenue Stream from Journey Medical Corporation Future revenue based on sales of our dermatology products, ~~especially~~ Qbrexza, Accutane, Amzeeq, Zilxi, ~~Ximino,~~ Targadox, ~~and~~ Exelderm **and Luxamend** , may be lower than expected or lower than in previous periods. The vast majority of our operating income for the foreseeable future is expected to come from the sale of our dermatology products through our partner company Journey. Any setback that may occur with respect to such products could significantly impair our **financial condition, cash flows and / or** operating results and / or reduce ~~our revenue and~~ the value of our Securities. Setbacks for such products could include, but are not limited to, issues related to: supply chain, shipping; distribution; demand; manufacturing; product safety; product quality; marketing; government regulation, including but not limited to pricing or reimbursement; licensing and approval; intellectual property rights; competition with existing or new products, including third- party generic competition; product acceptance by physicians, other licensed medical professionals, and patients; and higher than expected total rebates, returns or recalls. Also, a significant portion of Journey' s sales derive from products that are without patent protection and / or are or may become subject to third party generic competition; the introduction of new competitor products, or increased market share of existing competitor products, could have a significant adverse effect on our operating income. We face challenges as our products face generic competition and / or losses of exclusivity. Journey' s products do and may compete with well- established products, both branded and generic, with similar or the same indications. We face increased competition from manufacturers of generic pharmaceutical products, who may submit applications to FDA seeking to market generic versions of our products. In connection with these applications, the generic drug companies may seek to challenge the validity and enforceability of our patents through litigation. When patents ~~covering~~ **37covering** certain of our products (if applicable) expire or are successfully challenged through litigation or in USPTO proceedings, if a generic company launches a competing product " at risk, " or when the regulatory or licensed exclusivity for our products (if applicable) expires or is otherwise lost, we may face generic competition as a result. A significant portion of our sales derive from products that are without patent protection and / or are or may become subject to third- party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse impact on our operating income. ~~Four~~ **Three** of our marketed products, Qbrexza, Amzeeq ~~,~~ **and** Zilxi ~~and Ximino~~ , as well as **one of our product candidates,** DFD- 29, currently have patent protection. Three of our marketed products, Accutane, Targadox, and Exelderm, do not have patent protection or otherwise are not eligible for patent protection. Accutane currently competes in the Isotretinoin market with five other therapeutically equivalent A / B rated products. Targadox currently competes with one therapeutically equivalent A / B rated generic product. Exelderm may face A / B rated generic competition in the future. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required to be utilized before or in preference to the branded version ~~under~~ **by** third- party **payors** ~~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. ~~33Any~~ -- **Any reduction in sales of our products or the prices we receive for our products as a result of generic competition could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline. Any** disruptions to the capabilities, composition, size or existence of Journey' s field sales force may have a significant adverse impact on our existing revenue stream. Further, our ability to effectively market and sell any future products that we may develop **and for which we receive marketing authorization,** will depend on our ability to establish and maintain sales and marketing capabilities or to enter into agreements with third parties to market, distribute and sell any such products. Journey' s field sales force has been and is expected to continue to be an important contributor to our commercial success. Any disruptions to our relationship with such field sales force or the professional employer organization that employs our field sales force, could materially adversely affect our product sales. Journey currently relies, and may continue to rely, on professional employer organizations and staffing organizations for the employment of its field sales force. The establishment, development, and / or expansion of a field sales force, either by us or certain of our partners or vendors, or the establishment of a contract field sales force to market any products for which we may have or receive marketing approval is expensive and time- consuming and could delay any such product launch or compromise the successful commercialization of such products. If we are unable to establish and maintain sales and marketing capabilities or any other non- technical capabilities necessary to commercialize any products that may be successfully developed, we will need to contract with third parties to market and sell such products. We may not be able to establish or maintain arrangements with third parties on commercially reasonable terms, or at all. If our products are not included in managed care organizations' formularies or coverage by other organizations, our products' utilization and market shares may be negatively impacted, which could have a material adverse effect on our business and financial condition. In the United States, continued sales and coverage, including formulary inclusion without the need for a prior authorization or step edit therapy, of our products for commercial sale will depend in part on the availability of reimbursement from third- party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third- party payors are increasingly examining the medical necessity and cost- effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third- party reimbursement may not be available for our products to enable us to realize an appropriate return on our investment of our currently marketed products or those which we may acquire or develop in the future. ~~Managed~~ **38Managed** care organizations and other third- party payors try to negotiate the pricing of medical services and products to control their costs. Managed care organizations and pharmacy benefit managers typically develop formularies to reduce their cost for medications. Formularies are based on the prices and therapeutic benefits of available products. Due to their lower costs, generic products are often favored. The breadth of the products covered by formularies varies considerably from one managed care organization to another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of our products. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic products, this could have a material adverse effect on our business ~~and~~ **,** financial condition **, cash flows and results of operations and could cause the market value of our Securities to decline** . Reimbursement for our products and product candidates may be limited or unavailable in certain market segments, which could make it difficult for us to sell our products profitably. We have obtained approval for some products, and intend to seek approval for other product candidates, to commercialize in both the United States and in countries and territories outside the United States. If we obtain approval in one or more foreign countries, we will be subject to rules and regulations in those countries relating to such products. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, market acceptance and sales of our product candidates **, if approved,** will depend significantly on the availability of adequate coverage and reimbursement from third- party payors for any of our product candidates and may be affected by existing and future healthcare reform measures. ~~34Government~~ -- **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~~ **product candidates** in combination with each other, there can be no guarantee that we will obtain coverage and reimbursement for any of our products together, or that such reimbursement will incentivize the use of our products in combination with each other as opposed to in combination with other agents which may be priced more favorably to the medical community. Legislative and regulatory changes to the healthcare systems of the United States and certain foreign countries could impact our ability to sell our products profitably. Several federal agencies including FDA, CMS **, DEA** and HHS, in addition to state and local governments, regulate drug product development and marketing. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (" MMA ") changed the way Medicare covers and pays for pharmaceutical products by revising the payment methodology for many products reimbursed by Medicare, resulting in lower

rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. In addition, this law provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions ~~of~~ **39of** this law and future laws could decrease the coverage and price that we will receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Therefore, any limitations in reimbursement that results from the MMA may result in reductions in payments from private payors. Since 2003, there have been several other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the " Affordable Care Act " or " ACA, " was enacted ~~in 2010~~ and made significant changes to the United States' healthcare system. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business ~~. The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015. At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. 35The Bipartisan Budget Act of 2018, the " BBA, " which set government spending levels for Fiscal Years 2018 and 2019, revised certain provisions of the ACA. Specifically, beginning in 2019, the BBA increased manufacturer point- of- sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50 % to 70 %, ultimately increasing the liability for brand drug manufacturers. Further, this mandatory manufacturer discount applied to biosimilars beginning in 2019~~ . In the United States there is significant interest in containing healthcare costs and increasing the scrutiny of pharmaceutical pricing practices. Congress has continually explored legislation intended to address the cost of prescription drugs. Notably, the **Inflation** ~~major committees of jurisdiction in the Senate (Finance Committee, Health, Education~~ - **Reduction Act** ~~, Labor and Pensions Committee, and Judiciary Committee), regularly evaluate and hold hearings on legislation intended to address various elements~~ of **2022 contains substantial** ~~the prescription drug supply chain and prescription~~ drug pricing ~~. Proposals~~ **reforms,** ~~include~~ **including** ~~a significant overhaul of~~ the **establishment of a drug price negotiation program within the U. S. Department of Health and Human Services that would require manufacturers to charge a negotiated " maximum fair price " for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under** Medicare **Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on** Part D **drugs. Substantial penalties can be assessed for noncompliance with** ~~benefit design, addressing patent " loopholes ", and efforts to cap~~ the ~~increase in~~ drug **pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the** prices **we can charge** ~~, create drug price,~~ and ~~efforts to allow the Secretary~~ **reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results** of ~~HHS to negotiate drug prices with prescription drug manufacturers~~ **operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known** . While we cannot predict what **additional** proposals may ultimately become law, the elements under consideration could significantly change the landscape in which the pharmaceutical market operates ~~. The former Trump Administration took several regulatory steps and proposed numerous prescription drug cost control measures. Similarly, the Biden Administration has identified promoting competition and lowering drug prices as a priority~~ . State legislatures are similarly active in proposing and passing legislation and regulations aimed at controlling pharmaceutical and biological prices and drug cost transparency. There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services, including prescription drugs. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and prescription drugs may adversely affect: ● the demand for any products for which we may obtain regulatory approval; ● our ability to set a price that we believe is fair for our products; ● our ability to generate revenues and achieve or maintain profitability; ● the level of taxes that we are required to pay; and ● the availability of capital. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the payment that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. ~~Legislative~~ **40Legislative** 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. ~~36Risks~~ -- **Risks** Pertaining to our Business Strategy, Structure and OrganizationWe have entered, and will likely in the future enter, into certain collaborations or divestitures which may cause a reduction in our business' size and scope, market share and opportunities in certain markets, or our ability to compete in certain markets and therapeutic categories. We have also entered into several arrangements under which we have agreed to contingent dispositions of subsidiaries, partner companies and / or their assets. The failure to consummate any such transaction may impair the value of such companies and / or assets, and we

may not be able to identify or execute alternative arrangements on favorable terms, if at all. We have entered into and consummated several partnerships and / or contingent sales of our assets and subsidiaries, including an equity investment and contingent acquisition agreement between Caelum and AstraZeneca (the acquisition component of which has consummated) and a development funding and contingent asset purchase between Cyprium and Sentynl (the acquisition component of which has not yet consummated). Each of these arrangements has been time- consuming and has diverted management' s attention. As a result of these consummated / contingent sales, as with other similar transactions that we may complete, we may experience a reduction in the size or scope of our business, our market share in particular markets, our opportunities with respect to certain markets, products or therapeutic categories or our ability to compete in certain markets and therapeutic categories. In addition, in connection with any transaction involving a (contingent or non- contingent) sale of one of our subsidiaries, partner companies or their assets, we may surrender our ability to realize long- term value from such asset or company, in the form of foregone product sales, royalties, milestone payments, sublicensing revenue or otherwise, in exchange for upfront and / or other payments. In the event, for instance, that a product candidate underpinning any such asset or company is granted FDA approval for commercialization following the execution of documentation governing the sale by us of such asset or company, the transferee of such asset or company may realize tremendous value from commercializing such product, which we would have realized for ourselves had we not executed such sale transaction and been able to achieve applicable approvals independently. Should we seek to enter into collaborations or divestitures with respect to other assets or companies, we may be unable to consummate such arrangements on satisfactory or commercially reasonable terms within our anticipated timelines. In addition, our ability to identify, enter into and / or consummate collaborations and / or divestitures may be limited by competition we face from other companies in pursuing similar transactions in the biotechnology and pharmaceutical industries. Any collaboration or divestiture we pursue, whether we are able to complete it or not, may be complex, time consuming and expensive, may divert from management' s attention, may have a negative impact on our customer relationships, cause us to incur costs associated with maintaining the business of the targeted collaboration or divestiture during the transaction process and also to incur costs of closing and disposing the affected business or transferring the operations of the business to other facilities. In addition, if such transactions are not completed for any reason, the market price of our Common Stock may reflect a market assumption