

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

**FORM 10-Q**  
(Mark one)

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

**For the quarterly period ended September 30, 2021**

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)

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

**9237 E Via de Ventura Blvd., Suite 105, Scottsdale, AZ 85258**  
(Address of principal executive offices and zip code)

**(480) 434-6670**  
(Registrant's telephone number, including area code)

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

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, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES  NO

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

Large Accelerated Filer	<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 registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

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 December 15, 2021
Common Stock A, \$0.0001 par value	6,000,000
Common Stock, \$0.0001 par value	10,659,646

**JOURNEY MEDICAL CORPORATION**  
**Quarterly Report on Form 10-Q**

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## SUMMARY OF RISK FACTORS

Our business is subject to a number of risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. These risks are more fully described in the section titled “Risk Factors” of this quarterly report on Form 10-Q. Please read the information in the section entitled “Risk Factors,” for a more thorough description of these and other risks.

### **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.
- 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. Two of our marketed products, Qbrexza 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.
- 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.
- If our products do not achieve broad market acceptance, including by government and third-party payors, the revenues from any such product will likely be limited.

### **Risks Related to Our Reliance on Third Parties**

- We rely on third parties for our several aspects of our operations, which limits our control over product development, marketing, 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 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.
- 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 CROs (including, in the context of DFD-29, our licensor/seller Dr. Reddy’s laboratories) 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.
- We may be required to expend substantial resources relating to litigation for infringement of third-party intellectual property rights or enforcing our or our licensors' patents.
- 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). For example, Perrigo filed a Paragraph IV certification pertaining to the patents covering Qbrexza, which ultimately led to a district court patent litigation.
- 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.
- 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. Two of our marketed products, Qbrexza 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 AB rated products. Targadox will likely face additional AB rated generic entrants over the next six months. Exelderm may face AB rated generic competition in the future.

**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

**Risks Related to the COVID-19 Pandemic**

- Major public health issues, and specifically the pandemic caused by the COVID-19 outbreak, could have an adverse effect on our product revenues and any future clinical trials.

**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 controls a voting majority of our common stock, through its ownership of our Class A 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. FINANCIAL INFORMATION**

**Item 1. Unaudited Condensed Consolidated Financial Statements**

**JOURNEY MEDICAL CORPORATION**  
**Unaudited Condensed Consolidated Balance Sheets**  
(\$ in thousands except for share and per share amounts)

	September 30, 2021	December 31, 2020
<b>ASSETS</b>		
Current Assets		
Cash	21,689	8,246
Accounts receivable, net	31,738	23,928
Inventory	11,614	1,404
Prepaid expenses and other current assets	1,754	1,664
Total current assets	<u>66,795</u>	<u>35,242</u>
Intangible asset, net	13,043	15,029
Operating lease right-of-use asset, net	111	175
Deferred tax assets	8,361	1,454
Other assets	749	6
<b>Total assets</b>	<b><u>\$ 89,059</u></b>	<b><u>\$ 51,906</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities		
Accounts payable	\$ 28,180	\$ 1,839
Accounts payable - related party	600	117
Accrued expenses	26,048	21,498
Accrued expenses – related party	433	—
Installment payments – licenses, short-term (net of debt discount of \$ 567 and \$778 as of September 30, 2021 and December 31, 2020, respectively)	4,433	4,522
Operating lease liabilities, short-term	96	85
Total current liabilities	<u>59,790</u>	<u>28,061</u>
Income tax payable	—	99
Note payable, related party	14,972	5,220
Installment payments – licenses, long-term (net of debt discount of \$461 and \$863 as of September 30, 2021 and December 31, 2020, respectively)	3,539	8,137
Derivative warrant liability	4,365	—
Convertible class A preferred stock settled note (net of debt discount of \$ 1,923 as of September 30, 2021)	18,078	—
Operating lease liabilities, long-term	24	97
<b>Total liabilities</b>	<b><u>100,768</u></b>	<b><u>41,614</u></b>
<b>Commitments and contingencies (Note 14)</b>		
<b>Stockholders' equity (deficit)</b>		
Common stock, \$.0001 par value, 50,000,000 shares authorized, 3,161,333 and 3,151,333 shares issued and outstanding as of September 30, 2021, and December 31, 2020, respectively	—	—
Common stock - Class A, \$.0001 par value, 50,000,000 shares authorized, 6,000,000 shares issued and outstanding as of September 30, 2021, and December 31, 2020	1	1
Additional paid-in capital	5,413	5,171
(Accumulated deficit) retained earnings	(17,123)	5,120
Total stockholders' (deficit) equity	<u>(11,709)</u>	<u>10,292</u>
<b>Total liabilities and stockholders' equity</b>	<b><u>\$ 89,059</u></b>	<b><u>\$ 51,906</u></b>

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

**JOURNEY MEDICAL CORPORATION**  
**Unaudited Condensed Consolidated Statements of Operations**  
(\$ in thousands except for share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Product revenue, net</b>	\$ 19,610	\$ 9,447	\$ 45,617	\$ 30,808
<b>Operating expenses</b>				
Cost of goods sold - product revenue	11,167	3,379	22,559	10,313
Research and development	718	—	747	—
Research and development - licenses acquired	76	—	13,819	—
Selling, general and administrative	10,755	5,829	24,776	16,270
Wire transfer fraud loss	9,540	—	9,540	—
Total operating expenses	32,256	9,208	71,441	26,583
(Loss) income from operations	(12,646)	239	(25,824)	4,225
Other expense				
Interest expense	1,373	187	2,936	492
Change in fair value of derivative liability	2	—	184	—
Total other expense	1,375	187	3,120	492
<b>Net (loss) income before income taxes</b>	<b>(14,021)</b>	<b>52</b>	<b>(28,944)</b>	<b>3,733</b>
Income tax (benefit) expense	(3,375)	23	(6,701)	952
<b>Net (loss) income</b>	<b>\$ (10,646)</b>	<b>\$ 29</b>	<b>\$ (22,243)</b>	<b>\$ 2,781</b>
Net (loss) income per common share - basic	\$ (1.16)	\$ 0.00	\$ (2.43)	\$ 0.30
Net (loss) income per common share - diluted	\$ (1.16)	\$ 0.00	\$ (2.43)	\$ 0.26
Weighted average common shares outstanding - basic	9,161,333	9,133,333	9,160,344	9,133,333
Weighted average common shares outstanding - diluted	9,161,333	10,800,475	9,160,344	10,817,678

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

**JOURNEY MEDICAL CORPORATION**  
**Unaudited Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit)**  
(\$ in thousands except for share amounts)

	Common Stock		Common Stock A		Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
<b>Balance as of June 30, 2021</b>	<b>3,161,333</b>	<b>\$ —</b>	<b>6,000,000</b>	<b>\$ 1</b>	<b>\$ 5,684</b>	<b>\$ (6,477)</b>	<b>\$ (792)</b>
Stock-based compensation expense	—	—	—	—	8	—	8
Distribution of capital – extinguishment of related party payable	—	—	—	—	(279)	—	(279)
Net loss	—	—	—	—	—	(10,646)	(10,646)
<b>Balance as of September 30, 2021</b>	<b>3,161,333</b>	<b>\$ —</b>	<b>6,000,000</b>	<b>\$ 1</b>	<b>\$ 5,413</b>	<b>\$ (17,123)</b>	<b>\$ (11,709)</b>

	Common Stock		Common Stock A		Paid-In Capital	Retained Earnings	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
<b>Balance as of June 30, 2020</b>	<b>3,133,333</b>	<b>\$ —</b>	<b>6,000,000</b>	<b>\$ 1</b>	<b>\$ 3,867</b>	<b>\$ 2,589</b>	<b>\$ 6,457</b>
Stock-based compensation expense	—	—	—	—	32	—	32
Contribution of capital – extinguishment of related party payable	—	—	—	—	305	—	305
Net income	—	—	—	—	—	29	29
<b>Balance as of September 30, 2020</b>	<b>3,133,333</b>	<b>\$ —</b>	<b>6,000,000</b>	<b>\$ 1</b>	<b>\$ 4,204</b>	<b>\$ 2,618</b>	<b>\$ 6,823</b>

	Common Stock		Common Stock A		Paid-In Capital	Retained Earnings (Accumulated) Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
<b>Balance as of December 31, 2020</b>	<b>3,151,333</b>	<b>\$ —</b>	<b>6,000,000</b>	<b>\$ 1</b>	<b>\$ 5,171</b>	<b>\$ 5,120</b>	<b>\$ 10,292</b>
Stock-based compensation expense	—	—	—	—	41	—	41
Exercise of stock options for cash	10,000	—	—	—	7	—	7
Contribution of capital – extinguishment of related party payable	—	—	—	—	194	—	194
Net loss	—	—	—	—	—	(22,243)	(22,243)
<b>Balance as of September 30, 2021</b>	<b>3,161,333</b>	<b>\$ —</b>	<b>6,000,000</b>	<b>\$ 1</b>	<b>\$ 5,413</b>	<b>\$ (17,123)</b>	<b>\$ (11,709)</b>

	Common Stock		Common Stock A		Paid-In Capital	Retained Earnings (Accumulated) Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
<b>Balance as of December 31, 2019</b>	<b>3,133,333</b>	<b>\$ —</b>	<b>6,000,000</b>	<b>\$ 1</b>	<b>\$ 2,914</b>	<b>\$ (163)</b>	<b>\$ 2,752</b>
Stock-based compensation expense	—	—	—	—	131	—	131
Contribution of capital – extinguishment of related party payable	—	—	—	—	1,159	—	1,159
Net income	—	—	—	—	—	2,781	2,781
<b>Balance as of September 30, 2020</b>	<b>3,133,333</b>	<b>\$ —</b>	<b>6,000,000</b>	<b>\$ 1</b>	<b>\$ 4,204</b>	<b>\$ 2,618</b>	<b>\$ 6,823</b>



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

**JOURNEY MEDICAL CORPORATION**  
**Unaudited Condensed Consolidated Statements of Cash Flows**  
(\$ in thousands)

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash Flows from Operating Activities:</b>		
Net (loss) income	\$ (22,243)	\$ 2,781
<b>Reconciliation of net loss to net cash provided by operating activities:</b>		
Depreciation expense	—	4
Bad debt (reserve) expense	(67)	47
Amortization of debt discount	648	—
Accretion of convertible preferred shares	1,034	—
Non-cash interest	616	492
Extinguishment of related party income tax payable	—	908
Amortization of product revenue license fee	1,983	1,065
Amortization of operating lease right-of-use assets	64	68
Stock-based compensation expense	41	131
Change in fair value of derivative liability	184	—
Deferred taxes (benefit) provision	(6,701)	44
Research and development-licenses acquired, expense	13,819	—
<b>Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:</b>		
Accounts receivable	(7,743)	(2,205)
Inventory	(10,210)	(195)
Income tax payable	(99)	(14)
Prepaid expenses and other current assets	174	353
Other assets	(743)	(200)
Accounts payable	25,852	5,961
Accounts payable, related party	695	42
Accrued expenses	3,350	(9,136)
Accrued expenses, related party	433	—
Lease liabilities	(62)	(68)
Net cash provided by operating activities	<u>1,025</u>	<u>78</u>
<b>Cash Flows from Investing Activities:</b>		
Purchase of research and development licenses	(8,800)	(1,000)
Net cash used in investing activities	<u>(8,800)</u>	<u>(1,000)</u>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from the exercise of stock options	7	—
Proceeds from Fortress note	9,540	—
Payment of license note payable	(5,300)	—
Proceeds from convertible preferred shares	18,967	—
Payment of debt issuance costs associated with convertible preferred shares	(1,996)	—
Net cash provided by financing activities	<u>21,218</u>	<u>—</u>
Net increase (decrease) in cash	13,443	(922)
Cash at beginning of period	8,246	4,801
<b>Cash at end of period</b>	<u>\$ 21,689</u>	<u>\$ 3,879</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for income taxes	\$ 157	\$ 98
<b>Supplemental disclosure of non-cash financing and investing activities:</b>		
Unpaid debt offering cost	\$ 214	\$ —
Unpaid deferred offering cost	\$ 264	\$ —
Derivative warrant liability associated with convertible preferred shares	\$ 362	\$ —
Extinguishment of related party payable relates to deferred tax assets	\$ 194	\$ 251
Unpaid intangible assets	\$ —	\$ 3,727

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

**JOURNEY MEDICAL CORPORATION**  
**Notes to Unaudited Condensed Consolidated Financial Statements**

**NOTE 1. ORGANIZATION AND PLAN OF BUSINESS OPERATIONS**

Journey Medical Corporation (collectively “Journey” or the “Company”) was formed on July 18, 2014. 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 current product portfolio includes five branded and three authorized generic prescription drugs for dermatological conditions that are marketed in the U.S. The Company acquires 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 their exclusive field sales organization.

