

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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2022

or

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

For the Transition Period from to

Commission File Number 001-41063

JOURNEY MEDICAL CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)
9237 E Via de Ventura Blvd., Suite 105
Scottsdale, AZ
(Address of Principal Executive Offices)

47-1879539
(I.R.S. Employer Identification No.)

85258
(Zip Code)

Registrant's telephone number, including area code: (480) 434-6670
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	DERM	NASDAQ Capital Market

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

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

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
Emerging growth company <input checked="" type="checkbox"/>	

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes No

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

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

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

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2022, the last business day of the registrant's most recently completed second quarter, was \$644,139 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Capital Market on that date of \$3.74.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class of Common Stock	Outstanding Shares as of March 29, 2023
Class A Common Stock, \$0.0001 par value	6,000,000
Common Stock, \$0.0001 par value	11,834,362

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2023 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

JOURNEY MEDICAL CORPORATION
ANNUAL REPORT ON FORM 10-K
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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended (the “Securities Act”), and the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words “anticipate,” “believe,” “estimate,” “may,” “expect,” “will,” “could,” “project,” “should,” “intend” and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in or implied by these forward-looking statements due to a variety of factors, including, without limitation:

- the fact that our products and product candidates are subject to time and cost intensive regulation and clinical testing and as a result, may never be successfully developed or commercialized;
- a substantial 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;
- 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;
- our revenue is dependent mainly upon sales of our dermatology products and any setback relating to the sale of such products could impair our operating results;
- competition could limit our products’ commercial opportunity and profitability, including competition from manufacturers of generic versions of our products;
- the risk that our products do not achieve broad market acceptance, including by government and third-party payors;
- our reliance third parties for several aspects of our operations;
- our dependence on our ability to identify, develop, and acquire or in-license products and integrate them into our operations, at which we may be unsuccessful;
- the dependence of the success of our business, including our ability to finance our company and generate additional revenue, on the successful development and regulatory approval of the DFD-29 product candidate and any future product candidates that we may develop, in-license or acquire;
- clinical drug development is very expensive, time consuming, and uncertain and our clinical trials may fail to adequately demonstrate the safety and efficacy of our current or any future product candidates;
- our competitors could develop and commercialize products similar or identical to ours;
- risks related to the protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products;
- our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or our third parties’ cybersecurity;
- the effects of major public health issues, epidemics or pandemics on our product revenues and any future clinical trials;
- our potential need to raise additional capital;
- Fortress controls a voting majority of our common stock, which could be detrimental to our other shareholders; and
- the risks described in under the section titled “*Risk Factors*” in this Annual Report.

The forward-looking statements contained in this report reflect our views and assumptions as of the effective date of this report. New risks and uncertainties arise from time to time, and it is impossible for us to predict these events or how they may affect us. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

SUMMARY OF RISK FACTORS

Our business is subject to a number of risks which you should be aware of before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in our common stock and are not the only risks we face. These risks are more fully described in the section titled “Risk Factors” of this report on Form 10-K and include the following:

Risks Related to Our Business, Industry and Existing Operating Revenue Stream

- Our products and product candidates are subject to time and cost intensive regulation and clinical testing. As a result, they may never be successfully developed or commercialized. Further, any approved product may be subject to post-marketing requirements, including studies or clinical trials, the results of which could cause such product to be withdrawn from the market.
- A substantial 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.
- 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.
- Our revenue is dependent mainly upon sales of our dermatology products and any setback relating to the sale of such products could impair our operating results.
- Our competitors may develop treatments for our products’ target indications, which could limit our products’ commercial opportunity and profitability.

Risks Related to Our Reliance on Third Parties

- We rely on third parties for several aspects of our operations, which limits our control over product development, marketing, manufacturing, and sale processes and may hinder our ability to develop and commercialize our products in a cost-effective and timely manner.

Risks Related to Our Growth

- Our future growth may depend on our ability to identify, develop, and acquire or in-license products and integrate them into our operations, at which we may be unsuccessful.
- We may expend resources on unsuccessful product candidates or indications and may fail to capitalize on more profitable or successful product candidates or indications.

Risks Related to Development and Regulatory Approval of Our Product Candidates (DFD-29)

- The success of our business, including our ability to finance our company and generate additional revenue, may depend on the successful development and regulatory approval of the DFD-29 product candidate and any future product candidates that we may develop, in-license or acquire.
- Clinical drug development is very expensive, time consuming, and uncertain. Our clinical trials may fail to adequately demonstrate the safety and efficacy of our current or any future product candidates, which could prevent or delay regulatory approval and commercialization.
- We expect to rely on third-party contract research organizations (“CROs”) and other third parties to conduct and oversee our clinical trials, other aspects of our product development and our regulatory submission process for our product candidates. If these third parties do not meet our requirements, conduct the trials as required or otherwise provide services as anticipated, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or successfully commercialize, our current or any future product candidates when expected or at all.

Risks Pertaining to Intellectual Property, Generic Competition and Paragraph IV Litigation

- If we are unable to maintain sufficient patent protection for our technology and products, our competitors could develop and commercialize products similar or identical to ours.
- Any dispute with our licensors may affect our ability to develop or commercialize our product candidates.
- 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 (“USPTO”). Such challenges may subject us to costly and time-consuming litigation and/or USPTO proceedings.
- As a result of the loss of any patent protection from such litigation or USPTO proceedings, or the “at-risk” launch by a generic competitor of our products, our products could be sold at significantly lower prices, and we could lose a significant portion of sales of that product in a short period of time, which could adversely affect our business, financial condition, operating results and prospects.

Risks Related to our Platform and Data

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

Risks Related to Our Finances and Capital Requirements

- Due to the numerous risks and uncertainties associated with pharmaceutical product development, we may incur losses and may be unable to maintain profitability.
- If we are unable to raise capital as needed, we may be forced to delay, reduce, or eliminate our operations.

Risks Relating to Owning our Common Stock

- Our operating results have fluctuated in the past and we expect them to continue to do so. Any such fluctuation may cause our performance to fall below expectations, and our stock price may suffer.

Risks Related to our Relationship with Fortress Biotech, Inc. (“Fortress”)

- Fortress controls a voting majority of our common stock, which could be detrimental to our other shareholders. Further, Fortress’ ownership qualifies us as a “controlled company” under the Nasdaq listing standards.
- Fortress’ financial obligations and any potential risk of default may adversely affect the Company or constrain our ability to take certain actions.

PART I

Item 1. Business

OVERVIEW

We are a commercial-stage pharmaceutical company founded in October 2014 that focuses on the development and commercialization of pharmaceutical products for the treatment of dermatological conditions. Our current portfolio includes eight branded and three authorized generic prescription drugs for dermatological conditions that are marketed in the U.S. We are managed by experienced life science executives with a track record of creating value for their stakeholders and bringing novel medicines to the market, enabling patients to experience increased quality of life, and enabling physicians and other licensed medical professionals to provide better care for their patients. We aim to acquire rights to future products by licensing or otherwise acquiring an ownership interest in, funding the research and development of, and eventually commercializing, these products through our field sales organization. Since inception, we have made significant investments to build out our commercial product portfolios, which we believe, coupled with our experienced dermatology sales leadership team and our recently expanded field sales force, will position our business for growth. We are a majority-owned subsidiary of Fortress.

2022 Highlights and Events

On December 30, 2022, we filed a shelf registration statement on Form S-3 (File No. 333-269079), which was declared effective by the Securities and Exchange Commission (“SEC”) on January 26, 2023. This shelf registration statement covers the offering, issuance and sale by us of up to an aggregate of \$150.0 million of our common stock, preferred stock, debt securities, warrants, and units (the “2022 Shelf”). At December 31, 2022, \$150.0 million remains available under the 2022 Shelf. In connection with the 2022 shelf, we have entered into an At Market Issuance Sales Agreement (the “Sales Agreement”) with B. Riley Securities, Inc. (“B. Riley”), relating to shares of our common stock. In accordance with the terms of the Sales Agreement, we may offer and sell up to 4,900,000 shares of our common stock, par value \$0.0001 per share, from time to time through or to B. Riley acting as our agent or principal.

On March 14, 2022, we dosed the first patient in our Phase 3 clinical trial evaluating DFD-29 (Minocycline Modified Release Capsules 40 mg) for the Treatment of Rosacea. In January 2023 we achieved 100% enrollment in the trial, with a top-line data readout expected in the second quarter of 2023. We plan to submit the NDA for DFD-29 in the second half of 2023 and FDA approval is anticipated in the second half of 2024. In the Phase 2 clinical trials, DFD-29 (40mg) demonstrated nearly double the efficacy when compared against Oraycea® (European equivalent of Oracea®) on both co-primary endpoints. For the first co-primary endpoint, Investigator’s Global Assessment (“IGA”) treatment success, Oraycea only had a 33.33% IGA treatment success rate, while DFD-29 achieved a 66.04% IGA treatment success rate. For the second co-primary endpoint, the change in total inflammatory lesion count, Oraycea only had a 10.5 reduction in inflammatory lesions, while DFD-29 achieved a 19.2 reduction in inflammatory lesions.

On February 11, 2022, we announced that our exclusive licensing partner in Japan, Maruho Co., Ltd. (“Maruho”), received marketing and manufacturing approval for Rapifort® Wipes 2.5% (Qbrexza®), for the treatment of primary axillary hyperhidrosis, triggering a net \$2.5 million milestone payment to us. The net payment reflects a milestone payment of \$10 million to us from our exclusive licensing partner Maruho, offset by a \$7.5 million payment to Dermira, Inc. (“Dermira”), the company from which we acquired global rights to Qbrexza® in May 2021, pursuant to the terms of the Asset Purchase Agreement between us and Dermira. Under the terms of the licensing agreement with Maruho, the milestone payment was due from Maruho within 30 days of the approval. The period ended December 31, 2022 also reflects total year-to-date royalties of \$0.2 million from Maruho on sales of Rapifort® Wipes 2.5% in Japan.

On January 12, 2022, we acquired Amzeeq® (minocycline) topical foam, 4%, and Zilxi® (minocycline) topical foam, 1.5%, two FDA-Approved Topical Minocycline Products and Molecule Stabilizing Technology (MST)[™] from VYNE Therapeutics Inc., which expanded our product portfolio to eight actively marketed branded dermatology products.

These proprietary foam-based products optimize the topical delivery of minocycline, an active pharmaceutical ingredient that was previously available only in oral form. Approved by the FDA nearly 50 years ago, minocycline is a well-established molecule that has been prescribed, in oral formulation, over 30 million times in the past decade.

AMZEEQ (minocycline) topical foam, 4%, is the first and only topical formulation of minocycline to be approved by the FDA for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and children 9 years and older. According to the American Academy of Dermatology (“AAD”), acne is the most common skin condition in the United States, affecting up to 50 million Americans annually.

Approved by the FDA in May 2020, ZILXI (minocycline) topical foam, 1.5%, is the first and only topical minocycline treatment for inflammatory lesions due to rosacea in adults. Rosacea is a common skin disease that affects 16 million Americans, according to AAD. Market research shows that over 70% of patients with rosacea are seeking better alternatives to current treatments.

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

In September 2021, we were the victim of a cybersecurity incident that affected our accounts payable function and led to approximately \$9.5 million in wire transfers being misdirected to fraudulent accounts. The matter was reported to the Federal Bureau of Investigation (“FBI”) and remains under their investigation. The cybersecurity incident does not appear to have compromised any personally identifiable information or protected health information. Fortress, as our controlling stockholder and supporting partner in our back-office functions, provided us with \$9.5 million to ensure our accounts payable operations continued to function smoothly. The \$9.5 million of support was in the form of a related party note, which was approved by the board of directors of both companies, and the balance of which was fully converted into 1,476,044 shares of our common stock upon the consummation of our IPO in November 2021 at the IPO price. The federal government has been able to trace and seize the fraudulently transferred cryptocurrency assets associated with the breach. The seized cryptocurrency has been transferred into U.S. government-controlled custodial wallets. Subsequently, the forfeiture process will be initiated by the U.S. Attorney’s Office. The process includes mandatory waiting periods for filing of claims. Once the cryptocurrency has been converted back into U.S. dollars, we expect to receive a notification letter to initiate the return of the cash to the Company. This process could take several months to a year or possibly longer to complete before funds can be returned. Given the recent market declines, volatility, and liquidity issues with cryptocurrency, there is no certainty as to the amount we will ultimately recover. See “*Risk Factors — Risks Related to our Platform and Data — Our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or third parties’ cybersecurity.*”

CORPORATE INFORMATION

Journey Medical Corporation was incorporated in Delaware in 2014. Our executive offices are located at 9237 E Via de Ventura Blvd. Suite 105, Scottsdale, AZ 85258. Our telephone number is 480-434-6670, and our e-mail address is info@jmcderm.com or ir@jmcderm.com.

We maintain a website with the address www.jmcderm.com. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC’s website address is <http://www.sec.gov>.

Our Market, Products and Relevant Disease States

As of December 31, 2022, our major actively marketed products, which have been approved by the U.S. Food and Drug Administration (“FDA”) for sale in the United States, include:

- Qbrexza® (a medicated cloth towelette for the treatment of primary axillary hyperhidrosis), acquired and launched in May 2021;
- Accutane® (an oral isotretinoin drug for the treatment of severe recalcitrant nodular acne), licensed in July 2020 and launched in March 2021;
- Amzeeq® (minocycline) topical foam, 4% (a topical formulation of minocycline for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and children 9 years and older), acquired and launched in January 2022;
- Zilxi® (minocycline) topical foam, 1.5% (a topical minocycline treatment for inflammatory lesions due to rosacea in adults), acquired and launched in January 2022.
- Ximino® (an oral minocycline drug for the treatment of moderate to severe acne), acquired and launched in August 2019;
- Exelderm® Cream and Solution (a broad-spectrum antifungal intended for topical use), acquired and launched in October 2018; and
- Targadox® (an oral doxycycline drug for adjunctive therapy for severe acne), licensed in March 2015 and launched in October 2016.

Additionally, we sell three authorized generic products:

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

Our Products and Relevant Disease States

Excessive Underarm Sweating and the Current Standard of Care

Excessive underarm sweating, commonly referred to as primary axillary hyperhidrosis (“PAH”), is a rare disorder characterized by excessive sweating in the armpits. The exact cause of PAH is not known, and the disorder affects males and females equally. When excessive sweating occurs as part of some other disorder, it is said to be secondary hyperhidrosis, which is a more commonly encountered condition than is primary hyperhidrosis. According to a 2016 article published in the Archives of Dermatological Research, there are approximately 10 million people who suffer from PAH in the United States. The symptoms of PAH typically begin during childhood or puberty and may often, although not always, persist throughout a person’s life. Affected individuals may experience a heightened reaction to certain stimuli that can cause sweating such as anxiety, pain, exercise, tension, caffeine, and/or nicotine. The symptoms of this disorder develop due to overactivity of certain sweat glands, and incidences may be precipitated by social and/or physical stress. Some people with PAH experience relief from the symptoms during adulthood without treatment or obvious reason for the remission.

Pharmacological treatment options for PAH include topical, oral and iontophoretic treatments.

Qbrexza® (glycopyrronium 2.4% cloth) for the Treatment of Primary Axillary Hyperhidrosis

Our Qbrexza® (glycopyrronium 2.4%) product is a topical, once-daily anticholinergic cloth that was approved by the FDA in June 2018 for the treatment of PAH in adult and pediatric patients nine years of age and older. Anticholinergics are a class of pharmaceutical products that exert their effect by blocking the action of acetylcholine, a neurotransmitter that transmits signals within the nervous

system that are responsible for the activation of sweat glands. Qbrexza is applied directly to the skin and is designed to block underarm sweat production by inhibiting sweat gland activation. Qbrexza has Orange Book-listed patents that extend through February of 2033.

The PAH market had approximately 450,000 prescriptions in 2022 according to Symphony Health, excluding over-the-counter (“OTC”) clinical strength anti-perspirants.

Acne and the Current Standard of Care

Acne, also known as acne vulgaris, is a common skin disorder characterized by a blockage of hair follicles, which are clogged with oil and dead skin cells. According to the AAD, acne is the most common skin condition in the US, affecting up to 50 million individuals annually.

Approximately 85% of people between the ages of 12 and 24 experience at least a minor form of acne. The disease is classified as mild, moderate or severe based on the severity of the disease progression, which is useful in identifying an appropriate treatment regimen. Mild acne is characterized by clogged hair follicles (known as comedones) that are either exposed to air (blackheads) or closed (whiteheads), with occasional inflammatory lesions which occur primarily on the face. Moderate acne is characterized by a higher presence of inflammatory lesions known as papules and pustules across the face and extending to the trunk. Severe acne is characterized by painful, deep lesions called nodules across the face, with extensive involvement of the trunk frequently.

Treatment options are based on the severity of disease, with certain drugs being reserved for more severe forms of the disease. Mild acne is addressed with dietary and lifestyle changes, along with OTC and prescription topical agents. Other therapies with varying degrees of success include dermabrasion and chemical peels, light therapy and hormonal therapy such as birth control pills or spironolactone. Moderate acne is treated with more aggressive therapy including topical and oral antibiotics such as tetracyclines, which are particularly effective due to their antibacterial and anti-inflammatory properties, and other topical agents including benzoyl peroxide and retinoids. Severe acne is treated with combination therapies, often including oral antibiotics. For resistant cases, physicians may use a potent drug known as isotretinoin (a vitamin A analog), which requires Risk Evaluation and Mitigation Strategy (“REMS”) (safety) monitoring with regard to pregnancy. The current U.S. market size for treatment of acne is considerable and estimated at approximately \$3 billion annually, according to the American Medical Association.

Accutane® for the Treatment of Severe Recalcitrant Nodular Acne

Accutane® (isotretinoin 10mg, 20mg, 30mg, and 40mg capsules USP) is indicated for the treatment of severe recalcitrant nodular acne. Accutane is used to treat a type of severe recalcitrant nodular acne that has not been helped by other treatments, including antibiotics. Severe recalcitrant nodular acne occurs when many red, swollen, tender lumps form in the skin. Patients with severe nodular acne are at higher risk of scarring. Accutane belongs to a class of drugs that affects all four major pathogenic processes in acne: increased sebum production, irregular follicular desquamation, propionibacterium acnes proliferation and inflammation. Accutane has achieved a strong market position and is well known in the dermatology community.

The oral isotretinoin market had over 2 million prescriptions in 2022 according to Symphony Health.

Targadox® for the Treatment of Severe Acne

Targadox® (doxycycline hyclate immediate release 50mg tablets) is indicated as adjunctive therapy for severe acne, which is part of a class of oral antibiotics known as tetracyclines. The tetracycline class, which includes minocycline, doxycycline, sarecycline and tetracycline, is particularly effective in treatment for more severe forms of acne due to its antibacterial and anti-inflammatory properties. Targadox is gluten-free, lactose-free, animal byproduct-free, and GMO-free.

The oral doxycycline market had more than 25 million prescriptions in 2022 according to Symphony Health.

Amzeeq® for the Treatment of Moderate-to-Severe Acne

Amzeeq® (4% minocycline foam), formerly known as FMX101, was approved by the FDA in October 2019 and became available in pharmacies nationwide in January 2020. Amzeeq is a once-daily novel topical antibiotic foam formulation of minocycline for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients nine years of age and older. Amzeeq utilizes proprietary MST™ technology and is the first topical minocycline to be approved by the FDA for any condition. We believe

that the combination of a well-established antibiotic in a well-tolerated, easy to use foam makes Amzeeq a very attractive treatment option for patients.

The topical acne market had almost 20 million prescriptions in 2022 according to Symphony Health, presenting significant unmet needs of patients and healthcare providers to be addressed. As the first topical minocycline to be approved by the FDA for any condition, we believe that Amzeeq may provide a new treatment alternative for patients and healthcare providers who are unsatisfied with their current therapies. Amzeeq has Orange Book-listed patents that extend through September of 2037.

Ximino® for the Treatment of Inflammatory Lesions of Non-Nodular Moderate to Severe Acne

Ximino® (minocycline hydrochloride extended-release 45mg, 90mg, and 135mg capsules) is indicated for the treatment of inflammatory non-nodular lesions (pimples and red bumps) associated with moderate to severe acne. Minocycline is part of a class of oral antibiotics known as tetracyclines. Ximino encloses a small, uniform amount of the active pharmaceutical ingredient in a patented polymer wrapper through a controlled dosing capsular technology, known as Capsular Minotab Technology®, and provides a steady, controlled release of minocycline. The polymer technology in Ximino capsules is partially resistant to dissolution, so the minocycline is released over time, in a controlled manner. Ximino has Orange Book-listed patents that extend through April of 2027.

The oral minocycline market had just under 3 million prescriptions in 2022 according to Symphony Health.

Fungal Infections of the Skin and the Current Standard of Care

Fungal skin infections, collectively referred to as dermatomycoses, are common infections caused by ringworms (tinea) and include such conditions as athlete's foot, jock itch and ringworm of the body. Tinea pedis, commonly known as athlete's foot, is a form of ringworm that usually develops between the toes. Symptoms include peeling, cracking and scaly feet, blisters, and skin that is red, softened, itching, or burning. Tinea cruris, commonly known as jock itch, is a form of ringworm that affects the groin. Tinea corporis, commonly known as ringworm of the body, is a fungal infection that appears on the body in which the outer part of the sore might be raised while the skin in the middle appears normal. Fungal infections caused by ringworm cause skin rashes that present as itchy, red, raised and scaly rings. These infections are easily transmissible between people, pets or contaminated objects or surfaces but are usually not serious in nature.

Treatment options typically involve topical OTC and prescription antifungal medications. Where difficult to administer topically, oral options (such as for toenail fungus or oral thrush) or suppositories (such as for vaginal yeast infections) have proven to be more effective. OTC products typically include known antifungal ingredients such as clotrimazole, miconazole, terbinafine or ketoconazole. Prescription treatments are often reserved for more serious infection or for those in hard-to-treat areas. In conjunction with OTC or prescription medications, lifestyle adjustments, including daily washing of bedding and clothing during an infection, drying thoroughly after bathing, wearing loose clothing in affected areas and actively treating infected areas, can all contribute to disinfecting your surroundings and preventing a prolongation or recurrence of infection.

Exelderm® for the Treatment of Fungal Skin Infections

Exelderm® (sulconazole nitrate 1%, cream and solution) is a broad-spectrum antifungal agent indicated for the treatment of ringworm-caused fungal infections including tinea pedis, tinea cruris, tinea corporis and tinea versicolor. The active pharmaceutical ingredient (sulconazole) acts by inhibiting fungal cell division and growth and has been shown to have broad activity against candida species, aspergillus species and dermatophytes. Exelderm cream or solution is administered externally only, whereby a small amount of cream or solution is gently massaged into the affected and surrounding areas and only requires a convenient once or twice daily application. However, when used to treat tinea pedis, for which Exelderm cream is also indicated, twice daily application is required.

The topical antifungal market had more than 11 million prescriptions in 2022 according to Symphony Health.

Pruritus (Itch) and the Current Standard of Care

Pruritus or itch is defined as an unpleasant sensation of the skin that provokes the urge to scratch. It is a characteristic feature of many skin diseases and an unusual sign of some systemic diseases. Pruritus may be localized or generalized and can occur as an acute or chronic condition. Itch can be caused by a number of conditions, including skin conditions such as dry skin, eczema, psoriasis, scabies,

parasites, burns, scars, insect bites and hives. Depending on the cause of itchiness, skin may appear normal, red, rough or bumpy. Repeated scratching can cause raised thick areas of skin that might bleed or become infected.

Treatment for itch may include moisturizing daily, using gentle cleansers, and bathing with lukewarm water. Long-term relief requires identifying and treating the underlying cause of itchy skin. Common treatments are prescription medicated creams and lotions, moist dressings, and oral anti-itch medicines.

Anti-Itch Product for the Treatment of Pruritus

Our acquired anti-itch product is indicated to treat pruritis, scabies, and other skin itch conditions (“Anti-itch Product”). Our Anti-itch Product delivers prescription relief and is non-steroidal and antihistamine free. Topical steroids are effective against itch because they reduce inflammation that can cause itch. However, they are not recommended for long-term use. Antihistamines are also effective in treating some types of itch, but they too have drawbacks with continued use. We plan on launching our Anti-itch Product through our field sales force during the second half of 2023.

Rosacea and the Current Standard of Care

Rosacea is a chronic, relapsing, inflammatory skin condition that most commonly presents with symptoms such as deep facial redness, acne-like inflammatory lesions (papules and pustules) and spider veins (telangiectasia). According to The National Rosacea Society, it is estimated that rosacea affects well over 16 million Americans and as many as 415 million people worldwide. Rosacea is most frequently seen in adults between 30 and 50 years of age. Surveys conducted by The National Rosacea Society report more than 90% of rosacea patients said their condition had lowered their self-confidence and self-esteem, and 41% reported that it had caused them to avoid public contact or cancel social engagements. Among rosacea patients with severe symptoms, 88% said the disorder had adversely affected their professional interactions, and 51% said they had missed work because of their condition. The rosacea market had 3.6 million prescriptions in 2022 and 3.4 million prescriptions in 2021 according to Symphony Health.

The tetracycline class of antibiotics (minocycline and doxycycline) are considered to be effective options for treatment of papulopustular rosacea, likely due to anti-inflammatory activities that are usually manifested at doses much lower than those prescribed for treatment of bacterial infections. A sub-antimicrobial dose of doxycycline (i.e., 40 mg taken once daily) as oral formulation has been approved for the treatment of only inflammatory lesions (papules and pustules) of rosacea and is available under the proprietary name Oracea® in the US. Oracea is generally considered to be the current standard of care. Minocycline, first introduced in 1971, is widely believed to be the most effective tetracycline agent due to its high lipophilicity, which is anticipated to permit greater permeation into, and accumulation in, the sebaceous follicles and layers of the epidermis. We offer two products, Zilxi and, if approved, DFD-29, that we believe provide a new treatment alternative for patients and healthcare providers who are unsatisfied with their current rosacea therapies.

Zilxi® for the Treatment of Papulopustular Rosacea

Zilxi® (1.5% minocycline foam), was approved by the FDA in May 2020 and became available in pharmacies nationwide in October 2020. Zilxi is a once-daily novel antibiotic foam formulation of minocycline for the treatment of inflammatory lesions of rosacea in adults. Similar to Amzeeq, Zilxi leverages MST™ technology and is the first minocycline product of any form to be approved by the FDA for use in rosacea. We believe the anti-inflammatory properties of minocycline delivered in our innovative foam technology make Zilxi a highly appealing treatment option for rosacea patients. Zilxi has Orange Book-listed patents that extend through October of 2030.