that such transactions will occur, and a failure to complete such transactions could result in a negative perception by the market of us generally and a decline in the market price of our **Securities** ~~Common Stock~~ . ~~We~~ **41We** act, and are likely to continue acting, as guarantor and / or indemnitor of the obligations, actions or inactions of certain of our subsidiaries and partner companies. We have also entered into, and may again enter into, certain arrangements with our subsidiaries, partner companies and / or third parties pursuant to which a substantial number of shares of our Common Stock may be issued. Depending on the terms of such arrangements, we may be contractually obligated to pay substantial amounts to third parties, or issue a substantially dilutive number of shares of our Common Stock, based on the actions or inactions of our subsidiaries and / or partner companies, regulatory agencies or other third parties. We act, and are likely to continue acting, as indemnitor of potential losses or liabilities that may be experienced by one or more of our subsidiaries, partner companies and / or their partners or investors. If we become obligated to pay all or a portion of such indemnification amounts, our business and the market value of our Common Stock **, Preferred Stock** and / or debt securities may be materially adversely affected. ~~37Additionally~~ -- **Additionally** , we have agreed in the past, and may agree in the future, to act as guarantor in connection with equity or debt raises by our partner companies, pursuant to which we may become obligated either to pay what could be a significant amount of cash or issue what could be a significant number of shares of ~~Fortress~~ Common Stock or ~~perpetual preferred~~ **Preferred** ~~stock~~ **Stock** if certain events occur or do not occur, which could lead to a depletion of resources or dilution to our Common Stock, or both. Our future growth depends in part on our ability to identify and acquire or in- license products and product candidates, and if we are unable to do so, or to integrate acquired products into our operations, we may have limited growth opportunities. An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in- licensing products, businesses or technologies. Future in- licenses or acquisitions, however, may entail numerous operational and financial risks, including, but not necessarily limited to: ● exposure to unknown liabilities; ● disruption of our business and diversion of our management' s time and attention to develop acquired products or technologies; ● difficulty or inability to secure financing to fund development activities for such acquired or in- licensed technologies in the current economic environment; ● incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions; ● higher than expected acquisition and integration costs; ● increased amortization expenses; ● difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel; ● impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and ● inability to retain key employees of any acquired businesses. We have limited resources to identify and execute the acquisition or in- licensing of third- party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger biopharmaceutical companies and other competitors in our efforts to establish new collaborations and in- licensing opportunities. These competitors may have access to greater financial resources than us and / or may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in- licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. ~~38Certain~~ **42Certain** of our officers and directors serve in similar roles at our partner ~~companiess~~ - **companies** , subsidiaries, related parties and / or other entities with which we transact business or in which we hold significant minority ownership positions, which could result in conflicts of interests relating to ongoing and future relationships and transactions with these parties. We share directors and / or officers with certain of our subsidiaries, partner companies, related parties and other entities with which we transact business or in which we hold significant minority ownership positions, and such arrangements could create conflicts of interest in the future, including with respect to the allocation of corporate opportunities. While we believe that we have put in place policies and procedures to identify and mitigate such conflicts, and that any existing agreements that may give rise to such conflicts and any such policies or procedures were

negotiated at arm' s length in conformity with fiduciary duties, such conflicts of interest, or the appearance of conflict of interest, may nonetheless arise. The existence and consequences of such potential or perceived conflicts could expose us to lost profits, claims by our investors and creditors, and harm to our **financial condition, cash flows and / or** results of operations. Certain of our executives, directors and principal stockholders, whose interests may be adverse to those of our other stockholders, can control our direction and policies. Certain of our executive officers, directors and stockholders own nearly or more than 10 % of our outstanding Common Stock and, together with their affiliates and related persons, beneficially own a significant percentage of our capital stock. If these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. In addition, this concentration of ownership might adversely affect the market price of our Common Stock by: ● delaying, deferring or preventing a change of control of us; ● impeding a merger, consolidation, takeover or other business combination involving us; or ● discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. If we acquire, ~~or~~ enter into joint ventures with **,** or obtain a controlling interest in, companies in the future, our **financial condition,** operating results and the value of our Securities may be adversely affected, thereby diluting stockholder value, disrupting our business and / or diminishing the value of our holdings in our partner companies. As part of our growth strategy, we might acquire, enter into joint ventures with, or obtain significant ownership stakes in other companies. Acquisitions of, joint ventures with and investments in other companies involve numerous risks, including, but not necessarily limited to: ● risk of entering new markets in which we have little to no experience; ● diversion of financial and managerial resources from existing operations; ● successfully negotiating a proposed acquisition or investment timely and at a price or on terms and conditions favorable to us; ● the impact of regulatory reviews on a proposed acquisition or investment; ● the outcome of any legal proceedings that may be instituted with respect to the proposed acquisitions or investment; ● with respect to an acquisition, difficulties in integrating operations, technologies, services and personnel; and ● potential inability to maintain relationships with customers of the companies we may acquire or invest in. ~~39If~~ **43If** we fail to properly evaluate potential acquisitions, joint ventures or other transaction opportunities, we might not achieve the anticipated benefits of any such transaction, we might incur higher costs than anticipated, and management resources and attention might be diverted from other necessary or valuable activities. ~~Russian~~ **Our results of operations could be adversely affected by economic and political conditions and the effects of these conditions on our business activities. Any terrorist attack, other act of violence or war, including** military ~~action~~ **conflicts, could result** in **increased volatility** ~~Europe may impact foreign countries~~ in **,** ~~which certain of our~~ **or damage** ~~partner companies may have enrolled, or had planned~~ to ~~enroll patients in clinical trials~~ **, the worldwide financial markets** and **economy** ~~any such clinical trials may be delayed or suspended~~ . ~~In~~ **This includes Russia' s** February 2022 **invasion of Ukraine , the conflict between Israel and the Hamas and Hezbollah extremist groups, recent attacks by armed groups on cargo ships in the Red Sea, and tensions across the Taiwan Strait. For instance, the United States or other countries may impose sanctions that restrict doing business in the effected countries and increased military conflict may affect third-party vendors and cause delays. This risk may be