As of September 30, 2021 and December 31, 2020, the Company is a majority-owned subsidiary of Fortress Biotech, Inc. (“Fortress” or “Parent”).

***Liquidity and Capital Resources***

Since inception, the Company’s operations have been financed primarily through a working capital note from Fortress, cash received from customers and proceeds from the Company’s 8% Cumulative Convertible Class A Preferred Offering. For the next twelve months from the issuance of these unaudited interim condensed consolidated financial statements the Company will be able to fund its operations through a combination of its operating activities and the East West Bank Working Line of Credit of \$7.5 million, see Note 12.

On November 16, 2021, the Company completed an initial public offering (collectively the “Journey IPO” or “IPO”) of its common stock, which resulted in net proceeds of approximately \$31.2 million, after deducting underwriting discounts and other offering costs.

The Company regularly evaluates market conditions, its liquidity profile, and various financing alternatives for opportunities to enhance its capital structure. The Company may seek to raise capital through debt or equity financings to expand its product portfolio. If such funding is not available or not available on terms acceptable to the Company, the Company’s current plans for expansion of its product portfolio will be curtailed.

In addition to the foregoing, the Company experienced minimal impact on revenue levels and its liquidity due to the worldwide spread of COVID-19.

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

***Basis of Presentation and Principles of Consolidation***

The accompanying unaudited interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. Certain information and footnote disclosures normally included in the Company’s annual consolidated financial statements prepared in accordance with GAAP have been condensed or omitted. These unaudited interim condensed consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period. The Company’s unaudited interim condensed 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 upon completion of a public offering would meet the definition of an emerging growth company and would elect 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 unaudited condensed 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 product returns, coupons, rebates, chargebacks, discounts, allowances and distribution fees paid to certain wholesalers, inventory realization and useful lives of amortizable intangible assets. 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.

### ***Cash***

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash at September 30, 2021 and December 31, 2020 consisted entirely of cash in institutions in the United States. Balances at certain institutions have exceeded Federal Deposit Insurance Corporation insured limits.

### ***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 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 16 for significant customers.

### ***Revenue Recognition***

The Company records revenue in accordance with the provisions of Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers* (“ASC 606”). The core principle of this revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The 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 trade discounts, rebates, coupons and right of return. Revenues are recorded net of provisions for variable consideration, including discounts, rebates, governmental rebate programs, price adjustments, returns, chargebacks, promotional programs and other sales allowances. Accruals for these provisions are presented in the unaudited interim condensed consolidated financial statements as reductions in determining net sales and as a contra asset in 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.

*Trade Discounts and Other Sales Allowances*— The Company provides trade discounts and allowances to its wholesale customers for sales order management, data, and distribution services. The Company also provides for prompt pay discounts if payment is received within the payment term days which generally range from 30 to 75 days. These discounts and allowances have been recorded as a reduction of revenue and a reduction to accounts receivables.

*Product Returns* — Consistent with industry practice, the Company offers customers a right to return any unused product and such 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 price less 5%. The Company estimates the amount of its product sales that may be returned by its customers and accrues this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return reserves using available industry data and its own sales information, including its visibility and estimates into the inventory remaining in the distribution channel.

The Company currently estimates products returns to be approximately 3% of gross sales to the wholesalers. The 3% rate is estimated by using both historical and industry data. On a quarterly basis, the Company monitors products returns and will adjust this percentage if needed. The Company does not estimate returns for sales made to the specialty pharmacies as their historical ordering pattern is approximately every two weeks and as such, inventory turns every two weeks.

*Government Chargebacks* — Chargebacks for fees and discounts to indirect qualified government healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified U.S. Department of Veterans Affairs hospitals and 340B entities at prices lower than the list prices charged to customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the statutory selling price to the qualified government entity. These allowances are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivables, net. The chargeback amount from the Company’s direct customer is generally determined at the time of their resale to the qualified government healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of its direct customers’ resale to the qualified government healthcare provider, and the Company generally issues credits for such amounts within a few weeks of its direct customer’s notification to the Company of the resale. The allowance for chargebacks is based on expected sell-through levels by the Company’s direct customers to indirect customers, as well as estimated wholesaler inventory levels.

*Government Rebates* — The Company is subject to discount obligations under state Medicaid programs and Medicare. These accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. For Medicaid programs, the Company estimates the portion of sales attributed to Medicaid patients and records a liability for the rebates to be paid to the respective state Medicaid programs. The Company’s liability for these rebates consists of invoices received for: claims from prior quarters that have not been paid or for which an invoice has not yet been received; estimates of claims for the

current quarter; and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

*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. Approximately 85% of the Company's product revenues are sold through the specialty pharmacy channel, which has a shorter cycle from the Company's sales date to the fulfillment of the prescription by the specialty pharmacy customer, resulting in less inventory in this channel. Coupons are processed and redeemed at the time of prescription fulfillment by the pharmacy, and the Company is charged for the coupons redeemed monthly. The majority of coupon liability at the end of the period represents coupons that have been redeemed and for which the Company has been billed, and an accrual for expected redemptions for product in the distribution channel. This element of the liability requires the Company to estimate the distribution channel inventory at period end, the expected redemption rates, and the cost per coupon claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel at the end of each reporting period. The estimate of product remaining in the distribution channel is comprised of actual inventory at the wholesaler as well as an estimate of inventory at the specialty pharmacies, which the Company estimates based upon historical ordering patterns, which consist of reordering approximately every two weeks. 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.

*Managed Care Rebates* — The Company offers managed care rebates to certain providers. The Company calculates rebate payment amounts due under this program based on actual qualifying products and applies a contractual discount rate. The accrual is based on an estimate of claims that the Company expects to receive and inventory in the distribution channel. The accrual is recognized at the time of sale, resulting in a reduction of product revenue.

#### ***Accounts Receivable***

Accounts receivable consists of amounts due to the Company for product sales. The Company's accounts receivable reflects discounts for estimated early payment. Accounts receivable are stated at amounts due from customers, net of an allowance for doubtful accounts. Accounts that are outstanding longer than the contractual payment terms are considered past due. The Company determines its allowance for doubtful accounts by considering a number of factors, including the length of time trade accounts receivable are past due and the customer's current ability to pay its obligation to the Company. The Company writes off accounts receivable when they become uncollectible. The allowance for doubtful accounts was \$0.1 million at both September 30, 2021 and December 31, 2020.

#### ***Inventories***

Inventories comprise raw materials and finished goods, which are valued at the lower of cost and net realizable value, on a first-in, first-out basis. The Company evaluates the carrying value of inventories on a regular basis, taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand. The acquired Qbrezxa finished goods inventory includes a fair value step-up of \$6.5 million, which will be expensed within cost of sales, as the inventory is sold to customers. All of the step-up finished goods inventory is expected to be sold in 2021. The Qbrezxa finished goods inventory fair value step-up expensed as a component of cost of goods sold for the three and nine months ended September 30, 2021, was \$3.0 million and \$4.2 million, 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.

### ***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 primarily using the straight-line method.

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

### ***Impairment of Long-Lived Assets***

The Company reviews long-lived assets, including property and equipment, for impairment at least annually or whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. 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.

### ***Leases***

Effective January 1, 2019, the Company accounts for its leases under ASC 842, *Leases*. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the consolidated balance sheet as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line rent expense over the lease term. 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.

### ***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.

### ***Stock-based Compensation***

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards and actual forfeitures.

The fair value of the Company's common stock underlying the stock options is also an input to the Black-Scholes option pricing model. The Company engages 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.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, which requires the use of a number of 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 stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. Forfeitures are recorded as they occur. All stock-based compensation costs are recorded in selling, general and administrative ("SG&A") expense in the unaudited condensed consolidated statements of operations.

#### ***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, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations.

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.

#### ***Allocated Parent Cost***

Certain Parent costs associated with the activities of the Company have been allocated. The expense allocations to Journey are employee and stock-based compensation for finance and accounting services provided to the Company based on time spent on Journey projects. The allocations were based on assumptions that management believes are reasonable. For the three months ended September 30, 2021 and 2020, the allocated expenses were approximately \$0.2 million and nil, respectively, and were recorded to selling, general and administration expenses. For the nine months ended September 30, 2021 and 2020, the allocated expenses were approximately \$0.4 million and nil, respectively, and were recorded to selling, general and administration expenses.

#### ***Income Taxes***

As of September 30, 2021 and December 31, 2020, the Company is included in the Fortress consolidated federal tax return and consolidated or combined state tax returns in multiple jurisdictions. The Company's unaudited interim condensed consolidated financial statements recognize the current and deferred income tax consequences that result from the Company's activities during the current and preceding periods pursuant to the provisions of ASC Topic 740, *Income Taxes*, as if the Company were a separate taxpayer rather than a member of the Fortress consolidated income tax return group. Fortress has agreed that the Company does not have to make payments to Fortress for the Company's use of net operating losses ("NOLs") of Fortress (including other Fortress group members) alternatively any Company NOLs will accrue to the benefit of Fortress. Since Fortress does not require the Company to pay in any form for the utilization of the consolidated group's NOLs, the tax benefit the Company realizes has been recorded as a capital contribution and any Company NOLs accrued to Fortress' benefit would be a deemed dividend.

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 management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. Management has considered the Company's history of cumulative tax and book income incurred since inception, and the other positive and negative evidence, and has concluded that it is more likely than not that the Company will realize the benefits of the net deferred tax assets as of September 30, 2021 and December 31, 2020.

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. As of September 30, 2021 and December 31, 2020, the Company had no unrecognized tax benefits and does not anticipate any significant change to the unrecognized tax benefit balance. The Company would classify interest and penalties related to uncertain tax positions as income tax expense, if applicable. There was no interest expense or penalties related to unrecognized tax benefits recorded in 2021 or 2020.

#### ***Earnings Per Share***

Basic net income (loss) per share of common stock is calculated by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the reporting period. Diluted earnings per share is calculated by dividing net income by the weighted-average number of shares of common stock outstanding during the reporting period after giving effect to dilutive potential common shares for stock options and restricted stock units ("RSUs"), determined using the treasury stock method. See Note 18 below.

#### ***Comprehensive Income***

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

#### ***Recently Adopted Accounting Pronouncements***

In December 2019, the FASB issued Accounting Standards Update ("ASU") No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in ASC 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. On January 1, 2021, the Company's adoption of this guidance did not have a material impact on its financial statements.

#### ***Recently Issued Accounting Pronouncements***

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)*. This ASU reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This ASU provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. This ASU will be effective for all entities for fiscal years beginning after December 15, 2021. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including adoption in an interim period. The adoption of ASU 2021-04 is not expected to have a material impact on the Company's financial statements or disclosures.

In August 2020, the FASB issued ASU 2020-06 “Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815 – 40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, and it also simplifies the diluted earnings per share calculation in certain areas. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption will be permitted. The Company is currently evaluating the impact of this standard on its financial statements.