DFD-29 for the Treatment of Rosacea

DFD-29, is a low-dose minocycline (40 mg) extended release capsule formulation for oral use, for the treatment of papulopustular rosacea. The rationale of selecting DFD-29 doses lower than the approved minocycline dose, is based on the lower protein binding and higher lipophilicity of minocycline. A Phase 1 PK study (DFD-29-CD-001) in 24 healthy subjects demonstrated the systemic exposure of minocycline from DFD-29 (minocycline HCl) ER capsules 40 mg was much lower than that seen with the approved antibiotic dose of minocycline (not a head-to-head study). A Phase 2 study (DFD-29-CD-002) in 205 subjects with papulopustular rosacea, demonstrated that DFD-29 (40 mg) was significantly superior to placebo and Oracea®, on the co-primary endpoints of IGA treatment success and absolute inflammatory lesion count reduction. The study also showed DFD-29 was well-tolerated and safe. DFD-29 is currently in advanced stages of Phase 3 clinical studies for papulopustular rosacea.

Our Strategy

We are a highly focused, pharmaceutical company dedicated to developing and commercializing therapies for the treatment of dermatologic conditions that seeks to deliver value to patients, physicians and the healthcare system, as well as to our stakeholders. Our strategic priorities include continuing to augment and grow our product portfolio and organization in order to maximize the probabilities of sustainable long-term value creation. This will consist of both commercial execution on our existing product portfolio, including lifecycle management, as well as investing in additional growth strategies through product and company acquisitions, licensing, or developing new products.

An important part of our growth strategy is to identify new business development opportunities, including development stage and commercial drugs that we may acquire from other pharmaceutical companies. We are in various stages of discussion for other opportunities, both commercial and development stage, that could drive additional growth in the business. Successful development and commercialization of any future in-licensed development stage or commercial drugs will require us to navigate the many laws and regulations of governmental authorities and regulatory agencies around the world, including the FDA, relating to the manufacture, development, approval and commercialization of investigational drugs. For development stage drugs, we may require financial resources significantly in excess of those received by us upon completion of our IPO in November 2021 and our current cash on hand, and it may take many years for us to receive marketing approval, if ever, for any in-licensed or acquired product candidate.

Competitive Strengths

To successfully execute our strategy, we must continue to capitalize on our following core strengths:

- *Commercial leadership of our management team with a track record of commercial execution* We have a highly skilled and customer-focused management team in critical leadership positions across our Company. Our senior management team has over 135 years of collective sales and marketing experience in the pharmaceutical industry and a proven track record of developing businesses and creating value. Members of our management team have developed, launched, commercialized, and managed brands, generating over \$3 billion in peak sales, collectively, at leading dermatology organizations. This experience includes improving business performance through organic revenue growth, maximizing operational efficiencies and through the identification, consummation and integration of licensing and acquisition opportunities. Our senior management team has extensive roots in the dermatology industry, with many of them having worked at and held senior positions with Medicis Pharmaceutical, Inc. leading up to the company's acquisition by Valeant Pharmaceuticals, Inc. (now Bausch Health Pharmaceuticals, Inc.) for \$2.6 billion in 2012. Our strategic approach leverages our management team's experience with the capabilities of our field sales force to drive performance based on prescribing habits, brand preferences, promotional strategies and profit optimization while focusing on customer service excellence for our providers and their patients. Our execution to date has led to market-leading positions for three of our established brands, Targadox, Ximino, and Exelderm, in each of their respective markets.
- *Performance and experience of our accomplished field sales force.* Our current seasoned field sales force includes approximately 65 professionals with an average tenure of over 11 years of experience in dermatology sales. Each of these individuals have deep-rooted and longstanding customer relationships in their respective territories. We have strategically optimized our sales outreach to cover over 80% of dermatologists in the top 50 U.S. metropolitan statistical areas and over 70% of the overall dermatology prescribing market. We are able to leverage the experience of our field sales force to create a tailored and entrepreneurial compensation plan that incentivizes our field sales force and aligns their activities with our corporate performance and growth objectives. We intend to continue to build a team of committed, experienced employees and to engage with patients and members of the dermatology community. Additionally, we believe that consolidation in the medical dermatology industry has resulted in an enhanced opportunity for a medical dermatology-focused company to build relationships with these stakeholders and has made available a large and growing talent pool of experienced individuals who can make significant contributions to our Company.
- *Specialized and differentiated access and distribution model.* We have a specialized and differentiated access and distribution network of over 600 specialty pharmacies and wholesalers, where we directly sell our products, with limited distribution through traditional national wholesalers. This decentralized approach allows us to maximize our brand equity across our product portfolio through strategic relationships directly with pharmacies and allows us to provide exceptional customer service and access to patients and physicians.

- *Active business development initiative.* Business development plays a vital role in our growth strategy as we look to build scale. We consistently evaluate both strategic add-on deals that leverage our existing infrastructure, as well as more transformative assets that would require building out or restructuring our field sales force. We have extensive relationships in the industry that help us stay abreast of developments in our space and continually monitor new opportunities. We believe that we are an ideal partner for development stage companies with limited or no commercial capabilities, as well as established pharmaceutical companies looking to deprioritize their dermatology portfolio. We have ongoing discussions with an array of companies, including traditional large pharma, mid-size specialty pharma companies and smaller companies that focus on research and development, although we have not entered into any definitive agreements or arrangements.
- *Focus on cost management and efficient capital allocation.* We have operated in a cost-conscious and capital efficient manner since inception. In addition to our internal leadership and management team, we have access to over 30 Fortress employees who possess significant expertise in one or more of the following areas: business development, legal, accounting, regulatory affairs, clinical operations and manufacturing. In November 2021, we entered into a shared services agreement with Fortress whereby Fortress would continue to provide consulting services and for the continued use of its personnel. As part of our emphasis on cost effectiveness with our resources, we endeavor to structure licenses and product acquisitions for future product opportunities in a capital efficient manner that allows us to minimize indebtedness and compensate partner companies through future profits and commercial benchmarks.

Major Customers

We primarily sell our prescription products to specialty pharmacies, independent wholesalers, and distributors with limited sales through the traditional national wholesaler channels. Our wholesalers and distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies and managed care organizations. Customers in the managed care market include health maintenance organizations, group purchasing organizations, nursing homes, clinics, pharmacy benefit management companies and mail order customers.

License & Collaboration Agreements and Acquisitions

We continue to seek to enhance our product line and develop a balanced portfolio of differentiated products through product acquisitions and in-licensing or acquiring rights to products and technologies from third parties. We intend to enter into strategic alliances and collaborative arrangements with third parties, which will give us rights to develop, manufacture, market and/or commercialize pharmaceutical products, the rights to which are primarily owned by these third parties. These alliances and arrangements can take many forms, including licensing arrangements, co-development and co-marketing agreements, co-promotion arrangements, research collaborations and joint ventures. Such alliances and arrangements will potentially enable us to share the risk of incurring all research and development expenses that do not lead to revenue-generating products. However, because profits from alliance products are shared with the counterparties to the collaborative arrangement, the gross margins on alliance products are generally lower, sometimes substantially so, than the gross margins that could be achieved had we not opted for a development partner.

Environmental Matters

Our operations are subject to substantial federal, state and local environmental laws and regulations concerning, among other matters, the generation, handling, storage, transportation, treatment and disposal of, and exposure to, hazardous substances. Violation of these laws and regulations, which may change, can lead to substantial fines and penalties. Many of our third-party operations require environmental permits and controls to prevent and limit pollution of the environment. We believe that the facilities of our third-party service providers are in substantial compliance with applicable environmental laws and regulations and we do not believe that future compliance will have a material adverse effect on our business, financial condition, results of operations or cash flows.

Employees and Human Capital Management

Our current headcount is 80 employees and contractors. Of these, we employ a total of 20 employees, of which 20 are full-time employees. These employees and contractors include 65 in sales as well as 13 in marketing, general and administrative positions, and 2 in research and development positions. We currently rely, and may continue to rely, on professional employer organizations and staffing organizations for the employment of our field sales force. Additionally, we have retained a number of expert advisors and consultants that 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.

Additionally, we have access to Fortress employees and consultants, who possess significant expertise in one or more of the following areas: business development, legal, accounting, regulatory affairs, clinical operations and manufacturing.

Geographic Areas

All of our product revenues are generated from operations or otherwise earned within the U.S. We receive royalties for Rapifort® Wipes 2.5% (Qbrexza®), for the treatment of primary axillary hyperhidrosis, from our exclusive licensing partner in Japan, Maruho Co., Ltd. We do not consider royalty revenue to be a material source of our consolidated revenue.

Seasonality of Business

Our business is affected by the standard annual insurance deductible resets, as well as the purchasing patterns and concentration of our customers; however, our business is not materially impacted by seasonality. There are no assurances that these historical trends will continue in the future.

Relationship with Fortress

General

We have an eight-year operating history. We are a majority owned subsidiary of Fortress. Fortress is a biopharmaceutical company dedicated to acquiring, developing and commercializing pharmaceutical and biotechnology products and product candidates at its majority-owned and majority-controlled subsidiaries and joint ventures, and at entities founded by Fortress and in which it maintains significant minority ownership positions. Fortress has a talented and experienced business development team, comprised of scientists, doctors, and finance professionals, who identify, evaluate, and propose for our consideration promising products and product candidates.

Fortress Note

From the Company's inception in October 2014 until its initial public offering ("IPO"), Fortress funded the Company's operations through a working capital loan future advance promissory note (the "Fortress Note"). In connection with the closing of our IPO on November 16, 2021, the balance of the Fortress Note reflecting \$14.8 million converted into 1,476,044 shares of Journey common stock. The Fortress Note is no longer outstanding.

Product Licensing Agreements and Asset Acquisitions

Rapifort® Wipes 2.5% (Qbrexza)

On February 11, 2022, we announced that our exclusive licensing partner in Japan, Maruho Co., Ltd. ("Maruho"), received marketing and manufacturing approval for Rapifort® Wipes 2.5% (Qbrexza®), for the treatment of primary axillary hyperhidrosis, triggering a net \$2.5 million milestone payment to us. The net payment reflects a milestone payment of \$10 million to us from our exclusive licensing partner in Maruho, offset by a \$7.5 million payment to Dermira, pursuant to the terms of the Asset Purchase Agreement between us and Dermira. In conjunction with the terms of the licensing agreement with Maruho, the milestone payment was due from Maruho within 30 days of the approval. We acquired global rights to Qbrexza® from Dermira in 2021.

Amzeeq, Zilxi, FCD105 and the Molecule Stabilizing Technology Platform

On January 12, 2022, we entered into an Asset Purchase Agreement (the "APA") with VYNE Therapeutics Inc. ("VYNE") to acquire VYNE's Molecule Stabilizing Technology™ franchise (the "Acquisition") for an upfront payment of \$20.0 million, with an additional \$5.0 million payment due on the one-year anniversary of the closing of the Acquisition. The APA also provides for contingent net sales milestone payments: in the first calendar year in which annual sales reach each of \$100 million, \$200 million, \$300 million, \$400 million and \$500 million, we will be required to make a one-time payment of \$10 million, \$20 million, \$30 million, \$40 million and \$50 million, respectively, in that year only, per product, totaling up to \$450.0 million. In addition, Journey will pay VYNE 10% of any upfront

payment received by Journey from a licensee or sublicensee of the products in any territory outside of the United States, subject to exceptions for certain jurisdictions as detailed in the APA. There are no subsequent milestone payments or royalties beyond the aforementioned payments. The Acquisition included two FDA-approved products (Amzeeq and Zilxi), and a development-stage dermatology program (FCD105), along with the Molecule Stabilizing Technology proprietary platform.

DFD-29 Agreement

On June 29, 2021, we entered into a license, collaboration, and assignment agreement with Dr. Reddy's Laboratories, Ltd. ("DRL") to obtain the global rights for the development and commercialization of DFD-29, a late-stage development modified release oral minocycline that is being evaluated for the treatment of inflammatory lesions of rosacea (the "DFD-29 Agreement"). We acquired global rights to DFD-29, including in the U.S. and Europe, except that DRL has retained certain rights to the program in select markets including Brazil, Russia, India and China. Pursuant to the DFD-29 Agreement, we agreed to make an upfront payment of \$10.0 million, comprised of a \$2 million payment upon execution and \$8 million which was paid on September 29, 2021, 90 days following execution, with additional contingent regulatory, commercial, and corporate-based milestone payments, totaling up to \$158.0 million. Royalties ranging from ten percent to twenty percent are payable on net sales of the product. Royalties are payable in each country until the last-to-expire patent in such country expires. Royalties are subject to a 50% reduction in the event that a generic competitor launches in an applicable country where we market and sell the product. We are responsible for the prosecution and enforcement of patents licensed under the DFD-29 Agreement. The DFD-29 Agreement contains customary representations, warranties, and indemnities, and title transfers to us on the date of achievement of certain regulatory milestones set forth in the agreement, after which our licenses become our acquired assets. Each party may also terminate the DFD-29 Agreement for material breach by the other party or for certain bankruptcy or insolvency related events. Additionally, we agreed to fund and oversee the Phase III clinical trials, approximating \$24.0 million, based upon the most recent development plan and budget, which is subject to change.

The DFD-29 Agreement will remain in effect on a country-by-country basis until the expiration of the revenue percentage term in the relevant country, which period begins on the first commercial sale of a product in that country and ends upon the expiration or invalidation date of the last revenue generating patent in such country. The DFD-29 Agreement terminates in its entirety upon the expiry of the revenue percentage term in the last country covered under the DFD-29 Agreement.

Qbrexza Agreement

On March 31, 2021, we executed an asset purchase agreement for Qbrexza® (the "Qbrexza APA") with Dermira, pursuant to which we acquired global ownership to Qbrexza® (glycopyrronium), a prescription cloth towelette approved to treat primary axillary hyperhidrosis in people nine years of age and older. The transaction closed on May 14, 2021, and pursuant to the Qbrexza APA, we made an upfront \$12.5 million cash payment to Dermira. We are obligated to make payments to Dermira of up to \$144 million in the aggregate upon the achievement of certain milestones. For the first two years, we are required to pay royalties on sales ranging from the mid-thirty to the mid-twenty percent and, thereafter royalties ranging from the lower teen digits to the upper teen digits are payable on net sales of Qbrexza products. Subject to certain reductions, royalties are payable for a period of eight years. The agreement contains customary representations, warranties, and indemnities. Each party may also terminate the Qbrexza APA for material breach by the other party or for certain bankruptcy or insolvency related events.

As part of the Qbrexza APA, we were assigned an exclusive license agreement with Rose University ("Rose U") pursuant to which we obtained a worldwide exclusive license within a field of use including hyperhidrosis to practice, enforce and otherwise exploit certain patent rights, know-how and data related to Qbrexza. The license agreement with Rose U included a sublicense of certain data and an assignment of certain regulatory filings which Rose U had obtained from Stiefel Laboratories ("Stiefel"). In connection with the license agreement, we assumed Rose U's obligations to Stiefel to use commercially reasonable efforts to develop and commercialize products using the licensed patent rights, know-how and data.

Pursuant to these agreements with Rose U and the related agreement with Stiefel with respect to Qbrexza, we are obligated to pay Rose U low-to-mid single-digit royalties on net product sales and low double-digit royalties on sublicense fees and certain milestone, royalty and other contingent payments received from sublicensees, to the extent such amounts are in excess of the milestone and royalty payments we are obligated to pay Rose U directly upon the events or sales triggering such payments.

We are permitted to grant sublicenses to the licensed rights and may assign the agreements upon our acquisition or that of our assets that relate to the license agreement. We may terminate the license agreement if Rose U experiences certain insolvency events or if Rose U commits a material breach of the license agreement, subject to applicable cure provisions. Rose U may terminate the license in certain

circumstances if we experience certain insolvency events or if we commit a material breach of the license agreement or if we cause Rose U to be in material breach of its license agreement with Stiefel, subject in each case to applicable cure provisions. Subject to earlier termination, the license agreement remains in effect until 15 years following the first commercial sale of a licensed product have elapsed or, if later, the date that the last patent or patent application in the licensed patent rights has expired or been revoked, invalidated or abandoned. As of December 31, 2022, the last-to-expire issued patent relating to Qbrexza that we license under the license agreement with Rose U expires in 2029.

Accutane Agreement

On July 29, 2020, we entered into a license and supply agreement for Accutane® (“Accutane Agreement”) with DRL. Pursuant to the Accutane Agreement, we agreed to pay \$5.0 million, comprised of an upfront payment of \$1.0 million paid upon execution, with additional milestone payments totaling \$4.0 million. To date, we have paid \$3.0 million of the additional milestone payments. Three additional milestone payments totaling \$17.0 million are contingent upon the achievement of certain net sales milestones. Royalties in the low-double digits based on net sales, subject to specified reductions are also due.

The term of the Accutane Agreement is ten years and renewable upon mutual agreement. We are required to pay royalties during the term of the Accutane Agreement. The agreement contains customary representations, warranties, and indemnities. Each party may also terminate the Accutane Agreement for material breach by the other party or for certain bankruptcy or insolvency related events and we may terminate for upon 180 days written notice to the other party. We commenced sales of this product in April 2021.

Anti-Itch Product Agreement

On December 18, 2020, we entered an asset purchase agreement for our Anti-itch Product (the “Anti-itch APA”) with Sun Pharmaceutical Industries, Inc. (“Sun”). Pursuant to the Anti-itch APA, total consideration is \$4.0 million, comprised of an upfront payment of \$2.0 million, payable upon execution. Through December 31, 2022, we have paid \$4.0 million and have no additional payments. The Anti-itch APA contains customary representations, warranties, and indemnities. There are no subsequent milestone payments or royalties beyond the aforementioned payments. We intend to launch this product during the second half of 2023.

Ximino Agreement

On July 22, 2019, we entered into an asset purchase agreement for Ximino® (the “Ximino APA”) with Sun. Pursuant to the Ximino APA, total consideration is \$9.4 million, with an upfront payment of \$2.4 million, which was payable within 60 days after execution on September 22, 2019.

The remaining \$7.0 million will be made starting on the second anniversary and for the next four anniversaries of the Ximino APA thereafter. In addition, we are obligated to pay royalties in the mid-single digits based on net sales of Ximino, subject to specified reductions until the end of 2022. The Ximino APA contains customary representations, warranties, and indemnities. Each party may also terminate the Ximino APA for material breach by the other party or for certain bankruptcy or insolvency related events. No additional licensing or milestone payments are required. We commenced sales of this product in August 2019.

Exelderm Agreement

On August 31, 2018, we entered into an asset purchase agreement for Exelderm® (the “Exelderm APA”) with Sun. Pursuant to the Exelderm APA, total consideration is \$1.6 million, comprised of an upfront payment of \$1.2 million, which was payable within 60 days after execution on October 31, 2018. The remaining milestone payment was contingent upon net sales reaching a certain threshold, at which point a \$0.4 million payment became due. This threshold was achieved in 2020 and paid in early 2021. We are obligated to pay royalties in the low-double digits based on net sales of Exelderm until the end of 2023, and no additional licensing or milestone payments are required. We commenced sales of this product in August 2018.

Targadox Agreement

On March 10, 2015, we entered into a license and supply agreement (as amended) for Targadox® (the “Targadox Agreement”) with PuraCap International LLC n/k/a Caribe Holdings, Inc. (“Caribe”). We made an upfront payment of \$1.3 million. Further payments will be made based on a revenue sharing arrangement and no additional licensing or milestone payments are required. The term of the Targadox Agreement is ten years and automatically renews for three-year periods unless either party provides notice of its intent not to

renew at least 180 days prior to the expiration of the applicable term. Under our revenue sharing arrangement, we are entitled to retain a majority of the net profits and pay Caribe a portion of the net profits after deducting certain commercial, marketing and sales expenses during the term of the Targadox Agreement. The Targadox Agreement contains customary representations, warranties, and indemnities. Each party may also terminate the Targadox Agreement for material breach by the other party or for certain bankruptcy or insolvency related events. We commenced sales of this product in October 2016.

Research and Development

As discussed above, on June 29, 2021, we obtained the global rights for the development and commercialization of DFD-29, a late-stage development modified release oral minocycline that is being evaluated for the treatment of inflammatory lesions of rosacea. Through this collaboration, the parties will work together to complete the development of DFD-29, which includes conducting two Phase III studies to assess the efficacy, safety and tolerability of oral DFD-29 for the treatment of rosacea and the regulatory submission of a new drug application (“NDA”) under Section 505(b)(2) of the United States Federal Food, Drug and Cosmetic Act (“FDCA”). DRL will provide development support, including the monitoring of two Phase III clinical trials.

On March 17, 2022, we dosed the first patient in our Phase 3 clinical trials evaluating DFD-29 (Minocycline Modified Release Capsules 40 mg) for the Treatment of Rosacea. As of January 10, 2023, we achieved 100 % enrollment in the trials, with a top-line data readout expected in the second quarter of 2023. We plan to submit the NDA for DFD-29 in the second half of 2023 and FDA approval is anticipated in the second half of 2024. In the Phase 2 clinical trials, DFD-29 (40mg) demonstrated nearly double the efficacy when compared against Oraycea® (European equivalent of Oracea®) on both co-primary endpoints. For the first co-primary endpoint, IGA treatment success, Oraycea only had a 33.33% IGA treatment success rate, while DFD-29 achieved a 66.04% IGA treatment success rate. For the second co-primary endpoint, the change in total inflammatory lesion count, Oraycea only had a 10.5 reduction in inflammatory lesions, while DFD-29 achieved a 19.2 reduction in inflammatory lesions.

The Phase II study, conducted in Germany, was a multi-center, randomized, double-blinded, parallel group, controlled study that assessed the efficacy, safety and tolerability of oral DFD-29 (20mg and 40mg) extended release minocycline hydrochloride capsules for the treatment of inflammatory lesions of rosacea over 16 weeks. Initial patient enrollment in the Phase II study included 205 male and female subjects with papulopustular rosacea. 160 subjects completed the study. Each subject was allocated to one of the following treatment groups, and received one capsule once daily, in the morning, for 16 weeks: i) DFD-29 40 mg extended release capsules (with 47 subjects at completion); ii) DFD-29 20mg extended release capsules (with 38 subjects at completion); iii) Oraycea® (doxycycline) capsules (with 40 subjects at completion); and iv) placebo capsules (with 35 subjects at completion). The study showed that DFD-29 40mg had statistical significance to both placebo and the active control, Oraycea® (German equivalent of U.S. marketed Oracea®), on both co-primary endpoints - proportion of subjects with IGA treatment success (grade 0 or 1 with at least a two grade reduction from baseline at week 16 and total inflammatory lesion count reduction from baseline to week 16. More information on the DFD-29 Phase II study can be found at clinicaltrials.gov. Highly statistically significant difference in IGA success could be shown for DFD-29 40mg compared to placebo ($p < 0.0001$) as well as compared to Oraycea ($p = 0.0010$). Highly statistically significant treatment difference was also observed in the co-primary endpoint mean change in total inflammatory lesion count as well in both DFD-29 40mg compared to placebo ($p < 0.0001$) and DFD-29 40mg compared to Oraycea ($p = 0.0004$). All statistical tests used were two-sided, with $\alpha = 0.05$ as level of significance. There were no related serious adverse events reported during the study for those subjects who were studied with DFD-29 40mg.

Intellectual Property

General

We rely on a combination of contractual provisions, confidentiality policies and procedures and patent, trademark, copyright and trade secrecy laws to protect the proprietary aspects of our technology and business. Three of our marketed products, Accutane, Targadox, and Exelderm, do not have patent protection and/or otherwise not eligible for patent protection. As part of our development and acquisition strategy, we place a strong emphasis on the patent protection for potential products.

Four of our marketed products, Qbrexza, Amzeeq, Zilxi, and Ximino, as well as DFD-29, currently have patent protection.

Qbrezza Patents

We own or have an exclusive license to 22 issued U.S. patents and 41 issued foreign patents, which include granted European patent rights that have been validated in selected European Patent Organization (“EPO”) member states (Switzerland, Germany, Spain, France, Great Britain, Ireland, and Italy), Australia, Canada, Mexico, Israel, Japan, Hong Kong, Korea, and New Zealand, Singapore, and South Africa, and six pending U.S. patent applications, one pending Patent Cooperation Treaty application, and 16 pending foreign patent applications. Of these patents and patent applications:

There are 15 issued U.S. patents, 28 issued foreign patents (AU, CA, selected EP member states, Mexico, Japan, Hong Kong, Korea, New Zealand, Singapore, and South Africa), four pending U.S. patent applications and eight pending foreign applications (in Canada, the European Patent Office, Mexico, Japan, Hong Kong, and Korea) as well as one pending PCT application, all relating to Qbrezza. We own 11 of the issued U.S. patents, three of the pending U.S. patent applications, 18 of the issued foreign patents, and six of the pending foreign applications, and have exclusively licensed from Rose U worldwide rights to four of the issued U.S. patents, one pending U.S. patent application, ten issued foreign patents, and two pending foreign patent applications. The issued Qbrezza patents contain claims directed to individually packaged wipes for the treatment of hyperhidrosis where the wipes contain a composition comprising Qbrezza or other related compounds, and methods of alleviating hyperhidrosis using such compositions and contain claims directed to compositions comprising Qbrezza or other related compounds, individually packaged wipes comprising such compositions, absorbent pads comprising Qbrezza pharmaceutical compositions and methods of treating hyperhidrosis with topical administration of Qbrezza or other related compounds. The issued U.S. and foreign patents relating to Qbrezza will expire between 2028 and 2033 and the pending U.S. and foreign patent applications relating to Qbrezza, if issued, will expire between 2028 and 2034.

Amzeeq, Zilxi & the Molecular Stabilizing Technology Platform

We own 25 issued U.S. patents and 10 issued foreign patents, and 7 pending U.S. patent applications, 1 pending Patent Cooperation Treaty application, and 6 pending foreign patent applications. Of these patents and patent applications:

- There are 12 issued U.S. patents, 10 issued foreign patents (Australia, Canada, Israel, Mexico, South Africa), 3 pending U.S. patent applications and 5 pending foreign applications (India, Canada, EPO, Israel, Mexico) as well as 0 pending PCT applications, all relating to Amzeeq. The issued Amzeeq patents contain claims directed to compositions and use of the compositions (method claims). The issued U.S. and foreign patents relating to Amzeeq will expire between 2030 and 2037 and the pending U.S. and foreign patent applications relating to Amzeeq will expire between 2030 and 2037.
- There are 8 issued U.S. patents, 9 issued foreign patents (Australia, Canada, Israel, Mexico, South Africa), 2 pending U.S. patent applications and 4 pending foreign applications (India, EPO, Canada), all relating to Zilxi. The issued Zilxi patents contain claims directed to compositions and use of the compositions (method claims). The issued U.S. and foreign patents relating to Zilxi will expire between 2030 and 2037 and the pending U.S. and foreign patent applications relating to Zilxi will expire between 2030 and 2037.
- Other Patents related to molecular stabilizing platform but not products directly are 11 issued U.S. patents, 3 pending U.S. patent applications, and 2 pending foreign applications (Canada and Taiwan) as well as 1 pending PCT application. The issued U.S. patents will expire between 2028 and 2030 and the pending U.S. and foreign patent applications will expire between 2020 and 2040.

