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): May 12, 2023

IMPEL PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40353**	**26-3058238**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

201 Elliott Avenue West, Suite 260 **Seattle, WA**	**98119**
(Address of principal executive offices)	**(Zip Code)**

(206) 568-1466
(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

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 (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, $0.001 Par Value Per Share	IMPL	The Nasdaq Stock Market LLC

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).

Emerging growth company ☒

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 May 12, 2023, Impel Pharmaceuticals Inc. issued a press release announcing its financial results for the quarter ended March 31, 2023. A copy of the press release is attached as Exhibit 99.1 to this report.

The information in this Item 2.02, including Exhibit 99.1 to this report, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Impel Pharmaceuticals Inc. regarding its financial results for quarter ended March 31, 2023, dated May 12, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

IMPEL PHARMACEUTICALS, INC.

Date: May 12, 2023

By: /s/ Michael Kalb

Michael Kalb
Chief Financial Officer

IMPEL PHARMACEUTICALS ANNOUNCES FIRST QUARTER 2023 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

Trudhesa® Achieved nTRx of Over 18.5K in Q1 2023; Increase of 112% vs. Q1 2022

Trudhesa Net Product Revenue in Q1 2023 Increased 149% vs. Q1 2022 to $4.4 Million

Impel to Host Investor Conference Call Today at 8:30 a.m. ET

SEATTLE, May 12, 2023 — Impel Pharmaceuticals Inc. (NASDAQ: IMPL), a commercial-stage biopharmaceutical company with a mission to develop transformative therapies for people suffering from diseases with high unmet medical needs, today reported financial results for the first quarter ended March 31, 2023 and provided a business update.

"Following our strategic reprioritization to focus the company on maximizing the growth potential of Trudhesa®, we are pleased with the significant increases in reimbursed prescriptions and new patient starts over the first quarter of 2023," said Adrian Adams, Chairman of the Board and Chief Executive Officer of Impel Pharmaceuticals. "Additionally, the ongoing feedback we are receiving from our growing prescriber base on the compelling safety and efficacy profile of Trudhesa reinforces the value-creation opportunity for our shareholders. This is further reflected in the prescription momentum we are seeing in the second quarter of this year."

Recent Corporate Highlights

Trudhesa® (Dihydroergotamine Mesylate) Nasal Spray (0.725 Mg Per Spray)

- To-date, Trudhesa continues a strong trajectory with more than 87,000 prescriptions generated since launch. Based on third-party data, it is estimated that at the end of April 2023, Trudhesa accounted for 4.7 percent of branded acute migraine prescriptions (nTRx) among prescribers.
- We continue to see the benefits from increasing the sales force in July of 2022. New Trudhesa patients increased by 18 percent from Q4 2022 to Q1 2023, driven by an expanded, more efficient and increasingly productive sales force.
- Reimbursement of all shipments was 72 percent in Q1 2023, compared with 60 percent in Q4 2022.
- Refill rates have remained solid and consistently high at 62 percent launch-to-date.
- Company recently presented Trudhesa data at the 2023 American Academy of Neurology (AAN) Annual Meeting in April suggesting Trudhesa is safe to use when co-administered with commonly prescribed migraine medications, including an analysis from the first-ever pharmacokinetic and pharmacodynamic evaluation of potential drug-drug interactions between Trudhesa and orally administered gepants. Additional analyses from the pivotal STOP 301 trial show concomitant use of Trudhesa with triptans and erenumab (a preventive CGRP medication) were well-tolerated with limited treatment-emergent adverse events reported.

Company Developments

- Earlier this week, Impel announced the appointment of Michael W. Kalb, CPA, as Chief Financial Officer, effective May 10, 2023, following his tenure as Executive Vice President & Chief Financial Officer of CinCor Pharma, Inc. (NASDAQ: CINC), where he played an integral role in the company's recent acquisition by AstraZeneca for up to $1.8 billion. Mr. Kalb has more than 30 years of experience in the pharmaceutical and financial service industries.
- In April 2023, Impel announced the appointment of Darren Cline to its Board of Directors. Mr. Cline brings more than 30 years of experience in the biopharmaceutical industry, including extensive commercial and operational expertise.

