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): November 7, 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 November 7, 2023, Journey Medical Corporation (the "Company" or "Journey") issued a press release to provide a corporate update and to announce its financial results for the three months ended September 30, 2023. 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 November 7, 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: November 7, 2023

Journey Medical Corporation (Registrant)

By:

/s/ Claude Maraoui Claude Maraoui Chief Executive Officer, President and Director



Journey Medical Corporation Reports Third Quarter 2023 Financial Results and Recent Corporate Highlights

Company generated total net revenues of \$34.5 million in the third quarter of 2023, a 101% increase from \$17.2 million in the second quarter of 2023

GAAP net income increased to \$16.8 million, or \$0.91 per share basic and \$0.80 per share diluted, for the third quarter of 2023, compared to a GAAP net loss of \$10.1 million, or \$0.57 per share basic and diluted for the third quarter of 2022

Received an upfront payment of \$19.0 million upon entering into an exclusive license agreement with Maruho Co., Ltd. for Qbrexza® in South Korea and other Asian nations New Drug Application for DFD-29 expected to be submitted to FDA around the end of 2023

Company to hold conference call today at 4:30 p.m. ET

Scottsdale, AZ - November 7, 2023 - Journey Medical Corporation (Nasdaq: DERM) ("Journey Medical" or "the Company"), a commercial-stage pharmaceutical company that primarily focuses on the selling and marketing of U.S. Food and Drug Administration ("FDA") approved prescription pharmaceutical products for the treatment of dermatological conditions, today announced financial results and recent corporate highlights for the third quarter ended September 30, 2023.

Claude Maraoui, Journey Medical's Co-Founder, President and Chief Executive Officer, said, "In the third quarter of 2023, our total net revenues, which included the Maruho Co., Ltd. ("Maruho") out-licensing upfront payment, were \$34.5 million, a 101% increase from \$17.2 million in the second quarter, and a 114% increase from \$16.1 million in the third quarter of 2022. We are also extremely pleased with the positive topline results from our two Phase 3 clinical trials evaluating DFD-29 for the treatment of rosacea. We expect to submit a New Drug Application ("NDA") to the FDA for DFD-29 around year-end."

Financial Results:

- Total net revenues in the third quarter of 2023 were \$34.5 million, an increase of \$18.4 million, or 114%, compared to the third quarter of 2022. The increase is due to
 the Company's entry into a new license agreement with Maruho resulting in \$19.0 million of revenue during the third quarter.
- Cost of goods sold decreased by \$0.8 million, or 11%, to \$6.4 million for the three-month period ended September 30, 2023, from \$7.2 million for the three-month period ended September 30, 2022. The decrease is primarily due to the contractual reduction in our Qbrexza® royalty from period-to-period.
- Selling, general and administrative expenses ("SG&A") decreased by \$7.0 million, or 45%, to \$8.6 million for the third quarter of 2023, from \$15.6 million for the third quarter 2022. The decrease is mainly attributable to the Company's expense reduction efforts, primarily in sales and marketing and other SG&A areas. The impact of the cost reduction initiatives is expected to result in a reduction of greater than \$17.0 million of annual SG&A expenses in 2023, surpassing our earlier target of \$12.0 million.
- Research and Development ("R&D") expenses decreased by \$0.6 million, or 21%, to \$2.2 million for the third quarter of 2023, from \$2.8 million for the third quarter 2022. The decrease is related to lower clinical trial expenses to develop our DFD-29 product, as the two Phase 3 studies have concluded.
- GAAP net income was \$16.8 million, or \$0.91 per share basic and \$0.80 per share diluted, for the third quarter of 2023, compared to GAAP net loss of \$(10.1) million, or \$(0.57) per share basic and diluted, for the third quarter of 2022.
- The Company's non-GAAP results in the table below reflect Adjusted EBITDA of \$20.8 million, or \$1.13 per share basic and \$0.99 per share diluted, for the third quarter of 2023, compared to Adjusted EBITDA of \$(4.0 million), or \$(0.23) per share basic and diluted for the third quarter of 2022. Adjusted EBITDA and Adjusted EBITDA per share basic and 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 September 30, 2023, the Company had \$24.8 million in cash and cash equivalents, compared to \$32.0 million in cash and cash equivalents as of December 31, 2022.
- In July 2023, the Company voluntarily repaid the entire \$10.0 million outstanding term loan. The repayment satisfied all of the Company's outstanding debt obligations under its debt facility. The Company therefore has no further debt obligations.