DFD-29 Patents

With regard to DFD-29, we have an exclusive license to one U.S. patent family including 2 issued U.S. patents, 1 allowed U.S. patent application, and one U.S. continuation application, as well as 8 foreign pending patent applications (one in each of Australia, Canada, Europe, Japan, Korea, Mexico, New Zealand, and South Africa) covering methods of treating an inflammatory skin condition by selecting and administering an oral composition comprising reduced dose of minocycline and the relevant pharmacokinetic parameters, and we intend to pursue composition-of-matter patents, where possible, and dosage and formulation patents, as well as method-of-use patents on novel indications for known compounds. The two issued U.S. patents will expire in 2039.

Ximino Patents

We have an exclusive license to patents related to Ximino, including 6 issued U.S. patents. These patents cover the Ximino, methods of treatment, and related dosage forms and strengths, and will expire between 2025 and 2027.

Additional Intellectual Property and Proprietary Right Protection

We also use other forms of protection, such as trademark, copyright, and trade secret protection, to protect our intellectual property, particularly where we do not believe patent protection is appropriate or obtainable. We aim to take advantage of all of the intellectual property rights that are available to us and believe that this comprehensive approach will provide us with proprietary positions for our product candidates, where available. Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, to preserve our trade secrets, and to 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 any product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

Patents and other proprietary rights are crucial to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents, supported by regulatory exclusivity, or are effectively maintained as trade secrets.

Generally, patent applications in the U.S. are maintained in secrecy for a period of 18 months or more. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us, we may have to participate in derivation proceedings declared by the USPTO to determine proper inventorship of a claimed invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. However, the life of a patent covering a product that has been subject to regulatory approval may be extended through the patent term restoration program, although any such extension could still be minimal.

If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license under such patent or to develop or obtain alternative technology, neither of which may be possible. In the event of litigation involving a third-party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license under the disputed rights of such third party, and/or require us to cease use of the technology. Moreover, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would involve substantial costs.

Other Intellectual Property Rights

We depend upon trademarks, trade secrets, and continuing technological advances to develop and maintain our competitive position. We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. This knowledge and experience we call "know-how." To help protect our proprietary know-how that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, scientific advisors, consultants, collaborators and other contractors, upon commencement of a relationship with us, to enter into confidentiality agreements, which prohibit the disclosure of confidential information and, in the case of parties other than our research and development collaborators, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship

with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

There can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition or that our confidentiality agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that other third parties will not otherwise gain access to our trade secrets and other intellectual property.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our intellectual property or trade secrets or to determine the scope and validity of the proprietary rights of others. Litigation is costly and time-consuming and there can be no assurance that our litigation expenses will not be significant in the future or that we will prevail in any such litigation.

Competition

Pharmaceutical Industry

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry, we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

Dermatology Sector

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

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

Our major competitors, including Galderma Laboratories, Ammirall, Verrica Pharmaceuticals, MC2 Therapeutics, Novan Therapeutics, Sun Pharma, Leo Pharma, Arcutis Biotherapeutics, Mayne Pharma, Dermavant Sciences, Botanix Pharmaceuticals, and Ortho Dermatologics, among others, vary depending on therapeutic and product category, dosage strength and drug-delivery systems, among other factors.

Generic Competition

We face increased competition from manufacturers of generic pharmaceutical products, who may submit applications to the FDA seeking to market generic versions of our products. In connection with these applications, the generic drug companies may seek to challenge the validity and enforceability of our patents through litigation. When patents covering certain of our products (if applicable) expire or are successfully challenged through litigation or in USPTO proceedings, if a generic company launches a competing product “at risk,” or when the regulatory or licensed exclusivity for our products (if applicable) expires or is otherwise lost, we may face generic competition as a result. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required to be utilized before or in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefits management organizations, we

must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care. Generic products generally face intense competition from other generic equivalents (including authorized generics) and therapeutically similar branded or generic products.

Supply and Manufacturing

We have limited experience in manufacturing products for clinical or commercial purposes, and we currently do not have any internal manufacturing capabilities. We currently rely upon multiple contract manufacturers to produce our products and clinical supply of product candidates and will continue to rely upon contract manufacturers for any current or future product candidates under current Good Manufacturing Practice (“cGMP”) regulations for use in pre-clinical and clinical activities. Due to the risks associated with reliance on third-party manufacturing risk, as part of our current and future strategy of licensing, acquiring, or the future development of assets, we currently, and will continue to, secure manufacturing agreements with either a counterparty to a transaction, with one or more of our contract manufacturers or additional contract manufacturers. As with any supply program, obtaining raw materials of the correct quality cannot be guaranteed, and we cannot ensure that we will be successful. Our third-party manufacturers have a limited number of facilities in which our product candidates can be produced and may have limited experience in manufacturing our product candidates in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control. We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration and corresponding state and European agencies to ensure strict compliance with cGMPs and other state and federal regulations. We do not have control over third-party manufacturers’ compliance with these regulations and standards, other than through contractual obligations. If they are deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped, and supplies could be delayed or otherwise disrupted.

If we need to change manufacturers during the clinical or development stage for product candidates or after commercialization for our approved products, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

Government and Industry Regulations - Overview

FDA Regulations

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon any potential clinical development and the manufacture and marketing of our products. Before marketing in the U.S., any drug that we may develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FDCA. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, lot traceability, individual serialization, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, sale and distribution of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. In the event that we acquire or develop a clinical stage asset, we will be required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a product candidate’s safety and efficacy before we can secure FDA approval to market or sell a product in the U.S. The approval process may take many years, depending on the stage of development of a target asset, and requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies or surveillance.

Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an Investigational New Drug (“IND”) Application unless exempted.

For purposes of NDA approval, clinical trials are typically conducted in the following sequential phases:

Phase 1:

➤The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion and clinical pharmacology.

Phase 2:

➤Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.

Phase 3:

➤Studies establish safety and efficacy in an expanded patient population.

Phase 4:

➤The FDA may require Phase 4 post-marketing studies to find out more about the drug's long-term risks, benefits, and optimal use, or to test the drug in different populations.

The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination in future clinical trials, or that may increase the costs of these trials, include:

- slow patient enrollment 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;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site's review board;
- longer treatment time required to demonstrate efficacy or determine the appropriate product dose;
- insufficient supply of the drug candidates;
- adverse medical events or side effects in treated patients; and
- ineffectiveness of the drug candidates.

In addition, the FDA, equivalent foreign regulatory authority, or a data safety monitoring committee for a trial may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health risk, or for futility. Any drug is likely to produce some toxicity or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or clinical trials of drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

Sponsors of drugs may apply for a special protocol assessment ("SPA") from the FDA. The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for an NDA. However, final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 trial. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product safety or efficacy.

Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA, Abbreviated NDA (“ANDA”), 510(K) or Biologics License Application (“BLA”) containing the pre-clinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, and proposed labeling, among other things. The FDA may refuse to accept an NDA, ANDA, 510(K) or BLA for filing if certain content criteria are not met and, even after accepting an NDA, ANDA, 510(K) or BLA, the FDA may often require additional information, including clinical data, before approval of marketing a product.

It is also becoming more common for the FDA to request a Risk Evaluation and Mitigation Strategy (“REMS”), as part of an NDA, ANDA, 510(K) or BLA. The REMS plan contains post-market obligations of the sponsor to train prescribing physicians, monitor off-label drug use, and conduct sufficient Phase 4 follow-up studies and registries to ensure the continued safe use of the drug.

As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer’s quality control and manufacturing procedures conform to cGMP. Manufacturers must expend significant time, money and effort to ensure continued compliance, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMPs, as interpreted by the FDA, and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, then the FDA may not allow us to market products that have been affected by the failure.

If the FDA grants approval, the approval will be limited to those conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA, ANDA, 510(K), or BLA. Certain changes to an approved BLA, including, with certain exceptions, any significant changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing monitoring and regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will generally be limited to those specified in FDA approved labeling, and the advertising of our products will be subject to comprehensive monitoring and regulation by the FDA. Drugs whose review was accelerated may carry additional restrictions on marketing activities, including the requirement that all promotional materials are pre-submitted to the FDA. Claims exceeding those contained in approved labeling will constitute a violation of the FDCA. Violations of the FDCA or regulatory requirements at any time during the product development process, approval process, or marketing and sale following approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, warning letters, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

Pharmaceutical Coverage, Pricing and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance, and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor’s decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific details, information on cost-effectiveness, and clinical support for the use of a product to each payor separately. This can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and related services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

At the state level, there are also new laws and ongoing ballot initiatives that create additional pressure on drug pricing and may affect how pharmaceutical products are covered and reimbursed. A number of states have adopted or are considering various pricing actions,

such as those requiring pharmaceutical manufacturers to publicly report proprietary pricing information, limit price increases or to place a maximum price ceiling or cap on certain products. Existing and proposed state pricing laws have added complexity to the pricing of pharmaceutical drug products.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, that it will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available, or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

International Regulations

In addition to regulations in the United States, there are a variety of foreign regulations governing clinical trials and commercial sales and distribution of any product candidates. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes.

PHRMA Code and April 3, 2003 Department of Health and Human Services Office of Inspector General, OIG Compliance Program for Pharmaceutical Manufacturers

We have established and implemented a corporate compliance program designed to prevent, detect and correct violations of state and federal healthcare laws, including laws related to advertising and promotion of our products that are in compliance with the PHRMA Code and the Health and Human Services Office of Inspector General ("OIG") Compliance Program requirements for Pharmaceutical Manufacturers.

Healthcare Fraud, Waste and Abuse

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, violations of which can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs.

These laws are potentially applicable to us as both a manufacturer and a supplier of products reimbursed by federal healthcare programs, and they also apply to physicians and other potential purchasers of our products.

The federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b) prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Remuneration is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, coupons, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Under the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b, a person or entity need not have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim, including items or services resulting from a violation of 42 U.S.C. § 1320a-7b, constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The federal Anti-Kickback Statute and implementing regulations provide for certain exceptions for "safe harbors" for certain discounting, rebating or personal services arrangements, among other things. However, the lack of uniform court interpretation of the Anti-Kickback Statute, coupled with novel

enforcement theories by government authorities, make compliance with the law difficult. Violations of the federal Anti-Kickback Statute can result in significant criminal fines, exclusion from participation in Medicare and Medicaid and follow-on civil litigation, among other things, for both entities and individuals.

In October 2019, the OIG issued a proposed rule to, among other things, add new safe harbors for certain value-based arrangements. Although the value-based proposals would not include pharmaceutical manufacturers among the entities that could permissibly enter into such contracting arrangements, the general trend toward outcomes and value-based contracts in the healthcare industry may continue. It is possible that payors, among other customers, could push manufacturers for novel contracting approaches, including those that would incorporate value-based principles, and these efforts could affect our business.

The civil False Claims Act and similar state laws impose liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act and similar state laws allow a private individual to bring civil actions on behalf of the federal or state government and to share in any monetary recovery. The Federal Physician Payments Sunshine Act and similar state laws impose reporting requirements for various types of payments to physicians and teaching hospitals. Failure to comply with reporting requirements under these laws could subject manufacturers and others to substantial civil money penalties.

Other Healthcare Laws and Compliance Requirements

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

Drug Quality and Security Act (“DQSA”)

DQSA was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (“DSCSA”), outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. This is intended to enhance the FDA’s ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system is also intended to improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

Additionally, the DSCSA directs FDA to establish national licensure standards for wholesale distributors and third-party logistics providers, and requires these entities report licensure and other information to FDA annually. The implementation and enforcement of complete unit level traceability of verifiable return serialization, including aggregation throughout the whole supply chain, is not required until November 27, 2023.

We are subject to, and required to be in compliance with, the DQSA. Our Company remains in compliance with the requirements promulgated by the DSCSA and intends on remaining vigilant with regards to any potential modifications to the act. For purposes of our business, we are considered both manufacturers and re-packagers under the act. Currently, we are in compliance with the DSCSA as it relates to our business and operations.

DSCSA: Recent FDA Announcement Regarding Certain Wholesale Distributor and Dispenser Verification Requirements Under DSCSA

On October 22, 2020, the FDA announced a final guidance regarding enforcement of the DSCSA requirements for wholesale distributor verification of saleable returned products and dispenser verification of the product identifier for suspect and illegitimate product.

- FDA does not intend to take action against wholesale distributors who do not, prior to November 27, 2023, verify a product identifier prior to further distributing returned product as required under the DSCSA. This provides wholesale distributors three additional years to comply with this requirement.
- FDA also does not intend to take action against dispensers who do not, prior to November 27, 2023, verify the product identifier for suspect or illegitimate product in the dispenser’s possession or control. This provides dispensers three additional years to comply with this requirement.

Although the rule regarding wholesale distributor verification of saleable returned products does not directly apply to our Company, we will be required to assist our wholesale distributor customers by setting in place mechanics that would allow for traceability of returns in the supply chain. If we are not able to come into compliance of this rule, our wholesale distributor customers may not accept our returns on our behalf.

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this report and our other public filings, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Business, Industry and Existing Operating Revenue Stream

Future revenue from sales of our dermatology products 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. Any setback that may occur with respect to such products could significantly impair our operating results and/or reduce our revenue and the value of our securities. Setbacks for such products could include, but are not limited to, issues related to: supply chain, shipping; distribution; demand; manufacturing; product safety; product quality; marketing; government regulation; pricing; reimbursement; licensing and approval; intellectual property rights; competition with existing or new products; product acceptance by physicians, other licensed medical professionals and patients; and higher than expected total rebates, returns or recalls.

Also, the majority 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 increased market share of existing competitor products, any of which could have a significant adverse effect on our operating income.

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

Our 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 the FDA seeking to market generic versions of our products. In connection with these applications, the generic drug companies may seek to challenge the validity and enforceability of our patents through litigation. When patents covering certain of our products 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 expires or is otherwise lost, we may face generic competition as a result.

The majority of our sales derive from products that are without patent protection and/or are or may become subject to third-party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse impact on our operating income. Four of our marketed products, Qbrexza, Amzeeq, Zilxi, and Ximino, as well as DFD-29, currently have patent protection. Three of our marketed products, Accutane, Targadox, and Exelderm, do not have patent protection or otherwise are not eligible for patent protection. Accutane currently competes in the Isotretinoin market with five other therapeutic equivalent (“AB rated”) products. Targadox faces AB rated generic competition. Exelderm may face AB rated generic competition in the future.

Generic versions are generally significantly less expensive than branded versions, and, where available, may be required to be utilized before or in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care. If we fail to do so, our results of operations, financial condition or cash flows may be materially adversely affected.

Any disruptions to the capabilities, composition, size or existence of our field sales force may have a significant adverse impact on our existing revenue stream. Further, our ability to effectively market and sell any future products that we may develop will depend 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.

Our 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 our field sales force or the professional employer organization that employs our field sales force, could materially adversely affect our product sales. We currently rely, and may continue to rely, on professional employer organizations and staffing organizations for the employment of our 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, which would have a material adverse effect on our business, prospects, results of operations, financial condition or cash flows.

Our current and potential future product candidates may not receive regulatory approval, or such approval may be delayed, which would have a material adverse effect on our business and financial condition. Further, even if a product receives regulatory approval, such product will remain subject to substantial regulatory scrutiny.

Our current and potential future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and abroad. Our failure to obtain marketing approval for any current or future product candidates will prevent us from commercializing the product candidates. Further, any products or future products candidates we license or acquire will be subject to ongoing requirements and review by such regulatory authorities.

We have limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties to assist us in this process. To secure marketing approval, we will be required to establish a product candidate's safety and efficacy by submitting extensive preclinical and clinical data and supporting information for each therapeutic indication. We will further be required to submit information about the product manufacturing and to undergo regulatory inspection of our third-party manufacturing facilities to ensure ongoing compliance with cGMP requirements.

Any of our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or prevent or limit commercial use. If our current or future product candidates receive(s) marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

The marketing approval process, both in the United States and abroad, is time consuming and expensive. Approval may take many years, and if it is granted can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; the FDA or comparable foreign regulatory authorities may disagree with our development strategy; we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication or is suitable to identify appropriate patient populations; the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks.

Changes to marketing approval policies or the regulatory landscape during the development period may cause rejection of or delays in the approval of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or decide that our data is insufficient for approval and require costly additional preclinical studies or clinical trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval

commitments that render the approved product not commercially viable. If we experience delays in obtaining or fail to obtain or maintain any necessary approvals of any current or future product candidates, receive approval for fewer or more limited indications than we request or without including the labeling claims we desire, our future commercial prospects may be harmed and our ability to generate revenue may be materially impaired. Even if we do receive approval, it may be contingent on the performance of costly post-marketing clinical trials to verify whether or not the drug provides the anticipated clinical benefit, in order to maintain the approval.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective. If the FDA or any regulatory authority limits the scope of our indication, or if we are unable to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected. Further, we are only permitted to promote our products for those indications specifically approved by the FDA and we are restricted from making communications regarding uses not approved and described in the product's labeling. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to advisory or enforcement action by these authorities. In addition, our failure to follow FDA requirements or guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

If any of our contract manufacturers fails to produce our products in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of this product candidate or be unable to meet market demand, and may lose potential revenues.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. Any termination or disruption of any current or future relationships relating to product development may materially harm our business and financial condition and frustrate any commercialization efforts for affected current or future product candidates.

Any current or future contract manufacturers we engage must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its establishment inspection program. Despite the existence of contract manufacturing agreements and shared cGMP responsibilities, our contract manufacturers' may ignore these contractual provisions, or otherwise fail to meet the minimum standards set forth in the cGMP regulations, resulting in manufacturing non-compliance. This may go unnoticed or uncorrected despite our best efforts to regulatory audit or confirm the CMOs regulatory responsibilities. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recalls, re-stocking costs, damage to our reputation and potential for product liability claims.

If the CMOs upon which we rely to manufacture any current products, and any potential product candidates we may in-license or acquire, fail to deliver the required commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

If serious adverse or unacceptable side effects are identified during the development of any current or future product candidates, we may need to abandon or limit our development of some of the other potential product candidates.

If any current or future product candidates are associated with undesirable side effects, toxicities, or other negative characteristics, we may need to abandon such products' commercialization, development or limit development to more narrow uses or subpopulations. Such side effects may affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims. Many compounds that show initial promise in early-stage testing are later found to cause side effects that prevent further development. If our clinical trials reveal severe or prevalent side effects, our trials could be suspended or terminated, we may be unable to recruit patients and enrolled patients may be unable to complete the trials, and the FDA or comparable foreign regulatory authorities could order issue a clinical hold, or order us to cease further development or deny approval of the product candidate. The FDA may also request additional data, which it has done with increased prevalence in recent years, which has resulted in substantial delays in new drug approvals. Undesirable side effects caused by any current or future product candidates could also result in the inclusion of unfavorable information in our product labeling, denial of regulatory approval by the FDA or other regulatory authorities

for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of such product candidate.

If one or more of our current products or any future product candidate receives marketing approval and we or others later identify undesirable adverse events or side effects caused by this product, or we fail to comply with post-market regulatory requirements, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any current or future product candidate or could substantially increase our commercialization costs and expenses, which could delay or prevent us from generating significant revenues.

All of our current and future products will remain subject to substantial regulatory scrutiny even after receiving regulatory approval.

Any products or current or future product candidates we may license or acquire will be subject to ongoing regulatory and compliance requirements and oversight by the FDA and other regulatory authorities. These requirements include labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and other licensed medical professionals and recordkeeping of the drug. The Food and Drug Administration Amendments Act of 2007 granted significant expanded authority to the FDA, much of which was aimed at improving the safety of drug products before and after approval. The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for only their approved indications, we may be subject to enforcement action for off-label marketing. While physicians and other healthcare providers may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "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, including the clinical behavior of physicians and other healthcare providers in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use.

Violations of the FDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products or their manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;

- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits;
- suspension or withdrawal of marketing or regulatory approvals;
- suspension of any ongoing clinical trials;
- denial of permits to import or export our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current or future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of our current products or current or future product candidates for which we obtain marketing approval. Our current and future arrangements with third-party payors for the sales of our products and sales to customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute ("AKS") and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any current products or current or future product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. 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:

- AKS, 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. The OIG continues to make modifications to existing AKS safe harbors which may increase liability and risk as well as adversely impact sales relationships. The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor;
- 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 (“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, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program, which requires manufacturers of 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 (“CMS”), information related to “payments or other transfers of value” made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members.;
- Increased OIG scrutiny on the sale of our products through specialty pharmacies by means of direct investigation or by issuance of unfavorable Opinion Letters which may curtail or hinder the sales of our products based on risk of enforcement upon our-selves or our buyers;
- 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 business. 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 business.

We have established and implemented a corporate compliance program designed to prevent, detect and correct violations of state and federal healthcare laws, including laws related to advertising and promotion of our products. Nonetheless, enforcement agencies or private plaintiffs may take the position that we are not in compliance with such requirements and, if such noncompliance is proven, the Company and, in some cases, individual employees, may be subject to significant liability, including the aforementioned administrative, civil and criminal sanctions.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our licensed products profitably. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the “PPACA”

or collectively, the “ACA”), was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA: increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain “branded prescription drugs” to specified federal government programs; implemented a new methodology under which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded the eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation (“CMMI”) at the CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On January 20, 2017, President Trump signed an executive order stating that his administration intended to seek prompt repeal of the Affordable Care Act, and, pending repeal, directed the U.S. Department of Health and Human Services and other executive departments and agencies to take all steps necessary to limit any fiscal or regulatory burdens of the Affordable Care Act. On January 28, 2021, President Biden signed an Executive Order on Strengthening Medicaid and the Affordable Care Act and stated his administration’s intentions to reverse the actions of his predecessor and strengthen the ACA. As part of this Executive Order, the Department of Health and Human Services, United States Treasury, and the Department of Labor are directed to review all existing regulations, orders, guidance documents, policies, and agency actions to consider if they are consistent with ensuring both coverage under the ACA and making high-quality healthcare affordable and accessible to Americans. On March 11, 2021, President Biden signed into law the American Rescue Plan Act of 2021 to further strengthen Medicaid and the ACA and on April 5, 2022, President Biden signed the Executive Order on Continuing to Strengthen Americans’ Access to Affordable, Quality Health Coverage in which he celebrated the significant progress his administration believes has been made across the U.S. in making healthcare more affordable and accessible. In this Executive Order, President Biden directed agencies “with responsibilities related to Americans’ access to health coverage” to “review agency actions to identify ways to continue to expand the availability of affordable health coverage.” The continued expansion of the government’s role in the U.S. healthcare industry may further lower rates of reimbursement for pharmaceutical products. While we are unable to predict the likelihood of changes to the ACA or other healthcare laws which may negatively impact our profitability, we continue to closely monitor all changes.

President Biden intends, as his predecessor did, to take action against drug prices which are considered “high.” Drug pricing continues to be a subject of debate at the executive and legislative levels of U.S. government. The American Rescue Plan Act of 2021 signed into law by President Biden on March 14, 2021 includes a provision that will eliminate the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. With the elimination of the rebate cap, manufacturers may be required to compensate states in an amount greater than what the state Medicaid programs pay for the drug. Additionally, the Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated “maximum fair price” for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

These and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any current product or future product candidate. 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 products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of any current or future product candidates, if any, may be. In addition, increased Congressional scrutiny of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Public concern regarding the safety of any of our current or future drug products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to incur additional costs.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products, and the establishment of risk management programs. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving any other potential future product candidate, our ability to obtain of such product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of any potential future product candidate, the indications for which such product candidate is approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize potential future product candidate may be otherwise adversely impacted.

If we experience delays or difficulties in the enrollment of patients in any future clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate any future clinical trials for any current or future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors may have ongoing clinical trials for product candidates that treat the same indications as our current or potential future product candidates, and patients who would otherwise be eligible for any future clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is affected by other factors, including:

- the severity of the disease under investigation;
- the eligibility criteria for a study;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for any future clinical trials would result in significant delays and could require us to abandon any future clinical trials altogether. Enrollment delays in any future clinical trials may result in increased development costs for any current or future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

We expect intense competition for our products and current or future product candidates, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.

We face, and will continue to face, competition in the development and marketing of products from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies, including specialty and other large pharmaceutical companies, and OTC companies and generic manufacturers. The dermatology competitive landscape is highly fragmented, with many mid-size and smaller companies competing in the prescription sector. Our competitors are pursuing the development and/or acquisition of pharmaceuticals, medical devices and OTC products targeting the same diseases, conditions, and indications as our products. There can be no assurance that our competitors' developments, including the development of other drug technologies and methods of preventing the incidence of disease, will not render our current products or current or future product candidates obsolete or noncompetitive.

If patents covering any of our currently marketed products expire or are successfully challenged, or when the regulatory or licensed exclusivity for our products expires or is otherwise lost, we will face increased competition from generic versions of our products. Generic versions are generally significantly less expensive than branded versions and third-party reimbursement programs may require or prefer that a generic version is used before the branded version. Accordingly, when a branded product loses market exclusivity, the product faces intense price competition from generic versions. To successfully compete for business with managed care and pharmacy benefits management organizations, we must demonstrate that our products offer medical and cost advantages when compared with other forms.

Competitive factors vary by product line and geographic area in which the products are sold. The principal methods of competition for our products include quality, efficacy, market acceptance, price, and marketing and promotional efforts. The commercial opportunity for our products and/or product future candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed intellectual property. Many of our potential competitors have substantially greater capital resources, development resources, including personnel and technology, clinical trial and regulatory experience, expertise in the prosecution of intellectual property rights, and manufacturing, distribution, and sales and marketing than we do.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize any current or future product candidates. Our competitors may also develop drugs or products that are more effective, safe, useful and less costly than ours and may be more successful than us in manufacturing and marketing their drugs or products. If we are unable to compete effectively, our business, our business, prospects, results of operations, financial condition or cash flows may be materially adversely affected.

If our products do not achieve broad market acceptance, including by government and third-party payors, the revenues that we generate from sales will be limited.

