UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): March 29, 2023

Journey Medical Corporation

(Exact Name of Registrant as Specified in Charter)

001-41063 (Commission File Number) 47-1879539 (IRS Employer Identification No.)

Delaware (State or Other Jurisdiction of Incorporation)

> 9237 E Via de Ventura Blvd, Suite 105 Scottsdale, AZ 85258 (Address of Principal Executive Offices)

> > (480) 434-6670

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act.

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.

□ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

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	DERM	Nasdaq Capital Market				

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02. Results of Operations and Financial Condition.

On March 29, 2023, Journey Medical Corporation issued a press release to provide a corporate update and to announce its financial results for the three months and full year ended December 31, 2022. A copy of such press release is being furnished as Exhibit 99.1 to this report.

The information, including Exhibit 99.1, in this Form 8-K is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall otherwise be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are furnished herewith:

Exhibit Description 99.1 Press release issued by Journey Medical Corporation, dated March 29, 2023. 104 Cover Page Interactive Data File, formatted in Inline Extensible Business Reporting Language (iXBRL).

SIGNATURES

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

Date: March 29, 2023

Journey Medical Corporation (Registrant)

By: <u>/s/ Claude Maraoui</u> Claude Maraoui Chief Executive Officer, President and Director



Journey Medical Corporation Reports Full-Year 2022 Financial Results and Recent Corporate Highlights

Generated record total revenues of \$73.7 million for the full year 2022

Completed enrollment in Phase 3 clinical program evaluating DFD-29 for the treatment of papulopustular rosacea; topline data are expected in the first half of 2023

Company to hold conference call on March 29, 2023 at 4:30 p.m. ET

Scottsdale, AZ – March 29, 2023 – Journey Medical Corporation (Nasdaq: DERM) ("Journey Medical"), a commercial-stage pharmaceutical company that focuses on the development and commercialization of pharmaceutical products for the treatment of dermatological conditions, today announced financial results and recent corporate highlights for the fourth quarter and full year ended December 31, 2022.

Claude Maraoui, Journey Medical's Co-Founder, President and Chief Executive Officer, said, "Our first year as a public company had many achievements and challenges, including the impact of generic competition on our Targadox® brand and supply chain issues for Ximino® and Exelderm®, which were resolved in 2022. Looking beyond these challenges, and forward into 2023, we have accomplished a great deal over this past year, particularly revenue growth for Qbrexza® and Accutane® in addition to the revenue contribution of Amzeeq® and Zilxi®, acquired in January 2022. These four products accounted for approximately 77% of our total revenue for the year. In 2023, we look forward to continued revenue growth from these products and achieving clinical milestones in our Phase 3 clinical trials evaluating DFD-29 for the treatment of rosacea. We expect a top-line data read out from the DFD-29 Phase 3 clinical trials in the second quarter of 2023 and to file a New Drug Application ("NDA") in the second half of 2023."

Financial Results:

- Total revenues were \$73.7 million for the full year 2022, a record high for the Company, compared to total revenues of \$63.1 million for the full year 2021, representing 17% growth. This includes total revenues of \$16.0 million for the fourth quarter of 2022, compared to net revenues of \$17.5 million generated in the fourth quarter of 2021, representing a 9% decline from period-to-period primarily due to generic competition for Targadox.
- Selling, general and administrative expenses were \$59.5 million for the full year 2022, compared to \$39.8 million for 2021. The increase is primarily attributable to the
 expansion of our salesforce, marketing expenses related to the expanded product portfolio of four products, additional headcount costs, legal expenses associated with
 successful patent litigation and other professional fees associated with being a public company that we did not incur as a privately held company prior to our IPO in
 November 2021.
- Selling, general and administrative expenses were \$14.0 million for the fourth quarter of 2022, compared to \$15.1 million for the fourth quarter of 2021. The decrease is
 primarily attributable to our expense optimization efforts as the Company continues to improve its operational efficiencies post IPO, while ensuring continued focus on
 the development and commercialization of DFD-29.
- Research and development costs were \$10.9 million for the full year 2022, compared to \$16.6 million for the full year 2021. The full year 2021 included \$13.8 million for the license acquisition of DFD-29.
- Research and development costs were \$4.3 million for the fourth quarter of 2022, compared to \$2.0 million for the fourth quarter of 2021 due to clinical trial expenses
 related to the development of our DFD-29 product candidate, for which our Phase 3 clinical trials are 100% enrolled.
- Net loss was \$29.6 million, or \$1.69 per share basic and diluted, for the full year 2022, compared to net loss of \$44.0 million or \$4.32 per share basic and diluted for the full year 2021, reflecting a decrease of \$14.4 million from period-to-period. Net loss was \$10.6 million, or \$0.60 per share basic and diluted, for the fourth quarter of 2022, compared to net loss of \$21.8 million or \$1.64 per share basic and diluted for the fourth quarter of 2021, reflecting a decrease of \$11.2 million from period-to-period.
- The Company's non-GAAP results in the table below reflect Adjusted EBITDA of \$(7.3 million), or \$(0.42) per share basic and diluted, for the full year 2022, compared to Adjusted EBITDA of \$(10.9 million), or \$(1.07) per share basic and diluted for the full year 2021. The Company's non-GAAP results in the table below reflect Adjusted EBITDA of \$(3.0 million), or \$(0.17) per share basic and diluted, for the fourth quarter of 2022, compared to Adjusted EBITDA of \$(1.7 million), or \$(0.13) per share basic and diluted for the fourth quarter of 2021. Adjusted EBITDA per share basic and Adjusted EBITDA per share diluted are non-GAAP financial measures, each of which are reconciled to the most directly comparable financial measures calculated in accordance with GAAP below under "Use of Non-GAAP Measures."
- At December 31, 2022, Journey Medical's cash and cash equivalents totaled \$32.0 million, compared to \$34.9 million on September 30, 2022, and \$49.1 million at December 31, 2021, a decrease of \$2.9 million for the quarter and a decrease of \$17.1 million year-over-year.

Recent Corporate Highlights:

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

- In December 2022, Journey Medical announced positive PK comparability data of DFD-29. The study successfully demonstrated that the systemic exposure of DFD-29 (40 mg) was significantly lower than that of SOLODYN[®] (105 mg). Additionally, the study showed that food did not have a significant effect on the pharmacokinetics of DFD-29.
- In May 2022, Journey Medical entered into three separate settlement agreements (the "Settlement Agreements") with Padagis for the patent infringement lawsuits that the Company filed to enforce the patents covering Qbrexza, Amzeeq and Zilxi. Pursuant to the terms of the Settlement Agreements, Padagis is prohibited from launching generic versions of Qbrexza, Amzeeq and Zilxi until August 15, 2030, July 1, 2031, and April 1, 2027, respectively. Subsequently, in December 2022, Journey Medical entered into a settlement with Teva pharmaceuticals for a patent infringement lawsuit filed by the Company related to the patents covering Qbrexza.
- In January 2022, Journey Medical received notice from its exclusive licensing partner in Japan, Maruho Co., Ltd. ("Maruho"), that Japan's Ministry of Health, Labor and Welfare approved Rapifort® Wipes 2.5% (glycopyrronium tosylate hydrate, Japanese equivalent of Qbrexza) for the treatment of primary axillary hyperhidrosis. This approval triggered a milestone payment of \$10.0 million to Journey Medical, \$7.5 million of which was paid to Dermira, Inc. ("Dermira") pursuant to the terms of the Asset Purchase Agreement between Journey Medical and Dermira, with net proceeds of \$2.5 million paid to Journey Medical. Journey Medical is entitled to receive royalties and commercial milestones from Maruho's sales of Rapifort, which was commercially launched in May 2022.
- Also in January 2022, Journey Medical acquired two FDA-approved topical minocycline products, Amzeeq and Zilxi, and a Molecule Stabilizing Technology™ platform from Vyne Therapeutics Inc. for an upfront payment of \$20.0 million and an additional \$5.0 million, which were was paid on January 12, 2022 and on the one (1)-year anniversary of the closing, respectively.
- Regarding the cybersecurity breach that resulted in losses of \$9.5 million in September 2021, the federal government has been able to seize cryptocurrency assets associated with the breach. Once the cryptocurrency has been converted back into U.S. dollars, Journey Medical will receive a notification letter to initiate the return of the cash to the Company. The final amount and timing of return of funds is still uncertain and yet to be determined.