Recent Corporate Highlights:

• The Company is pleased to announce results from the Phase 3 studies (MVOR-1 & MVOR-2) for DFD-29 on a secondary endpoint related to erythema (redness) assessment. DFD-29 showed significantly superior reduction in Clinicians Erythema Assessment (CEA) compared to placebo in both MVOR-1 and MVOR-2 clinical trials. Srinivas Sidgiddi, M.D., Vice President, Research & Development of Journey Medical, said, "Erythema is an important sign of rosacea severity and the beneficial effect of DFD-29 on erythema is very relevant to rosacea treatment. Also, erythema improvement is likely to be a significant differentiator for DFD-29 over the current standard of care."

CEA Results from MVOR-1 and MVOR-2

Proportion of Subjects with at Least a 2-Grade Reduction in CEA								
STUDY	DFD-29 (40 mg)	Placebo	Difference (95% CI)	P-values				
MVOR-1	39/122 (31.7%)	11/80 (13.8%)	18.1% (7.32%, 28.96%)	0.006				
MVOR-2	30/123 (24.5%)	10/82 (12%)	13.9% (3.71%, 23.99%)	0.023				

 In October 2023, Journey Medical had a productive pre-NDA meeting with the FDA for DFD-29 (Minocycline Hydrochloride Modified Release Capsules, 40 mg) to treat rosacea in adults. The Company expects to provide an update following receipt of the meeting minutes.

- In October 2023, Journey Medical announced data from a comparative bioavailability (bridging) study of DFD-29 (40 mg) vs. Solodyn® (Minocycline Hydrochloride Extended-Release Tablets, 105 mg), which were presented at the 43rd Annual Fall Clinical Dermatology Conference. The data demonstrated systemic exposure of DFD-29 was significantly lower than that of Solodyn (105 mg), and no significant safety issues were noted for DFD-29.
- In September 2023, Journey Medical entered into an exclusive license agreement with Maruho, a Japanese company specializing in dermatology as well as Journey Medical's exclusive licensing partner that developed and is commercializing Qbrexza® (Rapifort®) in Japan. Under the terms of the Agreement, Journey Medical received a \$19.0 million nonrefundable upfront payment and granted Maruho an exclusive license to develop and commercialize Qbrexza (Rapifort / DRM04 / glycopyrronium tosylate hydrate) for the treatment of hyperhidrosis in South Korea, Taiwan, Hong Kong, Macau, Thailand, Indonesia, Malaysia, Philippines, Singapore, Vietnam, Brunei, Cambodia, Myanmar and Laos (the "Territory"). Maruho is responsible for all development and commercialization costs for the program throughout the Territory.
- In July 2023, Journey Medical announced positive topline data from its two DFD-29 Phase 3 clinical trials for the treatment of rosacea. The Phase 3 clinical trials achieved the co-primary and all secondary endpoints and subjects completed the 16-week treatment with no significant safety issues. DFD-29 demonstrated statistical superiority over both the standard of care Oracea® and placebo for Investigator's Global Assessment treatment success and the reduction in the total inflammatory lesion count in both studies. Journey Medical plans to file an NDA to the FDA for DFD-29 around the end of 2023 and anticipates potential approval from the FDA in the fourth quarter of 2024.