The commercial success of our products or any current or future product candidates will depend upon their acceptance by the medical community and coverage and reimbursement for our products by third-party payors, including government payors. The degree of market acceptance of our products or any other potential product candidate we may develop, license or acquire will depend on a number of factors, including:

- the success of any potential clinic studies during the drug development process;
- limitations or warnings contained in the product's FDA-approved labeling;
- changes in the standard of care for the targeted indications for any current or future product candidates, which could reduce the marketing impact of any superiority claims that we could make following FDA approval;
- ability to be listed on formularies (lists of recommended or approved medicines and other products) and reimbursement lists by demonstrating the qualities and treatment benefits of our products within their approved indications; and
- potential advantages over, and availability of, alternative treatments.

Our ability to effectively promote and sell our products and any other current or future product candidates we may develop, license or acquire in the marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and achieve acceptance of the product onto formularies, as well as our ability to obtain sufficient third-party coverage or reimbursement. Since many insurance plans are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract customers in the marketplace will also depend on our ability to effectively promote any current or future product candidates to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with any current or future product candidates. If any current or future product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of any current or future product candidates may require significant resources and may never be successful.

Further, in both domestic and foreign markets, any future product sales will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our current or future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Risks Related to Our Reliance on Third Parties

If we are unable to maintain sales, marketing, and distribution capabilities, or to enter into agreements with third parties to market and sell current or future product candidates, we may not be successful in generating revenues from selling and commercializing any such product candidates.

In order to commercialize any current or future product candidates that have not yet received marketing approval or for which we have not yet acquired rights, we may need to build additional marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services tailored to those products, and we may not be successful in doing so. In the event of successful development and regulatory approval of any potential new product candidate, or a new product acquisition we expect to build a targeted specialist field sales force to market or co-promote that specific product. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a field sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a future product candidate or acquired product for which we recruit a field sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to maintain our current products' marketing and sales organizations and/or commercialize any future products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians and other healthcare providers or persuade adequate numbers of physicians and other healthcare providers to prescribe any future products;
- the lack of complementary or other products to be offered by sales personnel, which may put us at a competitive disadvantage from the perspective of sales efficiency relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We are dependent on third parties to supply raw materials used in our products, to manufacture our products, and to provide services for certain core aspects of our business. Any interruption or failure by these suppliers, distributors, and collaboration partners to meet their contractual obligations to us or obligations pursuant to applicable laws and regulations may materially adversely affect our business, financial condition, results of operations and cash flows.

We rely on third parties to supply raw materials, to manufacture, warehouse, and distribute our products, as well as to provide customer service support, medical affairs services, clinical studies, sales, and other technical and financial services. All third-party suppliers and contractors are subject to FDA requirements, as well as those of comparable regulatory authorities. Our business and financial viability are dependent on the continued supply of goods and services by these third parties, the regulatory compliance of these third parties and on the strength, validity and terms of our various contracts with these third parties. Any interruption or failure by our suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us on schedule or in accordance with our expectations, misappropriation of our proprietary information, including trade secrets and know-how, or any termination by these third parties of their arrangements with us, which, in each case, could be the result of one or many factors outside of our control, could delay or prevent the future development, future approval, manufacture or commercialization of our products, result in non-compliance with applicable laws and regulations, cause us to incur failure-to-supply penalties with our wholesale customers, disrupt our operations or cause reputational harm to our company, any or all of which could have a material adverse effect on our business, financial condition, results of operations and cash flows. We may also be unsuccessful in resolving any underlying issues with such suppliers, distributors and partners or replacing them within a reasonable time and on commercially reasonable terms.

We do not expect to have the resources or capacity to commercially manufacture any future approved product candidates ourselves. We will likely continue to be heavily dependent upon third-party manufacturers, over whose manufacturing practices and processes we will have oversight, but not direct control, which may adversely affect our ability to develop and commercialize products in a timely or cost-effective manner, if at all. If any of our third-party manufacturers should become unavailable to us for any reason, including as a result of capacity constraints, differing priorities, financial difficulties or insolvency, we would likely incur added costs and delays in identifying or qualifying replacements. We may be unable to establish agreements with such replacement manufacturers or to do so on terms acceptable to us, and our reputation, business, financial condition and results of operations could be negatively impacted.

The pharmaceutical manufacturing process requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. Further, the CMOs with which we contract must comply with strictly enforced federal, state, and foreign regulations, including the cGMP requirements enforced by the FDA. We will rely on our CMOs to comply with all such regulatory requirements, including cGMP requirements, and failure to do so may result in fines and civil penalties, suspension of production, suspension, delay, or withdrawal of product approval, product seizure or recall, and may limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims. The FDA would likely hold us ultimately responsible for any product our CMO manufactures and regulatory enforcement for failure to meet FDA requirements would impact both the CMO and ourselves. The FDA considers the owners of drug products to be ultimately responsible for their products, even where a CMO or other third-party manufacturer fails to meet FDA requirements specific to manufacturing activities. Despite the fact that we have limited oversight, and no direct control over these manufacturing activities, any failure by a CMO to meet the requirements of the regulations would have an adverse impact on both the CMO and ourselves.

We also may rely on third-party manufacturers to purchase from third-party suppliers the materials necessary to produce our current or future 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 any 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. Any significant delay in the supply of raw material components related to an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval.

We rely, and expect to continue to rely, on third parties to conduct any future preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such trials or to comply with applicable regulatory requirements.

We expect to rely on third-party contract and clinical research organizations, clinical data management organizations, and medical institutions and clinical investigators to conduct future preclinical studies and clinical trials. Any future agreements with these third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay any future product development activities.

Our reliance on any third parties for research and development activities will reduce our own control over these activities but will not relieve us of our responsibilities. We will remain responsible for ensuring that each of any future preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that any future preclinical studies are conducted in accordance with good laboratory practice (“GLP”) as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices (“GCPs”) for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our future 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 require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that any such regulatory authority, upon inspection of any future clinical trial, will determine that such clinical trial complies with cGMP regulations. In addition, any future clinical trials must be conducted with product produced under cGMP regulations and subject to an IND. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third parties with whom we may contract to help perform future preclinical studies or clinical trials may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any current or future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates.

If any of our future relationships with these third-party contract research organizations or clinical research organizations terminate, we may not be able to enter into arrangements with alternative contract research organizations or clinical research organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or clinical research 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 clinical research organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we will carefully manage any future relationships with contract research organizations or clinical research organizations, there can be no assurance that we will not encounter similar challenges or delays in the future.

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

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

If successful product liability claims are brought against us, we may incur substantial liability, and may have to limit the commercialization of certain current or future products or product candidates.

The use of our products and any current or future product candidate we may license, acquire or develop 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 or product candidate we develop or sell allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Product liability claims might be brought against us by consumers, health care providers or others who use, administer, or sell 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:

- termination of clinical trial sites or entire trial programs or withdrawal of clinical trial participants;
- regulatory investigations by governmental authorities related to regulatory issues or alleged non-compliances;
- litigation costs and potential monetary awards to patients or other claimants;

- harm to our reputation and/or decreased demand for our products and corresponding revenue loss;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our current products or any current or future product candidates.

We have obtained or will obtain limited product liability insurance coverage for any and all current or future 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. Our current insurance coverage includes the sale of commercial products, but we may be unable to maintain or obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and materially adversely affect our business, results of operations, financial condition or cash flows.

We began marketing and promoting Accutane®, an isotretinoin product in the second quarter of 2021. Isotretinoin has a black box warning for use in pregnant women. Isotretinoin also has warnings for side effects related to psychiatric disorders and inflammatory bowel disease, among others. Historically, isotretinoin has been the subject of significant product liability claims, mainly related to irritable bowel disease. Currently, there is no significant isotretinoin product liability litigation. In 2014, the federal multi-district litigation (“MDL”) court ruled that the warning label for isotretinoin was adequate and dismissed all remaining federal isotretinoin cases. The MDL dissolved in 2015, effectively ending federal isotretinoin lawsuits. Isotretinoin cases continued in New Jersey state court until 2017, when the trial court judge dismissed the remaining isotretinoin product liability cases. Accordingly, we have substantial defenses should a product liability claim arise related to isotretinoin. However, we cannot predict the ultimate outcome of any litigation and the Company may be required to pay significant amounts as a result of settlement or judgments should any new product liability claim be brought.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. 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.

Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur 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 against us in connection with our storage or disposal of biological, hazardous or radioactive 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. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to our Growth

A significant part of our future growth may depend on our ability to identify and acquire or in-license products, and if we do not successfully identify and acquire or in-license related product candidates or integrate them 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, product candidates, businesses or technologies that we believe are a strategic fit with our focus on the dermatological marketplace. Future in-licenses or acquisitions may entail numerous operational and financial risks, including:

- 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, current or future product candidates, businesses, and technologies and to integrate them into our current infrastructure. As a result, we focus on research programs and product candidates that we identify for specific indications, which may cause us to forego or delay pursuit of opportunities with other product candidates or for other indications that may have greater commercial potential. Further, we may devote resources to potential acquisitions or in-licensing opportunities that are ultimately not completed or of which we do not realize the anticipated benefits. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Additionally, we may compete with larger pharmaceutical companies and other competitors for new collaborations and in-licensing opportunities. These competitors likely will have greater financial resources than we do and may have greater expertise in identifying and evaluating new opportunities. The realization of any of the foregoing risks related to our acquisition and in-license strategy could materially adversely affect our business, results of operations, financial condition or cash flows.

Our growth is subject to economic and political conditions.

Our business is affected by global and local economic and political conditions as well as the state of the financial markets, inflation, recession, financial liquidity, currency volatility, growth, and policy initiatives. There can be no assurance that global economic conditions and financial markets will not worsen and that we will not experience any adverse effects that may be material to our consolidated cash flows, results of operations, financial position or our ability to access capital, such as the adverse effects resulting from a prolonged shutdown in government operations both in the United States and internationally. Political changes, including war or

other conflicts, some of which may be disruptive, could interfere with our supply chain, our customers and all of our activities in a particular location.

Our operating history may make it difficult to evaluate our business and prospects as it relates to clinical trials or regulatory approvals.

We were incorporated in October 2014 and have only been conducting commercial operations with respect to our products since 2015. We have not yet demonstrated an ability to successfully complete clinical trials or obtain regulatory approvals. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing future pharmaceutical products.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to expand our capabilities to support any future commercial activities. We may not be successful in adding such capabilities.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any past quarterly period as an indication of future operating performance.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and commercial, sales, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede sales growth of our branded and generic products, the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We may decide to sell assets, which could adversely affect our prospects and opportunities for growth.

We may from time to time consider selling certain assets if we determine that such assets are not critical to our strategy or we believe the opportunity to monetize the asset is attractive or for various other reasons, including for the reduction of indebtedness. Although our expectation is to engage in asset sales only if they advance or otherwise support our overall strategy, we may be forced to sell assets in response to liquidation or other claims described herein, and any such sale could reduce the size or scope of our business, our market share in particular markets or our opportunities with respect to certain markets, products or therapeutic categories. As a result, any such sale could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Risks Related to Development and Regulatory Approval of Our Product Candidates

Our business is dependent on the successful development and regulatory approval of our current and any future product candidates.

As of December 31, 2022, our major marketed products that have been approved by the FDA for sale in the United States include Qbrexza®, Accutane®, Amzeeq®, Zilxi®, Ximino®, Exelderm® and Targadox®. However, our business remains dependent on the successful development and regulatory approval of additional product candidates.

On June 29, 2021, we entered into a license, collaboration, and assignment agreement with DRL to initiate a Phase III clinical development program for a collaborative product candidate, DFD-29, that is being evaluated for the treatment of inflammatory lesions of rosacea. The success of our business, including our ability to finance our company and generate additional revenue in the future, may depend on the successful development and regulatory approval of the DFD-29 product candidate and any future product candidates that we may develop, in-license or acquire.

The clinical success of our current and any future product candidates will depend on a number of factors, including the following:

- our ability to raise additional capital on acceptable terms, or at all;

- timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors as well as our ability to timely recruit and enroll patients in our clinical trials, which may be delayed due to numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same or similar indications;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our current or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our current or any future product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our current or any future product candidates;
- the prevalence, duration and severity of potential side effects experienced with our current or any future product candidates;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our current or any future product candidates;
- our ability to successfully obtain the substances and materials used in our current or any future product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing;
- the ability of third parties with whom we contract to manufacture clinical trial supplies of our current or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP; and
- a continued acceptable safety profile during clinical development of our current or any future product candidates.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully complete and obtain regulatory approvals of our current or any future product candidates, which could materially adversely affect our business, results of operations, financial condition or cash flows.

Clinical drug development is very expensive, time-consuming and uncertain. Our clinical trials may fail to adequately demonstrate the safety and efficacy of our current or any future product candidates, which could prevent or delay regulatory approval and commercialization.

Clinical drug development is very expensive, time-consuming and difficult to design and implement, and its outcome is inherently uncertain. Before obtaining regulatory approval for the commercial sale of a product candidate, we must demonstrate through clinical trials that a product candidate is both safe and effective for use in the target indication. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization. The clinical trials for these product candidates may take significantly longer than expected to complete. In addition, we, any partner with which we currently or may in the future collaborate, the FDA, an institutional review board ("IRB") or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including:

- discovery of serious or unexpected adverse events, toxicities, or side effects experienced by study participants or other safety issues;
- lack of effectiveness of any product candidate during clinical trials or the failure of a product candidate to meet specified endpoints;

- slower than expected rates of subject recruitment and patient enrollment in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, such as atopic dermatitis;
- difficulty in retaining subjects who have initiated participation in a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- difficulty in obtaining IRB approval for studies to be conducted at each site;
- delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;
- changes in applicable laws, regulations and regulatory policies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective CROs, clinical trial sites and other third-party contractors;
- inability to add a sufficient number of clinical trial sites;
- uncertainty regarding proper dosing;
- failure of our contract research organizations ("CROs") or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug and biologic products;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- insufficient data to support regulatory approval.

We or any partner with which we may collaborate may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. In the event that we or our potential partners abandon or are delayed in the clinical development efforts related to our current or any future product candidates, we may not be able to execute on our business plan effectively and our business, financial condition, operating results and prospects would be harmed.

We expect to rely on third-party CROs and other third parties to conduct and oversee our clinical trials, other aspects of our product development and our regulatory submission process for our product candidates. If these third parties do not meet our requirements, conduct the trials as required or otherwise provide services as anticipated, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or successfully commercialize, our current or any future product candidates when expected or at all.

We expect to rely on third-party CROs and other third parties to conduct and oversee our clinical trials, other aspects of our product development and our regulatory submission process. We will also rely upon various medical institutions, clinical investigators and

contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and GCPs, which are meant to protect the rights, integrity, and confidentiality of study subjects and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties play a significant role in the conduct of our clinical trials, the subsequent collection and analysis of data from the clinical trials, the preparation for and submission of our filings with the FDA and comparable foreign regulatory authorities and the successful commercialization of our product.

We rely heavily on third parties for the execution of our clinical trials and preclinical studies, and control only certain aspects of their activities. For example, our agreement with DRL for the regulatory submission and approval for DFD-29 is heavily reliant on DRL's ability to conduct clinical manufacturing for clinical supply of product, attending FDA meetings, advising on the Phase III study design, assisting in identifying third-party CROs, and drafting and advising on the NDA and other regulatory submissions. We and our CROs and other third-party contractors are required to comply with GCP and GLP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may not accept or data, or may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot provide assurances that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or preclinical studies complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with products manufactured and produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our CROs or clinical trial sites terminate their involvement in our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites in a timely manner, or do so on commercially reasonable terms or at all. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trial unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash 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 may be questioned by the FDA and comparable foreign regulatory authorities.

Additionally, the regulatory submission process for a product candidate is complex. We expect to rely on a third-party service provider for the preparation and submission of filings with the FDA and comparable foreign regulatory authorities for approval of our current and any future product candidates. Our reliance on third-party CROs may adversely affect our development timelines if the third-party CROs do not meet the requirements or satisfy the obligations required to obtain regulatory approval. Any significant delays caused by our collaboration partner or third-party CROs may have an adverse effect on our development timelines or otherwise may delay approval and commercialization of DFD-29. If our relationship with such service provider is terminated prior to completion of our regulatory submission process, we may not be able to enter into an arrangement with an alternative service provider in a timely manner, or do so on commercially reasonable terms, and our submission may be substantially delayed.

We are currently dependent on DRL for the manufacture and clinical supply of DFD-29 drug product. Any interruption in our supply may cause serious delays in the timing of our clinical trials, increase our costs and adversely impact our financial results.

Pursuant to the terms of our agreement with DRL for the exclusive, worldwide rights to develop and commercialize DFD-29 for the evaluation of treatment, among other potential indications, inflammatory lesions of rosacea (the "DFD-29 Agreement"), DRL is responsible for the manufacture and supply to us of DFD-29 drug product and we are completely reliant upon DRL to provide us with adequate supply for our use. We may experience an interruption in supply if, among other reasons, we incorrectly forecast our supply requirements, DRL allocates supply to its own development programs, DRL incorrectly plans its manufacturing production or DRL is unable to manufacture DFD-29 drug product in a timely manner to match our development or commercial needs. Transferring technology to a new manufacturer will require additional processes, technologies and validation studies, which are costly, may take considerable amounts of time, may not be successful and require review and approval by the FDA and applicable foreign regulatory bodies. Such manufacturer must comply with cGMP requirements enforced by the FDA and applicable foreign regulatory bodies through facilities inspection programs and review of submitted technical information.

We may be unable to obtain regulatory approval for our current or any of our future product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact our business and our operating results.

We may never obtain regulatory approval to commercialize our current or any future product candidates. The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export and reporting of safety and other post-market information related to our current and any future product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country. We are not permitted to market any of our current or any future product candidates in the United States until we receive approval of an NDA, BLA or other applicable regulatory filing from the FDA. We are also not permitted to market our product or our current or any future product candidates in any foreign countries until we receive the requisite approval from the applicable regulatory authorities of such countries.

To gain approval to market a new drug, the FDA and foreign regulatory authorities must receive preclinical, clinical and chemistry, manufacturing and controls data that adequately demonstrate the safety, purity, potency, efficacy and compliant manufacturing of the product for the intended indication applied for in an NDA, BLA or other applicable regulatory filing. The development and approval of new drug products and biologic products involves a long, expensive and uncertain process. A delay or failure can occur at any stage in the process. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in clinical trials, including in Phase 3 clinical development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we or our partners may conduct.

The FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons, including:

- the FDA or the applicable foreign regulatory body may disagree with the design, implementation, choice of dose, analysis plans or interpretation of the outcome of one or more clinical trials;
- the FDA or the applicable foreign regulatory body may not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate's safety or other perceived risks to out-weigh its clinical or other benefits;
- the FDA or the applicable foreign regulatory body may not find the data from preclinical studies and clinical trials, including the number of subjects in the safety database, sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval;
- the FDA or the applicable foreign regulatory body may disagree with our interpretation of data from pre-clinical studies or clinical trials performed by us or third parties, or with the interpretation of any partner with which we may collaborate;
- the data collected from clinical trials may not be sufficient to support the submission and approval of an NDA, BLA or other applicable regulatory filing;
- the FDA or the applicable foreign regulatory body may require additional preclinical studies or clinical trials;
- the FDA or the applicable foreign regulatory agency may identify deficiencies in the formulation, manufacturing, quality control, labeling or specifications of our current or any future product candidates;
- the FDA or the applicable foreign regulatory agency may require clinical trials in pediatric patients in order to establish pharmacokinetics or safety for this more drug-sensitive population;
- the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional post-approval clinical trials;

- the FDA or the applicable foreign regulatory agency may grant approval but impose substantial and costly post-approval requirements;
- the FDA or the applicable foreign regulatory agency may approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested;
- the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our current or any future product candidates;
- the FDA or the applicable foreign regulatory body may not approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with which we contract; or
- the FDA or the applicable foreign regulatory body may change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

Of the large number of drugs and biologics in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. Our current and any future product candidates may not be approved by the FDA or applicable foreign regulatory agencies even though they meet specified endpoints in our clinical trials. The FDA or applicable foreign regulatory agencies may ask us to conduct additional costly and time-consuming clinical trials in order to obtain marketing approval or approval to enter into an advanced phase of development, or may change the requirements for approval even after such agency has reviewed and commented on the design for the clinical trials. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our current and any future product candidates and would harm our business, financial condition, operating results and prospects.

We may conduct clinical trials for our current and any future product candidates, in whole or in part, outside of the United States and the FDA and applicable foreign regulatory authorities may not accept data from such trials, which would likely result in additional costs to us and delay our business plan.

We may in the future choose to conduct, one or more of our clinical trials outside the United States. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our business plan.

Risks Related to Intellectual Property, Generic Competition and Paragraph IV Litigation

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to our products or any current or future product candidates that we may license or acquire and our manufacturing methods, as well as successfully defending these patents and trade secrets against third-party challenges, which is expensive and time-consuming. A patent is the grant of a property right which allows its holder to exclude others from, among other things, selling the subject invention in, or importing such invention into, the jurisdiction that granted the patent. We have obtained, acquired or in-licensed a number of patents and patent applications covering key aspects of certain of our principal products. In the aggregate, our patents are of material importance to our business taken as a whole. We seek to protect our proprietary position by filing or obtaining licenses under patent applications in the United States and abroad related to our products and any other current or future

product candidates. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents cover them. Our success is predicated, in part, by our ability to maintain the integrity of our trade secrets.

It is possible that we or our licensors will fail to timely identify patentable aspects of our research and development output before it is too late to obtain patent protection, which may result in third parties using our proprietary information, impairing our abilities to compete in the market, to generate revenues, and to 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 our patents. Therefore, such patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. 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.

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 U.S. The patent situation outside the U.S. is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until eighteen (18) months after a first filing, if at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In the event that a third party has also filed a U.S. patent application relating to any current or future product candidates or a similar invention, we may have to participate in derivation proceedings declared by the USPTO to determine proper inventorship of a claimed invention. The costs of these proceedings could be substantial, and it is possible that our efforts 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 patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (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 provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office 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, which became effective on March 16, 2013. Courts continue to consider the constitutionality of certain provisions of the Leahy-Smith Act, including the Supreme Court in a recent decision *affecting inter partes* review procedures. 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.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or other administrative proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us. We may also be unable to manufacture or commercialize products without infringing third-party patent rights, under which a license might not be available. 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 our current or future product candidates.

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.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Generic drug approvals and successful challenges against the validity of our patents may cause us to lose exclusivity of some of our products.

In the U.S., the Hatch-Waxman Act provides non-patent regulatory exclusivity for five years from the date of the first FDA approval of a new drug compound in an NDA. The FDA, with one exception, is prohibited during those five years from accepting for filing a generic, or ANDA that references the NDA. In reference to the foregoing exception, if a patent is indexed in the FDA Orange Book for the new drug compound, a generic may file an ANDA four years from the NDA approval date if it also files a Paragraph IV Certification with the FDA challenging the patent. Protection under the Hatch-Waxman Act will not prevent the filing or approval of another full NDA. However, the NDA applicant would be required to conduct its own pre-clinical and adequate and well-controlled clinical trials to independently demonstrate safety and effectiveness.

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 USPTO. Such challenges may subject us to costly and time-consuming litigation and/or USPTO proceedings). Such challenges may subject us to costly and time-consuming litigation and/or USPTO proceedings. As a result of the loss of any patent protection from such litigation or USPTO proceedings, or the “at-risk” launch by a generic competitor of our products, our products could be sold at significantly lower prices, and we could lose a significant portion of sales of that product in a short period of time, which could adversely affect our business, financial condition, operating results and prospects.

Enforcing our proprietary rights is difficult and costly and we may be unable to ensure their protection.

The degree of future protection for our proprietary rights is uncertain, as legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate our products or our current or future product candidates’ technologies;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the issued patents covering our products or any current or future product candidates may not provide a basis for commercially viable active products, may not provide us with any competitive advantages, or may be challenged and defeated by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- patent rights of others may have an adverse effect on our business.

Furthermore, competitors may infringe our issued patents or other intellectual property (collectively, our “IP”), which may require us to file infringement claims, which is expensive and time consuming, and the outcome uncertain. Any claims we assert against perceived infringers could provoke counterclaims alleging that our IP rights are invalid, unenforceable, or not infringed or that we have infringed

upon misappropriated others' intellectual property. In response, a court may decide that a patent of ours is wholly or partially invalid or unenforceable, construe the patent's claims narrowly, or refuse to stop the accused party from using the technology at issue.

Additionally, some of our products, including Accutane, Targadox and Exelderm, do not have patent protection because they are not eligible or qualify for such protection. This creates greater risk of competition with generic drug manufacturers and may otherwise adversely affect our business or result of operations.

Further, we rely on trade secrets, including unpatented know-how, to maintain our competitive position. We enter into non-disclosure and confidentiality agreements to protect these trade secrets but cannot guarantee that counterparties will not breach the agreements and disclose our proprietary information, including trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated trade secrets is costly, difficult, and time consuming, and we may be unable to obtain adequate remedy. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market and sell our products or any current or future product candidates depends upon our ability to avoid infringing the proprietary rights of third parties. There are many U.S. and foreign issued patents and pending patent applications owned by third parties in the dermatology field that cover numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending against intellectual property claims raised by third parties, which could have a material adverse effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, 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 commercial activities relating to our products or current or future product candidates may infringe. There could also be existing patents of which we are not aware that our products or current or future product candidates may inadvertently infringe.

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 infringe on their products or technology, in addition to costly and time-consuming litigation, we could face a number of issues, including:

- diversion of management's attention from our core business;
- substantial damages for past infringement;
- injunctions prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- requirements that we pay substantial royalties or grant cross licenses under our patents;
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time; and
- harm to our reputation and subsequent adverse effect on the valuation of our securities and revenue.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the valuation of our securities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than

we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. The occurrence of any of the above-described risks could materially adversely affect our business, results of operations, financial condition or cash flows.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of our products or current or future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products or current or future product candidates, in which case we would be required to obtain a license from these third parties, if available, on commercially reasonable terms, or our business could be harmed, possibly materially. Our inability to obtain such rights on acceptable terms, or at all, could materially adversely affect our business, results of operations, financial condition or cash flows.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, or if we breach an agreement under which we license rights to any product or future product candidate, we could lose rights that are important to our business.

If we fail to comply with our obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture, or market any product or utilize any technology that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially and adversely affect the value of a product candidate being developed under any such agreement or could restrict our drug discovery activities. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Further, any uncured, material breach under our license agreement with any current or future licensor could result in our loss of rights to our products or current or future product candidates and may lead to a complete termination of any future product development efforts.