**NOTE 3. INVENTORY**

The Company’s inventory consists of the following:

<i>(Sin thousands)</i>	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Raw materials	\$ 5,453	\$ —
Work-in-process	—	—
Finished goods	6,161	1,404
Total inventories	<u>\$ 11,614</u>	<u>\$ 1,404</u>

The acquired Qbrexza finished goods inventory includes a fair value step-up of \$6.5 million, which will be expensed within cost of sales, as the inventory is sold to customers. All of the step-up finished goods inventory is expected to be sold in 2021. For additional information on the Company’s acquisition of Qbrexza, please refer to Note 5.

**NOTE 4. PROPERTY AND EQUIPMENT**

The Company’s property and equipment consisted of the following:

<i>(Sin thousands)</i>	<u>Useful Life (Years)</u>	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Leasehold improvements	2	11	11
Total property and equipment		11	11
Less: Accumulated depreciation		(11)	(11)
Property and equipment, net		<u>\$ —</u>	<u>\$ —</u>

The Company’s depreciation expense for the three months ended September 30, 2021 and 2020 was nil and \$1,000, respectively. The Company’s depreciation expense for the nine months ended September 30, 2021 and 2020 was nil and \$4,000, respectively. Depreciation expense is recorded as a component of selling, general and administrative expense in the unaudited condensed consolidated statements of operations.

**NOTE 5. INTANGIBLES**

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® (glycopyrronium), a prescription cloth towelette to treat primary axillary hyperhidrosis in patients nine years of age or older. Upon HSR acceptance, which was received on May 13, 2021, the Company paid the upfront fee of \$12.5 million to Dermira. In addition, Dermira is eligible to receive 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 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. Trial in the Patent Litigation is scheduled for September 19, 2022. The Company cannot make any predictions about the final outcome of this matter or the timing thereof.

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 September 30, 2021 and December 31, 2020, respectively:

<i>(Sin thousands)</i>	Estimated Useful Lives (Years)	September 30, 2021 (Unaudited)	December 31, 2020
Ceracade®	3	\$ 300	\$ 300
Luxamend®	3	50	50
Targadox®	3	1,250	1,250
Ximino®	7	7,134	7,134
Exelderm®	3	1,600	1,600
Accutane	5	4,727	4,727
Anti-itch product <sup>(1)</sup>	3	3,942	3,945
Total intangible assets		19,003	19,006
Accumulated amortization		(5,960)	(3,977)
Net intangible assets		<u>\$ 13,043</u>	<u>\$ 15,029</u>

(1) As of September 30, 2021, this asset has not yet been placed in service, therefore no amortization expense was recognized on this asset for the three or nine months ended September 30, 2021. Commercial launch of this product is expected in the first half of 2022.

The Company’s amortization expense for the three months ended September 30, 2021 and 2020 was approximately \$0.7 million and \$0.4 million, respectively. The Company’s amortization expense for the nine months ended September 30, 2021 and 2020 was approximately \$2.0 million and \$1.1 million, respectively. Amortization expense is recorded as a component of cost of goods sold in the Company’s unaudited condensed consolidated statements of operations.

The table below provides a summary for the nine months ended September 30, 2021, of the Company's recognized expense related to its product licenses, which was recorded in costs of goods sold on the unaudited condensed consolidated statement of operations:

<i>(Sin thousands)</i>	Intangible Assets, Net
Beginning balance at January 1, 2021	\$ 15,029
Reductions:	
Anti-itch Product license acquisition adjustment	(3)
Amortization expense	(1,983)
Ending balance at September 30, 2021	<u>\$ 13,043</u>

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

<i>(Sin thousands)</i>	Ximino®	Accutane®	Total Amortization
Three months ending December 31, 2021	\$ 255	\$ 236	\$ 491
Year ended December 31, 2022	1,019	946	1,965
Year ended December 31, 2023	1,019	945	1,964
Year ended December 31, 2024	1,019	946	1,965
Year ended December 31, 2025	1,019	945	1,964
Thereafter	595	157	752
Sub-total	<u>\$ 4,926</u>	<u>\$ 4,175</u>	<u>\$ 9,101</u>
Assets not yet placed in service:			
Anti-itch product license acquisition	—	—	3,942
Total	<u>\$ 4,926</u>	<u>\$ 4,175</u>	<u>\$ 13,043</u>

#### NOTE 6. LICENSES ACQUIRED

On June 29, 2021, the Company entered a license, collaboration, and assignment agreement (the "DFD 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 agreed to pay \$10.0 million, of which \$2.0 million (the "First Installment") was paid upon execution and \$8.0 million (the "Second Installment") is payable 90 days following June 29, 2021. Additional contingent regulatory and commercial milestone payments totaling up to \$163.0 million are also payable. Royalties ranging from approximately 10% to approximately 15% are payable on net sales of the DFD-29 product.

In accordance with ASC 730-10-25-1, *Research and Development*, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future use. The licenses purchased 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 nine months ended September 30, 2021 for the purchase price of licenses acquired were classified as research and development-licenses acquired in the condensed consolidated statement of operations.

Additionally, the Company is required to fund and oversee the Phase 3 clinical trials approximating \$24.0 million, based upon the current development plan and budget. 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 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.

The DFD Agreement also includes contingent payments to be made to DRL in the event of an Initial Public Offering (“IPO”) of the Company or sale of the Company, See Note 7.

#### **NOTE 7: FAIR VALUE MEASUREMENTS**

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,

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.

#### *Placement Agent Warrants*

In connection with the Company’s Class A Preferred Stock offering (see Note 15), the Company will issue upon a Qualified Financing (an external financing of \$25.0 million or greater) to the placement agent warrants (“the Placement Agent Warrants”) to purchase 5% of the shares of common stock into which the Class A Preferred Stock converts. The Placement Agent Warrants have a term of 5 years.

At September 30, 2021, the value of the placement agent warrants was deemed to be \$0.5 million. In connection with the Company’s IPO the company issued 111,567 shares of common stock in related to the conversion of all of the warrants.

#### *Contingent Payment Derivative*

In connection with the DFD Agreement, the Company agreed to pay DRL additional consideration upon either an initial public offering of the Company’s common stock (“IPO”) 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. In connection with the Company’s IPO on November 16, 2021, calculated using a 15-day VWAP of \$9.1721 per share, we issued 545,131 unregistered shares of common stock in the Company to DRL. The restrictions on the unregistered shares of common stock are governed by the terms set forth in the DFD Agreement and applicable securities laws.

In the event the IPO contingency was not satisfied, and the Company or its affiliate executes a definitive agreement for an acquisition event during the period beginning on June 29, 2021 and ending twenty-four (24) months after the regulatory approval of DFD-29 (“Acquisition Event”), the Company shall pay to DRL: (a) 20% of the value of DFD-29 attributable to the acquisition event, if such acquisition event occurs between closing and New Drug Application (“NDA”) approval; or (b) 12% of the value of DFD-29 attributable to the acquisition event, if such acquisition event occurs within 24 months after NDA approval. However, since the IPO contingency was satisfied on November 12, 2021 there is no further obligation to make a payment to DRL in the event of an Acquisition Event.

The Company valued the contingent payment discussed above utilizing a Probability Weighted Expected Return Method (PWERM) model. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the Company’s derivative liability that are categorized within Level 3 of the fair value hierarchy as of September 30, 2021 were as follows:

	September 30, 2021
Discount rate	30 %
Expected dividend yield	—
Expected term	3 months to 5 years

At September 30, 2021 the value of the contingent payment warrant is \$3.8 million, and was recorded on the unaudited condensed consolidated balance sheet. No liability was recorded at December 31, 2020.

The following table classifies into the fair value hierarchy of the Company’s financial instruments, measured at fair value as of September 30, 2021:

	Fair Value Measurement as of September 30, 2021			
	Level 1	Level 2	Level 3	Total
<i>(\$ in thousands)</i>				
<b>Liabilities</b>				
Derivative warrant liabilities	\$ —	\$ —	\$ 4,365	\$ 4,365
<b>Total</b>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,365</u>	<u>\$ 4,365</u>

The table below provides a roll-forward of the changes in fair value of Level 3 financial instruments as of September 30, 2021:

	Warrants liabilities
<i>(\$ in thousands)</i>	
Balance at December 31, 2020	\$ —
Additions:	
Contingent payment warrant	3,819
Placement agent warrant	362
Change in fair value of warrant liability	184
Balance at September 30, 2021	<u>\$ 4,365</u>

During the nine-month period ended September 30, 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 initial public offering. To date, Fortress employees have provided services to the

Company totaling approximately \$0.5 million. Upon completion of the Company's initial public offering, the amount converted into 52,438 shares of Journey common stock at the initial public offering price of \$10.00 per share.

In addition, in the normal course of business, the Company reimburses Fortress for various payroll related costs and selling, general and administrative costs. As of September 30, 2021 and December 31, 2020, the Company had a balance of approximately \$1.0 million and \$0.1 million, respectively, recorded as accounts payable and accrued expenses – related party on the condensed consolidated balance sheets.

#### ***Fortress Note***

Since the Company's inception in October 2014, Fortress has funded the Company's operations through a working capital loan pursuant to the terms of a future advance promissory note (the "Fortress Note"). The Fortress Note matures on or before December 31, 2024.

On September 30, 2021, the 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. The \$9.5 million contribution was approved by the boards of directors of both the Fortress and Journey and will ensure that Journey's accounts payable function will continue to operate smoothly. This contribution, along with \$5.2 million already outstanding under the Journey Promissory Note converted into 1,476,044 shares of Journey common stock upon the consummation of the Journey IPO at the Journey IPO price of \$10.00 per share.

At September 30, 2021 and December 31, 2020, the Company's outstanding balance under the related party note was approximately \$14.7 million and \$5.2 million, respectively. The related party note to Fortress is recorded as a long-term note payable on the condensed consolidated balance sheets and is an interest-free note.

#### ***Fortress Income Tax***

At September 30, 2021, the Company is 93% owned by Fortress and has been filing consolidated federal tax returns and consolidated or combined state tax returns in multiple jurisdictions with Fortress. In connection with the filing of the consolidated tax return, the Company's tax liabilities for the year ended December 31, 2020 of \$1.9 million was satisfied utilizing NOLs generated by Fortress. Extinguishment of these liabilities to Fortress was recorded on the Company's condensed consolidated balance sheets as a contribution of capital.

Additionally, see Note 17 below for a discussion of income taxes.

#### ***Avenue Secondment with Journey***

Effective June 1, 2021, Avenue and the Company entered into a secondment agreement for a certain Avenue employee to be seconded to the Company. During the secondment, the Company will have the authority to supervise the Avenue employee and will reimburse Avenue for the employee's salary and salary-related costs. The term of this agreement lasts until the approval of IV tramadol by the FDA or until the employee's services are needed again by the Fortress. The amount reimbursable to Avenue is approximately \$ 0.1 million for the three and nine months ended September 30, 2021.