Conference Call and Webcast Information

Journey Medical management will conduct a conference call and audio webcast on Tuesday, November 7, 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/10183424/fab4c8de00. 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 a commercial-stage pharmaceutical company that primarily focuses on the selling and marketing of U.S. Food and Drug Administration-approved prescription pharmaceutical products for the treatment of dermatological conditions through its efficient sales and marketing model. The company currently markets eight branded and two generic 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 www.journeymedicalcorp.com.

Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, 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," "potential" 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 results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: the fact that our products and product candidates are subject to time and cost intensive regulation and clinical testing and as a result, may never be successfully developed or commercialized; a substantial portion of our sales derive from products that may become subject to third- party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse impact on our operating income; we operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations; our revenue is dependent mainly upon sales of our dermatology products and any setback relating to the sale of such products could impair our operating results; competition could limit our products' commercial opportunity and profitability, including competition from manufacturers of generic versions of our products; the risk that our products do not achieve broad market acceptance, including by government and third-party payors; our reliance third parties for several aspects of our operations; our dependence on our ability to identify, develop, and acquire or in-license products and integrate them into our operations, at which we may be unsuccessful; the dependence of the success of our business, including our ability to finance our company and generate additional revenue, on the successful development and regulatory approval of the DFD-29 product candidate and any future product candidates that we may develop, in-license or acquire; clinical drug development is very expensive, time consuming, and uncertain and our clinical trials may fail to adequately demonstrate the safety and efficacy of our current or any future product candidates; our competitors could develop and commercialize products similar or identical to ours; risks related to the protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products; our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or our third parties' cybersecurity; the substantial doubt about our ability to continue as a going concern; the effects of major public health issues, epidemics or pandemics on our product revenues and any future clinical trials; our potential need to raise additional capital; Fortress controls a voting majority of our common stock, which could be detrimental to our other shareholders; 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 to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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JOURNEY MEDICAL CORPORATION

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

	Sept	tember 30, 2023	De	<u>cember 31,</u> 2022
ASSETS				
Current assets				
Cash and cash equivalents	\$	24,749	\$	32,003
Accounts receivable, net of reserves		7,989		28,208
Inventory		11,024		14,159
Prepaid expenses and other current assets		924		3,309
Total current assets		44,686		77,679
Intangible assets, net		21,102		27,197
Operating lease right-of-use asset, net		124		189
Other assets		6		95
Total assets	\$	65,918	\$	105,160
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities	\$	28,164	¢	26.570
Accounts payable Due to related party	\$	28,164	\$	36,570 413
Accrued expenses		1,093		19,388
Accrued interest		10,020		19,388
Income taxes payable		130		35
Line of credit		150		2,948
Deferred cash payment (net of discount of \$9)				4,991
Installment payments – licenses, short-term		3,000		2,244
Operating lease liability, short-term		97		83
Total current liabilities		48,510		66.832
		40,510		00,852
Term loan, long-term (net of debt discount of \$174)		-		19.826
Installment payments – licenses, long-term		-		1,412
Operating lease liability, long-term		34		108
Total liabilities		48,544		88,178
		,.	_	
Stockholders' equity				
Common stock, \$.0001 par value, 50,000,000 shares authorized, 12,496,782 and 11,765,700 shares issued and outstanding as				
of September 30, 2023 and December 31, 2022, respectively		1		1
Common stock - Class A, \$.0001 par value, 50,000,000 shares authorized, 6,000,000 shares issued and outstanding as of				
September 30, 2023 and December 31, 2022		1		1
Additional paid-in capital		87,584		85,482
Accumulated deficit		(70,212)		(68,502)
Total stockholders' equity		17,374		16,982
Total liabilities and stockholders' equity	\$	65,918	\$	105,160