Conference Call and Webcast Information

Journey Medical management will conduct a conference call and audio webcast on March 29, 2023, at 4:30 p.m. ET.

To listen to the conference call, interested parties within the U.S. should dial 1-866-777-2509 (domestic) or 1-412-317-5413 (international). All callers should dial in approximately 10 minutes prior to the scheduled start time and ask to be joined into the Journey Medical conference call. Participants can register for the conference here: https://dpregister.com/sreg/10175797/f5f355fdea. Please note that registered participants will receive their dial-in number upon registration.

A live audio webcast can be accessed on the News and Events page of the Investors section of Journey Medical's website, <u>www.journeymedicalcorp.com</u>, and will remain available for replay for approximately 30 days after the meeting.

About Journey Medical Corporation

Journey Medical Corporation (Nasdaq: DERM) ("Journey Medical") is focused on identifying, acquiring, developing and strategically commercializing innovative, differentiated dermatology products through its efficient sales and marketing model. The company currently markets eight products that help treat and heal common skin conditions. The Journey Medical team comprises industry experts with extensive experience in developing and commercializing some of dermatology's most successful prescription brands. Journey Medical is located in Scottsdale, Arizona and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). Journey Medical's common stock is registered under the Securities Exchange Act of 1934, as amended, and it files periodic reports with the U.S. Securities and Exchange Commission ("SEC"). For additional information about Journey Medical, visit <u>www.journeymedicalcorp.com</u>.

Forward-Looking Statements

This press release may contain "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, as amended. As used below and throughout this press release, the words "the Company", "we", "us" and "our" may refer to Journey Medical. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. The words "anticipate," "believe," "estimate," "may," "expect," "will," "could," "project," "intend" and similar expressions are generally intended to identify forward-looking statements. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating tersults, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials, including disruptions that may result from hostilities in Europe; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; potential recovery of funds lost from previously disclosed cyber security breaches; as well as other risks described in Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2022, subsequent Reports on Form 10-Q, and our other filings we make with the SEC. We expressly disclaim any obligation or undertaking t

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JOURNEY MEDICAL CORPORATION

Condensed Consolidated Balance Sheets

(\$ in thousands except for share and per share amounts)

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

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

		Three-month periods ended December 31,			Twelve-month periods ended December 31,			
	2022 20		2021		2022		2021	
Revenue:								
Product revenue, net	\$	15,921	\$	17,517	\$	70,995	\$	63,134
Other revenue		45		-		2,674		-
Total Revenue		15,966		17,517		73,669		63,134
Operating expenses								
Cost of goods sold – product revenue		7,718		9,525		30,775		32,084
Research and development		4,256		1,992		10,943		2,739
Research and development - licenses acquired		-		-		-		13,819
Selling, general and administrative		13,987		15,057		59,468		39,833
Wire transfer fraud loss		-		-		-		9,540
Total operating expenses		25,961		26,574		101,186		98,015
Loss from operations		(9,995)		(9,057)		(27,517)		(34,881)

Other expense				
Interest income	(50)	-	(60)	(2)
Interest expense	617	4,096	2,019	7,034
Foreign exchange transaction losses	67	-	89	-
Change in fair value of derivative liability	-	263	-	447
Total other expense	 634	 4,359	 2,048	 7,479
Loss before income taxes	(10,629)	 (13,416)	 (29,565)	(42,360)
Income tax expense	13	8,335	63	1,634
Net Loss	\$ (10,642)	\$ (21,751)	\$ (29,628)	\$ (43,994)
Net loss per common share:				
Basic and diluted	\$ (0.60)	\$ (1.64)	\$ (1.69)	\$ (4.32)
Weighted average number of common shares:				
Basic and diluted	17,729,238	13,244,773	17,531,274	10,189,844

Use of Non-GAAP Measures:

In addition to the GAAP financial measures as presented in our Form 10-K that will be filed with the Securities and Exchange Commission ("SEC"), the Company has, in this press release, included certain non-GAAP measurements, including Adjusted EBITDA, Adjusted EBITDA per share basic and Adjusted EBITDA per share diluted. We define Adjusted EBITDA as net income (loss) excluding interest, taxes and depreciation, less certain other non-cash and infrequent items not considered to be normal, recurring operating expenses, including, share-based compensation expense, amortization of acquired intangible assets, inventory step-ups from the purchases of intangibles assets and products, severance, wire transfer fraud loss and foreign exchange transaction losses. In particular, we exclude the following matters for the reasons more fully described below:

- Share-Based Compensation Expense: We exclude share-based compensation from our adjusted financial results because share-based compensation expense, which is non-cash, fluctuates from period to period based on factors that are not within our control, such as our stock price on the dates share-based grants are issued.
- Non-core and Short-term Research and Development Expense: We exclude research and development costs incurred in connection with our DFD-29 product candidate, which is the only product in our portfolio not currently approved for marketing and sale, because we do not consider such costs to be normal, recurring operating expenses that are core to our long-term strategy. Instead, our long-term strategy is focused on the marketing and sale of our core of licensed and FDA-approved dermatological products.
- Amortization of Acquired Intangible assets. We exclude the impact of certain amounts recorded in connection with the acquisitions of intangible assets that are either non-cash or not normal, recurring operating expenses due to their nature, variability of amounts, and lack of predictability as to occurrence and/or timing. These amounts may include non-cash items such as the amortization of acquired intangible assets and amortization of step-ups of acquisition accounting adjustments to inventories.

Adjusted EBITDA per share basic and Adjusted EBITDA per share diluted are determined by dividing the resulting Adjusted EBITDA by the number of shares outstanding on an actual and fully diluted basis.

Management believes use of these non-GAAP measures provide meaningful supplemental information regarding the Company's performance because (i) it allows for greater transparency with respect to key measures used by management in its financial and operational decision-making, (ii) it excludes the impact of non-cash or, when specified, non-recurring items that are not directly attributable to the Company's core operating performance and that may obscure trends in the Company's core operating performance and (iii) it is used by institutional investors and the analyst community to help analyze the Company's results. However, Adjusted EBITDA, Adjusted EBITDA per share basic, Adjusted EBITDA per share diluted and any other non-GAAP financial measures should be considered as a supplement to, and not as a substitute for, or superior to, the corresponding measures calculated in accordance with GAAP. Further, non-GAAP financial measures used by the Company and the manner in which they are calculated may differ from the non-GAAP financial measures of the same non-GAAP financial measures used by other companies, including the Company's competitors.

The table below provides a reconciliation from GAAP to non-GAAP measures:

JOURNEY MEDICAL CORPORATION

Reconciliation of GAAP to Non-GAAP Adjusted EBITDA (Adjusted Operating Net Loss)

(Dollars in thousands except for share and per share amounts)

	Three-month periods ended December 31,				periods Ended ber 31,		
	2022 2021		2022		2021		
GAAP Net Loss	\$ (10,642)	\$	(21,751)	\$ (29,628)	\$	(43,994)	
EBITDA:							
Interest	567		4,096	1,959		7,032	
Taxes	13		8,335	63		1,634	
Depreciation	-		-	-		-	
Amortization of acquired intangible assets	1,227		491	4,277		2,474	
EBITDA	(8,835))	(8,829)	(23,329)		(32,854)	
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Non-GAAP Adjusted EBITDA:							
Share-based compensation	1,440		2,425	4,425		2,466	
Change in fair value of derivative liabilities	-		263	-		447	
Inventory step-up expense	110		2,299	635		6,538	
Wire transfer fraud loss	-		-	-		9,540	
R&D	4,217		1,992	10,870		2,739	
Foreign exchange transaction losses	67		-	89		-	
Severance	-		175	27		175	
Non-GAAP Adjusted EBITDA	\$ (3,001)	\$	(1,675)	\$ (7,283)	\$	(10,949)	

Net loss per common share Basic and diluted:				
GAAP Net loss	\$ (0.60)	\$ (1.64)	\$ (1.69)	\$ (4.32)
Non-GAAP Net loss	\$ (0.17)	\$ (0.13)	\$ (0.42)	\$ (1.07)
Weighted average number of common shares Basic and diluted:	17,729,238	13,244,773	17,531,274	10,189,844