**NOTE 9. ACCRUED EXPENSES**

Accrued expenses consisted of the following:

<i>(Sin thousands)</i>	<b>September 30, 2021</b>	<b>December 31, 2020</b>
	<b>(Unaudited)</b>	
Accrued expenses:		
Accrued employee compensation	\$ 2,411	\$ 2,041
Research and development - license fees	629	—
Accrued royalties payable	4,496	2,682
Accrued coupon and rebates	12,449	12,869
Reserve for product returns	3,652	2,580
Other	2,411	1,326
Total accrued expenses	<u>\$ 26,048</u>	<u>\$ 21,498</u>

**NOTE 10. INSTALLMENT PAYMENTS — LICENSES**

The following tables show the details of the Company's installment payments – licenses for the periods presented:

<i>(Sin thousands)</i>	<b>September 30, 2021</b>			
	<b>Ximino <sup>1</sup></b>	<b>Accutane <sup>2</sup></b>	<b>Anti-Itch Product <sup>3</sup></b>	<b>Total</b>
Installment payments - licenses, short-term	\$ 2,000	\$ 2,000	\$ 1,000	\$ 5,000
Less: imputed interest	(472)	(84)	(11)	(567)
Sub-total installment payments - licenses, short-term	<u>\$ 1,528</u>	<u>\$ 1,916</u>	<u>\$ 989</u>	<u>\$ 4,433</u>
Installment payments - licenses, long-term	\$ 3,000	\$ 1,000	\$ —	\$ 4,000
Less: imputed interest	(428)	(33)	—	(461)
Sub-total installment payments - licenses, long-term	<u>\$ 2,572</u>	<u>\$ 967</u>	<u>\$ —</u>	<u>\$ 3,539</u>
Total installment payments - licenses	<u>\$ 4,100</u>	<u>\$ 2,883</u>	<u>\$ 989</u>	<u>\$ 7,972</u>

<i>(Sin thousands)</i>	<b>December 31, 2020</b>			
	<b>Ximino <sup>1</sup></b>	<b>Accutane <sup>2</sup></b>	<b>Anti-Itch Product <sup>3</sup></b>	<b>Total</b>
Installment payments - licenses, short-term	\$ 2,000	\$ 500	\$ 2,800	\$ 5,300
Less: imputed interest	(602)	(122)	(54)	(778)
Sub-total installment payments - licenses, short-term	<u>\$ 1,398</u>	<u>\$ 378</u>	<u>\$ 2,746</u>	<u>\$ 4,522</u>
Installment payments - licenses, long-term	\$ 5,000	\$ 3,000	\$ 1,000	\$ 9,000
Less: imputed interest	(775)	(88)	—	(863)
Sub-total installment payments - licenses, long-term	<u>\$ 4,225</u>	<u>\$ 2,912</u>	<u>\$ 1,000</u>	<u>\$ 8,137</u>
Total installment payments - licenses	<u>\$ 5,623</u>	<u>\$ 3,290</u>	<u>\$ 3,746</u>	<u>\$ 12,659</u>

Note 1: Imputed interest rate of 11.96% and maturity date of July 22, 2024.

Note 2: Imputed interest rate of 4.03% and maturity date of July 29, 2023.

Note 3: Imputed interest rate of 4.25% and maturity date of January 1, 2022.



**NOTE 11. OPERATING LEASE OBLIGATIONS**

The Company leases 3,681 square feet of office space in Scottsdale, Arizona. In August 2020, the Company amended its office lease and extended the lease term for an additional 25 months at an annual rate of approximately \$0.1 million. The term of the amended lease commenced on December 1, 2020 and will expire on December 31, 2022.

The Company recorded rent expense as follows:

<i>(Sin thousands)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Lease cost</b>				
Operating lease cost	23	23	67	70
Variable lease cost	1	—	3	—
<b>Total lease cost</b>	<b>\$ 24</b>	<b>\$ 23</b>	<b>\$ 70</b>	<b>\$ 70</b>

The following table summarizes quantitative information about the Company’s operating leases:

<i>(Sin thousands)</i>	Nine Months Ended September 30,	
	2021	2020
Operating cash flows from operating leases	\$ 67	\$ 70
Weighted-average remaining lease term – operating leases	1.1	0.3
Weighted-average discount rate – operating leases	4.0 %	6.0 %

As of September 30, 2021, future minimum lease payments under lease agreements associated with the Company’s operations were as follows:

<i>(Sin thousands)</i>	Future Lease Liability
Three Months Ended December 31, 2021	\$ 24
Year Ended December 31, 2022	100
Total	124
Less: present value discount	(4)
Operating lease liabilities	<u>\$ 120</u>

**NOTE 12. LINE OF CREDIT**

*East West Bank Working Capital Line of Credit*

On March 31, 2021, the Company entered into an agreement with East West Bank (“EWB”) in which EWB agreed to provide a \$7.5 million working capital line of credit. The line of credit is secured by the Company’s receivables and cash. Interest on the line is the greater of 4.25% or the Prime Rate plus 1%. The agreement matures in 36 months. There have been no amounts drawn upon this line of credit during the three or nine months ended September 30, 2021.

**NOTE 13. INTEREST EXPENSE AND FINANCING FEES**

Interest expense and financing fees for the periods consisted of the following:

<i>(Sin thousands)</i>	Three Months Ended September 30,					
	2021			2020		
	<i>Interest</i>	<i>Fees<sup>1</sup></i>	<i>Total</i>	<i>Interest</i>	<i>Fees<sup>1</sup></i>	<i>Total</i>
Convertible preferred shares	\$ 450	\$ 378	\$ 828	\$ —	\$ —	\$ —
Dividend payable	365	—	365	—	—	—
Installment payments - licenses <sup>2</sup>	170	—	170	187	—	187
Anti-itch product Note	10	—	10	—	—	—
<b>Total Interest Expense and Financing Fee</b>	<b>\$ 995</b>	<b>\$ 378</b>	<b>\$ 1,373</b>	<b>\$ 187</b>	<b>\$ —</b>	<b>\$ 187</b>

<i>(Sin thousands)</i>	Nine Months Ended September 30,					
	2021			2020		
	<i>Interest</i>	<i>Fees<sup>1</sup></i>	<i>Total</i>	<i>Interest</i>	<i>Fees<sup>1</sup></i>	<i>Total</i>
Convertible preferred shares	\$ 1,034	\$ 648	\$ 1,682	\$ —	\$ —	\$ —
Dividend payable	628	—	628	—	—	—
Installment payments - licenses <sup>2</sup>	616	—	616	492	—	492
Anti-itch product Note	10	—	10	—	—	—
<b>Total Interest Expense and Financing Fee</b>	<b>\$ 2,288</b>	<b>\$ 648</b>	<b>\$ 2,936</b>	<b>\$ 492</b>	<b>\$ —</b>	<b>\$ 492</b>

Note 1: Amortization of fees in connection with debt raises.

Note 2: Imputed interest expense related to Ximino, Accutane and anti-itch cream acquisitions.

The conversion premium relates to the 15% discount at which the Class A Preferred Stock converts, see Note 15. In accordance with the measurement and recognition guidance of ASC 835-30 Imputation of Interest, the Company will accrete the convertible preferred share settled notes to the estimated settlement amount of \$14.7 million.

**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 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 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.

#### *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.

#### **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") in an aggregate minimum amount of \$12.5 million and an aggregate maximum amount of \$30.0 million. The Class A Preferred Offering terminated on July 18, 2021. 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 is completed, the Class A Preferred Stock will 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 has completed five closings in connection with the Class A Preferred Offering ("Closings"). In connection with the Closings, 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 in connection with the conversion of all of the preferred stock.

The Company evaluated the terms of the Class A Preferred Offering under ASC 480, *Distinguishing Liabilities from Equity*, and determined the instrument met the criteria to be recorded as a liability. The value at conversion does not vary with the value of Journey's common shares, therefore the settlement provision would not be considered a conversion feature. Accordingly, the Company determined liability classification is appropriate and as such, this instrument is accounted for as a liability on the Company's condensed consolidated balance sheet.

Dividends on the Class A Preferred Stock will be paid quarterly in shares of Fortress common stock based upon a 7.5% discount to the average trading price over the 10-day period preceding the dividend payment date. As consideration for the foregoing, the Company will issue to Fortress additional shares of common stock, debt securities, or a combination of the two for the amount of such dividend. At September 30, 2021, the Company recorded \$0.4 million representing the dividend payable on September 30, 2021 to the Class A Preferred Stock shareholders. This amount is recorded in accrued expenses, related party.

**Stock Options**

In 2015, the Company's Board of Directors adopted, and stockholders approved, the Journey Medical 2015 Stock Plan (the "Plan") authorizing the Company to grant up to 3,000,000 shares of common stock to eligible employees, directors, and consultants in the form of restricted stock, stock options and other types of grants. In August 2020, the Company's Board of Directors approved an increase to the shares available for issuance under the Plan by 642,857 shares. The amount, terms, and exercisability provisions of grants are determined by the Board of Directors. As of September 30, 2021 and December 31, 2020, 1,158,667 and 34,000 shares, respectively, were available for issuance under the Plan.

The following table summarizes the Company's stock option activities:

	Number of shares	Weighted average exercise price	Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Outstanding options at December 31, 2020	2,142,000	\$ 0.80	\$ 7,934,320	5.72
Exercised	(10,000)	0.68	—	—
Forfeited	(22,666)	1.37	—	—
Outstanding options at September 30, 2021	2,109,334	\$ 0.79	\$ 7,825,129	4.94
Options vested and exercisable at September 30, 2021	1,988,416	\$ 0.75	\$ 7,448,011	4.78

During the nine months ended September 30, 2021, exercises of stock options resulted in total proceeds of approximately \$7,000. For the three months ended September 30, 2021 and 2020, the Company recognized approximately \$8,000 and \$32,000, respectively, of stock-based compensation expense related to options. For the nine months ended September 30, 2021 and 2020, the Company recognized approximately \$41,000 and \$131,000, respectively of stock-based compensation expense related to options. Stock option expense is recorded as a component of SG&A in the Company's unaudited interim condensed consolidated statements of operations.

As of September 30, 2021, the Company had unrecognized stock-based compensation expense related to all unvested options of \$4,000, which the Company expects to recognize over a weighted-average period of approximately 1.2 years.

**Restricted Stock Units**

	Number of shares	Weighted average grant price
Unvested balance at December 31, 2020	815,524	\$ 3.37
Restricted stock units forfeited	(107,000)	3.37
Unvested balance at September 30, 2021	708,524	\$ 3.37

The unvested RSUs vest contingent upon a change of control, sale of the Company or an initial public offering event occurring within five years of the grant date. As of September 30, 2021, no stock-based compensation expense has been recorded related to these grants. Stock-based compensation expense for these awards in the amount of \$2.8 million, the fair value as calculated on the grant date, will be recorded if and when it becomes probable that one of the contingent vesting events will be achieved.

**NOTE 16. REVENUES FROM CONTRACTS AND SIGNIFICANT CUSTOMERS*****Disaggregation of Net Revenues***

The Company has the following marketed products, Qbrexza®, Accutane®, Targadox®, Ximino®, Exelderm®, Luxamend® and Ceracade®. Substantially all of the Company's product revenues are recorded in the U.S. Revenues by product are summarized as follows (dollars in thousands):

Revenue	Three months ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Targadox®	\$ 5,184	\$ 7,214	\$ 18,110	\$ 22,195
Ximino®	2,864	1,031	6,277	5,854
Exelderm®	1,366	1,226	4,319	2,913
Accutane®	3,531	—	5,672	—
Qbrexa®	6,636	—	11,204	—
Other branded revenue	29	(24)	35	(154)
Total Product revenue, net	<u>\$ 19,610</u>	<u>\$ 9,447</u>	<u>\$ 45,617</u>	<u>\$ 30,808</u>

***Significant Customers***

For the three months ended September 30, 2021, one of the Company's customers accounted for more than 10% of its total gross product revenue. For the nine months ended September 30, 2021, none of the Company's customers accounted for more than 10% of its total gross product revenue.

As of September 30, 2021, two of the Company's customers accounted for more than 10% of its total accounts receivable balance at 20.7% and 14.9%.

**NOTE 17. INCOME TAXES**

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 management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. Management has considered the Company's history of cumulative tax and book income incurred since inception, and the other positive and negative evidence, and has concluded that it is more likely than not that the Company will realize the benefits of the net deferred tax assets as of September 30, 2021 and 2020.

For the nine months ended September 30, 2021 and 2020, income tax expense or (benefit) was (\$6.7 million) and \$1.0 million, respectively, resulting in an effective income tax rate of 23.19% and 25.43%, respectively. The change in effective tax rate is due to changes in unfavorable permanent book tax differences.

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. As of September 30, 2021, the Company had no unrecognized tax benefits and does not anticipate any significant change to the unrecognized tax benefit balance. The Company would classify interest and penalties related to uncertain tax positions as income tax expense, if applicable. There was no interest expense or penalties related to unrecognized tax benefits recorded through September 30, 2021.