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

	Three-Month Periods Ended September 30,					Nine-Month Periods Ended September 30,			
	 2023		2022		2023		2022		
Revenue:	 								
Product revenue, net	\$ 15,279	\$	16,043	\$	44,405	\$	55,074		
Other revenue	19,260		73		19,519		2,629		
Total revenue	34,539		16,116		63,924		57,703		
Operating expenses									
Cost of goods sold – product revenue	6,429		7,221		20,645		23,057		
Research and development	2,229		2,812		6,036		6,687		
Selling, general and administrative	8,636		15,575		34,069		45,481		
Loss on impairment of intangible assets	-		-		3,143		-		
Total operating expenses	17,294		25,608		63,893		75,225		
Income (loss) from operations	17,245	_	(9,492)	_	31	_	(17,522)		
Other expense (income)									
Interest income	(8)		(3)		(209)		(10)		
Interest expense	268		559		1,674		1,402		
Foreign exchange transaction losses	101		22		181		22		
Total other expense (income)	 361		578		1,646		1,414		

Income (loss) before income taxes		16,884	 (10,070)	 (1,615)	 (18,936)
Income tax expense		95	10	95	50
Net income (loss)	\$	16,789	\$ (10,080)	\$ (1,710)	\$ (18,986)
	<u> </u>		 		
Net income (loss) per common share:					
Basic	\$	0.91	\$ (0.57)	\$ (0.09)	\$ (1.09)
Diluted		0.80	(0.57)	(0.09)	(1.09)
Weighted average number of common shares:					
Basic		18,416,368	17,618,064	18,078,437	17,464,561
Diluted		21,034,758	17,618,064	18,078,437	17,464,561

The weighted average number of common shares Basic in the above table is used to calculate both basic and diluted loss per share for the three and nine-month periods ended September 30, 2022, and basic and diluted loss per share for the nine-month period ended September 30, 2023, as the net loss for these periods is antidilutive and the effect would be to reduce the loss per share.

Use of Non-GAAP Measures:

In addition to the GAAP financial measures, 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 and impairment of acquired intangible assets, inventory step-ups from the purchases of intangibles assets and products, severance, non-core research and development expense 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 acquired and/or licensed FDA-approved dermatological products.
- Amortization and impairments 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, impairments 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 diluted and operation of the 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

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

		Three-month periods ended September 30,					Nine-month periods ended September 30,			
	2023		2022	202	23		2022			
GAAP Net Income (Loss)	\$ 16,789	\$	(10,080)	\$	(1,710)	\$	(18,986)			
EBITDA:										
Interest	260		556		1,465		1,392			
Taxes	95		10		95		50			
Depreciation			-		-					
Amortization of acquired intangible assets	814		1,016		2,952		3,050			
EBITDA	17,958		(8,498)		2,802		(14,494)			
Non-GAAP Adjusted EBITDA:										
Share-based compensation	558		1,438		2,077		2,985			
Loss on impairment of intangible assets			-		3,143		-			
Inventory step-up expense			214		-		525			

Non-core & short-term R&D	2,206	2,778	5,949	6,653
Foreign exchange transaction losses	100	22	181	22
Severance	-	27	711	27
Non-GAAP Adjusted EBITDA	\$ 20,822	\$ (4,019)	\$ 14,863	\$ (4,282)
Net income (loss) per common share:				
Basic				
GAAP Net Income (Loss)	\$ 0.91	\$ (0.57)	\$ (0.09)	\$ (1.09)
Non-GAAP Net Income (Loss)	\$ 1.13	\$ (0.23)	\$ 0.82	\$ (0.25)
Diluted				
GAAP Net Income (Loss)	\$ 0.80	\$ (0.57)	\$ (0.09)	\$ (1.09)
Non-GAAP Net Income (Loss)	\$ 0.99	\$ (0.23)	\$ 0.72	\$ (0.25)
Weighted average number of common shares:				
Basic	18,416,368	17,618,064	18,078,437	17,464,561
Diluted	21,034,758	17,618,064	20,588,661	17,464,561

The weighted average number of common shares Basic in the above table is used to calculate both GAAP and Non-GAAP basic and diluted loss per share for the three and nine-month periods ended September 30, 2022, and GAAP basic and diluted loss per share for the nine-month period ended September 30, 2023, as the net loss for these periods is antidilutive and the effect would be to reduce the loss per share.