Financial Results for First Quarter 2023

- **Net Product Revenue:** The Company's net revenue from sales of Trudhesa was $4.4 million for Q1 2023. This compared to net revenues of $1.8 million for Q1 2022. The increase is due to growth in Trudhesa sales volume and improvements in net price realization.
- **Research and Development (R&D) Expenses:** R&D expenses were $3.0 million for Q1 2023, compared with $3.7 million for Q1 2022. The decrease is primarily due to lower personnel costs and program costs as the Company redirected its resources from R&D activities and pivoted its focus to supporting commercial operations rather than R&D in Q1 2023.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses were $22.0 million for Q1 2023, compared with $19.8 million for Q1 2022. The increase in SG&A spending was primarily due to the continued ramp-up in spending to support the commercial, sales and marketing activity in support of Trudhesa.
- **Net Loss:** Net losses for Q1 2023 were $30.1 million, or $1.27 per common share. This compared to net losses of $27.0 million, or $1.17 per common share, for Q1 2022.
- **Cash on Hand/Cash Runway:** As of March 31, 2023, Impel had approximately $35.5 million in cash and cash equivalents. The Company believes, based on its current operating plan, that it has sufficient capital to fund operations into Q3 2023.

Trudhesa Guidance for 2023

- The Company continues to project that Trudhesa will deliver prescriptions within the range of 80,000 – 110,000 TRx for full-year 2023.

Conference Call Information

Impel Pharmaceuticals' Executive Management will host a live conference call and webcast at 8:30 a.m. ET today to discuss the first quarter 2023 financial results and provide a corporate and business update. To access the live conference call, please register using the conference link: Conference Registration (vevent.com). A live webcast of the event will be available on the Investors section of the Impel Pharmaceuticals website at https://investors.impelpharma.com/. A replay of the webcast and accompanying slides will be available on the Impel Pharmaceuticals website following the event.

About Impel Pharmaceuticals

Impel Pharmaceuticals is a commercial-stage pharmaceutical company developing transformative therapies for people suffering from diseases with high unmet medical needs. Impel offers treatments that pair its proprietary POD® technology with well-established therapeutics. In September 2021, Impel received U.S. FDA approval for its first product, Trudhesa® nasal spray, which is approved in the U.S. for the acute treatment of migraine with or without aura in adults. In addition to Trudhesa, the Company continues to address patient needs via licensing and partnerships.

About Impel's Precision Olfactory Delivery (POD®) Technology:

Impel's proprietary POD® technology is able to deliver a range of therapeutic molecules and formulations into the vascular-rich upper nasal space, believed to be a gateway for unlocking the previously unrealized full potential of these molecules. By delivering predictable doses of drug directly to the upper nasal space, Impel's precision performance technology has the goal of enabling increased and consistent absorption of drug, overriding the high variability associated with other nasal delivery systems, yet without the need for an injection. While an ideal target for drug administration, to date no technology has been able to consistently deliver drugs to the upper nasal space. By utilizing this route of administration, Impel Pharmaceuticals has been able to demonstrate blood concentration levels for its investigational therapies that are comparable to intramuscular (IM) administration and can even reach intravenous (IV)-like systemic levels quickly, which could transform the treatment landscape for a broad range of disorders. Importantly, the POD® technology offers propellant-enabled delivery of dry powder and liquid formulations that eliminates the need for coordination of breathing, allowing for self- or caregiver-administration in a manner that may improve patient outcome, comfort, and potentially, compliance.

About Trudhesa®

Indication

Trudhesa® is used to treat an active migraine headache with or without aura in adults. Do not use Trudhesa to prevent migraine when you have no symptoms. It is not known if Trudhesa is safe and effective in children.

Important Safety Information

Serious or potentially life-threatening reductions in blood flow to the brain or extremities due to interactions between dihydroergotamine (the active ingredient in Trudhesa) and strong CYP3A4 inhibitors (such as protease inhibitors and macrolide antibiotics) have been reported rarely. As a result, these medications should not be taken together.