**NOTE 18. NET INCOME PER COMMON SHARE**

The following shares of potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding, as the effect of including such securities would be anti-dilutive for the three and nine months ended September 30, 2021:

	<u>Three Months Ended</u>	<u>Nine Months Ended</u>
	<u>September 30, 2021</u>	
Unvested restricted stock units	718,415	750,857
Outstanding Options	1,730,717	1,734,157
Total potential dilutive effect	<u>2,449,132</u>	<u>2,485,014</u>

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 three and nine months ended September 30, 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 three and nine months ended September 30, 2021. The following is a reconciliation of the numerator and denominator of the diluted net income per share computations for the three and nine-month periods ended September 30, 2020 (in thousands except for share and per share amounts):

	<u>Three Months Ended</u>	<u>Nine Months Ended</u>
	<u>September 30, 2020</u>	
Net income	\$ 29	\$ 2,781
Weighted average shares outstanding - basic	9,133,333	9,133,333
Stock options	1,667,142	1,684,345
Weighted average shares outstanding - diluted	<u>10,800,475</u>	<u>10,817,678</u>
Per share data:		
Basic	\$ —	\$ 0.30
Diluted	\$ —	\$ 0.26

**NOTE 19. SUBSEQUENT EVENT***Journey Initial Public Offering (the "Journey IPO")*

The Journey IPO closed on November 16, 2021, resulting in the issuance of 3,520,000 shares of Journey's common stock. The shares were issued at \$10.00 per share, resulting in net proceeds of approximately \$31.2 million, after deducting underwriting discounts and other offering costs.

## **Item 2. 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 unaudited condensed consolidated financial statements and the related notes included elsewhere in this Form 10-Q. Our unaudited condensed 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”), including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words “expect,” “anticipate,” “intend,” “believe,” “may,” “plan,” “seek” or similar language. All forward-looking statements included in this document are based on information available to us on the date hereof and we assume no obligation to update any such forward-looking statements. For such 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. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. 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, 2020. As used below, the words “we,” “us” and “our” may refer to Journey Medical Corporation.*

### **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 five 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 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 exclusive field sales organization.

Since inception, our operations have been primarily financed through a working capital note from Fortress Biotech, Inc. (Nasdaq: FBIO) (“Fortress”), referred to herein as the “Fortress Note,” cash generated by operations and cash raised in our private offering of our 8% Cumulative Convertible Class A Preferred Stock (“Class A Preferred Stock”). We expect 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.

On November 16, 2021, we completed an initial public offering (“IPO”) of our common stock, which resulted in net proceeds of approximately \$31.2 million, after deducting underwriting discounts and other offering costs.

We are a majority-owned subsidiary of Fortress.

### **Critical Accounting Policies and Uses of Estimates**

This management’s discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. In accordance with GAAP, we evaluate our estimates and judgments on an ongoing basis, including those related to accrued expenses, estimated useful lives for intangible assets, and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the

carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our unaudited condensed consolidated financial statements appearing elsewhere in this quarterly report on Form 10-Q, we believe the following are the critical accounting policies used in the preparation of our condensed consolidated financial statements that require significant estimates and judgments.

There have been no material changes in our significant accounting policies to those previously disclosed in the condensed consolidated financial statements included elsewhere in this quarterly report on Form 10-Q, other than the accounting for our share-settled notes and sequencing.

#### ***Class A Preferred Stock***

Our Class A Preferred Stock includes settlement features that result in liability classification. The initial carrying value of our Class A Preferred Stock is accreted to the expected settlement value, a fixed monetary amount to be settled by issuing a variable number of our common shares or in certain circumstances issuance of Fortress common stock. The discount to the settlement value is accreted to interest expense using the effective interest method.

#### ***Revenue Recognition***

We record revenue in accordance with the provisions of ASC Topic 606, Revenue from Contracts with Customers (“ASC 606”). The core principle of this revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. Our revenues primarily result from contracts with customers, which are generally short-term and have a single performance obligation — the delivery of product. Our 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 we expect 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 our products sold are subject to trade discounts, rebates, coupons and right of return. Revenues are recorded net of provisions for variable consideration, including discounts, rebates, governmental rebate programs, price adjustments, returns, chargebacks, promotional programs, and other sales allowances customary to the pharmaceutical industry. Accruals for these provisions are presented in the condensed consolidated financial statements as reductions in determining net sales and as a contra asset in 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 our provisions for variable consideration and how such provisions are estimated.

*Trade Discounts and Other Sales Allowances* — We provide trade discounts and allowances to our wholesale customers for sales order management, data, and distribution services. We also provide for prompt pay discounts if payment is received within the payment term days which generally range from 30 to 75 days. These discounts and allowances 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.

*Product Returns* — Consistent with industry practice, we offer customers a right to return any unused product and such 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 or contracted price less 5%. We estimate the amount of our product sales that may be returned by our customers and accrue this estimate as a reduction of revenue in the period the related product revenue is recognized.



We currently estimate products returns to be approximately 3% of gross sales to the wholesalers. The 3% rate is estimated by using both historical and industry data. On a quarterly basis, we monitor products returns and will adjust this percentage if needed. We do not estimate returns for sales made to the specialty pharmacies as their historical ordering pattern is approximately every two weeks and as such, inventory turns every two weeks.

*Government Chargebacks* — Chargebacks for fees and discounts to indirect qualified government healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified U.S. Department of Veterans Affairs hospitals and 340B entities at prices lower than the list prices charged to customers who directly purchase the product from the us. Customers charge us for the difference between what they pay for the product and the statutory selling price to the qualified government entity. These allowances are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivables, net. The chargeback amount from our direct customer is generally determined at the time of their resale to the qualified government healthcare provider by customers, and we generally issue credits for such amounts within a few weeks of our direct customers' resale to the qualified government healthcare provider, and we generally issue credits for such amounts within a few weeks of our direct customer's notification to us of the resale. The allowance for chargebacks is based on expected sell-through levels by our direct customers to indirect customers, as well as estimated wholesaler inventory levels.

*Government Rebates* — We are subject to discount obligations under state Medicaid programs and Medicare. These accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. For Medicaid programs, we estimate the portion of sales attributed to Medicaid patients and record a liability for the rebates to be paid to the respective state Medicaid programs. Our liability for these rebates consists of invoices received for: claims from prior quarters that have not been paid or for which an invoice has not yet been received; estimates of claims for the current quarter; and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

*Coupons* — We offer 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. Approximately 85% of our product revenues are sold through the specialty pharmacy channel which has a shorter cycle from our sales date to the fulfillment of the prescription by the specialty pharmacy customer. This results in less inventory in this channel. Coupons are processed and redeemed at the time of prescription fulfillment by the pharmacy and we are charged for the coupons redeemed monthly. The majority of coupon liability at the end of the period represent coupons that have been redeemed for which we have been billed and an accrual for expected redemptions for product in the distribution channel. The expected liability requires us to estimate the distribution channel inventory at period end, the expected redemption rates and the cost per coupon claim that we expect to receive associated with product that has been recognized as revenue but remains in the distribution channel at the end of each reporting period. The estimate of product remaining in the distribution channel is comprised of actual inventory at the wholesaler as well as an estimate of inventory at the specialty pharmacies, which we estimate based upon historical ordering patterns which consist of reordering approximately every two weeks. 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.

*Managed Care Rebates* — We offer managed care rebates to certain providers. We calculate rebate payment amounts due under this program based on actual qualifying products and applies a contractual discount rate. The accrual is based on an estimate of claims that we expect to receive and inventory in the distribution channel. The accrual is recognized at the time of sale, resulting in a reduction of product revenue.

#### ***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 primarily using the straight-line method.

During the ordinary course of business, we have entered into certain asset purchase agreements. Potential milestone payments such as sales targets or regulatory milestones are not probable and estimable and therefore, have not been recorded as liabilities. Upon a milestone payment being achieved, the milestone payment will be capitalized and amortized over the remaining useful life. Certain potential royalty payments other than those due for existing product sales, are not probable and estimable, and therefore have not been recorded as liabilities. When royalty payments become due, these costs are recorded as cost of goods sold as sales are recognized.

#### ***Stock-based Compensation***

We expense stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards and actual forfeitures. The fair value of our common stock underlying the stock options is also an input to the Black-Scholes option pricing model. We engaged an independent third-party valuation firm to provide an estimate of the fair value of our common stock for the year ended December 31, 2018, utilizing input from management. The fair value of our common stock was determined considering several 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 our common stock and the general and industry-specific economic outlook.

We estimate the fair value of stock option grants using the Black-Scholes option pricing model, which requires the use of a number of 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 stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. Forfeitures are recorded as they occur. All stock-based compensation costs are recorded in selling, general and administrative ("SG&A") expense in the condensed consolidated statements of operations.

#### ***Income Taxes***

As of September 30, 2021 and December 31, 2020, we are included in the Fortress consolidated federal tax return and consolidated or combined state tax returns in multiple jurisdictions. Our unaudited interim condensed consolidated financial statements recognize the current and deferred income tax consequences that result from our activities during the current and preceding periods pursuant to the provisions of ASC Topic 740, Income Taxes, as if we were a separate taxpayer rather than a member of the Fortress consolidated income tax return group. Fortress has agreed that we do not have to make payments to Fortress for our use of net operating losses ("NOLs") of Fortress (including other Fortress group members) alternatively any Journey NOLs will accrue to the benefit of Fortress. Since Fortress does not require us to pay in any form for the utilization of the consolidated group's NOLs, the tax benefit that we realize has been recorded as a capital contribution and Journey NOLs accrued to Fortress' benefit would be a deemed dividend.

We record 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. We establish a valuation allowance if management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. Management has considered our history of cumulative tax and book income incurred since inception, and the other positive and negative evidence, and has concluded that it is more likely than not that we will realize the benefits of the net deferred tax assets as of September 30, 2021, December 31, 2020 and December 31, 2019.

For tax positions that are more likely than not of being sustained upon audit, we recognize 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, we do not recognize any portion of the benefit. As of September 30, 2021, we had no unrecognized tax benefits and does not anticipate any significant change to the unrecognized tax benefit balance. We would classify interest and penalties related to uncertain tax positions as income tax expense, if applicable. There was no interest expense or penalties related to unrecognized tax benefits recorded through September 30, 2021.

## Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements included elsewhere in this quarterly report on Form 10-Q 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.

## Smaller Reporting Company Status

We are a “smaller reporting company,” meaning that the market value of our shares held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K, have reduced disclosure obligations regarding executive compensation, and smaller reporting companies are permitted to delay adoption of certain recent accounting pronouncements discussed in Note 2 to our unaudited condensed consolidated financial statements located in “Part 1 – Financial Information, Item 1. Financial Statements” in this Quarterly Report on Form 10-Q.

## Results of Operations

### Summary

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Product revenue, net</b>	\$ 19,610	\$ 9,447	\$ 45,617	\$ 30,808
<b>Operating expenses</b>				
Cost of goods sold - product revenue	11,167	3,379	22,559	10,313
Research and development	718	—	747	—
Research and development - licenses acquired	76	—	13,819	—
Selling, general and administrative	10,755	5,829	24,776	16,270
Wire transfer fraud loss	9,540	—	9,540	—
<b>Total operating expenses</b>	<b>32,256</b>	<b>9,208</b>	<b>71,441</b>	<b>26,583</b>
(Loss) income from operations	(12,646)	239	(25,824)	4,225

Our net product reviews were \$19.6 million and \$9.4 million for the three months ended September 30, 2021 and 2020, respectively, and \$45.6 million and \$30.8 million for the nine months ended September 30, 2021 and 2020, respectively, reflecting sales of our branded and generic products through specialty pharmacy channels, and to lesser extent traditional wholesaler channels. The increases for the three- and nine-month periods ended September 30, 2021 were mainly driven by incremental revenues as a result of our newly launched products, Accutane, launched in the first quarter of 2021, and Qbrexza, launched during the second quarter of 2021. In addition, our legacy products, Excelderm and Ximino, increased for the three- and nine-month periods ended September 30, 2021 as the products continue their momentum in the channels.