Risks Related to our Platform and Data

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

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information, including, but not limited to, information related to our intellectual property and proprietary business information, personal information, and other confidential information. It is critical that we maintain such confidential information in a manner that preserves its confidentiality 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.

While we recently implemented internal security and business continuity measures, 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, 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, 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, we were the victim of a cybersecurity incident that affected our accounts payable function and led to approximately \$9.5 million in wire transfers being misdirected to fraudulent accounts. The matter was reported to the FBI and remains under their investigation. The cybersecurity incident does not appear to have compromised any personally identifiable information or protected health information. Fortress, as our controlling stockholder and supporting partner in our back-office functions, provided us with \$9.5 million to ensure our accounts payable operations continued to function smoothly. The \$9.5 million of support was in the form of a related party note which the boards of both companies have agreed and converted into 1,476,044 shares of our common stock upon the consummation of our IPO in November 2021 at the IPO price. The federal government has been able to trace and seize the fraudulently transferred cryptocurrency associated with the breach. Once the cryptocurrency has been converted back into U.S. dollars, we expect to receive a notification letter to initiate the return of the cash to the Company. This process could take as long as six months or more to complete. Given the recent market declines, volatility, and liquidity issues with cryptocurrency, there is no certainty as to the amount we will ultimately recover. We may incur additional expenses and losses as a result of this cybersecurity incident, including related to investigation fees and remediation costs.

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

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

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

have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Risks Related to Our Finances and Capital Requirements

We have incurred net losses in recent fiscal years, and we may incur losses for the foreseeable future and may not be able to achieve or maintain profitability.

Even though we are a cash generating, commercial organization, we have a limited operating history. We have focused primarily on in-licensing, developing, commercializing and/or manufacturing and selling our products. Potential future losses, among other things, will have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with commercialization and/or developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or if we will be able to maintain profitability. Any future net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if:

- our current or any future product candidates are approved for commercial sale, due to our ability to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;
- we acquire or in-license new products for development and/or sale;
- we are required by the FDA, or foreign regulatory authorities, to perform studies in addition to those currently expected;
- there are any delays in completing our clinical trials or the development of our current or any future product candidates;
- we execute other collaborative, licensing or similar arrangements that require us to make payments and/ or expend funds;
- there are variations in the level of expenses related to our future development programs;
- there are any product liability or intellectual property infringement lawsuits in which we may become involved;
- there are any regulatory developments affecting our products, current or future product candidates, or the product candidates of our competitors; and
- the level of underlying demand for our products and wholesalers' buying patterns.

Our ability to maintain profitability depends upon our ability to generate and sustain revenue. Our ability to generate and sustain revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain and maintain regulatory approval for our products, or any other current or future product candidates that we may license or acquire;
- manufacture commercial quantities of our current products or current or future product candidates, if approved, at acceptable cost levels; and
- maintain and/or expand our commercial organization and the supporting infrastructure required to successfully market and sell our products or current or future product candidates, if approved.

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

We may need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate any future product development programs or commercialization, manufacture and/or sales efforts.

Selling and developing products for dermatological use, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs that we may develop is expensive. We may need to raise additional capital to:

- fund our operations and continue our efforts to hire additional personnel;
- qualify and outsource the commercial-scale manufacturing of our products under cGMP; and
- acquire, in-license and/ or develop additional product candidates.

Our future funding requirements will depend on many factors, including, but not limited to:

- the potential for delays in our efforts to seek regulatory approval for any current or future product candidates, and any costs associated with such delays;
- the costs of maintaining and/or establishing a commercial organization to sell, market and distribute our products and/or current or future product candidates;
- the rate of progress and costs of our efforts to prepare for the submission of NDA or BLA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with any current or future product candidates, including any such costs we may be required to expend if licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of our products and current or future product candidates from our contract manufacturers in preparation for commercialization, manufacture, and/or sale;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of our branded products; and
- the success of sales efforts of our current products and/or the commercialization of any current or future product candidates.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

We may need to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of future development programs, acquisition plans or our future commercialization efforts, which could materially adversely affect our business, prospects and the trading price of our common stock.

Raising additional capital 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 through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate future product development or current or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

If we fail to raise the additional funds needed to complete the development of our current products or current or future product candidates, or the funds needed to complete the development of our current or future product candidates, we will be unable to execute our current business plan.

Risks Related to Owning our Common Stock

If we fail to maintain or implement effective internal controls, we may not be able to report financial results accurately or on a timely basis, or to detect fraud, which could have a material adverse effect on our business and the per share price of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures, and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are also continuing to improve our internal control over financial reporting. We have expended, and anticipate that we will continue to expend, significant resources in order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting.

Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and ineffective internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on The Nasdaq Capital Market (“Nasdaq”).

Our independent registered public accounting firm is not required to audit the effectiveness of our internal control over financial reporting until after we are no longer an “emerging growth company” (“EGC”), as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating.

Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business and operating results, and cause a decline in the market price of our common stock.

Our charter documents and Delaware law could discourage takeover attempts and other corporate governance changes.

Our Third Amended and Restated Certificate of Incorporation and bylaws contain provisions that could delay or prevent a change in control of our Company. These provisions could also make it difficult for stockholders to elect directors that are not nominated by the

current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions include certain provisions that:

- permit the board of directors to establish the number of directors and fill any vacancies and newly created directorships;
- provide that, after a removal for cause, vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- prohibit cumulative voting in the election of directors;
- require majority voting to amend our certificate of incorporation and bylaws;
- authorize the issuance of “blank check” preferred stock that our board of directors could use to implement a stockholder rights plan;
- restrict the forum for certain litigation against us to Delaware or federal courts;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- bestow majority control of the stockholder vote to Fortress by virtue of their exclusive ownership of our Class A Common Stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a period of time without the approval of our board of directors. In addition, our credit facility includes, and other debt instruments we may enter into in the future may include, provisions entitling the lenders to demand immediate repayment of all borrowings upon the occurrence of certain change of control events relating to our company, which also could discourage, delay or prevent a business combination transaction.

Our Third Amended and Restated Certificate of Incorporation provides, subject to limited exceptions, that the Court of Chancery of the State of Delaware is the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders’ ability to obtain a chosen judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our Third Amended and Restated Certificate of Incorporation requires to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions must be brought in the Court of Chancery in the State of Delaware or, if that court lacks subject matter jurisdiction, another federal or state court situated in the State of Delaware. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our certificate of incorporation. In addition, our Third Amended and Restated Certificate of Incorporation provides that the federal district courts of the United States are the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act and the Exchange Act.

This choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum of its choosing for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our Third Amended and Restated Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

The requirements of being a public company may strain our resources, divert our management’s attention and affect our ability to attract and retain qualified board members.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and are required to comply with the applicable requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations. Compliance with these rules and

regulations increases our legal and financial compliance costs, makes some activities more difficult, time-consuming or costly and increases demand on our systems and resources. Among other things, the Exchange Act requires that we file annual, quarterly and current reports with respect to our business and operating results and maintain effective disclosure controls and procedures and internal controls over financial reporting. Significant resources and management oversight is required to maintain and, if required, improve our disclosure controls and procedures and internal controls over financial reporting to meet this standard. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we hired additional employees to comply with these requirements, we may need to hire even more employees in the future, which will increase our costs and expenses.

Reduced reporting and disclosure requirements applicable to us as an EGC could make our common stock less attractive to investors.

We are an EGC and, for as long as we continue to be an EGC, we may continue to avail ourselves of exemptions from various reporting requirements applicable to other public companies. Consequently, we are not required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act, and we are subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of the dates such pronouncements are effective for public companies. We could be an EGC for up to five years following the completion of our November 2021 public offering. We will cease to be an EGC upon the earliest of: (i) the end of the fiscal year following the fifth anniversary of the aforementioned offering, (ii) the first fiscal year after our annual gross revenue is \$1.235 billion or more, (iii) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in nonconvertible debt securities or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded \$700 million as of the end of the second quarter of that fiscal year. We cannot predict whether investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock, and the price of our common stock may be more volatile.

Our shares of common stock are subject to potential delisting if we do not continue to maintain the listing requirements of Nasdaq.

We list our shares of common stock on Nasdaq under the symbol "DERM." Nasdaq has rules for continued listing, including, without limitation, minimum market capitalization and other requirements. Failure to maintain our listing, or de-listing from Nasdaq, would make it more difficult for shareholders to sell our securities and more difficult to obtain accurate price quotations on our securities. This could have an adverse effect on the price of our common stock. Our ability to issue additional securities for financing or other purposes, or otherwise to arrange for any financing we may need in the future, may also be materially and adversely affected if our common stock is not traded on a national securities exchange.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains.

We currently intend to retain any earnings to finance the operation and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors. In addition, the terms of our existing debt arrangements preclude us from paying dividends and our future debt agreements, if any, may contain similar restrictions. As a result, you may only receive a return on your investment in our common stock if the market price of our common stock increases.

The trading price of the shares of our common stock is likely to be volatile, and purchasers of our common stock could incur substantial losses.

The trading price of our common stock fluctuates substantially. These fluctuations could cause you to incur substantial losses, including all of your investment in our common stock. Factors that could cause fluctuations in the trading price of our common stock include the following:

- significant volatility in the market price and trading volume of companies in our industry;

- announcements of new solutions or technologies, commercial relationships, acquisitions, or other events by us or our competitors;
- price and volume fluctuations in the overall stock market from time to time;
- changes in how customers perceive the benefits of our products and future offerings;
- the public’s reaction to our press releases, other public announcements, and filings with the SEC;
- fluctuations in the trading volume of our shares or the size of our public float;
- actual or anticipated changes or fluctuations in our results of operations or financial projections;
- changes in actual or future expectations of investors or securities analysts;
- litigation involving us, our industry, or both;
- governmental or regulatory actions or audits;
- regulatory developments applicable to our business, including those related to privacy in the United States or globally;
- general economic conditions and trends;
- major catastrophic events in our domestic and foreign markets; and
- departures of key employees.

Risks Related to our Relationship with Fortress Biotech, Inc.

Fortress controls a voting majority of our common stock, which could be detrimental to our other shareholders.

Pursuant to the terms of the Class A Common Stock held by Fortress, Fortress will be entitled to cast, for each share of Class A Common Stock held by Fortress, the number of votes that is equal to 1.1 times a fraction, the numerator of which is the number of shares of our outstanding common stock and the denominator of which is the number of shares of outstanding Class A Common Stock (the “Class A Common Stock Ratio”). Thus, Fortress will at all times have voting control of Journey. Further, for a period of (10) ten years from the date of the first issuance of shares of Class A Common Stock, the holders of record of the shares of Class A Common Stock (or other capital stock or securities issued upon conversion of or in exchange for the Class A Common Stock), exclusively and as a separate class, shall be entitled to appoint or elect the majority of the directors of Journey. This concentration of voting power may delay, prevent or deter a change in control of us even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their shares of common stock as part of a sale of Journey or our assets, and might affect the prevailing market price of our common stock.

We are a “controlled company” within the meaning of Nasdaq listing standards and, as a result, qualify for exemptions from certain corporate governance requirements. Although we do not presently intend to take advantage of these exemptions, we may do so in the future.

We are a “controlled company” within the meaning of Nasdaq listing standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a “controlled company” and may elect not to comply with certain corporate governance requirements of Nasdaq, including (i) the requirement that a majority of the Board of Directors consist of independent directors, (ii) the requirement that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee’s purpose and responsibilities and (iii) the requirement that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee’s purpose and responsibilities. Although we presently are not taking advantage of these exemptions, we may do so in the future. Accordingly, our stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the

corporate governance requirements of Nasdaq. Investors may find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We may have received better terms from unaffiliated third parties than the terms we receive in our arrangements with Fortress.

We have arrangements with Fortress in connection with management and administration services for the Company. While we believe the terms of these arrangements are reasonable, they might not reflect terms that would have resulted from arm's-length negotiations between unaffiliated third parties. The terms of the arrangement relate to, among other things, systems, insurance, accounting, legal, finance, tax and human resources. We might have received better terms from third parties because, among other things, third parties might have competed with each other to win our business.

The ownership by our executive officers and some of our directors of shares of equity securities of Fortress and/or rights to acquire equity securities of Fortress might create, or appear to create, conflicts of interest.

Because of their current or former positions with Fortress, some of our executive officers and directors own shares of Fortress common stock and/or options to purchase shares of Fortress common stock. Their individual holdings of common stock and/or options to purchase common stock of Fortress may be significant compared to their total assets. Ownership by our directors and officers, after our separation, of common stock and/or options to purchase common stock of Fortress might appear to create conflicts of interest when these directors and officers are faced with decisions that could have different implications for Fortress than for us.

Fortress' current or future financial obligations and arrangements, or an event of default thereon, may change the ownership dynamic of us by Fortress.

Any default or breach by Fortress under any current or future credit agreement or arrangements may have an adverse effect on our business. Fortress has pledged as collateral to certain of its creditors equity in the Company. If Fortress were to default on its obligations to any such creditor, that creditor, whose interests may not align with those of our other stakeholders, could acquire a controlling interest in the Company. In addition, Fortress' current credit agreement with Oaktree Capital (the "Oaktree Credit Agreement") contains certain affirmative and negative covenants and events of default that apply in different instances to Fortress itself, its private subsidiaries, its public subsidiaries, or combinations of the foregoing. Although we are not a party to the Oaktree Credit Agreement, because Fortress controls our stockholder vote, Fortress may not permit us to effect certain actions which we feel would be in the Company's best interests, but which Fortress cannot allow so as to remain in compliance with the Oaktree Credit Agreement.

General Risks

Failure to manage our growth effectively could cause our business to suffer and have an adverse effect on our business, operating results and financial condition.

We have experienced significant growth in a short period of time. To manage our growth effectively, we must continually evaluate and evolve our organization. We must also manage our employees, operations, finances and capital investments efficiently. Our efficiency, productivity and the quality of our products may be adversely impacted if we do not train our new personnel, particularly our sales and support personnel, quickly and effectively, or if we fail to appropriately coordinate across our organization. Additionally, our rapid growth may place a strain on our resources, infrastructure and ability to maintain the quality of our products. You should not consider our revenue growth and levels of profitability in recent periods as indicative of future performance. In future periods, our revenue or profitability could decline or grow more slowly than we expect. Failure to manage our growth effectively could cause our business to suffer and have an adverse effect on our operating results and financial condition.

If securities or industry analysts do not publish research or reports about our business, or publish inaccurate or unfavorable research reports about our business, our share price and trading volume could decline.

The trading market for our common stock partially depends on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us should downgrade our shares or change their opinion of our business prospects, our share price would likely decline. If one or more of these analysts ceases coverage of our company or fails to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States. If our estimates or judgments relating to our critical accounting policies prove to be incorrect, our results of operations could be adversely affected.

U.S. generally accepted accounting principles (“GAAP”) are subject to interpretation by the Financial Accounting Standards Board (“FASB”), the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported results of operations and could affect the reporting of transactions already completed before the announcement of a change.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes appearing elsewhere in this report on Form 10-K. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in the section titled “*Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates.*” The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities and equity, and the amount of revenue and expenses that are not readily apparent from other sources. Significant estimates, judgments, and assumptions used in our financial statements include, but are not limited to, those related to revenue recognition, accounts receivable and related reserves, useful lives and realizability of long-lived assets, research and development costs, assumptions used in the valuation of warrants, accounting for share-based compensation, and valuation allowances against deferred tax assets. These estimates are periodically reviewed for any changes in circumstances, facts, and experience. Our results of operations may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

Global and national financial events may have an impact on our business and financial condition in ways that we currently cannot predict.

A credit crisis, turmoil in the global or U.S. financial system, recession or similar possible events in the future could negatively impact us. A financial crisis or recession may limit our ability to raise capital through credit and equity markets. The prices for the products and services that we intend to provide may be affected by a number of factors, and it is unknown how these factors may be impacted by a global or national financial event.

If our estimates or judgments relating to our critical accounting policies are erroneous or based on assumptions that change or prove to be incorrect, our operating results could fall below the expectations of securities analysts and investors, resulting in a decline in our stock price.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates on our best judgment, historical experience, information derived from third parties and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in the section titled “*Management’s Discussion and Analysis of Financial Condition and Results of Operations,*” the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. Our operating results may be adversely affected if our judgments prove to be wrong, assumptions change or actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price. Significant assumptions and estimates used in preparing our consolidated financial statements include those related to revenue recognition, share-based compensation and income taxes.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our executive offices are located at 9237 E Via de Ventura Blvd. Suite 105, Scottsdale, AZ 85258. We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

In August 2020, we amended our lease and entered into a new 25-month extension of the office space in Scottsdale, AZ at an average annual rent of \$0.1 million. The term of this amended lease commenced on December 1, 2020 and expired on December 31, 2022. In September 2022, we amended our lease and entered into a new 25-month extension of the same office space in Scottsdale, AZ at an average annual rent of \$0.1 million. The term of this amended lease commenced on January 1, 2023 and will expire on January 31, 2025.

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II**Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities****Market information**

Our common stock is listed on the Nasdaq Capital Market and trades under the symbol “DERM.” We commenced trading on the Nasdaq Capital Market on November 12, 2021. Prior to November 12, 2021 there was no public market for our common stock.

Equity Compensation Plans

We do not maintain any deferred compensation, retirement, pension or profit-sharing plans. Our board of directors has adopted an incentive plan, allowing for the grant of equity and cash-based awards to our employees and directors.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides certain information as of December 31, 2022, with respect to all of our equity compensation plans in effect on that date:

Plan Category	Number of securities to be issued upon exercise of outstanding options (1)	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column 1) (2)
Equity compensation plans approved by security holders	2,960,000	\$ 1.76	1,146,620

(1) Reflects the number of shares of common stock to be issued upon exercise of outstanding options under our Journey Medical 2015 Stock Plan. This figure does not include 2,261,048 outstanding restricted stock units that were issued under the Journey Medical 2015 Stock Plan.

(2) Reflects 1,146,620 shares available for future issuance under the Journey Medical 2015 Stock Plan.

Subject to adjustment as provided in the 2015 Plan, the total aggregate number of shares of our common stock reserved and available for issuance pursuant to awards granted under the 2015 Plan is 7,642,857, of which 1,146,620 shares remain available for future issuance as of December 31, 2022.

Sales of Unregistered Securities

None.

Use of Proceeds from Sales of Registered Securities

On December 30, 2022, we filed a shelf registration statement on Form S-3 (File No. 333-269079), which was declared effective by the SEC on January 26, 2023. This shelf registration statement covers the offering, issuance and sale by us of up to an aggregate of \$150.0 million of the Company’s common stock, preferred stock, debt securities, warrants, and units (the “2022 Shelf”). At December 31, 2022, \$150.0 million remains available under the 2022 Shelf. In connection with the 2022 Shelf, we have entered into an At Market Issuance Sales Agreement (the “Sales Agreement”) with B. Riley, relating to shares of our common stock. In accordance with the terms of the Sales Agreement, we may offer and sell up to 4,900,000 shares of our common stock, par value \$0.0001 per share, from time to time through or to B. Riley acting as our agent or principal.

We currently intend to use the net proceeds from this offering for general corporate purposes, including working capital, research and development, payments for research and development — licenses acquired, sales and marketing activities, general administrative matters, operating expenses and capital expenditures.

Holders

As of March 29, 2023, there were approximately 164 holders of record for our common stock and 1 holder of record for our Class A common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never paid cash dividends on any of our capital stock and currently intend to retain our future earnings, if any, to fund the development and growth of our business.

Securities Authorized for Issuance under Equity Compensation Plans

Subject to adjustment as provided in the 2015 Plan, the total aggregate number of shares of our common stock reserved and available for issuance pursuant to awards granted under the 2015 Plan is 7,642,857, of which 1,146,620 shares remain available for future issuance as of December 31, 2022.

Item 6. [RESERVED.]

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

Forward-Looking Statements

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes included elsewhere in this Form 10-K. Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). Please see the section titled "Special Cautionary Note Regarding Forward-Looking Statements" elsewhere in this Annual Report on Form 10-K for more information. In evaluating our business, you should carefully consider the information set forth under the heading "Risk Factors" herein and in our Annual Report on Form 10-K for the year ended December 31, 2021. As used below, the words "we," "us" and "our" refer to Journey Medical Corporation and its consolidated subsidiaries.

Overview

We are a commercial-stage pharmaceutical company founded in October 2014 that focuses on the development and commercialization of pharmaceutical products for the treatment of dermatological conditions. Our current portfolio includes eight branded and three authorized generic prescription drugs for dermatological conditions that are marketed in the U.S. We are managed by experienced life science executives with a track record of creating value for their stakeholders and bringing novel medicines to the market, enabling patients to experience increased quality of life, and enabling physicians and other licensed medical professionals to provide better care for their patients. We aim to acquire rights to future products by licensing or otherwise acquiring an ownership interest in, funding the research and development of, and eventually commercializing, the products through our field sales organization. Since inception, we have made significant investments to build out our commercial product portfolios, which we believe, coupled with our experienced dermatology sales leadership team and our recently expanded field sales force, will position our business for growth. We are a majority-owned subsidiary of Fortress.

2022 Highlights and Events

On December 30, 2022, we filed a shelf registration statement on Form S-3 (File No. 333-269079), which was declared effective by the SEC on January 26, 2023. This 2022 Shelf covers the offering, issuance and sale by us of up to an aggregate of \$150.0 million of our common stock, preferred stock, debt securities, warrants, and units (the "2022 Shelf"). At December 31, 2022, \$150.0 million remains available under the 2022 Shelf. In connection with the 2022 shelf, we have entered into the Sales Agreement with B. Riley, relating to shares of our common stock. In accordance with the terms of the Sales Agreement, we may offer and sell up to 4,900,000 shares of our common stock, par value \$0.0001 per share, from time to time through or to B. Riley acting as our agent or principal.

On March 14, 2022, we dosed the first patient in our Phase 3 clinical trial evaluating DFD-29 (Minocycline Modified Release Capsules 40 mg) for the Treatment of Rosacea. As of January 10, 2023, we achieved 100% enrollment in the trial, with a top-line data readout expected in the second quarter of 2023. We plan to submit the NDA for DFD-29 in the second half of 2023 and FDA approval is anticipated in the second half of 2024. The Phase 2 clinical trials, DFD-29 (40mg) concluded with results indicating improved treatment by the investigational drug when compared to Oracea® (European equivalent of Oracea®) on both co-primary endpoints. For the first co-primary endpoint, IGA treatment success, Oracea only had a 33.33% IGA treatment success rate, while DFD-29 achieved a 66.04% IGA treatment success rate. For the second co-primary endpoint, the change in total inflammatory lesion count, Oracea only had a 10.5 reduction in inflammatory lesions, while DFD-29 achieved a 19.2 reduction in inflammatory lesions.

On February 11, 2022, we announced that our exclusive licensing partner in Japan, Maruho Co., Ltd. ("Maruho"), received marketing and manufacturing approval for Rapifort® Wipes 2.5% (Qbrexza®), for the treatment of primary axillary hyperhidrosis, triggering a net \$2.5 million milestone payment to us. The net payment reflects a milestone payment of \$10 million to us from our exclusive licensing partner Maruho, offset by a \$7.5 million payment to Dermira, pursuant to the terms of the Asset Purchase Agreement between us and Dermira. We acquired global rights to Qbrexza from Dermira in 2021. The period ended December 31, 2022 also reflects total year-to-date royalties of \$174,000 from Maruho on sales of Rapifort® Wipes 2.5% in Japan.

On January 12, 2022, we acquired Amzeeq® (minocycline) topical foam, 4%, and Zilxi® (minocycline) topical foam, 1.5%, two FDA-approved topical minocycline products and Molecule Stabilizing Technology (MST)TM from VYNE Therapeutics Inc., which expanded our product portfolio to eight actively marketed branded dermatology products.

These proprietary foam-based products optimize the topical delivery of minocycline, an active pharmaceutical ingredient that was previously available only in oral form. Approved by the FDA nearly 50 years ago, minocycline is a well-established molecule that has been prescribed, in oral formulation, over 30 million times in the past decade.

Amzeeq (minocycline) topical foam, 4%, is the first and only topical formulation of minocycline to be approved by the FDA for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and children 9 years and older. According to the American Academy of Dermatology (“AAD”), acne is the most common skin condition in the United States, affecting up to 50 million Americans annually.

Approved by the FDA in May 2020, Zilxi (minocycline) topical foam, 1.5%, is the first and only topical minocycline treatment for inflammatory lesions due to rosacea in adults. Rosacea is a common skin disease that affects 16 million Americans, according to AAD. Market research shows that over 70% of patients with rosacea are seeking better alternatives to current treatments.

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

In September 2021, we were the victim of a cybersecurity incident that affected our accounts payable function and led to approximately \$9.5 million in wire transfers being misdirected to fraudulent accounts. The matter was reported to the FBI and remains under their investigation. The cybersecurity incident does not appear to have compromised any personally identifiable information or protected health information. Fortress, as our controlling stockholder and supporting partner in our back-office functions, provided us with \$9.5 million to ensure our accounts payable operations continued to function smoothly. The \$9.5 million of support was in the form of a related party note which the boards of both companies have agreed and converted into 1,476,044 shares of our common stock upon the consummation of our IPO in November 2021 at the IPO price. The federal government has been able to trace and seize the fraudulently transferred cryptocurrency assets associated with the breach. The seized cryptocurrency has been transferred into U.S. government-controlled custodial wallets. Subsequently, the forfeiture process will be initiated by the U.S. Attorney’s Office. The process includes mandatory waiting periods for filing of claims. Once the cryptocurrency has been converted back into U.S. dollars, we expect to receive a notification letter to initiate the return of the cash to the Company. This process could take several months to a year or possibly longer to complete before funds can be returned. Given the recent market declines, volatility, and liquidity issues with cryptocurrency, there is no certainty as to the amount we will ultimately recover. See “Risk Factors — Risks Related to our Platform and Data — Our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or third parties’ cybersecurity.”

Critical Accounting Policies and Uses of Estimates

Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make difficult, subjective or complex judgments, often as a result of the need to make estimates and assumptions about the effect of matters that are inherently uncertain in the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2, “Basis of Presentation and Summary of Significant Accounting Policies” in our consolidated financial statements, appearing under Part II, Item 8 and beginning at page F-1 of this Annual Report on Form 10-K, we believe that the following accounting policies and estimates are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements in understanding our historical and future performance. These policies relate to the more significant areas involving management’s judgments and estimates.

Revenue Recognition

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

Recent Accounting Pronouncements

See Note 2, “Basis of Presentation and Summary of Significant Accounting Policies” in our consolidated financial statements, appearing under Part II, Item 8 and beginning at page F-1 of this Annual Report on Form 10-K for information about recent accounting pronouncements, the timing of their adoption, if applicable, and our assessment, if any, of their potential impact on our financial condition and results of operations.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”). Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited financial statements in our annual reports on Form 10-K, an exemption from the requirement to provide an auditor’s report on internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation and less extensive disclosure about our executive compensation arrangements. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act.