magnified in the case of the conflict between** Russia **and** ~~commenced a military invasion of~~ Ukraine. Russia' s invasion and the ensuing response by Ukraine may disrupt our partner companies' ability to conduct clinical trials in Russia, Ukraine, Belarus, and Georgia, and potentially other neighboring countries. Although the impact of Russia' s military action is highly unpredictable, certain clinical trial sites may be affected, including those of our partner company Checkpoint in Russia, Ukraine, Belarus, and Georgia. Those clinical trial sites may suspend or terminate trials, and patients could be forced to evacuate or choose to relocate, making them unavailable for initial or further participation in clinical trials **. For instance, Checkpoint had to terminate their Phase 3 NSCLC trial in the first quarter of 2023 as a result of such conflicts** . Alternative sites to fully and timely compensate for clinical trial activities in these areas may not be available, and we may need to find other countries to conduct these clinical trials. Clinical trial interruptions may delay our plans for clinical development and approvals for our product candidates, which could increase costs and jeopardize our ability to commence product sales and generate. Risks Pertaining to Reliance on Third PartiesWe rely predominantly on third parties to manufacture the majority of our preclinical and clinical pharmaceutical supplies, and we expect to continue to rely heavily on such third parties and other contractors to produce commercial supplies of our **product candidates and** products **, if approved** . Further, we rely solely on third parties to manufacture Journey' s commercialized products. Such dependence on third- party suppliers could adversely impact our businesses. We depend heavily on third party manufacturers for product supply. If our contract manufacturers cannot successfully manufacture material that conforms to applicable specifications and FDA regulatory requirements, we will not be able to secure and / or maintain FDA approval for those products. Our third- party suppliers will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA and comparable agencies and authorities in other jurisdictions to confirm such compliance. In the event that the FDA or such other authorities determine that our third- party suppliers have not complied with cGMPs or comparable regulations, the relevant clinical trials could be terminated or subjected to clinical hold until such time as we are able to obtain appropriate replacement material and / or applicable compliance, and commercial product could be unfit for sale, or if distributed, could be recalled from the market. Any delay, interruption or other issues that arise in the manufacture, testing, packaging, labeling, storage, or distribution of our products as a result of a failure of the facilities or operations of our third- party suppliers to comply with regulatory requirements, pass any regulatory agency inspection or otherwise perform under our agreements with them could significantly impair our ability to develop and commercialize our products and product candidates. In addition, several of our currently commercialized products, sold through our partner company Journey, are produced by a single manufacturer, and, although we closely monitor inventory prophylactically, disruptions to such supply arrangements could adversely affect our ability to meet product demand and therefore diminish revenues. We also rely on third- party manufacturers to purchase from third- party

suppliers the raw materials and equipment necessary to produce product candidates for anticipated clinical trials. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture those products. We do not have direct control over the process or timing of the acquisition of these raw materials by our third- party manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials since such agreements are entered into by our third- party manufacturers and their qualified suppliers. Any significant delay in the supply of raw material components ~~related~~ **44related** to an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval. ~~40We~~ **We** do not expect to have the resources or capacity to engage in our own commercial manufacturing of our product candidates, if they received marketing approval, and would likely continue to be heavily dependent upon third- party manufacturers. Our dependence on third parties to manufacture and supply clinical trial materials, as well as our planned dependence on third party manufacturers for any products that may be approved, may adversely affect our ability to develop and commercialize products in a timely or cost- effective manner, or at all. In addition to the manufacturing and supply functions they provide, third- party manufacturers also play a key role in our efforts to obtain marketing approval for our product candidates, by interacting with, providing important information to, and hosting inspections by, applicable regulatory authorities. If a given contract development and manufacturing organization upon whom we rely in such a capacity is unwilling or unable to perform these activities on our behalf, the successful development and / or approval of the applicable product candidate could be delayed significantly. In addition, because of the sometimes- limited number of third parties who specialize in the development, manufacture and / or supply of our clinical and preclinical materials, we are often compelled to accept contractual terms that we deem less than desirable, including without limitation as pertains representations and warranties, supply disruptions / failures, covenants and liability / indemnification. Especially as pertains liability and indemnification provisions, because of the frequent disparities in negotiating leverage, we are often compelled to agree to low caps on counterparty liability and / or indemnification language that could result in outsized liability to us in situations where we have zero or relatively little culpability. We rely heavily on third parties for the development and manufacturing of products and product candidates. To date, we have engaged primarily in intellectual property acquisitions, and evaluative and R & D activities; and we have not generated any revenues from product sales (except through Journey). We have incurred significant net losses since our inception. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of approximately $ ~~634~~ **694** . ~~2~~ **9** million. We may need to rely on third parties for activities critical to the product candidate development process, including but not necessarily limited to: ● identifying and evaluating product candidates; ● negotiating, drafting and entering into licensing and other arrangements with product development partners; and ● continuing to undertake pre- clinical development and designing and executing clinical trials. We have also not demonstrated the ability to perform the functions necessary for the successful commercialization of any of our development- stage product candidates, should any of them be approved for marketing. If we were to have any such product candidates approved, the successful commercialization of such products would be dependent on us performing or contracting with third parties for performance, of a variety of critical functions, including, but not necessarily limited to: ● advising and participating in regulatory approval processes; ● formulating and manufacturing products for clinical development programs and commercial sale; and ● conducting sales and marketing activities. Our operations have been limited to acquiring, developing and securing the proprietary rights for, and undertaking pre- clinical development and clinical trials of, product candidates, both at the Fortress level and via our subsidiaries and partner companies. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to develop and commercialize potential product candidates, as well as for you to assess the advisability of investing in our securities. ~~41We~~ **45We** rely on third parties to conduct clinical trials. If these third parties do not meet agreed- upon deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful, and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all. We rely on third- party contract research organizations and site management organizations to conduct most of our preclinical studies and all of our clinical trials for our product candidates. We expect to continue to rely on third parties, such as contract research organizations, site management organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct some of our preclinical studies and all of our clinical trials. These CROs, investigators, and other third parties will and do play a significant role in the conduct of our trials and the subsequent collection and analysis of data from the clinical trials. There is no guarantee that any CROs, investigators or other third parties upon which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fails to meet expected deadlines or fails to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of the clinical trial sites terminates for any reason, we may lose follow- up information on patients enrolled in our ongoing clinical trials unless the care of those patients is transferred to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisers or consultants to us from time to time and receive cash and / or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site, or the FDA' s willingness to accept such data, may be jeopardized. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities or potential liability. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with GLPs as appropriate. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed

unreliable and the FDA or comparable foreign regulatory authorities may refuse to accept such data, or require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP in strict conformity to cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register **certain** ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If any of our relationships with these third- party contract research organizations or site management organizations terminates, we may not be able to enter into arrangements with alternative contract research organizations or site management organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization or site management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or site management organizations, there can be no assurance that we will not encounter similar challenges or delays in the future. ~~42We~~ **We** rely on clinical and pre- clinical data and results obtained from and by third parties that could ultimately prove to be inaccurate or unreliable. As part of our strategy to mitigate development risk, we generally intend on developing product candidates with previously validated mechanisms of action and seek to assess potential clinical efficacy early in the development process. This ~~strategy~~ **46strategy** necessarily relies upon clinical and pre- clinical data and other results produced or obtained by third parties, which may ultimately prove to be inaccurate or unreliable. If the third- party data and results we rely upon prove to be inaccurate, unreliable **, not acceptable by regulatory authorities** or not applicable to our product candidates or acquired products, we could make inaccurate assumptions and conclusions about our current or future product candidates and our research and development efforts could be compromised. Collaborative relationships with third parties could cause us to expend significant resources and / or incur substantial business risk with no assurance of financial return. We anticipate substantial reliance on strategic collaborations for marketing and commercializing our existing product candidates and we may rely even more on strategic collaborations for R & D of other product candidates. We may sell product offerings through strategic partnerships with pharmaceutical and biotechnology companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited. If we enter into R & D collaborations during the early phases of drug development, success will, in part, depend on the performance of research collaborators. We may not directly control the amount or timing of resources devoted by research collaborators to activities related to product candidates. Research collaborators may not commit sufficient resources to our R & D programs. If any research collaborator fails to commit sufficient resources, the preclinical or clinical development programs related to the collaboration could be delayed or terminated. Also, collaborators may pursue existing or other development- stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to collaborators or to observe other obligations in agreements with them, the collaborators may have the right to terminate or stop performance of those agreements. Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaboration proposals based upon their assessment of our financial, regulatory or intellectual property positions. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of product candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, the related product revenues that might follow are likely to be lower than if we directly marketed and sold products. Such collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on, and such collaborations could be more attractive than the one with us for any future product candidate. Management of our relationships with collaborators will require: ● significant time and effort from our management team; ● coordination of our marketing and R & D programs with the respective marketing and R & D priorities of our collaborators; and ● effective allocation of our resources to multiple projects. ~~43The~~ -- **The** contractual provisions we may be forced to agree upon in services, manufacturing, supply and other agreements may be inordinately one- sided, vis- à- vis current or historical standard market terms (especially as pertains contractual liability and indemnification paradigms), and as a result we may be subject to liabilities that are not attributable to our own actions or the actions of our personnel. There is a finite number of service providers who can perform the services or produce the materials or product candidates that we need, and we therefore often have a limited number of options in choosing such service providers. The standard market terms in many of the agreements into which we customarily enter with such service providers are subject to evolution over time, often- times in favor of our counterparties. Also, some such agreements are " adhesion contracts " under which our contractual counterparties refuse to entertain any modifications to their template documentation. One area where service providers often have and exert leverage over us is the negotiation of liability language – specifically in broadly- scoped indemnification by us of service providers and / or the application of liability damages " caps " to certain of ~~such~~ **47such** service providers' indemnification obligations. In any circumstance where we' ve been compelled to agree to such language, it is conceivable that we will be liable to third parties for liabilities in excess of such caps that are attributable to the actions, forbearances and / or culpability of such service providers and their ~~indemnitiees~~ -- **indemnitees** (and not to those of us and our personnel). Risks Pertaining to Intellectual Property and Potential Disputes with Licensors ThereofIf we are unable to obtain and maintain sufficient patent protection for our technology and products, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired. Our success depends, in large part, on our ability to obtain patent protection for our product candidates and their formulations and uses. The patent application process is

subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in obtaining patents or what the scope of an issued patent may ultimately be. These risks and uncertainties include, but are not necessarily limited to, the following: ● patent applications may not result in any patents being issued, or the scope of issued patents may not extend to competitive product candidates and their formulations and uses developed or produced by others; ● our competitors, many of which have substantially greater resources than we or our partners do, and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that may limit or interfere with our abilities to make, use, and sell potential product candidates, file new patent applications, or may affect any pending patent applications that we may have; ● there may be significant pressure on the U. S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and ● countries other than the United States may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products. In addition, patents that may be issued or in- licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the PTO, or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our US patent positions. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technologies or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. ~~44In~~ **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~~ **48We** 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. ~~45Our~~ -- **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~~ **49Invents** 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. ~~46If~~ **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; **50** ● 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. ~~47We~~ **We** in- license from third parties a majority of the intellectual property needed to develop and commercialize products and product candidates. As such, any dispute with the licensors or non- performance of such license agreements may adversely affect our ability to develop and commercialize the applicable product candidates. The patents, patent applications and other intellectual property rights underpinning the vast majority of our existing product candidates were in- licensed from third parties. Under the terms of such license agreements, the licensors generally have the right to terminate such agreements in the event of a material breach. The licenses require us to make annual, milestone or other payments prior to commercialization of any product, and our ability to make these payments depends on the ability to generate cash in the future. These license agreements also generally require the use of diligent and reasonable efforts to develop and commercialize product candidates. If there is any conflict, dispute, disagreement or issue of non- performance between us or one of our partners, on the one hand, and the respective licensing partner, on the other hand, regarding the rights or obligations under the license agreements, including any conflict, dispute or disagreement arising from a failure to satisfy payment obligations under such agreements, the ability to develop and commercialize the affected product candidate may be adversely affected. The types of disputes that may arise between us and the third parties from whom we license intellectual property include, but are not necessarily limited to: ● the scope of rights granted under such license agreements and other interpretation- related issues; ● the extent to which our technologies and processes infringe on intellectual property of the licensor that is not subject to such license agreements; ● the scope and interpretation of the representations and warranties made to us by our licensors, including those pertaining to the licensors' right title and interest in the licensed technology and the licensors' right to grant the licenses contemplated by such agreements; **51** ● 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; ~~48~~ ● 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~~ **52Risks** Pertaining to the Commercialization of Product CandidatesIf any of our product candidates are successfully developed **and receive regulatory approval** but do not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that any such product candidates **, if approved,** generate from sales will be limited. Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates **, if approved** by third- party payors, including government payors, generally would also be necessary for commercial success. The degree of market acceptance of any approved products would depend on a number of factors, including, but not necessarily limited to: ● the efficacy and safety as demonstrated in clinical trials; ● the timing of market introduction of such ~~product~~ **products** ~~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 **such** ~~product~~ **products** ~~candidates~~ over alternative treatments; ● the safety of **such** ~~product~~ **products** ~~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~~ **such** ~~product~~ **products** ~~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; ~~49~~ ●

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~~ **53Even** if approved, any product candidates that we may develop and market may be later withdrawn from the market or subject to promotional limitations. We may not be able to obtain the desired labeling claims or scheduling classifications necessary or desirable for the promotion of our marketed products (or our product candidates if approved). We may also be required to undertake post- marketing clinical trials. If the results of such post- marketing studies are not satisfactory or if adverse events or other safety issues arise after approval while our products are on the market, the FDA or a comparable regulatory authority in another jurisdiction may withdraw marketing authorization or may condition continued marketing on commitments from us that may be expensive and / or time consuming to complete. In addition, if manufacturing problems occur, regulatory approval may be impacted or withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of such products if approved. We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for one or more of our product candidates or a future product candidate we may license or acquire and may have to limit their commercialization **, if approved** . The use of one or more of our product candidates and any future product candidate we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any product **candidate or product** we develop **, license, or acquire** allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the **product candidate or** product, negligence, strict liability or a breach of warranties. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● withdrawal of clinical trial participants; ● suspension or termination of clinical trial sites or entire trial programs; ● decreased demand for any product candidates or products that we may develop **, license or acquire** ; ● initiation of investigations by regulators; ● impairment of our business reputation; ● costs of related litigation; ~~50~~ ● substantial monetary awards to patients or other claimants; ● loss of revenues; ● reduced resources of our management to pursue our business strategy; and ● the ~~inability~~ -- **ability** to commercialize our product candidate or future product candidates ~~. Our partner company Journey acquired an isotretinoin product and began marketing that product under the Accutane ® brand name in Q2 2021. Isotretinoin has a black box warning for use in pregnant women. Isotretinoin also has warnings for side effects related to psychiatric disorders and inflammatory bowel disease~~ . **if approved** ~~among others. Historically, isotretinoin has been the subject of significant product liability claims, mainly related to irritable bowel disease. Currently, there is no significant isotretinoin product liability litigation. The federal multi- district litigation (" MDL ") court dismissed all remaining federal isotretinoin cases in 2014 after ruling that the warning label on the drug was adequate. The MDL dissolved in 2015, which effectively put an end to federal lawsuits. Cases continued in New Jersey state court until 2017, when the trial court judge dismissed the remaining the isotretinoin product liability cases. Thus, should a product liability claim against Journey be brought related to its isotretinoin product, we have substantial defenses. However, it is not feasible to predict the ultimate outcome of any litigation, and we could in the future be required to pay significant amounts as a result of settlement or judgments should such new product liability claims be brought~~ . We will obtain limited product liability insurance coverage for all of our upcoming clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. When needed we intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for one or more of our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in ~~class~~ **54class** 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; ~~51~~ ● restrictions on the labeling or marketing of a product; ● requirements to conduct post- marketing studies or clinical trials; ● warning ~~or~~ **letters,** untitled letters **, or Form 483s** ; ● recalls or other withdrawal of the products from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● fines; ● suspension or withdrawal of marketing or regulatory approvals; ● refusal