For the three months ended September 30, 2021 and 2020, our cost of goods sold reflected \$11.2 million, or 56.9%, and \$3.4 million, or 35.8%, of product revenue, net, respectively, in connection with the sale of our marketed products, compared to \$22.6 million, or 49.5%, and \$10.3 million or 33.5%, of product revenue, net, for the nine months ended September 30, 2021 and 2020, respectively. The increase in cost of goods sold for the three and nine months ended September 30, 2021 primarily reflects the step-up charge of approximately \$3.0 million and \$4.2 million, respectively, for the Qbrexza inventory sold related primarily to the step-up in inventory cost, as well as the increase in royalty expense related to Qbrexza.

As of September 30, 2021, we had an accumulated deficit of \$17.1 million. While we may in the future continue to generate revenue from our product sales, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will generate significant revenues in the future. In addition, we expect that our expenses will continue to increase in 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.

**Comparison of the Three Months Ended September 30, 2021 and 2020**

<i>(Sin thousands)</i>	Three Months Ended September 30,		Change	
	2021	2020	\$	%
Product revenue, net	19,610	9,447	10,163	108 %
<b>Operating expenses</b>				
Cost of goods sold – product revenue	11,167	3,379	7,788	230 %
Research and development	718	—	718	100 %
Research and development – licenses acquired	76	—	76	100 %
Selling, general and administrative	10,755	5,829	4,926	85 %
Wire transfer fraud loss	9,540	—	9,540	100 %
Total operating expenses	32,256	9,208	23,048	250 %
(Loss) income from operations	(12,646)	239	(12,885)	(5,391)%
Other expense				
Interest income	1,373	187	1,186	634 %
Change in fair value of derivative liability	2	—	2	100 %
Total other expense	1,375	187	1,188	635 %
<b>Net (Loss) income before income taxes</b>	<b>(14,021)</b>	<b>52</b>	<b>(14,073)</b>	<b>(27,063)%</b>
Income tax (benefit) expense	(3,375)	23	(3,398)	(14,774)%
<b>Net (loss) income</b>	<b>\$ (10,646)</b>	<b>\$ 29</b>	<b>\$ (10,675)</b>	<b>(36,810)%</b>
Net (loss) income attributable to common stockholders	\$ (1.16)	\$ 0.00	\$ (1.17)	(37,244)%
Net (loss) income attributable to common stockholders	\$ (1.16)	\$ 0.00	\$ (1.16)	(44,023)%

The following table reflects our net revenue by product:

<i>(Sin thousands)</i>	Three Months Ended September 30,		Change	
	2021	2020	\$	%
<b>Targadox®</b>	\$ 5,184	\$ 7,214	\$ (2,030)	(28)%
Ximino®	2,864	1,031	1,833	178 %
Exelderm®	1,366	1,226	140	11 %
Accutane®	3,531	—	3,531	100 %
Qbrexa®	6,636	—	6,636	100 %
Other branded revenue	29	(24)	53	(221)%
<b>Total product revenues, net</b>	<b>\$ 19,610</b>	<b>\$ 9,447</b>	<b>\$ 10,163</b>	<b>108 %</b>

	<u>Returns</u>	<u>Coupons</u>	<u>Managed Care</u>	<u>Government Rebates</u>	<u>Total</u>
<b>Balance at June 30, 2021</b>	\$ 2,099	\$ 17,527	\$ 1,082	\$ —	\$ 20,708
Current provision related to sales made in the current period	1,946	37,227	2,797	803	42,773
Checks/Credits Issued to third parties	(393)	(48,197)	(1,646)	(163)	(50,399)
<b>Balance at September 30, 2021</b>	<u>\$ 3,652</u>	<u>\$ 6,557</u>	<u>\$ 2,233</u>	<u>\$ 640</u>	<u>\$ 13,082</u>

Net revenue increased \$10.2 million, or 108%, to \$19.6 million for the three months ended September 30, 2021, from \$9.4 million for the three months ended September 30, 2020, primarily due to incremental revenues associated with newly launched products as well as increases in legacy products Excelderm and Ximino. We launched Accutane in the first quarter of 2021 and Qbrexza during the second quarter of 2021. Offsetting the net sales increases is a \$2.0 million decrease in Targadox net sales, primarily driven by increased promotional emphasis from our salesforce to Accutane, and increased reimbursement pressure.

Cost of goods sold increased \$7.8 million, or 230%, to \$11.2 million for the three months ended September 30, 2021, from \$3.4 million for the three months ended September 30, 2020, related primarily to the step-up in inventory cost of \$3.0 million related to Qbrexza, as well as the increase in royalty expense related to Qbrexza and Accutane of \$3.1 million and the expansion of our product portfolio.

Research and development expenses increased \$0.7 million for the nine months ended September 30, 2021 related to development costs incurred associated with DFD-29, and to a lesser extent, other development projects.

Selling, general and administrative expenses increased \$4.9 million, or 85%, to \$10.6 million for the three months ended September 30, 2021, from \$5.8 million for the three months ended September 30, 2020. The increase is primarily attributable to our increased sales and marketing costs associated with the expansion of our sales headcount related to our expanded product portfolio.

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. Any insurance proceeds will be recorded when considered probable.

Interest expense increased \$1.2 million to \$1.4 million for the three months ended September 30, 2021, from \$0.2 million for the three months ended September 30, 2020. The increase is primarily attributable to interest, fees and dividends payable related to our convertible preferred shares.

Income taxes for the three months ended September 30, 2021, and September 30, 2020 reflect a tax benefit of \$3.4 million and a tax expense of \$23,000, respectively, resulting in an effective tax rate of 22.80% and 30.02%, respectively. The decrease in the Company's income tax expense for the three months ended September 30, 2021, is primarily due to the wire fraud incident noted above, which resulted in \$9.5 million wire fraud loss.

Net loss increased \$10.7 million from net income of \$29,000 for the three months ended September 30, 2020 to a net loss of \$10.6 million for the three months ended September 30, 2021. The loss is primarily driven by the step-up charge of approximately \$3.0 million for Qbrexza, as well as the increase in royalty expense related to Qbrexza, increased selling, general and administrative expenses mainly due to increased sales and marketing costs associated with the expansion of our sales headcount related to our expanded product portfolio and the wire fraud related costs totaling approximately \$9.5 million noted above. In addition, we expect that our expenses will continue to increase in 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.

**Comparison of the Nine Months Ended September 30, 2021 and 2020**

<i>(Sin thousands)</i>	Nine Months Ended September 30,		Change	
	2021	2020	\$	%
Product revenue, net	45,617	30,808	14,809	48 %
<b>Operating expenses</b>				
Cost of goods sold – product revenue	22,559	10,313	12,246	119 %
Research and development	747	—	747	100 %
Research and development – licenses acquired	13,819	—	13,819	100 %
Selling, general and administrative	24,776	16,270	8,506	52 %
Wire transfer fraud loss	9,540	—	9,540	100 %
Total operating expenses	71,441	26,583	44,858	169 %
(Loss) income from operations	(25,824)	4,225	30,049	-771 %
<b>Other expense</b>				
Interest income	2,936	492	2,444	497 %
Change in fair value of derivative liability	184	—	184	100 %
Total other expense	3,120	492	2,628	534 %
<b>Net (Loss) income before income taxes</b>	<b>(28,944)</b>	<b>3,733</b>	<b>32,677</b>	<b>(875) %</b>
Income tax (benefit) expense	(6,701)	952	(7,653)	(804) %
<b>Net (loss) income</b>	<b>\$ (22,243)</b>	<b>\$ 2,781</b>	<b>\$ (25,024)</b>	<b>(900) %</b>
Net (loss) income attributable to common stockholders	\$ (2.43)	\$ 0.30	\$ (2.73)	(898) %
Net (loss) income attributable to common stockholders	\$ (2.43)	\$ 0.26	\$ (2.69)	(1,045) %

The following table reflects our net revenue by product:

<i>(Sin thousands)</i>	Nine Months Ended September 30,		Change	
	2021	2020	\$	%
Targadox <sup>®</sup>	\$ 18,110	\$ 22,195	\$ (4,085)	(18) %
Ximino <sup>®</sup>	6,277	5,854	423	7 %
Excelderm <sup>®</sup>	4,319	2,913	1,406	48 %
Accutane <sup>®</sup>	5,672	—	5,672	100 %
Qbrexa <sup>®</sup>	11,204	—	11,204	100 %
Other branded revenue	35	(154)	189	(123) %
<b>Total product revenues, net</b>	<b>\$ 45,617</b>	<b>\$ 30,808</b>	<b>\$ 14,809</b>	<b>48 %</b>

The following table presents information about revenue deductions:

	Returns	Coupons	Managed Care	Government Rebates	Total
<b>Balance at December 31, 2020</b>	\$ 2,580	\$ 12,769	\$ 100	\$ —	\$ 15,449
Current provision related to sales made in the current period	3,374	105,818	5,072	803	115,067
Checks/Credits Issued to third parties	(1,987)	(112,345)	(2,939)	(163)	(117,434)
Reclassifications between liability accounts	(315)	315	—	—	—
<b>Balance at September 30, 2021</b>	<b>\$ 3,652</b>	<b>\$ 6,557</b>	<b>\$ 2,233</b>	<b>\$ 640</b>	<b>\$ 13,082</b>

Net revenue increased \$14.8 million, or 48%, to \$45.6 million for the nine months ended September 30, 2021, from \$30.8 million for the nine months ended September 30, 2020, primarily due to incremental revenues associated with newly launched products as well as increases in our legacy products Excelderm and Ximino. We launched Accutane in the first

quarter of 2021 and Qbrexza during the second quarter of 2021. Offsetting the net sales increases is a \$4.1 million decrease in Targadox net sales, primarily driven by increased promotional emphasis from our salesforce to Accutane, and increased reimbursement pressure.

Cost of goods sold increased \$12.2 million, or 119%, to \$22.6 million for the nine months ended September 30, 2021, from \$10.3 million for the nine months ended September 30, 2020, related primarily to the step-up in inventory cost of \$4.2 million related to Qbrexza, as well as the increase in royalty expense related to Qbrexza and Accutane of \$4.9 million and the expansion of our product portfolio. We expect the total step-up in inventory value related to Qbrexza units sold of \$6.5 million to be incurred in 2021. However, this amount is based upon the Company forecast and may be higher or lower depending on actual units sold.

Research and development - licenses acquired expenses increased \$13.8 million for the nine months ended September 30, 2021 related to our in-process R&D acquired license upfront payment of \$10.0 million, in addition to the fair value related to our R&D license non-cash contingent payment of \$3.8 million.

Selling, general and administrative expenses increased \$8.5 million, or 52%, to \$24.8 million for the nine months ended September 30, 2021, from \$16.3 million for the nine months ended September 30, 2020. The increase is primarily attributable to our increased sales and marketing costs associated with the expansion of our sales headcount related to our expanded product portfolio.

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. Any insurance proceeds will be recorded when considered probable.

Interest expense increased \$2.4 million to \$2.9 million for the three months ended September 30, 2021, from \$0.5 million for the three months ended September 30, 2020. The increase is primarily attributable to interest, fees and dividends payable related to our convertible preferred shares.

Income taxes for the nine months ended September 30, 2021, and September 30, 2020 reflect a tax benefit of \$6.7 million and a tax expense of \$1.0 million, respectively, resulting in an effective tax rate of 23.19% and 25.43%, respectively. The decrease in the Company's income tax expense for the nine months ended September 30, 2021 is primarily due to research and development licenses acquired in connection with the DFD agreement of \$13.8 million and the wire fraud incident noted above, which resulted in \$9.5 million wire fraud loss.