We are also a “smaller reporting company,” meaning that either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) the market value of our shares held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K, have reduced disclosure obligations regarding executive compensation, and smaller reporting companies are permitted to delay adoption of certain recent accounting pronouncements discussed in Note 2. See Note 2, “Basis of Presentation and Summary of Significant Accounting Policies” in our consolidated financial statements, appearing under Part II, Item 8 and beginning at page F-1 of this Annual Report on Form 10-K.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

(\$ in thousands, except per share data)	For the Years Ended December 31,		Change	
	2022	2021	\$	%
Revenue:				
Product revenue, net	\$ 70,995	\$ 63,134	\$ 7,861	12 %
Other revenue	2,674	—	2,674	100 %
Total revenue	73,669	63,134	10,535	17 %
Operating expenses				
Cost of goods sold - product revenue	30,775	32,084	(1,309)	(4)%
Research and development	10,943	2,739	8,204	300 %
Research and development - licenses acquired	—	13,819	(13,819)	(100)%
Selling, general and administrative	59,468	39,833	19,635	49 %
Wire transfer fraud loss	—	9,540	(9,540)	(100)%
Total operating expenses	101,186	98,015	3,171	3 %
Loss from operations	(27,517)	(34,881)	7,364	(21)%
Other expense				
Interest income	(60)	(2)	(58)	2,900 %
Interest expense	2,019	7,034	(5,015)	(71)%
Foreign exchange transaction losses	89	—	89	100 %
Change in fair value of derivative liability	—	447	(447)	(100)%
Total other expense	2,048	7,479	(5,431)	(73)%
Loss before income taxes	(29,565)	(42,360)	12,795	(30)%
Income tax expense	63	1,634	(1,571)	(96)%
Net Loss	\$ (29,628)	\$ (43,994)	\$ 14,366	(33)%

Revenues

The following table reflects our revenue by product for the years ended December 31, 2022 and 2021:

(\$ in thousands)	For the Years Ended December 31,		Change	
	2022	2021	\$	%
Qbrexza®	\$ 26,715	\$ 17,056	\$ 9,659	57 %
Accutane®	18,373	10,053	8,320	83 %
Targadox®	7,972	22,378	(14,406)	(64)%
Amzeeq®	7,242	—	7,242	100 %
Ximino®	4,957	8,247	(3,290)	(40)%
Zilxi®	2,273	—	2,273	100 %
Exelderm®	3,463	5,363	(1,900)	(35)%
Other branded revenue	—	37	(37)	(100)%
Total net product revenue	\$ 70,995	\$ 63,134	\$ 7,861	12 %
Other revenue	2,674	—	2,674	100 %
Total revenue	\$ 73,669	\$ 63,134	\$ 10,535	17 %

Total revenues increased \$10.5 million, or 17%, to \$73.7 million for the year ended December 31, 2022, from \$63.1 million for the year ended December 31, 2021. Total net product revenue increased \$7.9 million, or 12%, to \$71.0 million for the year ended December 31, 2022, from \$63.1 million for the year ended December 31, 2021. The increase is primarily due to revenue growth from our newly acquired products, Qbrexza and Accutane, acquired and launched in the second quarter of 2021, as well as incremental growth from

Amzeeq and Zilxi (acquired in January 2022). Qbrexza, Accutane, Amzeeq and Zilxi reflected approximately 77% of our total net product revenues for the year ended December 31, 2022. Offsetting the increases is a decrease in the net product revenue of Targadox and its authorized generic as a result of continued generic competition. Additionally, net product revenues of Ximino and Exelderm and their authorized generics were negatively impacted by contract manufacturer product shortages earlier in the year. These shortages were resolved in the third quarter of 2022 and sales continue to normalize although they are not back to pre-shortage levels. We expect sales of Ximino and Exelderm to reach pre-shortage levels through 2023. The above table includes the authorized generic product within the line items for Targadox, Ximino and Exelderm.

Other revenue

The year ended December 31, 2022 includes a net \$2.5 million milestone payment from Maruho. In January 2022, Maruho received manufacturing and marketing approval in Japan for Rapifort® Wipes 2.5%, triggering the net payment. The net payment reflects a milestone payment of \$10.0 million to the Company from Maruho, offset by a \$7.5 million payment to Dermira. The year ended December 31, 2022 also reflects total year-to-date royalties of \$174,000 from Maruho on sales of Rapifort® Wipes 2.5% in Japan.

We record gross-to-net sales accruals for chargebacks, distributor service fees, prompt pay discounts, sales returns, coupons, managed care rebates, government rebates, and other allowances customary to the pharmaceutical industry.

Gross-to-net sales accruals and the balance in the related allowance accounts for the years ended December 31, 2022, 2021 and 2020 were as follows:

(\$'s in thousands)	Chargebacks and other allowances	Distributor Service Fees	Prompt Pay Discounts	Returns	Coupons	Managed Care Rebates	Gov't Rebates	Total
Balance as of December 31, 2020	\$ —	\$ —	\$ —	\$ 2,580	\$ 12,769	\$ 100	\$ —	\$ 15,449
Current provision related to sales in the current period	622	791	197	3,564	140,871	9,025	690	155,760
Checks/credits issued to third parties	—	—	—	(2,589)	(148,963)	(5,633)	—	(157,185)
Reclassifications between liability accounts	—	—	—	(315)	315	—	—	—
Balance as of December 31, 2021	\$ 622	\$ 791	\$ 197	\$ 3,240	\$ 4,992	\$ 3,492	\$ 690	\$ 14,024
Current provision related to sales in the current period	2,663	5,868	1,104	5,387	117,883	22,654	3,651	159,210
Checks/credits issued to third parties	(3,032)	(5,730)	(1,094)	(4,938)	(121,179)	(22,552)	(3,331)	(161,856)
Balance as of December 31, 2022	\$ 253	\$ 929	\$ 207	\$ 3,689	\$ 1,696	\$ 3,594	\$ 1,010	\$ 11,378

The change in our reserve from period-to-period is driven by the decrease in our reserve for coupons. The provision for coupons was \$1.7 million at December 31, 2022 compared to \$5.0 million at December 31, 2021. The change in the coupon reserve is primarily due to a decrease in sales of Minocycline as well as an increase primarily associated with initial program prefunding payments for Amzeeq and Zilxi.

Cost of Goods Sold

Cost of goods sold decreased by \$1.3 million, or 4%, to \$30.8 million for the year ended December 31, 2022, from \$32.1 million for the year ended December 31, 2021. The decrease is primarily due to a \$5.9 million decrease in inventory step-up costs. Approximately \$6.5 million of inventory step-up costs were charged against operations through cost of goods sold for the year ended December 31, 2021 as a result of the Qbrexza product acquisition in the second quarter of 2021, compared to \$0.6 million of inventory step-up costs for the year ended December 31, 2022, as a result of the Amzeeq and Zilxi product acquisitions in January 2022. In addition, royalty expenses decreased by \$1.7 million, or 12%, mainly due to the decrease in Targadox sales from period-to-period. The above decreases are offset in part by higher product costs of \$1.8 million driven by sales volumes, increased license amortization of \$1.8 million and increased Prescription Drug User Fee Act fees of \$0.6 million driven by the acquisition of Amzeeq and Zilxi. The decreases are also offset by increased costs of approximately \$2.1 million related to freight, destruction, product validation, stability testing costs, and the establishment of expired product and other inventory reserves for the year ended December 31, 2022.

Research and Development

Research and Development expense increased to \$10.9 million for the year ended December 31, 2022 from \$2.7 million for the year ended December 31, 2021 due to clinical trial expenses to develop our DFD-29 product, for which our Phase 3 clinical trial is 100% enrolled as of January 10th, 2023. We expect these expenses to increase through 2023 as the now fully enrolled two Phase 3 trials are completed and we incur other associated cost of the development program.

Research and Development – licenses acquired

Research and development expenses - licenses acquired decreased \$13.8 million, or 100%, from the year ended December 31, 2021. The year ended December 31, 2021 reflects the acquisition of our development stage asset from DRL, DFD-29, for \$10.0 million and the fair value of the contingent payment due DRL of \$3.8 million. We did not have any research and development license acquisition costs for the year ended December 31, 2022.

Selling, General and Administrative Expenses (“SG&A”)

Selling, general and administrative expenses increased by \$19.6 million, or 49%, to \$59.5 million for the year ended December 31, 2022, from \$39.8 million for the year ended December 31, 2021. The increase is primarily attributable to the expansion of our salesforce and marketing expenses related to expanding our product portfolio by four products, additional headcount costs (including non-cash stock compensation expenses), legal expenses associated with patent litigation, and compliance and other professional fees associated with being a public company that we did not incur as a privately held company prior to our IPO in November 2021.

Wire Transfer Fraud Loss

In September 2021, wire fraud-related costs totaled approximately \$9.5 million. These costs were attributable to funds erroneously wired to fraudulent accounts as a result of a sophisticated business email compromise fraud scheme. Please see “*Risk Factors – Our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or third parties’ cybersecurity*” for more information.

Interest Expense

Interest expense decreased \$5.0 million to \$2.0 million for the year ended December 31, 2022, from \$7.0 million for the year ended December 31, 2021. The year ended December 31, 2021 includes dividends and interest on our convertible preferred stock that converted in full, into shares of our common stock upon the closing of our IPO in November 2021. Interest expense for the year ended December 31, 2022 reflects interest and fees related to our EWB term loan and installment licenses.

Change in Fair Value of Derivative Liabilities

The change in fair value of derivative liabilities reflects the derivative mark-to-market accounting to mark to fair value the contingent payment liability to Dr. Reddy, the liability classified warrants and the placement agent warrants issued as partial compensation to the placement agent in our 2021 private financing as a result of the settlement and conversion of these warrant liabilities to our common stock. In connection with the our IPO we issued 111,567 shares of common stock for settlement of all of the placement agent warrants. In addition, we issued 545,131 shares of common stock to Dr. Reddy in a transaction exempt from registration under the Securities Act in settlement of the contingent payment. We have no derivative liabilities outstanding at December 31, 2022.

Income tax expense

Our effective tax rate for 2022 and 2021 was (0.21%) and (3.86)%, respectively. The negative effective tax rate of 0.21% for the year ended December 31, 2022 varies from the statutory rate principally due to our full valuation allowance position. The increase in the effective tax rate from 2021 to 2022 is primarily due to change in valuation allowance and state taxes. Our tax rate is affected by valuation allowances, recurring items, such as the U.S. federal and state statutory tax rates and the relative amounts of income we earn in those jurisdictions. It is also affected by discrete items that may occur in any given year but are not consistent from year to year.

Liquidity and Capital Resources

At December 31, 2022, we had \$32.0 million in cash and cash equivalents as compared to \$49.1 million at December 31, 2021.

On December 30, 2022, we filed a shelf registration statement on Form S-3 (File No. 333-269079), which was declared effective by the SEC on January 23, 2023. This shelf registration statement covers the offering, issuance and sale by us of up to an aggregate of \$150.0 million of our common stock, preferred stock, debt securities, warrants, and units (the “2022 Shelf”). At December 31, 2022, \$150.0 million remains available under the 2022 Shelf. In connection with the 2022 shelf, we have entered into the Sales Agreement with B. Riley, relating to shares of our common stock. In accordance with the terms of the Sales Agreement, we may offer and sell up to 4,900,000 shares of our common stock, par value \$0.0001 per share, from time-to-time through B. Riley acting as our agent or principal.

We are party to a Loan and Security Agreement, dated March 31, 2021, with EWB (as amended, the “EWB Facility”), under which EWB made a \$7.5 million line of credit available to us. On January 12, 2022, we entered into a third amendment of the loan and security agreement with EWB, which increased the borrowing capacity of our revolving line of credit to \$10.0 million, of which \$2.9 million was outstanding at December 31, 2022, and added a term loan not to exceed \$20.0 million. Both the revolving line of credit and the term loan mature on January 12, 2026. In January 2022 and August 2022, we borrowed \$15.0 million (to facilitate the Vyne Product Acquisition Agreement) and \$5.0 million, respectively, against the term loan. The term loans bear interest at a floating rate equal to 1.73% above the prime rate and are payable monthly. The term loans contain an interest-only payment period through January 12, 2024, with an extension through July 12, 2024, if certain covenants are met, after which the outstanding balance of each term loan is payable in equal monthly installments of principal, plus all accrued interest, through the term loan maturity date. We may elect to prepay all or any part of the term loan without penalty or premium, but we may not re-borrow any amount, once repaid. Any outstanding borrowing against the revolving line of credit bears interest at a floating rate equal to 0.70% above the prime rate. The EWB Facility includes customary financial covenants such as collateral ratios and minimum liquidity provisions. We are in compliance with all applicable financial covenants under the EWB Facility. The remaining \$7.1 million revolving line of credit is fully available to us without any restrictions, other than certain customary and ordinary closing conditions.

We expect that our expenses will increase substantially for the foreseeable future as we pursue business development opportunities, commercialize and market new products and incur additional costs associated with operating as a public company. To date, our business has not been materially impacted by COVID-19; however, depending on the extent of the ongoing pandemic, it is possible that our business, financial condition and results of operations could be materially and adversely affected by COVID-19 in the future. Additionally, the Federal Reserve has raised and is expected to continue to raise the federal funds interest rate throughout 2023 in its effort to take action against domestic inflation. Because our borrowings under the facility with EWB bear interest at a floating rate, rising interest rates affect the amount of the regular payments we are required to make to EWB. Accordingly, we may experience materially higher borrowing costs in future fiscal quarters than we historically have to date. We may require additional financing to pursue both development stage and commercial opportunities. In addition, we anticipate increased commercialization expenses related to the launch of newly acquired products, as well as increased costs related to development and regulatory approval of potential development stage product acquisitions, including DFD-29. As we continue to expand our product portfolio, we may need to fund possible future operating losses, and, if deemed appropriate, establish or secure through additional third-party manufacturing for our products, and expanded sales and marketing capabilities related to recent product acquisitions.

For the next twelve months from the issuance of these financial statements, we will be able to fund our operations through a combination of existing cash and cash equivalents generated from operations, and the EWB borrowing facility. In addition, we may seek to raise capital through additional debt or equity financing, which may include sales of securities under our 2022 Shelf or under a new registration statement. If such funding is not available or not available on terms acceptable to us, our current plans for expansion of our product portfolio may be scaled back, limited or curtailed. We regularly evaluate market conditions, our liquidity profile, and various financing alternatives for opportunities to enhance our capital structure.

Cash Flows for the Years Ended December 31, 2022 and 2021

(\$'s in thousands)	For the Years ended December 31,		Increase (Decrease)
	2022	2021	
Net cash used in operating activities	\$ (13,534)	\$ (2,181)	\$ 11,353
Net cash used in investing activities	(20,000)	(10,000)	10,000
Net cash provided by financing activities	16,456	53,016	(36,560)
Net change in cash and cash equivalents	\$ (17,078)	\$ 40,835	\$ 57,913

Operating Activities

Net cash used in operating activities increased by \$11.4 million, to \$13.5 million for the year ended December 31, 2022, from \$2.2 million for the year ended December 31, 2021. The increase was driven primarily by vendor, supplier, and other payments in the ordinary course of business, which were generally higher as a result of additional headcount costs, inventory purchases and marketing expenses related to our expanded product portfolio, legal expenses and compliance and other costs associated with being a public company that were not present in the prior year, pre-IPO, offset by accounts receivable cash collections.

Investing Activities

Net cash used in investing activities increased by \$10.0 million, to \$20.0 million for the year ended December 31, 2022, from \$10.0 million for the year ended December 31, 2021. The increase is primarily due to the \$20.0 million in consideration paid for the products acquired in the Vyne Product Acquisition Agreement in January 2022, compared to payments of \$10.0 million for the year ended December 31, 2021 for research and development licenses.

Financing Activities

Net cash provided by financing activities decreased by \$36.6 million, to \$16.5 million for the year ended December 31, 2022, from \$53.0 million for the year ended December 31, 2021. The decrease is primarily related to \$30.6 million and \$17.0 million of net proceeds received from the completion of our IPO in November 2021 and the issuance of our convertible preferred stock, respectively. In addition, we received proceeds of \$9.5 million from the Fortress note for the year ended December 31, 2021. This is compared to borrowings under the EWB term loan of \$20 million and net borrowings under the EWB revolving line of credit of \$2.1 million during the year ended December 31, 2022.

Material Cash Requirements

In the normal course of business, we enter into contractual obligations that contain cash requirements of which the most significant to date include the following:

- We are required to make regular payments under the EWB Facility, which was recently amended to increase the borrowing capacity of our revolving line of credit to \$10.0 million, \$2.9 million of which was outstanding at December 31, 2022, and to add a term loan not to exceed \$20.0 million. Based on the amount currently outstanding under the EWB facility and current interest rates, and assuming we do not make further draws under the EWB Facility, we expect to make the following payments:

	Total	Payments by Period			
		2023	2024	2025	2026
		(\$'s in thousands)			
Interest	\$ 4,448	\$ 1,877	\$ 1,790	\$ 777	\$ 4
Principal	22,948	2,948	5,556	13,333	1,111
Total	\$ 27,396	\$ 4,825	\$ 7,346	\$ 14,110	\$ 1,115

Should we elect to make further borrowings under the EWB facility, we would expect to repay additional amounts each year until maturity.

- Pursuant to the Vyne Product Acquisition Agreement, we agreed to pay to Vyne an additional \$5.0 million upon the one-year anniversary of the closing, January 12, 2023, completing our obligation to pay the full purchase price. Upon the achievement of net sales milestones with respect to the products purchased in the Vyne Product Acquisition, we are also required to pay contingent consideration consisting of a one-time payment, per product, of \$10 million, \$20 million, \$30 million, \$40 million and \$50 million upon each product reaching annual net sales of \$100 million, \$200 million, \$300 million, \$400 million and \$500 million, respectively. Each required payment must only be paid one time following the first achievement of the applicable annual net sales milestone amount.

- Pursuant to the DFD-29 Agreement with DRL, we paid an upfront payment of \$10.0 million. Additional contingent regulatory and commercial milestone payments totaling up to \$158.0 million may also be payable. Royalties ranging from ten percent to twenty percent are payable on net sales of the product. Additionally, we are required to fund and oversee the Phase 3 clinical trials, which we anticipate will cost approximately \$24.0 million, based upon the current development plan and budget.
- We are contractually obligated to make installment milestone payments on our acquired licenses as follows:

Product	Payments by Period		
	Total	2023	2024
	(\$'s in thousands)		
Ximino	\$ 3,000	\$ 1,500	\$ 1,500
Accutane	1,000	1,000	—
Total	<u>\$ 4,000</u>	<u>\$ 2,500</u>	<u>\$ 1,500</u>

- We are contractually obligated to make sales-based royalty payments to Dermira (for Qbrexza), Sun Pharmaceutical Industries (for Exelderm and Ximino) and PuraCap Caribe (for Targadox). Due to the contingent nature of these obligations, the amounts of these payments cannot be reasonably predicted.

Item 7A. Quantitative and Qualitative Disclosures About Market Risks

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act, designed to ensure that information required to be disclosed in our reports filed pursuant to the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

In designing and evaluating the disclosure controls and procedures, we recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and we were required to apply our judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation as of the end of the period covered by this Annual Report on Form 10-K under the supervision, and with the participation, of our management, including our Chief Executive Officer (who serves as our principal executive officer) and our Interim Chief Financial Officer (who serves as our principal financial officer), of the effectiveness of the design and operation of our disclosure controls and procedures.

Based on that evaluation, our Chief Executive Officer and Interim Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K in providing reasonable assurance of achieving the desired control objectives.

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting refers to the process designed by, or under the supervision of, our principal executive officer and principal financial officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making the assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control - Integrated Framework (2013)*. Based on the results of this assessment, management (including our Chief Executive Officer and our Interim Chief Financial Officer) has concluded that, as of December 31, 2022, our internal control over financial reporting was effective.

This Annual Report does not include an attestation report on internal control over financial reporting from our independent registered public accounting firm due to our status as an emerging growth company under the JOBS Act.

Remediation of previously reported material weakness

As previously disclosed, in September 2021, an employee email account was compromised by a third-party impersonator and payments intended for a vendor, approximating \$9.5 million, were fraudulently re-directed into an individual bank account controlled by this third-party impersonator. The impersonator had taken a number of steps to deceive our employees and reduce the likelihood of detection. As a result of the foregoing, we identified a material weakness as of September 30, 2021 due to our internal controls having not been adequately designed to prevent or timely detect unauthorized cash disbursements.

To remediate the material weakness identified, we enhanced and formalized cash disbursement controls to prevent and timely detect unauthorized cash disbursements and significantly enhanced our information technology infrastructure and security measures. As the implementation of the enhanced procedures and controls have functioned effectively for multiple quarters, we concluded that we have remediated the material weakness previously disclosed in 2021.

Changes in Internal Control over Financial Reporting

Other than as discussed above, there have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter ended December 31, 2022 to which this report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

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

Item 11. Executive Compensation

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

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

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

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

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

Item 14. Principal Accounting Fees and Services

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

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Financial Statements.

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

Report of Independent Registered Public Accounting Firm (KPMG LLP, Short Hills, New Jersey; PCAOB# 185)	F-2
Consolidated Balance Sheets as of December 31, 2022 and 2021	F-3
Consolidated Statements of Operations for the years ended December 31, 2022 and 2021	F-4
Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2022 and 2021	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021	F-6
Notes to Consolidated Financial Statements	F-7

(b) Exhibits.

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of Journey Medical Corporation, filed on March 28, 2022 and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Journey Medical Corporation, filed as Exhibit 3.2 to Form 10-K, filed on March 28, 2022 and incorporated herein by reference.
4.1	Form of Common Stock Certificate, filed as Exhibit 4.1 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.
4.2	Description of Securities of Journey Medical Corporation, filed as Exhibit 4.2 to Form 10-K, filed on March 28, 2022 and incorporated herein by reference.
10.1	Journey Medical Corporation 2015 Stock Plan, filed as Exhibit 10.1 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.#
10.2	Amendment to Journey Medical Corporation 2015 Stock Plan, filed as Exhibit 10.1 to Form 8-K filed on June 21, 2022 and incorporated herein by reference.#
10.3	Executive Employment Agreement with Claude Maraoui, dated September 22, 2014, filed as Exhibit 10.2 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.#
10.4	Executive Employment Agreement with Ernie De Paolantonio, filed as Exhibit 10.3 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.#
10.5	Non-Employee Director Compensation Plan, filed as Exhibit 10.2 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.#
10.6	Loan and Security Agreement, entered into by and between Journey Medical Corporation and East West Bank, dated March 31, 2021, filed as Exhibit 10.5 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.
10.7	First Amendment to Loan and Security Agreement, entered into by and between Journey Medical Corporation and East West Bank, dated March 31, 2021, filed as Exhibit 10.2 to Form 10-Q for the quarter ended March 31, 2022, filed May 10, 2022 and incorporated herein by reference.**
10.8	Second Amendment to Loan and Security Agreement, entered into by and between Journey Medical Corporation and East West Bank, dated November 4, 2021, filed as Exhibit 10.3 to Form 10-Q for the quarter ended March 31, 2022, filed May 10, 2022 and incorporated herein by reference.**
10.8	Third Amendment to Loan and Security Agreement, entered into by and between Journey Medical Corporation and East West Bank, dated January 12, 2022, filed as Exhibit 10.4 to Form 10-Q for the quarter ended March 31, 2022, filed May 10, 2022 and incorporated herein by reference.**
10.9	Asset Purchase Agreement for Obrexza, entered into by and between Journey Medical Corporation and Dermira, Inc., a subsidiary of Eli Lilly and Company, dated as of March 31, 2021, filed as Exhibit 10.6 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.**
10.10	Asset Purchase Agreement between VYNE Therapeutics Inc. and Journey Medical Corporation, dated as of January 12, 2022, filed as Exhibit 10.1 to Form 8-K filed on January 13, 2022 and incorporated herein by reference.**
10.11	License and Supply Agreement for Accutane, entered into by and between Journey Medical Corporation and Dr. Reddy's Laboratories Ltd., dated as of July 29, 2020, filed as Exhibit 10.7 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.**
10.12	License and Supply Agreement for Targadox, entered into by and between Journey Medical Corporation and Blu Caribe Inc., dated as of March 10, 2015, filed as Exhibit 10.8 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.**
10.13	First Amendment to the License and Supply Agreement for Targadox, entered into by and between Journey Medical Corporation and Blu Caribe Inc., dated as of August 26, 2015, filed as Exhibit 10.9 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.**
10.14	Asset Purchase Agreement for Exelderm, entered into by and between Journey Medical Corporation and Sun Pharmaceutical Industries, Inc., dated as of August 31, 2018, filed as Exhibit 10.10 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.**
10.15	Amendment 1 to the Asset Purchase Agreement for Exelderm, entered into by and between Journey Medical Corporation and Sun Pharmaceutical Industries, Inc., dated as of September 5, 2018, filed as Exhibit 10.11 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.**

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10.16	Asset Purchase Agreement for Ximino, entered into by and between Journey Medical Corporation and Sun Pharmaceutical Industries, Inc., dated as of July 22, 2019, filed as Exhibit 10.12 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.**
10.17	Asset Purchase Agreement for the Anti-itch Product, entered into by and between Journey Medical Corporation and Sun Pharmaceutical Industries, Inc., dated as of December 18, 2020, filed as Exhibit 10.13 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.**
10.18	License, Collaboration, and Assignment Agreement for DFD-29, entered into by and between Journey Medical Corporation and Dr. Reddy's Laboratories Ltd., dated as of June 29, 2021, filed as Exhibit 10.14 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.**
10.19	Asset Purchase Agreement between Journey Medical Corporation and VYNE Therapeutics Inc., dated as of January 12, 2022, filed as Exhibit 10.1 to the Form 8-K filed on January 13, 2022 and incorporated herein by reference. **
10.20	Fortress Promissory Note, dated as of June 6, 2015, filed as Exhibit 10.16 to Form S-1, filed on October 22, 2021 and incorporated herein by reference.
10.21	At Market Issuance Sales Agreement, dated as of December 30, 2022, by and between Journey Medical Corporation and B. Riley Securities, Inc., filed as Exhibit 1.2 to Form S-3, filed on December 30, 2022 and incorporated herein by reference.
21.1	List of Subsidiaries of Journey Medical Corporation.*
23.1	Consent of KPMG LLP.*
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. ***
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. ***
101	The following financial information from the Company's Quarterly Report on Form 10-K for the period ended December 31, 2022, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statement of Stockholders' Equity, (iv) the Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements.
104	Cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2021, formatted in Inline XBRL.