to permit the import or export of products; ● product seizure or detentions; ● injunctions or the imposition of civil or criminal penalties; and ● adverse publicity. If we or our suppliers, third- party contractors, clinical investigators or collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we or our collaborators may be subject to the actions listed above, including losing marketing approval for ~~products~~ **product candidates** when ~~and~~ **55and** if any of them are approved, resulting in decreased revenue from milestones, product sales or royalties **, which would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Securities to decline** . We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business. A pharmaceutical product cannot be marketed in the U. S. or other countries until the relevant governmental authority has completed a rigorous and extensive regulatory review process, including approval of a brand name. Any brand names we intend to use for our product candidates in the U. S. will require approval from the FDA regardless of whether we have secured a formal trademark registration from the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we ~~would~~ **could** lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates. ~~52Risks~~ -- **Risks** Pertaining to Legislation and Regulation Affecting the Biopharmaceutical and Other IndustriesOur current and future relationships with customers and third- party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Healthcare providers, physicians and third- party payors in the U. S. and elsewhere play a primary role in the recommendation and prescription of our product candidates for which we obtain marketing approval. Our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti- Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to: ● the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid; ● federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, ~~maintain~~ **56maintain** 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; ~~53~~ ● 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, **physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse- midwives** and teaching hospitals) and applicable manufacturers. Applicable group purchasing organizations also are required to report annually to CMS the ownership and investment interests held by the physicians and their immediate family members. The SUPPORT for Patients and Communities Act added to the definition of covered recipient practitioners including physician assistants, nurse

practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse- midwives effective in 2022; and ● analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our businesses. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our businesses. As we continue to execute our growth strategy, we may be subject to further government regulation which could adversely affect our financial results, including without limitation the Investment Company Act of 1940. If we engage in business combinations and other transactions that result in holding minority or non- control investment interests in a number of entities, we may become subject to regulation under the Investment Company Act of 1940, as amended (the " Investment Company Act "). If we do become subject to the Investment Company Act, we would be required to register as an investment company and could be expected to incur significant registration and compliance costs in the future. ~~General~~ **57General** and Other RisksOur business and operations would suffer in the event of computer system failures, cyber- attacks, or deficiencies in our or third parties' cybersecurity. We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information, including, but not limited to, information related to our intellectual property and proprietary business information, personal information, and other confidential information. It is critical that we maintain such confidential information in a manner that preserves its confidentiality, availability and integrity. Furthermore, we have outsourced elements of our operations to third party vendors, who each have access to our confidential information, which increases our disclosure risk. ~~54We~~ **We** are in the process of implementing our internal security and business continuity measures and developing our information technology infrastructure. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, third- party software, data center facilities, lab equipment, and connection to the internet, face the risk of breakdown or other damage or interruption from service interruptions, system malfunctions, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and / or other third parties, or from cyber- attacks by malicious third parties (including the deployment of harmful malware and other malicious code, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), each of which could compromise our system infrastructure or lead to the loss, destruction, alteration, disclosure, or dissemination of, or damage or unauthorized access to, our data or data that is processed or maintained on our behalf, or other assets. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, and could result in financial, legal, business, and reputational harm to us. For example, in 2021, our partner company Journey was the victim of a cybersecurity incident that affected its accounts payable function and led to approximately $ 9. 5 million in wire transfers being misdirected to fraudulent accounts. The details of the incident and its origin were investigated with the assistance of third- party cybersecurity experts working at the direction of legal counsel. The matter was reported to the Federal Bureau of Investigation and does not appear to have compromised any personally identifiable information or protected health information. The federal government has been able to seize a significant amount of cryptocurrency assets associated with the breach. Once the cryptocurrency has been converted back into U. S. dollars, Journey expects to receive a notification letter to initiate the return of the cash. This process could take as long as six months or more to complete. Fortress and Journey may incur additional expenses and losses as a result of this cybersecurity incident, including those related to investigation fees and remediation costs. In addition, the loss or corruption of, or other damage to, clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our drug candidates or any future drug candidates and to conduct clinical trials, and similar events relating to their systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Sophisticated cyber attackers (including foreign adversaries engaged in industrial espionage) are skilled at adapting to existing security technology and developing new methods of gaining access to organizations' sensitive business data, which could result in the loss of proprietary

information, including trade secrets. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. ~~55Any~~ -- **Any** security breach or other event leading to the loss or damage to, or unauthorized access, use, alteration, disclosure, or dissemination of, personal information, including personal information regarding clinical trial subjects, contractors, directors, or employees, our intellectual property, proprietary business information, or other confidential or proprietary ~~information~~ **58information** , could directly harm our reputation, enable competitors to compete with us more effectively, compel us to comply with federal and / or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, or otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Each of the foregoing could result in significant legal and financial exposure and reputational damage that could adversely affect our business. Notifications and follow- up actions related to a security incident could impact our reputation or cause us to incur substantial costs, including legal and remediation costs, in connection with these measures and otherwise in connection with any actual or suspected security breach. We expect to incur significant costs in an effort to detect and prevent security incidents and otherwise implement our internal security and business continuity measures, and actual, potential, or anticipated attacks may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third- party experts and consultants. We may face increased costs and find it necessary