Net loss increased \$25.0 million from net income of \$2.8 million for the nine months ended September 30, 2020 to a net loss of \$22.2 million for the nine months ended September 30, 2021. The loss is primarily driven by the step-up charge of approximately \$4.2 million for Qbrexza, as well as the increase in royalty expense related to Qbrexza, increased selling, general and administrative expenses mainly due to increased sales and marketing costs associated with the expansion of our sales headcount related to our expanded product portfolio, Research and development licenses acquired of \$13.8 million and the wire fraud related costs totaling approximately \$9.5 million noted above. We expect that our expenses will continue to increase in 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.

### **Liquidity and Capital Resources**

Since inception, our operations have been financed primarily through our Fortress Note and cash received from operations and our Class A Preferred Stock offering. We also have access to a working capital line of credit as discussed below. 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 new 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. We currently anticipate that our cash and cash equivalent balances at September 30, 2021 are sufficient to fund our anticipated operating cash requirements for at least one year from the filing

date of this quarterly report on Form 10-Q. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies.

On November 16, 2021, we completed an initial public offering (“IPO”) of our common stock, which resulted in net proceeds of approximately \$31.2 million, after deducting underwriting discounts and other offering costs. In connection with our IPO the Class A Preferred Stock converted into 2,231,346 shares of common stock. At September 30, 2021, the Company's outstanding balance under the related party note was approximately \$14.7 million, we issued 1,476,044 shares of common stock to Fortress to settle the promissory note upon our IPO.

*Line of Credit*

On March 31, 2021, we entered into a Loan and Security Agreement with East West Bank (“EWB Loan”) under which we may request advances in aggregate not exceeding the lesser of: (i) a revolving line of credit \$7.5 million and (ii) a borrowing base representing approximately 85% of our eligible accounts receivable. Advances bear interest on the outstanding daily balance, at a floating rate of 1.0% above the Prime Rate set by EWB. Interest is due and payable on the last day of the month. The EWB Loan matures on March 31, 2024.

*Class A Preferred Stock Offering*

In March 2021, we commenced an offering of 8% Cumulative Convertible Class A Preferred Stock (“Class A Preferred Offering”) in an aggregate minimum amount of \$12.5 million and an aggregate maximum amount of \$30.0 million. The Class A Preferred Offering terminated on July 18, 2021. Pursuant to the terms of the agreement, the Class A Preferred Stock automatically converts into our common stock upon a sale of 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 our option) at a discount of 15% to the per share qualified stock price. In the event that neither a sale nor a \$25.0 million financing is completed, the Class A Preferred Stock will 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.

We have completed five closings in connection with the Class A Preferred Offering (“Closings”). In connection with the Closings, we 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, we received \$17.0 million of net proceeds. In connection with our IPO the Class A Preferred Stock converted into 2,231,346 shares of common stock.

Dividends on the Class A Preferred Stock of 8% annually are paid on a quarterly basis by Fortress in the form of shares of Fortress’ common stock based upon a 7.5% discount to the average trading price over the 10-day period preceding the dividend payment date. Furthermore, Fortress is obligated to file one or more registration statements covering the issuance of shares that result from such dividends/exchange. As consideration for the foregoing issuances by Fortress of its securities, we will issue to Fortress additional shares of our common stock, debt securities, or a combination of the foregoing.



### *Cybersecurity Incident*

In September 2021, we were the victim of a business e-mail compromise cybersecurity incident affecting our accounts payable function that led to approximately \$9.5 million in wire transfers being misdirected to apparently fraudulent accounts. The details of the incident and its origin are under investigation with the assistance of third-party cybersecurity experts working at the direction of legal counsel. The incident does not appear to have compromised any personally identifiable information or protected health information. The matter has been reported to the Federal Bureau of Investigations.

We will record the \$9.5 million loss incurred as a result of this incident as an expense on our condensed consolidated income statement in the third quarter of 2021. As our controlling stockholder and supporting partner in our back-office functions, Fortress provided us with \$9.5 million to ensure our accounts payable operations continue to function smoothly. This payment was recorded as a related party payable note, which converted into our common stock upon the consummation of our initial public offering, at the offering price.

### **Cash Flows for the Nine Months Ended September 30, 2021 and 2020**

<i>(Sin thousands)</i>	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Statement of cash flows data:</b>		
Total cash (used in)/provided by:		
Operating activities	\$ 1,025	\$ 78
Investing activities	(8,800)	(1,000)
Financing activities	21,218	—
Net increase (decrease) in cash and cash equivalents	<u>\$ 13,443</u>	<u>\$ (922)</u>

#### *Operating Activities*

Net cash provided by operating activities increased to \$1.0 million for the nine months ended September 30, 2021 from \$0.1 million for the nine months ended September 30, 2020. The increase is primarily attributable to our net loss of \$22.2 million and increases in our deferred tax assets, accounts receivable, and inventory, offset by increases in accounts payable, accrued expenses and research and development licenses acquired. The increases reflect costs related to the continued commercialization and expansion of product portfolio, including the purchases of licenses and sales and marketing related costs as well as costs associated with being a new public company.

#### *Investing Activities*

Net cash used in investing activities increased by \$7.8 million, to \$8.8 million for the nine months ended September 30, 2021, from \$1.0 million for the nine months ended September 30. The increase is related to the purchase of research and development licenses.

#### *Financing Activities*

Net cash provided by financing activities was \$21.2 million for the nine months ended September 30, 2021, compared to zero for the nine months ended September 30, 2020. The incremental increase is substantially related to proceeds from the note from our parent and proceeds from our convertible preferred shares of \$9.5 million and \$19.0 million, respectively, offset by payments of our license note payable of \$5.3 million and \$2.0 million of payments for debt issuance costs associated with our convertible preferred shares.

#### *Off-Balance Sheet Arrangements*

We did not have during the periods presented, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

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 4. Controls and Procedures**

#### *Evaluation of Disclosure Controls and Procedures*

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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 due to our internal controls having not been adequately designed to prevent or timely detect unauthorized cash disbursements.

In light of the above incident, our management took immediate action to remediate the material weakness, including enhancing and formalizing cash disbursement controls to prevent and timely detect unauthorized cash disbursements and significantly enhancing our information technology infrastructure and security measures. However, given the identification of the material weakness during September 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2021, our disclosure controls and procedures were not effective at the reasonable assurance level. As of the date of this filing we believe this material weakness has been remediated.

#### *Changes in Internal Control over Financial Reporting*

Except for the remediation efforts described above taken to address the material weakness, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the most recent quarter with respect to our operations, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Part II. Other Information**

### **Item 1. Legal Proceedings.**

On March 31, 2021 we executed an Asset Purchase Agreement (the “Qbrexza APA”) with Dermira, Inc., a subsidiary of Eli Lilly and Company (“Dermira”), and the transaction closed on May 14, 2021. Pursuant to the terms of the agreement, we acquired the rights to Qbrexza® (glycopyrronium), a prescription cloth towelette to treat primary axillary hyperhidrosis in patients nine years of age or older. Upon closing of the Qbrexza purchase, we became substituted for Dermira as the plaintiff in, and are currently vigorously litigating, U.S. patent litigation commenced by Dermira on October 21, 2020 in the U.S. District Court of Delaware (the “Patent Litigation”) against Perrigo Pharma International DAC (“Perrigo”).

alleging infringement of certain patents covering Qbrexza (the “Qbrexza Patents”), which are included among the proprietary rights to Qbrexza to be acquired pursuant to the APA. 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, or 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. Trial in the Patent Litigation is scheduled for September 19, 2022. The Company cannot make any predictions about the final outcome of this matter or the timing thereof. See “*Risk Factors — Risks Related to Intellectual Property, Generic Competition and Paragraph IV Litigation.*”

#### **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. Additionally, many of these risks and uncertainties are currently elevated by and may or will continue to be elevated by the COVID-19 pandemic.*

#### **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, including but not limited to pricing or reimbursement; licensing and approval; intellectual property rights; competition with existing or new products, including third-party generic competition; product acceptance by physicians, other licensed medical professionals, and patients; and higher than expected total rebates, returns or recalls.

Also, 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 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.

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. Two of our marketed products, Qbrexza 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 AB rated products. Targadox will likely face

additional AB rated generic entrants over the next six months. Exelderim 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.

***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 on our ability to establish and maintain sales and marketing capabilities or to enter into agreements with third parties to market, distribute and sell any such products.***

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 such 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.

***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, the European Medicines Agency (the “EMA”), and similar regulatory authorities outside the United States. 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 only 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 current Good Manufacturing Practice (“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 our 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, if it is granted at all and 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 following: 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 that the FDA specifically approves and 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 potential future product candidate is approved and our contract manufacturer fails to produce the product 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 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' 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 (the "FDAAA"), 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 Federal Food, Drug and Cosmetic Act (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, operations, 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 will play a primary role in the recommendation and prescription of any 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 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:

- the federal Anti-Kickback Statute (“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 Health and Human Services Office of Inspector General (“OIG”) continues to make modifications to existing AKS safe harbors which may increase liability and risk as well as adversely impact sales relationships. On November 20, 2020, OIG issued the final rule for Safe Harbors under the Federal AKS. This new final rule creates additional safe harbors including ones pertaining to patient incentives. The final rule also removed safe harbor protections for rebates and other reductions in price paid by manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers acting under contract with plan sponsors, unless the reduction in price is required by law. OIG is able to modify safe harbors as well as regulatory compliance requirements, which could impact our business adversely. If the removal of safe harbors for rebates takes effect, our ability to negotiate coverage and formulary placement for Part D plans may be affected. 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, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to “payments or other transfers of value” made to 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. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end of each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014;

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our 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. 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 Centers for Medicare & Medicaid Services (“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. President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been enacted. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, a process that is commonly referred to as the “individual mandate.” In addition, the Further Consolidated Appropriations Act, 2020 permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, it also eliminated the health insurer tax. On December 14, 2018, the U.S. District Court for the Northern District of Texas ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court reversed the Fifth Circuit’s ruling, holding that the challengers lacked standing to sue and otherwise abstaining from reaching the merits of the case. There may be other efforts to challenge, repeal, or replace the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

President Joseph R. Biden, Jr. signed an Executive Order on Strengthening Medicaid and the Affordable Care Act, stating 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 coverage under the ACA and making high-quality healthcare affordable and accessible to Americans. We are unable to predict the likelihood of changes to the ACA or other healthcare laws which may negatively impact our profitability.

President Biden intends, as his predecessor did, to take action against drug prices which are considered “high.” Such measures could be addressed in a legislative package later in 2021 or with the reauthorization of the Prescription Drug User Fee Act, or PDUFA, in 2022 as part of a package bill. Drug pricing continues to be a subject of debate at the executive and legislative levels of U.S. government and we expect to see legislation focusing on this in the coming year. 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.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through December 31, 2021, unless additional congressional action is taken. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, to review the relationship between pricing and manufacturer patient assistance programs, and to reform government program reimbursement methodologies for pharmaceutical products. The Prescription Drug Pricing Reduction Act, or PDPRA, which was introduced in Congress in 2019, and again in 2020, proposed to, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D

beneficiaries, and proposes several changes to how drugs are reimbursed in Medicare Part B. A similar drug pricing bill, the Elijah E. Cummings Lower Drug Costs Now Act proposes to enable direct price negotiations by the federal government for certain drugs (with the maximum price paid by Medicare capped based on an international index), requires manufacturers to offer these negotiated prices to other payors, and restricts manufacturers from raising prices on drugs covered by Medicare Parts B and D. This Act passed in the House of Representatives when it was introduced in 2019, and it has been introduced again in the 2021 term. We cannot predict whether any proposed legislation will become law and the effect of these possible changes on our business cannot be predicted at this time.