* Filed herewith.

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

*** Furnished herewith.

Management Compensation Arrangement.

**Item 16. Form 10-K
Summary**

The Company has elected not to provide summary information.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

Journey Medical Corporation:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Journey Medical Corporation and subsidiary (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years then ended December 31, 2022, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years then ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

/s/ KPMG LLP

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

Short Hills, New Jersey
March 30, 2023

JOURNEY MEDICAL CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,	
	2022	2021
ASSETS		
Current assets		
Cash and cash equivalents	\$ 32,003	\$ 49,081
Accounts receivable, net of reserves	28,208	23,112
Inventory	14,159	9,862
Prepaid expenses and other current assets	3,309	2,438
Total current assets	77,679	84,493
Intangible assets, net	27,197	12,552
Operating lease right-of-use asset, net	189	89
Other assets	95	150
Total assets	\$ 105,160	\$ 97,284
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 36,570	\$ 22,812
Due to related party	413	641
Accrued expenses	19,388	22,733
Accrued interest	160	—
Income taxes payable	35	8
Line of credit	2,948	812
Deferred cash payment (net of discount of \$9)	4,991	—
Installment payments – licenses, short-term	2,244	4,510
Operating lease liability, short-term	83	98
Total current liabilities	66,832	51,614
Term loan (net of debt discount of \$ 180)	19,826	—
Installment payments – licenses, long-term	1,412	3,627
Operating lease liability, long-term	108	—
Total liabilities	88,178	55,241
Commitments and contingencies (Note 14)		
Stockholders' equity		
Common stock, \$.0001 par value, 50,000,000 shares authorized, 11,765,700 and 11,316,344 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	1	1
Common stock - Class A, \$.0001 par value, 50,000,000 shares authorized, 6,000,000 shares issued and outstanding as of December 31, 2022 and December 31, 2021	1	1
Additional paid-in capital	85,482	80,915
Accumulated deficit	(68,502)	(38,874)
Total stockholders' equity	16,982	42,043
Total liabilities and stockholders' equity	\$ 105,160	\$ 97,284

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

JOURNEY MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2022	2021
Revenue:		
Product revenue, net	\$ 70,995	\$ 63,134
Other revenue	2,674	—
Total revenue	<u>73,669</u>	<u>63,134</u>
Operating expenses		
Cost of goods sold – product revenue	30,775	32,084
Research and development	10,943	2,739
Research and development - licenses acquired	—	13,819
Selling, general and administrative	59,468	39,833
Wire transfer fraud loss	—	9,540
Total operating expenses	<u>101,186</u>	<u>98,015</u>
Loss from operations	(27,517)	(34,881)
Other expense (income)		
Interest income	(60)	(2)
Interest expense	2,019	7,034
Foreign exchange transaction losses	89	—
Change in fair value of derivative liability	—	447
Total other expense (income)	<u>2,048</u>	<u>7,479</u>
Loss before income taxes	(29,565)	(42,360)
Income tax expense	63	1,634
Net Loss	\$ (29,628)	\$ (43,994)
Net loss per common share:		
Basic and diluted	\$ (1.69)	\$ (4.32)
Weighted average number of common shares:		
Basic and diluted	17,531,274	10,189,844

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

JOURNEY MEDICAL CORPORATION
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock		Common Stock A		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2020	3,151,333	\$ —	6,000,000	\$ 1	\$ 5,171	\$ 5,120	\$ 10,292
Share-based compensation	—	—	—	—	2,466	—	2,466
Exercise of options for cash	10,000	—	—	—	7	—	7
Issuance of common stock related to equity plans	136,500	—	—	—	—	—	—
Issuance of common shares upon initial public offering, net of issuance costs of \$1,921 million	3,520,000	1	—	—	30,614	—	30,615
Conversion of class A preferred stock settled note to common stock	2,231,346	—	—	—	21,812	—	21,812
Conversion of related party payables to common stock	1,610,467	—	—	—	16,105	—	16,105
Conversion of placement agent warrants to common stock	111,567	—	—	—	948	—	948
Conversion of contingent payment warrants to common stock	545,131	—	—	—	3,680	—	3,680
Contribution of capital – extinguishment of related party payable	—	—	—	—	112	—	112
Net loss	—	—	—	—	—	(43,994)	(43,994)
Balance as of December 31, 2021	11,316,344	\$ 1	6,000,000	\$ 1	\$ 80,915	\$ (38,874)	\$ 42,043
Share-based compensation	—	—	—	—	4,425	—	4,425
Exercise of stock options for cash	155,649	—	—	—	142	—	142
Issuance of common stock for vested restricted stock units	293,707	—	—	—	—	—	—
Net loss	—	—	—	—	—	(29,628)	(29,628)
Balance as of December 31, 2022	11,765,700	\$ 1	6,000,000	\$ 1	\$ 85,482	\$ (68,502)	\$ 16,982

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

JOURNEY MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (29,628)	\$ (43,994)
Adjustments to reconcile net loss to net cash used in operating activities:		
Bad debt expense	284	48
Non-cash interest expense	770	781
Amortization of debt discount	63	2,572
Accretion of convertible preferred shares	—	2,845
Amortization of acquired intangible assets	4,277	2,474
Amortization of operating lease right-of-use assets	88	86
Share-based compensation	4,425	2,466
Deferred taxes	—	1,566
Change in fair value of derivative liability	—	447
Research and development-licenses acquired, expense	—	13,819
Changes in operating assets and liabilities:		
Accounts receivable	(5,380)	768
Inventory	1,744	(8,458)
Prepaid expenses and other current assets	(871)	(774)
Other assets	55	(144)
Accounts payable	14,343	20,388
Related party expenses	(228)	1,869
Accrued expenses	(3,568)	1,235
Accrued interest	160	—
Income tax payable	27	(91)
Lease liabilities	(95)	(84)
Net cash used in operating activities	(13,534)	(2,181)
Cash flows from investing activities		
Purchase of research and development licenses	—	(10,000)
Acquired assets	(20,000)	—
Net cash used in investing activities	(20,000)	(10,000)
Cash flows from financing activities		
Proceeds from the exercise of stock options	142	7
Proceeds from Fortress note	—	9,540
Payment of license installment note payable	(5,000)	(5,300)
Proceeds from convertible preferred shares	—	18,967
Payment of debt issuance costs associated with convertible preferred shares	(214)	(1,996)
Proceeds from line of credit	5,000	7,000
Repayment of line of credit	(2,864)	(6,188)
Proceeds from issuance of common stock - initial public offering	—	32,536
Proceeds from EWB term-loan, net of discount	19,763	—
Offering costs for the issuance of common stock - initial public offering	(371)	(1,550)
Net cash provided by financing activities	16,456	53,016
Net change in cash	(17,078)	40,835
Cash at the beginning of the period	49,081	8,246
Cash at the end of the period	\$ 32,003	\$ 49,081
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 993	\$ —
Cash paid for income taxes	\$ 168	\$ 158
Supplemental disclosure of non-cash financing and investing activities:		
Deferred payment for asset acquisition	\$ 4,740	\$ —
ROU assets obtained in exchange for lease liabilities	\$ 188	\$ —
Unpaid debt offering cost	\$ —	\$ 214
Unpaid initial public offering cost	\$ —	\$ 371
Derivative warrant liability associated with convertible preferred shares	\$ —	\$ 362
Conversion of class A preferred stock settled note to common stock	\$ —	\$ 21,812
Conversion of related party payables to common stock	\$ —	\$ 16,105
Conversion of placement agent warrants to common stock	\$ —	\$ 948
Conversion of contingent payment warrants to common stock	\$ —	\$ 3,680
Extinguishment of related party payable relates to deferred tax assets	\$ —	\$ 43

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

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

NOTE 1. ORGANIZATION AND PLAN OF BUSINESS OPERATIONS

Journey Medical Corporation (collectively “Journey” or the “Company”) is a commercial-stage pharmaceutical company that focuses on the development and commercialization of pharmaceutical products for the treatment of dermatological conditions. The Company’s current product portfolio includes eight branded and three authorized generic prescription drugs for dermatological conditions that are marketed in the U.S. The Company acquires rights to products and product candidates by licensing or otherwise acquiring an ownership interest in, funding the research and development of, and eventually commercializing, the products through its exclusive field sales organization.

At of December 31, 2022 and 2021, the Company is a majority-owned subsidiary of Fortress Biotech, Inc. (“Fortress” or “Parent”).

Liquidity and Capital Resources

At December 31, 2022, the Company had \$32.0 million in cash and cash equivalents as compared to \$49.1 million at December 31, 2021.

On December 30, 2022, the Company filed a shelf registration statement on Form S-3 (File No. 333-269079), which was declared effective by the Securities and Exchange Commission (“SEC”) on January 26, 2023. This shelf registration statement covers the offering, issuance and sale by the Company of up to an aggregate of \$150.0 million of the Company’s common stock, preferred stock, debt securities, warrants, and units (the “2022 Shelf”). At December 31, 2022, \$150.0 million remains available under the 2022 Shelf. In connection with the 2022 shelf, the Company has entered into an At Market Issuance Sales Agreement (the “Sales Agreement”) with B. Riley Securities, Inc. (“B. Riley”), relating to shares of the Company’s common stock. In accordance with the terms of the Sales Agreement, the Company may offer and sell up to 4,900,000 shares of its common stock, par value \$0.0001 per share, from time to time through or to B. Riley acting as the Company’s agent or principal.

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

The Company expects that expenses will increase substantially for the foreseeable future as it pursues business development opportunities, commercializes and markets new products and incurs additional costs associated with operating as a public company. To date, the Company has not been materially impacted by COVID-19; however, depending on the extent of the ongoing pandemic, it is possible that the Company, financial condition and results of operations could be materially and adversely affected by COVID-19 in the future. Additionally, the Federal Reserve has raised and is expected to continue to raise the federal funds interest rate throughout 2023 in its effort to take action against domestic inflation. Because the Company’s borrowings under the facility with EWB bear interest at a floating rate, rising interest rates affect the amount of the regular payments the Company is required to make to EWB. Accordingly, the Company may experience materially higher borrowing costs in future fiscal quarters than it historically has to date. The Company may require additional financing to pursue both development stage and commercial opportunities. In addition, The Company anticipates increased commercialization expenses related to the launch of newly acquired products, as well as increased costs related to development and regulatory approval of potential development stage product acquisitions, including DFD-29. As the Company continues to expand its product portfolio, it may need to fund possible future operating losses, and, if deemed appropriate, establish or secure through

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

additional third-party manufacturing for the Company's products, and expanded sales and marketing capabilities related to recent product acquisitions.

For the next twelve months from the issuance of these financial statements, the Company will be able to fund our operations through a combination of existing cash and cash equivalents generated from operations, and the EWB borrowing facility. In addition, the Company may seek to raise capital through additional debt or equity financing, which may include sales of securities under the 2022 Shelf or under a new registration statement. If such funding is not available or not available on terms acceptable to the Company, the current plans for expansion of the product portfolio may be scaled back, limited or curtailed. The Company regularly evaluates market conditions, its liquidity profile, and various financing alternatives for opportunities to enhance the Company's capital structure.

NOTE 2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The Company's consolidated financial statements include the accounts of the Company and the accounts of the Company's wholly-owned subsidiary, JG Pharma, Inc. ("JG" or "JG Pharma"). All intercompany balances and transactions have been eliminated.

Emerging Growth Company

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard-setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's unaudited interim condensed consolidated financial statements upon adoption. Under the Jumpstart Our Business Startups Act of 2012, as amended, the Company meets the definition of an emerging growth company and elected the extended transition period for complying with new or revised accounting standards, which delays the adoption of these accounting standards until they would apply to private companies.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates made by management include provisions for coupons, chargebacks, wholesaler fees, prompt-pay discounts, specialty pharmacy discounts, managed care rebates, product returns, government rebates and other allowances customary to the pharmaceutical industry. Significant estimates made by management also include inventory realization, valuation of intangible assets, useful lives of amortizable intangible assets and share-based compensation. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment, which reflects products for the treatment of dermatological conditions.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash. Periodically, the Company may maintain deposits in financial institutions in excess of government insured limits. Management believes

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

that the Company is not exposed to significant credit risk as the Company's deposits are held at financial institutions that management believes to be of high credit quality. The Company has not experienced any losses on these deposits.

The Company's accounts receivable primarily represent amounts due from drug wholesalers and specialty pharmacies in the United States. The Company performs periodic credit evaluations of customers and does not require collateral. An allowance for doubtful accounts is maintained for potential credit losses based on the aging of accounts receivable, historical bad debts experience, and the customer's current ability to pay its obligations to the Company. Accounts receivables balances are written off against the allowance when it is probable that the receivable will not be collected. See Note 17 for significant customers.

Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents at December 31, 2022 and 2021 consisted entirely of cash and cash equivalents in institutions within the United States. Balances at certain institutions have exceeded Federal Deposit Insurance Corporation insured limits.

Accounts Receivable, Net

The Company's accounts receivable consists of amounts due from customers related to product sales and have standard payment terms. For certain customers, the accounts receivable for the customer is net of prompt payment or specialty pharmacy discounts. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company reserves against accounts receivable for estimated losses that may arise from a customer's inability to pay, and any amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The Company has historically not experienced significant credit losses. The allowance for doubtful accounts was \$0.4 million and \$0.1 million at December 31, 2022 and 2021, respectively.

Inventories

Inventories are recorded at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. The Company periodically reviews the composition of inventory in order to identify excess, obsolete, slow-moving or otherwise non-saleable items taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand. If non-saleable items are observed and there are no alternate uses for the inventory, the Company records a write-down to net realizable value in the period that the decline in value is first recognized. The Company's inventory reserves were \$0.4 million and zero at December 31, 2022 and 2021, respectively.

Property and Equipment

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

Leases

Arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the consolidated balance sheet as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line rent expense over the lease term. Variable lease expenses are recorded when incurred.

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

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

Research and Development Costs

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

Research and development costs primarily consist of personnel related expenses, payments made to third parties for license and milestone costs related to in-licensed products and technology, and payments made to third party contract research organizations.

In accordance with Accounting Standards Codification ("ASC") 730-10-25-1, *Research and Development*, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. Such licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and have no alternative future use. Accordingly, the total purchase price for the licenses acquired during the period was reflected as research and development - licenses acquired in the Consolidated Statements of Operations for the year ended December 31, 2022 and 2021.

Contingencies

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

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

Fair Value Measurement

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

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

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

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

Certain of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as accounts payable, accrued expenses and other current liabilities.

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Intangible Assets

Intangible assets are reported at cost, less accumulated amortization and impairments. Intangible assets with finite lives are amortized over their estimated useful lives, which represents the estimated life of the product. Amortization is calculated using the straight-line method.

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

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including intangible assets with finite useful lives, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable (a “triggering event”). Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the long-lived asset in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. The Company has not recorded any impairment losses on long-lived assets for the years ended December 31, 2022 and 2021.

Share-based Compensation

The Company has a share-based compensation plan in place and records the associated share-based compensation expense over the requisite service period. The share-based compensation plan and related compensation expense are discussed more fully in Note 16 to the Company’s consolidated financial statements.

Compensation expense for service-based stock options is charged against operations on a straight-line basis over the vesting period, which is generally four years. Forfeitures are recorded as they occur. Share-based compensation costs are recorded in both research and development and selling, general and administrative expense in the Company’s consolidated statements of operations. Options granted have a term of 10 years from the grant date.

The Company estimates the fair value of all service-based stock option awards as of the grant date by applying the Black-Scholes option pricing valuation model. The application of this valuation model involves assumptions, including the fair value of the common stock, expected volatility, risk-free interest rate, expected dividends and the expected term of the option. The assumptions used in calculating the fair value of share-based awards represent management’s best estimates and involve inherent uncertainties and the application of management’s judgment. The following inputs are used in the Black-Scholes calculation.

Expected term—The Company has elected to use the “simplified method” for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years).

Expected volatility— Historical information is the primary basis for the selection of the expected volatility of options granted. However, as the Company has limited trading history for its common shares, the expected volatility was estimated based on the average volatility for comparable guideline publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.

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Risk-free interest rate— The risk-free interest rate is selected based upon yields of United States Treasury issues with a term equal to the expected life of the option being valued.

Expected dividend yield—The Company has not issued any dividends in our history and do not expect to issue dividends over the life of the options; therefore, the Company has estimated the dividend yield to be zero.

Restricted stock units (“RSU’s”) that are service based are recorded as deferred compensation and amortized into compensation expense on a straight-line basis over the vesting period, which ranges from three to four years in duration. Compensation cost for service based RSU’s is based on the grant date fair value of the award, which is the closing market price of the Company’s common stock on the grant date multiplied by the number of shares awarded.

Prior to the Company’s IPO, which closed on November 16, 2021, the fair value of the Company’s common stock underlying stock options was an input to the Black-Scholes option pricing model. The Company engaged an independent third-party valuation firm to provide an estimate of the fair value of its common stock annually, utilizing input from management. The fair value of the Company’s common stock was determined considering a number of objective and subjective factors, including valuations of guideline public companies, transactions of guideline public companies, discounts for lack of control transactions, lack of liquidity of the Company’s common stock, and the general and industry-specific economic outlook.

Net Loss (Income) Per Share

Basic net (loss) income per share of common stock is calculated by dividing net (loss) income by the weighted-average number of shares of common stock outstanding during the reporting period. Diluted earnings per share is calculated by dividing net income by the weighted-average number of shares of common stock outstanding during the reporting period after giving effect to dilutive potential common shares for stock options and restricted stock units, determined using the treasury stock method. See Note 19 below.

Revenue Recognition

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

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

Coupons — The Company offers coupons on products for qualified commercially-insured parties with prescription drug co-payments. Such product sales flow through both traditional wholesaler and specialty pharmacy channels. Coupons are processed and redeemed at the time of prescription fulfillment by the pharmacy. The majority of coupon reserve accrual at the end of the period reflects coupons that have been redeemed for which the Company has been billed in addition to an accrual for expected redemptions for product in the distribution channel. The expected accrual reserve requires us to estimate the distribution channel inventory at period end, the expected

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redemption rates, and the cost per coupon claim that the Company expects to receive. The estimate of product remaining in the distribution channel is comprised of estimated inventory at the wholesaler as well as an estimate of inventory on the shelves at the specialty pharmacies, which the Company estimates based upon historical ordering patterns. The estimated redemption rate is based on historical redemptions as a percentage of units sold. The cost per coupon is based on the coupon rate.

Chargebacks and Government Chargebacks — The Company sells a portion of its products indirectly through wholesaler distributors to contracted indirect customers, qualified government healthcare providers, qualified U.S. Department of Veterans Affairs hospitals, and 340B entities. The Company enters into specific agreements with or provides discounts to these indirect customers and entities to establish pricing for the Company's products, and in-turn, the indirect customers and entities independently purchase these products. Because the price paid by the indirect customers and/or entities is lower than the price paid by the wholesaler, the Company provides a credit, called a chargeback, to the wholesaler for the difference between the contractual price with the indirect customers and their purchase price. The Company's provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to the indirect customers and estimated wholesaler inventory levels as well as historical chargeback rates. The Company continually monitors its reserve for chargebacks and adjusts the reserve accordingly when expected chargebacks differ from actual experience.

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

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

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

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

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

Income Taxes

As of December 31, 2022, the Company was 57.34% owned by Fortress Biotech, Inc. ("Fortress") and was filing consolidated federal tax returns and consolidated or combined state tax returns in multiple jurisdictions with Fortress for tax years prior to 2021. As the Company completed its initial public offering on November 12, 2021, it deconsolidated from the Fortress consolidated group for federal income tax purpose. The financial statements recognize the current and deferred income tax consequences that result from the activities during the current and preceding periods, as if the Company were a separate taxpayer rather than a member of the Fortress consolidated

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income tax return group. Fortress has agreed that the Company does not have to make payments to Fortress for the use of net operating losses (“NOLs”) of Fortress (including other Fortress group members). Since Fortress does not require the Company to pay in any form for the utilization of the consolidated group’s NOLs, the tax benefit realized have been recorded as a capital contribution.

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company establishes a valuation allowance if it believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. The Company has considered its history of cumulative tax and book income/loss incurred since inception, and the other positive and negative evidence, and has concluded that it is not more likely than not that it will realize the benefits of the net deferred tax assets as of December 31, 2022 and 2021 and therefore a full valuation allowance on all of the deferred tax assets is required.

For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit. For the years ended December 31, 2022 and 2021, the Company had no unrecognized tax benefits and does not anticipate any significant change to the unrecognized tax benefit balance. The Company classifies interest and penalties related to uncertain tax positions as income tax expense, if applicable. There was no interest expense or penalties related to unrecognized tax benefits recorded through December 31, 2022 and 2021.

Comprehensive Income

The Company has no components of other comprehensive income, and therefore, comprehensive income equals net income.

Recently Adopted Accounting Pronouncements

There are no recent accounting pronouncements that are expected to have a material impact on the Company’s consolidated financial statements or related disclosures.

NOTE 3. INVENTORY

The Company’s inventory consisted of the following at December 31, 2022 and 2021:

<i>(\$'s in thousands)</i>	December 31, 2022	December 31, 2021
Raw materials	\$ 6,454	\$ 5,572
Work-in-process	395	—
Finished goods	7,739	4,290
Inventory at cost	14,588	9,862
Inventory reserves	(429)	—
Total Inventories	\$ 14,159	\$ 9,862

NOTE 4. ASSET ACQUISITION

On January 12, 2022, the Company entered into an agreement with Vyne Therapeutics Inc. (“Vyne”) to acquire two United States Food and Drug Administration (“FDA”) approved topical minocycline products, Amzeeq® (minocycline) topical foam, 4%, and Zilxi® (minocycline) topical foam, 1.5%, and a Molecule Stabilizing Technology™ proprietary platform from Vyne for an upfront payment of \$20.0 million and an additional \$5.0 million payment on the one year anniversary of the closing (the “Vyne Product Acquisition Agreement”). This expanded the Company’s product portfolio to eight marketed branded dermatology products. The Company also acquired the associated inventory related to the products.

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

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

<i>(\$'s in thousands)</i>	Aggregate Consideration Transferred
Consideration transferred to Vyne at closing	\$ 20,000
Fair Value of deferred cash payment due January 2023	4,740
Transaction costs	223
Total consideration transferred at closing	<u>\$ 24,963</u>

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

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

<i>(\$'s in thousands)</i>	Assets Recognized
Inventory	\$ 6,041
Identifiable Intangibles:	
Amzeeq Intangible	15,162
Zilxi Intangible	3,760
Fair value of net identifiable assets acquired	<u>\$ 24,963</u>

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

NOTE 5. INTANGIBLES

The Company executed the Vyne Product Acquisition Agreement on January 12, 2022. The Company recognized intangible assets of \$15.2 million for Amzeeq and \$3.8 million for Zilxi, the two FDA approved products acquired in the agreement.

On March 31, 2021, the Company executed an Asset Purchase Agreement (the "Qbrexza APA") with Dermira, Inc., a subsidiary of Eli Lilly and Company ("Dermira"). Pursuant to the terms of the agreement, the Company acquired the rights to Qbrexza® (glycoprronium), a prescription cloth towelette to treat primary axillary hyperhidrosis in patients nine years of age or older. The Company paid the upfront fee of \$12.5 million to Dermira. In addition, the Company is obligated to pay Dermira up to \$144 million in the aggregate upon the achievement of certain sales milestones. The royalty structure for the agreement is tiered with royalties for the first two years ranging from approximately 40% to 30%. Thereafter for a period of eight years royalties are approximately 12.0% to 19.0%. Royalty amounts are subject to 50% diminution in the event of loss of exclusivity due to the introduction of an authorized generic.

Upon closing of the Qbrexza® purchase, the Company became substituted for Dermira as the plaintiff in U.S. patent litigation commenced by Dermira on October 21, 2020 in the U.S. District Court of Delaware (the "Patent Litigation") against Perrigo Pharma

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International DAC (“Perrigo”) alleging infringement of certain patents covering Qbrexza® (the “Qbrexza® Patents”), which are included among the proprietary rights to Qbrexza®. The Patent Litigation was initiated following the submission by Perrigo, in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”), of an Abbreviated New Drug Application (“ANDA”). The ANDA seeks approval to market a generic version of Qbrexza® prior to the expiration of the Qbrexza® Patents and alleges that the Qbrexza® Patents are invalid. Perrigo is subject to a 30-month stay preventing it from selling a generic version, but that stay is set to expire on March 9, 2023. As of December 31, 2022, the Patent Litigation was settled by and between the parties and case subsequently has been dismissed.

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

The table below provides a summary of the Company’s intangible assets at December 31, 2022 and 2021, respectively:

<i>(\$'s in thousands)</i>	December 31, 2022			
	Estimated Useful Lives (Years)	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:				
Ceracade®	3	\$ 300	\$ (300)	\$ —
Luxamend®	3	50	(50)	—
Targadox®	3	1,250	(1,250)	—
Ximino®	7	7,134	(3,482)	3,652
Exelderm®	3	1,600	(1,600)	—
Accutane®	5	4,727	(1,733)	2,994
Amzeeq®	9	15,162	(1,597)	13,565
Zilxi®	6	3,760	(716)	3,044
		33,983	(10,728)	23,255
Non-amortizable intangible assets:				
Anti-itch product (1)	3	3,942	—	3,942
		\$ 37,925	\$ (10,728)	\$ 27,197

(1) As of December 31, 2022, this asset has not yet been placed in service, therefore no amortization expense was recognized on this asset for the year ended December 31, 2022. Commercial launch of this product is expected in 2023.

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<i>(\$'s in thousands)</i>	December 31, 2021			
	Estimated Useful Lives (Years)	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net
Amortizable intangible assets:				
Ceracade®	3	\$ 300	\$ (300)	\$ —
Luxamend®	3	50	(50)	—
Targadox®	3	1,250	(1,250)	—
Ximino®	7	7,134	(2,463)	4,671
Exelderm®	3	1,600	(1,600)	—
Accutane®	5	4,727	(788)	3,939
		15,061	(6,451)	8,610
Non-amortizable intangible assets:				
Anti-itch product (1)	3	3,942	—	3,942
		\$ 19,003	\$ (6,451)	\$ 12,552

(1) As of December 31, 2021, this asset has not yet been placed in service, therefore no amortization expense was recognized on this asset for the year ended December 31, 2021. The commercial launch of this product is expected in 2023.