or appropriate to expend substantial resources in the event of an actual or perceived security breach. The costs related to significant security breaches or disruptions could be material, and our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third- party systems where information important to our business operations or commercial development is stored or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Furthermore, if the information technology systems of our third- party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. We may not be able to hire or retain key officers or employees needed to implement our business strategy and develop products and businesses. Our success depends on the continued contributions of our executive officers, financial, scientific, and technical personnel and consultants, and on our ability to attract additional personnel as we continue to implement growth strategies and acquire and invest in companies with varied businesses. During our operating history, many essential responsibilities have been assigned to a relatively small number of individuals. However, as we continue to implement our growth strategy, the demands on our key employees will expand, and we will need to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel, or our inability to attract additional personnel to fill critical positions, could adversely affect our business. We currently depend heavily upon the efforts and abilities of our management team and the management teams of our partners. The loss or unavailability of the services of any of these individuals could have a material adverse effect on our business, prospects, financial condition and results. In addition, we have not obtained, do not own, and are not the beneficiary of key- person life insurance for any of our key personnel. We only maintain a limited amount of directors' and officers' liability insurance coverage. There can be no assurance that this coverage will be sufficient to cover the costs of the events that may occur, in which case, there could be a substantial impact on our ability to continue operations. ~~56Our~~ -- **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~~ **59Employee** , 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; ~~57~~ ● 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; **60** ● governmental regulation and legislation; ● unstable regional political and economic conditions; ● variations in our anticipated or actual operating results; and ● change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations. Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market prices of our securities, regardless of our actual operating performance. Sales or other issuances of a substantial number of shares of our Common Stock, or the perception that such sales or issuances may occur, may adversely impact the price of our Common Stock. Almost all of our outstanding shares of our Common Stock, inclusive of outstanding equity awards, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended (the " Securities Act "), or an effective registration statement. In addition, pursuant to our current shelf registration statements on Form S- 3, from time to time we may issue and sell shares of our Common Stock or Series A Preferred Stock having an aggregate offering price of up to $ ~~136~~ **100** . 1 million as of December 31, ~~2022~~ **2023** . Any sale of a substantial number of shares of our Common Stock or our Series A Preferred Stock could cause a drop in the trading price of our Common Stock or Series A Preferred Stock on the Nasdaq Stock Market. We may not be able to manage our anticipated growth, which may in turn adversely impact our business. We will need to continue to expend capital on improving our infrastructure to address our anticipated growth. Acquisitions of companies or products could place a strain on our management, and administrative, operational and financial systems. In addition, we may need to hire, train, and manage more employees, focusing on their integration with us and corporate culture. Integration and management issues associated with increased acquisitions may require a disproportionate amount of our management' s time and attention and distract our management from other activities related to running our business. ~~58A~~ **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~~ **61Our** ability to use our pre- change NOLs and other pre- change tax attributes to offset post- change taxable income or taxes may be subject to limitation. We may, from time to time, carry net operating loss carryforwards (" NOLs ") as deferred tax assets on our balance sheet. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an " ownership change " (generally defined as a greater than 50- percentage- point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three- year period), the corporation' s ability to use all of its pre- change NOLs and other pre- change tax attributes to offset its post- change taxable income or taxes may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership, some of which changes are outside our control. As a result, our ability to use our pre- change NOLs and other pre- change tax attributes to offset post- change taxable income or taxes may be subject to limitation. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. We, and / or third parties on our behalf, may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations

may also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our respective resources, and clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance to cover costs and expenses incurred due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted in connection with the storage or disposal of biological or hazardous materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. ~~59We~~ **We** have never paid and currently do not intend to pay cash dividends in the near future, except for the dividend we pay on our Series A Preferred Stock. As a result, capital appreciation, if any, will be the sole source of gain for our Common Stockholders. We have never paid cash dividends on our Common Stock, or made stock dividends, except for the dividend we pay on shares of our Series A Preferred Stock, and we currently intend to retain future earnings, if any, to fund the development and growth of our businesses, and retain our stock positions. In addition, the terms of existing and future debt agreements may preclude us from paying cash or stock dividends. Equally, each of our subsidiaries and partner companies is governed by its own board of directors with individual governance and decision- making regimes and mandates to oversee such entities in accordance with their respective fiduciary duties. As a result, we alone cannot determine the acts that could maximize value to you of such partner companies and subsidiaries in which we maintain ownership positions, such as declaring cash or stock dividends. As a result, capital appreciation, if any, of our Common Stock will be the sole source of gain for holders of our Common Stock for the foreseeable future. ~~Changes~~ **62Changes** in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business or the business of our partners. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, ability to accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business or the business of our partners. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough nonessential FDA employees and stop routine activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If the timing of FDA' s review and approval of new products is delayed, the timing of our or our partners' development process may be delayed, which could result in delayed milestone revenues and materially harm our operations or business. **We** ~~The COVID- 19 pandemic has caused considerable disruptions at FDA, namely with respect to diverting FDA' s attention and resources to facilitate vaccine development and ensure rapid review and emergency use authorization of vaccines intended to prevent COVID- 19. Continued focus on COVID- 19 countermeasures, and the reorganization and rededication or critical resources, both at FDA and within similar governmental authorities across the world, may impact the ability of new products and services from being developed or commercialized in a timely manner. 60We~~ 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. **63** ~~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. 61~~