Further, the Centers for Medicare & Medicaid Services (“CMS”) has significant regulatory authority to promulgate regulations and impose other compliance requirements that may increase our compliance costs and impact our ability to attain profitability and market our current products and any current or future product candidates. CMS sets coverage and reimbursement rates for Medicare and oversees the implementation of Medicaid at the state level. CMS could modify or impose coverage restrictions or modify reimbursement rates on any of our current products or any current or future product candidates in a manner that could adversely impact our business. For example, on January 8, 2021, CMS approved Tennessee’s Medicaid section 1115 demonstration application, granting the state the unprecedented ability to implement a closed drug formulary without foregoing the state’s entitlement to rebates under the Medicaid Drug Rebate Program. Implementation of a closed formulary could mean that our products could be excluded from coverage under Medicaid. It is unclear whether the Biden Administration will reverse or modify Tennessee’s section 1115 demonstration approval.

Within CMS, CMMI, as established by the ACA, has broad authority to design, implement, and test new health care payment models that could potentially lower health care spending while maintaining quality or increase quality without increasing spending. CMMI has considered implementing models that could have a significant adverse effect on our business. For example, on November 27, 2020, CMMI finalized a mandatory Medicare Part B drug payment model that would have aligned payment for drugs with international reference prices, entitled the Most Favored Nation (“MFN”) Model. The MFN Model was enjoined by a Federal court on December 28, 2020 for failure to comply with rulemaking procedural requirements. It is unclear whether the Biden Administration will propose and implement the same or a similar model in future rulemaking, and we cannot predict how future regulatory actions by CMMI or any other component of CMS may impact our business.

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 the study in question;
- 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 over the counter ("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 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, our 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**

The following are risks relating to our use of third-party vendors to execute parts of our business plan; however, we also rely on Fortress for many of our operational needs. See “*Risks Related to our Relationship with Fortress Biotech, Inc.*”

***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, 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, 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 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. 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, we could make inaccurate assumptions and conclusions about current or future product candidates and our research and development efforts could be compromised.

***If successful products 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 or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be used 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 adversely affect our business.

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.

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

We 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. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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.

***Our business and operations would suffer in the event of system failures.***

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our

manufacturing, sales or drug development programs. For example, the loss of clinical trial data from completed clinical trials for product candidates that we may license or acquire could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of future product candidate may be delayed.

#### **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, however, 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.

***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, 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 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 (DFD-29)**

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

As of September 30, 2021, our major marketed products, which have been approved by the U.S. Food and Drug Administration (“FDA”) for sale in the United States, include Qbrexza®, Accutane®, Targadox®, Ximino®, and Exelderm® Cream and Solution. 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 Dr. Reddy’s Laboratories, Ltd. (“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:

- the 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.

***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 contract research organizations ("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 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. We and our CROs and other third-party contractors are required to comply with GCP and good laboratory practice ("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. 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 outweigh 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 preclinical 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, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include 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, only became effective on March 16, 2013. Similarly, 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 a New Drug Application (“NDA”). The FDA, with one exception, is prohibited during those five years from accepting for filing a generic, or an Abbreviated New Drug Application (“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 as the Paragraph IV certification made by Perrigo pertaining to the patents covering Qbrexza. 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 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, which 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.

***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.

***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.

We are in the process of implementing our internal security and business continuity measures and developing our information technology infrastructure. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology

and other internal infrastructure systems, including corporate firewalls, servers, 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 details of the incident and its origin are under investigation with the assistance of third-party cybersecurity experts working at the direction of legal counsel. The matter was reported to the Federal Bureau of Investigation and does not appear to have compromised any personally identifiable information or protected health information. Fortress, as our controlling stockholder and supporting partner in our back-office functions, is providing us with \$9.5 million to ensure our accounts payable operations continue to function smoothly. 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. For example, third parties have in the past and may in the future illegally pirate our software and make that software publicly available on peer-to-peer file sharing networks or otherwise. 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 the COVID-19 Pandemic**

*The COVID-19 pandemic may continue to impact our product revenues, future clinical trials, and as a result, our financial condition and results of operations and other aspects of our business.*

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

The COVID-19 pandemic has and may continue to impact the global economy, disrupt global supply chains, and create significant volatility and disruption of financial markets.

To protect the health of our workforce, we asked our office-based employees to work remotely, have restricted domestic and international travel indefinitely, and restricted on-site staff to only those personnel and contractors who perform essential activities that must be conducted on-site. We intend to keep these precautionary measures in effect for the foreseeable future and may need to enact further measures to help minimize the risk of our employees being exposed to COVID-19. Although the impact of a remote working environment to our operations has been minimal, our continued reliance on remote work may negatively impact productivity, including our ability to generate revenues and product demand, prepare regulatory applications, and conduct data analysis, and may disrupt, delay, or otherwise adversely impact our business. In addition, continued remote working could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruption. COVID-19 may also compromise the ability of independent contractors who perform consulting services for us to deliver services or deliverables in a satisfactory or timely manner.

Some factors from the COVID-19 outbreak that may delay or otherwise adversely affect our product revenues, as well as adversely impact our business generally, include:

- the changes in buying patterns throughout our supply chain caused by lack of normal access by patients to the healthcare system and concern about the continued supply of medications, which may increase or decrease demand for our products;
- adverse effects on our manufacturing operations, supply chain and distribution systems, which may impact our ability to produce and distribute our products, as well as the ability of third parties to fulfill their obligations to us and could increase our expenses;
- the risk of shutdown in countries where we rely, or may rely, on CMOs to provide commercial manufacture of our products, clinical batch manufacturing of our product candidates, including DFD- 29, or the procurement of active pharmaceutical ingredients or other manufacturing components for our products or product candidates, which may cause delays or shortages in our product supply and/or the timing of any our clinical trials;

- the risk that the COVID-19 pandemic may intensify other risks inherent in our business; and
- the possibility that third parties on which we rely for certain functions and services, including CMOs, suppliers, distributors, logistics providers, and external business partners, may be adversely impacted by restrictions resulting from COVID-19, which could cause us to experience delays or incur additional costs.

#### **Risks Related to Our Finances and Capital Requirements**

*Although we have been cash flow positive since the end of 2017, we may incur losses in the foreseeable future and may not be able to regain or maintain profitability.*

Although 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 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 and the timing of payments we may make or receive under these arrangements;
- there are variations in the level of expenses related to our future development programs;
- 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
- maintaining and/or expanding 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 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
- in-license and 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 intravenous synthetic opioid analgesic; 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 or our future commercialization efforts.

***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 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.

We are not currently required to comply with the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Given our recent IPO, we will be required to provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report on Form 10-K. 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 Second 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 (the “DGCL”). 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 Second 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 Second 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 may 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 Second 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.

In March 2020, the Delaware Supreme Court issued a decision in *Salzburg et al. v. Sciabacucchi* which found that an exclusive forum provision providing for claims under the Securities Act to be brought in federal court is facially valid under Delaware law. It is unclear whether this decision will be appealed, or what the final outcome of this case will be. We intend to enforce this provision, but we do not know whether courts in other jurisdictions will agree with this decision or enforce it.

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 Second 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 Exchange Act, 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 The Nasdaq Capital Market, 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.

We also expect that being a public company and these new rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

***Reduced reporting and disclosure requirements applicable to us as an emerging growth company 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 recent 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 \$1.07 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 The Nasdaq Capital Market.***

We list our shares of common stock on The Nasdaq Capital Market, 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 following our recent IPO may fluctuate substantially. Given our recent IPO, the market price of our common stock may be higher or lower than the price you pay in the IPO, depending on many factors, some of which are beyond our control and may not be related to our operating performance. 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 ten (10) 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 do not presently intend to take 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.

***If the proposed shared services agreement with Fortress is terminated, we may incur significant costs and risks.***

In connection with our recently completed IPO, we intend to enter into a shared services agreement with Fortress for them to continue to provide consulting services and the use of their personnel. If we separate from Fortress and the shared services agreement is terminated, we may incur significant costs, which might exceed our estimates. Additionally, we may incur some negative effects from a termination of shared services with Fortress, as we will likely have substantially fewer resources than Fortress.

The termination of the shared services agreement with Fortress may be costly and time-consuming to the Company and may pose challenges, such as effecting the termination while carrying on operations and difficulty in retaining key officers and personnel, as well as difficulty separating corporate infrastructure, including insurance, accounting, legal, finance, tax, and human resources, each of which could have an adverse effect on our business, financial condition and results of operations.

***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 will partially depend 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 condensed consolidated financial statements and accompanying notes appearing elsewhere in this quarterly report on Form 10-Q. 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 stock-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 condensed consolidated financial statements include those related to revenue recognition, stock-based compensation and income taxes.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

On July 15, 2021, we held the fourth closing of a private placement offering (the “Private Placement”) of our 8% Cumulative Convertible Class A Preferred Stock (the “Class A Preferred Stock”), pursuant to a private placement agreement with National Securities Corporation, currently owned by B. Riley Securities, as placement agent. We issued and sold 177,400 shares of our Class A Preferred Stock at a purchase price of \$25.00 per share, for total gross proceeds of approximately \$4,435,000.

On July 20, 2021, we issued and sold 8,000 shares of our Class A Preferred Stock in a subsequent closing of the Private Placement at a purchase price of \$25.00 per share, for total gross proceeds of approximately \$200,000.

These issuances were made in reliance on an exemption from registration set forth in Section 4(a)(2) of the Securities Act, as transactions by an issuer not involving a public offering. The purchasers of securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to offer or sell, in connection with any distribution of the securities.

**Item 3. Defaults of Senior Securities**

None.

**Item 4. Mine Safety Disclosures.**

N/A

**Item 5. Other Information.**

None.

**Item 6. Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
31.1	<a href="#"><u>Certification of Chief Executive Officer of Journey Medical Corporation pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated December 15, 2021.</u></a>
31.2	<a href="#"><u>Certification of Principal Financial Officer of Journey Medical Corporation pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated December 15, 2021.</u></a>
32.1	<a href="#"><u>Certification of Chief Executive Officer of Journey Medical Corporation pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated December 15, 2021.</u></a>
32.2	<a href="#"><u>Certification of Principal Financial Officer of Journey Medical Corporation pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated December 15, 2021.</u></a>
101	The following financial information from the Company's quarterly report on Form 10-Q for the period ended September 30, 2021, formatted in Inline Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statement of Stockholders' Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements (filed herewith).
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

**SIGNATURES**

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

**Journey Medical Corporation  
(Registrant)**

Date: December 15, 2021

By: /s/ Claude Maraoui

Claude Maraoui  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: December 15, 2021

By: /s/ Ernest De Paolantonio

Ernest De Paolantonio  
Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Claude Maraoui, certify that:

1. I have reviewed this report on Form 10-Q of Journey Medical Corporation;
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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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.

/s/ Claude Maraoui

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Claude Maraoui  
President and Chief Executive Officer  
(Principal Executive Officer)  
December 15, 2021

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**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Ernest De Paolantonio, certify that:

1. I have reviewed this report on Form 10-Q of Journey Medical Corporation;
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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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.

/s/ Ernest De Paolantonio  
Ernest De Paolantonio  
Chief Financial Officer  
(Principal Financial Officer)  
December 15, 2021

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

I, Claude Maraoui, Chief Executive Officer of Journey Medical Corporation (the “Company”), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company’s quarterly report on Form 10-Q for the period ended September 30, 2021 (the “Report”) filed with the Securities and Exchange Commission:

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

/s/ Claude Maraoui

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Claude Maraoui

President and Chief Executive Officer

(Principal Executive Officer)

December 15, 2021

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

I, Ernest De Paolantonio, Principal Financial Officer of Journey Medical Corporation (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's quarterly report on Form 10-Q for the period ended September 30, 2021 (the "Report") filed with the Securities and Exchange Commission:

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

/s/ Ernest De Paolantonio  
Ernest De Paolantonio  
Chief Financial Officer  
(Principal Financial Officer)  
December 15, 2021

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