The table below provides a summary for the year ended December 31, 2022 and 2021, of the Company's recognized intangible amortization expense related to its product licenses, which was recorded in costs of goods sold on the consolidated statement of operations:

<i>(\$'s in thousands)</i>	Intangible Assets, Net
Balance at December 31, 2020	\$ 15,029
License acquisition adjustment	(3)
Amortization expense	(2,474)
Balance at December 31, 2021	\$ 12,552
VYNE License agreement	18,922
Amortization expense	(4,277)
Balance at December 31, 2022	\$ 27,197

The Company's amortization expense for the years ended December 31, 2022 and 2021 was approximately \$4.3 million and \$2.5 million, respectively. Amortization expense is recorded as a component of cost of goods sold in the Company's consolidated statements of operations.

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Future amortization of the Company's intangible assets is as follows:

<i>For the years ended</i>	Total Amortization
December 31, 2023	\$ 4,277
December 31, 2024	4,277
December 31, 2025	4,277
December 31, 2026	3,064
Thereafter	7,360
Subtotal	23,255
Asset not yet placed in service	3,942
Total	\$ 27,197

NOTE 6. LICENSES ACQUIRED

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

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

Additionally, the DFD-29 Agreement contained contingent consideration payable by the Company upon either an IPO of the Company's common stock or an acquisition of the Company. The Company recognized \$3.8 million of expense classified as research and development-licenses acquired upon execution of the DFD-29 Agreement associated with the contingent consideration. In connection with the closing of the Company's IPO on November 16, 2021, the Company issued 545,131 shares of its common stock to DRL in a transaction exempt from registration under the Securities Act calculated using a 5-day volume weighted average price ("VWAP") of \$9.1721 per share in full settlement of the contingent payment to DRL. The restrictions on the unregistered shares of common stock are governed by the terms set forth in the DFD-29 Agreement and applicable securities laws. See "Contingent Payment Derivative" in Note 7 for further details.

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

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NOTE 7: FAIR VALUE MEASUREMENTS

Financial assets and liabilities measured at fair value on a recurring basis are summarized below:

<i>(\$'s in thousands)</i>	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets				
Cash and cash equivalents	\$ 32,003	\$ —	\$ —	\$ 32,003
Total	\$ 32,003	\$ —	\$ —	\$ 32,003

<i>(\$'s in thousands)</i>	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets				
Cash and cash equivalents	\$ 49,081	\$ —	\$ —	\$ 49,081
Total	\$ 49,081	\$ —	\$ —	\$ 49,081

Placement Agent Warrants

Pursuant to the terms of the Company's Class A Preferred Stock offering (see Note 15), the Company was required to issue upon a Qualified Financing (an external financing of \$25.0 million or greater) warrants to the placement agent ("the Placement Agent Warrants") to purchase 5% of the shares of common stock into which the Class A Preferred Stock converts. This condition was met by the Company's IPO. The Placement Agent Warrants have a term of five years and are exercisable at a 15% discount to the Qualified Financing price. The Company valued the Placement Agent Warrants using a Monte Carlo simulation valuation methodology. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Journey's warrant liability that are categorized within Level 3 of the fair value hierarchy before the conversion was as follows:

Risk-free interest rate	0.98 %
Expected dividend yield	—
Expected term in years	1.0
Expected volatility	50 %

In connection with the Company's IPO, the Company issued 111,567 shares of common stock related to the conversion of all of the Placement Agent Warrants.

Contingent Payment Derivative

In connection with the DFD-29 Agreement, the Company agreed to pay DRL additional consideration upon either an IPO of the Company's common stock or an acquisition of the Company, the agreement further specifies that only one payment can be made. The contingent payment associated with an IPO of the Company's common stock, is deemed to be achieved if upon the completion of an IPO the Company's market capitalization on a fully diluted basis is \$150 million or greater at the close of business on the date of such IPO. The payment due for the achievement of the IPO criteria is as follows: (a) issue to DRL a number of shares of the Company's common stock equal to \$5.0 million as calculated using a fifteen (15) day volume weighted average price ("VWAP") of the Company's closing price, measured fifteen (15) days following the IPO; or (b) make a cash payment to DRL equal to \$5.0 million. As a result of the IPO on November 16, 2021, calculated using a 15-day VWAP of \$9.1721 per share, the Company issued 545,131 shares of Journey common stock to DRL in a transaction exempt from registration under the Securities Act. The restrictions on the shares of common stock issued in such transaction are governed by the terms set forth in the DFD-29 Agreement and applicable securities laws.

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The Company valued the contingent payment discussed above utilizing a Probability Weighted Expected Return Method (PWERM) model using a discount rate of 30% and expected term of 3 - 5 months.

The table below provides a roll-forward of the changes in fair value of Level 3 financial instruments as of December 31, 2022 and 2021:

<i>(Sin thousands)</i>	Warrant liabilities
Fair value at December 31, 2020	\$ —
Additions:	
Contingent payment warrant	3,819
Placement agent warrant (see note 15)	362
Change in fair value of warrant liabilities:	
Contingent payment warrant	(139)
Placement agent warrant	586
Settlement of warrant liabilities in connection with IPO:	
Conversion of contingent payment warrants to common shares	(3,680)
Conversion of placement agent warrants to common shares	(948)
Fair value at December 31, 2021	<u>\$ —</u>
Fair value at December 31, 2022	<u>\$ —</u>

During the years ended December 31, 2022 and 2021, no transfers occurred between Level 1, Level 2, and Level 3 instruments.

NOTE 8. RELATED PARTY AGREEMENTS

Shared Services Agreement with Fortress

On November 12, 2021, the Company and Fortress entered into an arrangement to share the cost of certain legal, finance, regulatory, and research and development employees. Fortress's Executive Chairman and Chief Executive Officer is the Executive Chairman of the Company. Under the terms of the Agreement, the Company will reimburse Fortress for the salary and benefit costs associated with these employees based upon actual hours worked on Journey related projects following the completion of their IPO. For the years ended December 31, 2022 and 2021, the Company incurred expenses to Fortress employees totaling \$0.1 million and \$0.6 million, respectively. Upon completion of the Company's IPO, the Company's outstanding balance owed to Fortress of \$0.5 million converted into 52,438 shares of Journey common stock at the IPO price of \$10.00 per share.

In the normal course of business, the Company reimburses Fortress for various payroll related costs and selling, general and administrative costs. As of December 31, 2022 and 2021, the Company had a balance of approximately \$0.4 million and \$0.6 million, respectively, recorded as due to related party on the consolidated balance sheets.

Fortress Note

From the Company's inception in October 2014 until the IPO, Fortress funded the Company's operations through the Fortress Note for a total of \$5.2 million.

On September 30, 2021, Fortress increased the Journey promissory note by \$9.5 million in response to a cyber incident that occurred at Journey and resulted in \$9.5 million of fraudulent payments being made by the Company. In lieu of repayment a \$9.5 million contribution was approved by the boards of directors of both the Fortress and Journey and was made with the purpose of ensuring that Journey's accounts payable function would continue to operate smoothly. This contribution, along with \$5.2 million already outstanding under the Fortress Note, was converted into 1,476,044 shares of the Company's common stock upon the closing of the Company's IPO at the IPO price of \$10.00 per share in full settlement of the amounts owed to Fortress.

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

NOTE 9. ACCRUED EXPENSES

Accrued expenses for the years ended December 31, 2022 and 2021 consisted of the following:

<i>(\$'s in thousands)</i>	December 31,	
	2022	2021
Accrued expenses and other short-term liabilities:		
Accrued coupons and rebates	\$ 7,604	\$ 10,603
Accrued compensation	2,586	2,702
Accrued royalties payable	2,627	3,833
Return reserve	3,689	3,240
Accrued Inventory	112	253
Accrued research and development	1,404	870
Accrued legal, accounting and tax	334	512
Accrued iPledge program	447	41
Accrued marketing and advertising	—	229
Other	585	450
Total accrued expenses	<u>\$ 19,388</u>	<u>\$ 22,733</u>

NOTE 10. INSTALLMENT PAYMENTS — LICENSES

The following tables show the details of the Company's installment payments – licenses for the years ended December 31, 2022 and 2021:

<i>(\$'s in thousands)</i>	December 31, 2022		
	Short-Term	Long-Term	Total
Installment payments - licenses	\$ 2,500	\$ 1,500	\$ 4,000
Less: imputed interest	(256)	(88)	(344)
Sub-total installment payments - licenses	<u>\$ 2,244</u>	<u>\$ 1,412</u>	<u>\$ 3,656</u>

<i>(\$'s in thousands)</i>	December 31, 2021		
	Short-Term	Long-Term	Total
Installment payments - licenses	\$ 5,000	\$ 4,000	\$ 9,000
Less: imputed interest	(490)	(373)	(863)
Sub-total installment payments - licenses	<u>\$ 4,510</u>	<u>\$ 3,627</u>	<u>\$ 8,137</u>

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

NOTE 11. OPERATING LEASE OBLIGATIONS

The Company leases 3,681 square feet of office space in Scottsdale, Arizona. The lease was set to expire on December 31, 2022. In September 2022, the Company amended the lease to extend the lease term for an additional 25 months at an annual rate of approximately \$0.1 million. The amended lease will expire on January 31, 2025.

The Company recorded rent expense as follows (dollars in thousands):

	For the Years Ended December 31,	
	2022	2021
Operating lease cost	\$ 93	\$ 89
Variable lease cost	4	4
Total lease cost	\$ 97	\$ 93

The following table summarizes quantitative information about the Company's operating leases (dollars in thousands):

	For the Years Ended December 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities	\$ 100	\$ 91
Right-of-use assets exchanged for new operating lease liabilities	\$ 188	\$ —
Weighted-average remaining lease term - operating leases	2.1	1.0
Weighted-average discount rate - operating leases	6.25 %	4.0 %

As of December 31, 2022, future payments of operating lease liabilities are as follows:

For the year ended December 31,	(\$'s in thousands)
2023	\$ 92
2024	102
2025	9
Total lease payments	203
Less: present value discount	(12)
Total operating lease liabilities	\$ 191

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

NOTE 12. DEBT

The Company's Debt obligations at December 31, 2022 and 2021 were as follows:

<i>(\$'s in thousands)</i>	December 31, 2022		
	Principal Balance	Unamortized Discount & Fees	Net Carry Amount
Deferred cash payment	\$ 5,000	\$ 9	\$ 4,991
EWB Revolving LOC	2,948	—	2,948
Total Short-Term Debt	\$ 7,948	\$ 9	\$ 7,939
EWB Term Loan (Long-term)	\$ 20,000	\$ 174	\$ 19,826
Total Debt & Obligations	\$ 27,948	\$ 183	\$ 27,765
December 31, 2021			
EWB Revolving LOC (Short-term)	\$ 812	\$ —	\$ 812

East West Bank Line of Credit and Long-Term Debt

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

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

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

NOTE 13. INTEREST EXPENSE AND FINANCING FEES

Interest expense and financing fees for the years ended December 31, 2022 and 2021 consisted of the following:

	Year Ended December 31,	
	2022	2021
Interest payments on EWB term loan and LOC	\$ 1,153	\$ —
Imputed Interest on acquired intangible assets	519	781
Amortization/Accretion	347	2,572
Interest and Fees on convertible preferred shares	—	2,845
Dividends payable on convertible preferred shares	—	820
EWB LOC Fees	—	16
Total Interest Expense and Financing Fees	\$ 2,019	\$ 7,034

NOTE 14. COMMITMENTS AND CONTINGENCIES*License Agreements*

The Company has undertaken to make contingent milestone payments to the licensors of its portfolio of drug products and candidates. In addition, the Company shall pay royalties to such licensors based on a percentage of net sales of each drug candidate following regulatory marketing approval. For additional information on future milestone payments and royalties, see Note 4 and Note 5.

NOTE 15. STOCKHOLDERS' EQUITY AND CLASS A PREFERRED STOCK*Common Stock*

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 50,000,000 shares of \$0.0001 par value Common Stock of which 6,000,000 shares are designated and authorized as Class A Common Stock.

Voting Rights

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

Each holder of Class A Common Stock is entitled to a number of votes that is equal to 1.1 times a fraction, the numerator of which is the sum of the shares of outstanding Common Stock, including the Class A Common Stock and the denominator of which is the number of outstanding shares of Class A Common Stock. Thus, the holders of the Class A Common Stock will at all times constitute a voting majority.

Dividends

The holders of the Company's outstanding shares of Common Stock and Class A Common Stock are entitled to receive dividends, if any, as may be declared from time to time by the Company's Board of Directors out of legally available funds.

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

Liquidation

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

Rights and Preference

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

On November 16, 2021, the Company completed an IPO of its common stock and issued 3,520,000 shares of its common stock at \$10.00 per share, which resulted in net proceeds of approximately \$30.6 million, after deducting underwriting discounts and other offering costs. In addition, as a result of the IPO, the Company issued shares of its Common stock based on the following.

8% Cumulative Convertible Class A Preferred Offering

In March 2021, the Company commenced an offering of 8% Cumulative Convertible Class A Preferred Stock ("Class A Preferred Offering"). The Class A Preferred Offering terminated on July 18, 2021 and raised gross proceeds of \$19 million. The Class A Preferred Stock automatically converts into the Company's Common Stock upon a sale of the Company or a financing in an amount of at least \$25.0 million within a year of the closing date of the Class A Preferred Offering (extendable by another six months at the Company's option) at a discount of 15% to the per share qualified stock price. In the event that neither a sale of the Company nor a \$25.0 million financing was completed, the Class A Preferred Stock was to be exchanged for shares of Fortress common stock, at a 7.5% discount to the average Fortress common stock trading price over the 10-day period preceding such exchange.

The Company issued an aggregate of 758,680 Class A Preferred shares at a price of \$25.00 per share, for gross proceeds of \$19.0 million. Following the payment of placement agent fees of \$1.9 million, and other expenses of \$0.1 million, the Company received \$17.0 million of net proceeds. In connection with the Company's IPO, the company issued 2,231,346 shares of common stock resulting from the conversion of all of the Class A Preferred Stock.

NOTE 16. SHARE-BASED COMPENSATION

In 2015, the Company's Board of Directors adopted, and stockholders approved, the Journey Medical Corporation 2015 Stock Plan (the "Plan") authorizing the Company to grant up to 4,642,857 shares of Common Stock to eligible employees, directors, and consultants in the form of restricted stock, restricted stock units ("RSUs"), stock options and other types of grants. The amount, terms, and exercisability provisions of grants are determined by the Board of Directors. At the Company's 2022 Annual Meeting, held on June 21, 2022, the Company's stockholders approved, among other matters, an amendment to the Plan to increase the number of shares of Common Stock issuable under the Plan by 3,000,000 to 7,642,857. At December 31, 2022 there were 1,146,620 shares available for issuance under the Plan.

The Company grants stock options to employees, non-employees and Directors with exercise prices equal to the closing price of the underlying shares of the Company's common stock on the Nasdaq Capital Market on the date that the options are granted. Options granted have a term of ten years from the grant date. Options granted generally vest over four-year period. Compensation cost for stock options is charged against operations on a straight-line basis over the vesting period. The Company estimates the fair value of stock options on the grant date by applying the Black-Scholes option pricing valuation model.

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

Total compensation cost charged against operations related to the above plan for the years ended December 31, 2022 and 2021 was \$4.4 million and \$2.5 million, respectively. The following table summarizes the components of share-based compensation expense in the consolidated statements of operations for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
<i>(\$'s in thousands)</i>		
Research and development	\$ 73	\$ —
Selling, general and administrative	4,352	2,466
Total non-cash compensation expense related to share-based compensation included in operating expense	<u>\$ 4,425</u>	<u>\$ 2,466</u>

Stock Options

The weighted-average key assumptions used in determining the fair value of options granted for the year ended December 31, 2022 are as follows:

	2022
Risk-free interest rate	2.89% - 4.20%
Expected volatility	80.25% - 86.18%
Weighted average expected volatility	85.45%
Expected term (years)	5.60 - 6.35
Expected dividend yield	0%

The weighted average grant-date fair value of stock options issued during the year ended December 31, 2022 was \$3.67 per share. The Company did not grant any stock options during the year ended December 31, 2021.

The following table summarizes the Company's stock option activity for the year ended December 31, 2022:

	Number of Shares	Weighted average exercise price	Aggregate intrinsic value	Weighted average remaining contractual life (years)
Outstanding options at December 31, 2021	2,104,334	\$ 0.79	\$ 9,661,393	4.68
Granted	1,149,000	3.59	—	9.53
Exercised	(155,649)	1.01	141,019	—
Forfeited	(105,500)	3.20	9,805	—
Expired	(32,185)	1.39	17,058	—
Outstanding options at December 31, 2022	<u>2,960,000</u>	<u>\$ 1.76</u>	<u>\$ 2,217,815</u>	<u>5.65</u>
Options vested and exercisable at December 31, 2022	<u>1,897,500</u>	<u>\$ 0.76</u>	<u>\$ 2,209,600</u>	<u>3.50</u>

For the years ended December 31, 2022 and 2021, the Company issued 155,649 and 10,000 shares, respectively, of Common Stock upon the exercise of outstanding stock options and received proceeds of \$142,330 and \$6,800, respectively. For the years ended December 31, 2022 and 2021, approximately \$0.8 million and \$51,669, respectively, of stock option compensation cost was charged against operations. At December 31, 2022, the Company had unrecognized share-based compensation expense related to all unvested options of \$2.0 million, which the Company expects to recognize over a weighted-average period of approximately 2.4 years.

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

Restricted Stock Units

The following table summarizes the Company's RSU activity for the year ended December 31, 2022:

	Number of units	Weighted average grant date Fair value
Unvested balance at December 31, 2021	715,030	\$ 4.12
Granted	1,907,225	4.10
Vested	(293,707)	4.33
Forfeited	(67,500)	4.80
Unvested balance at December 31, 2022	2,261,048	\$ 4.05

For the years ended December 31, 2022 and 2021 the Company issued 293,707 and 136,500 shares of Common Stock, respectively, upon the vesting of RSU's amounting to \$0.9 million and \$1.4 million, respectively, in total aggregate fair market value. For the years ended December 31, 2022 and 2021, approximately \$3.6 million and \$2.5 million, respectively, of RSU compensation cost was charged against operations. The \$2.5 million of RSU compensation cost that was charged against operations for the year ended December 31, 2021 includes \$2.4 million of RSU compensation cost related to RSU's that fully vested upon the Company's IPO on November 12, 2021. At December 31, 2022 approximately 2,261,048 of RSU's remained unvested and there was approximately \$4.8 million of unrecognized compensation cost related to RSUs, which the Company expects to recognize over a weighted-average period of approximately 1.9 years.

NOTE 17. REVENUES FROM CONTRACTS WITH CUSTOMERS

Disaggregation of Net Revenues

The Company has the following actively marketed products, Qbrexza®, Amzeeq®, Zilxi®, Accutane®, Ximino®, Exelderm®, and Targadox®. All of the Company's product revenues are recorded in the U.S.

Revenues by product are summarized as follows:

<i>(\$ in thousands)</i>	Year Ended December 31,	
	2022	2021
Qbrexza®	\$ 26,715	\$ 17,056
Accutane®	18,373	10,053
Targadox®	7,972	22,378
Amzeeq®	7,242	—
Ximino®	4,957	8,247
Zilxi®	2,273	—
Exelderm®	3,463	5,363
Other branded revenue	—	37
Total product revenues	\$ 70,995	\$ 63,134

The Company recognized other revenue as follows:

<i>(\$ in thousands)</i>	Year Ended December 31,	
	2022	2021
Other revenue	\$ 2,674	\$ —
Total other revenue	\$ 2,674	\$ —

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

Other revenue for the year ended December 31, 2022 included a net \$2.5 million milestone payment from Maruho Co., Ltd, upon receipt of marketing and manufacturing approval for Rapifort® Wipes 2.5% (Qbrexza®), as well as \$0.2 million in royalties from Maruho on sales of Rapifort® Wipes 2.5% in Japan.

Significant Customers

As of December 31, 2022, two of the Company's customers accounted for more than 10% of its total accounts receivable balance at 16.7% and 10.4%. As of December 31, 2021, two of the Company's customers accounted for more than 10% of its total accounts receivable balance at 16.3% and 12.9%.

For the year ended December 31, 2022 and 2021, none of the Company's customers accounted for more than 10% of its total gross product revenue.

NOTE 18. INCOME TAXES

The components of the income tax provision are as follows:

<i>(\$'s in thousands)</i>	Years Ended December 31,	
	2022	2021
Current:		
Federal	\$ —	\$ —
State	63	67
Total current	63	67
Deferred:		
Federal	(6,701)	(7,829)
State	(1,737)	(1,474)
Total deferred	(8,438)	(9,303)
Valuation allowance	8,438	10,870
Total income tax expense	\$ 63	\$ 1,634

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

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

The significant components of the Company's deferred tax assets consisted of the following:

<i>(\$'s in thousands)</i>	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 6,553	\$ 3,113
Amortization of license fees	4,951	4,760
R&D capitalization	2,462	—
Stock compensation	1,293	667
Lease liability	48	25
Reserve on sales return, discount and bad debt	2,988	3,573
Accruals and reserves	574	505
Tax credits	1,152	193
Business interest expense deduction limit	322	41
State taxes	13	12
Total deferred tax assets	20,356	12,889
Less: valuation allowance	(19,307)	(10,870)
Deferred tax assets, net	\$ 1,049	\$ 2,019
Deferred tax liability:		
Section 481(a) adjustment on reserve on sales return, discount and bad debt	(1,001)	(1,996)
Right-of-use asset	(48)	(23)
Deferred tax assets, net	\$ —	\$ —

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

	Years Ended December 31,	
	2022	2021
Percentage of pre-tax income:		
U.S. federal statutory income tax rate	21 %	21 %
State taxes, net of federal benefit	4 %	4 %
Non-deductible items	(0)%	(5)%
Provision to return	0 %	0 %
Change in state rate	0 %	0 %
Change in valuation allowance	(28)%	(26)%
Other	3 %	2 %
Effective income tax rate	(0)%	(4)%

The Company has incurred NOLs in previous years. As of December 31, 2022, the Company had total federal NOLs of approximately \$7.0 million, of which \$7.6 million is subject to expiration and will begin to expire in the year 2033, total state NOLs of \$1.7 million, of which \$4.7 million is subject to expiration and will begin to expire in the year 2026, and federal income tax credits of \$1.2 million, which will begin to expire in 2031. Approximately \$19.4 million of the federal NOLs and \$12.3 million of the state NOLs can be carried forward indefinitely. The utilization of the Company's NOLs are subject to annual Internal Revenue Code Section 382 limitations (382 Limitations). Based on the analysis of the NOLs carryovers subject to the 382 Limitations, the Company has concluded that the 382 Limitations would not prevent the Company from utilizing all of its NOLs carryovers before expiration.

The Company is subject to U.S. federal and various state taxes. As of December 31, 2022, the earliest federal tax year open for the assessment of income taxes under the applicable statutes of limitations is its 2019 tax year. The expiration of the statute of limitations related to the various state income and franchise tax returns varies by state.

JOURNEY MEDICAL CORPORATION
Notes to Financial Statements

NOTE 19. NET (LOSS) INCOME PER COMMON SHARE

The Company accounts for and discloses net earnings (loss) per share using the treasury stock method. Net earnings (loss) per common share, or basic earnings (loss) per share, is computed by dividing net earnings (loss) by the weighted-average number of common shares outstanding. Net earnings (loss) per common share assuming dilutions, or diluted earnings (loss) per share, is computed by reflecting the potential dilution from the exercise of in-the-money stock options, and non-vested restricted stock units.

The Company's basic and diluted weighted-average number of common shares outstanding for years ended December 31, 2022 and 2021 were as follows:

	Year ended December 31,	
	2022	2021
Basic	17,531,274	10,189,844
Common stock equivalents:		
Unvested restricted stock units	2,261,048	715,030
Stock Options	1,566,131	1,879,378
Diluted	21,358,453	12,784,252

The Company's Common Stock equivalents, including unvested restricted stock and options have been excluded from the computation of diluted loss per share for the years ended December 31, 2022 and 2021, as the effect would be to reduce the loss per share. Therefore, the weighted average Common Stock outstanding used to calculate both basic and diluted income loss per share is the same for the years ended December 31, 2022 and 2021.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Journey Medical Corporation

By: /s/ Claude Maraoui

Name: Claude Maraoui

Title: President, Chief Executive Officer, and Director

March 30, 2023

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Claude Maraoui</u> Claude Maraoui	President, Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2023
<u>/s/ Lindsay A. Rosenwald, M.D.</u> Lindsay A. Rosenwald, M.D.	Executive Chairman	March 30, 2023
<u>/s/ Joseph Benesch</u> Joseph Benesch	Interim Chief Financial Officer (Principal Financial Officer)	March 30, 2023
<u>/s/ Neil Herskowitz</u> Neil Herskowitz	Director	March 30, 2023
<u>/s/ Jeff Paley, M.D.</u> Jeff Paley, M.D.	Director	March 30, 2023
<u>/s/ Justin Smith</u> Justin Smith	Director	March 30, 2023
<u>/s/ Miranda Toledano</u> Miranda Toledano	Director	March 30, 2023

JOURNEY MEDICAL CORPORATION

List of Subsidiaries

Subsidiaries of Journey Medical Corporation at December 31, 2022, with jurisdiction of incorporation or formation:

- JG Pharma Inc. (Delaware)
-

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (No. 333-263888 and 333-266125) on Form S-8 and (No. 333-269079) on Form S-3 of our report dated March 30, 2023, with respect to the consolidated financial statements of Journey Medical Corporation.

/s/ KPMG LLP

Short Hills, New Jersey
March 30, 2023

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

I, Claude Maraoui certify that:

- (1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 of Journey Medical Corporation. (the registrant);
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 30, 2023

By: /s/ Claude Maraoui
Claude Maraoui
President, Chief Executive Officer and Director
Principal Executive Officer

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

I, Joseph Benesch, certify that:

- (1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 of Journey Medical Corporation (the registrant);
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
- (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- (d) disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 30, 2023

By: /s/ Joseph Benesch
Joseph Benesch
Interim Chief Financial Officer
Principal Financial Officer

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

In connection with the Annual Report on Form 10-K of Journey Medical Corporation (the “Company”) for the period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Claude Maraoui, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

Dated: March 30, 2023

By: /s/ Claude Maraoui
Claude Maraoui
President, Chief Executive Officer and Director
Principal Executive Officer

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

In connection with the Annual Report on Form 10-K of Journey Medical Corporation (the “Company”) for the period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Joseph Benesch, Principal Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company, as of, and for, the periods presented in the Report.

Dated: March 30, 2023

By: /s/ Joseph Benesch
Joseph Benesch
Interim Chief Financial Officer
Principal Financial Officer