Do not use Trudhesa if you:

- Have any disease affecting your heart, arteries, or blood circulation.
- Are taking certain anti-HIV medications known as protease inhibitors (such as ritonavir or nelfinavir).
- Are taking a macrolide antibiotic such as clarithromycin or erythromycin.
- Are taking certain antifungals such as ketoconazole or itraconazole.
- Have taken certain medications such as triptans or ergot-type medications for the treatment or prevention of migraine within the last 24 hours.
- Have taken any medications that constrict your blood vessels or raise your blood pressure.
- Have severe liver or kidney disease.
- Are allergic to ergotamine or dihydroergotamine.

Before taking Trudhesa, tell your doctor if:

- You have high blood pressure, chest pain, shortness of breath, heart disease; or risk factors for heart disease (such as high blood pressure, high cholesterol, obesity, diabetes, smoking, strong family history of heart disease or you are postmenopausal, or male over 40); or problems with blood circulation in your arms, legs, fingers, or toes.
- You have or had any disease of the liver or kidney.
- You are taking any prescription or over-the-counter medications, including vitamins or herbal supplements.
- You are pregnant, planning to become pregnant or are nursing, or have ever stopped medication due to an allergy or bad reaction.
- This headache is different from your usual migraine attacks.

The use of Trudhesa should not exceed dosing guidelines and should not be used on a daily basis. Serious cardiac (heart) events, including some that have been fatal, have occurred following the use of dihydroergotamine mesylate, particularly with dihydroergotamine for injection, but are extremely rare.

You may experience some nasal congestion or irritation, altered sense of taste, sore throat, nausea, vomiting, dizziness, and fatigue after using Trudhesa.
Contact your doctor immediately if you experience:

- Numbness or tingling in your fingers and toes
- Severe tightness, pain, pressure, heaviness, or discomfort in your chest
- Muscle pain or cramps in your arms or legs
- Cold feeling or color changes in one or both legs or feet
- Sudden weakness
- Slurred speech

- Swelling or itching

The risk information provided here is not comprehensive. To learn more, talk about Trudhesa with your healthcare provider or pharmacist. The FDA-approved product labeling can be found at www.Trudhesa.com or 1-800-555-DRUG. You can also call 1-833-TRUDHESA (1-833-878-3437) for additional information.

Cautionary Note on Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, the potential clinical benefits of Trudhesa®, the market opportunities of Trudhesa within the migraine market, the speed of uptake and market growth of Trudhesa, the effectiveness of the Trudhesa sales force, and Impel's cash runway. Forward-looking statements can be identified by words such as: "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" or the negative or plural of these words or similar expressions. These statements are subject to numerous risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including but not limited to, Impel's ability to maintain regulatory approval of Trudhesa, its ability to execute its commercialization strategy for Trudhesa, its ability to develop, manufacture and commercialize any other product candidates including plans to address additional indications for which Impel may pursue regulatory approval, and the effects of macroeconomic conditions on business operations and any future clinical programs. Many of these risks are described in greater detail in Impel's filings with the Securities and Exchange Commission. Any forward-looking statements in this press release speak only as of the date of this press release. Impel assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Impel Pharmaceuticals Inc.
Condensed Consolidated Statement of Operations and Comprehensive Loss
(in thousands)

	For the Three Months Ended March 31,	
	2023	**2022**
Product revenue, net	$ 4,372	$ 1,759
Cost of goods sold	2,285	1,033
Gross profit	2,087	726
Operating expenses:		
Research and development	3,003	3,650
Selling, general and administrative	22,037	19,799
Restructuring	1,483	—
Total operating expenses	26,523	23,449
Loss from operations	(24,436)	(22,723)
Other income (expense), net :		
Interest income (expense), net	(2,933)	(4,427)
Other income (expense), net	(2,698)	180
Total other income (expense), net	(5,631)	(4,247)
Loss before income taxes	(30,067)	(26,970)
Provision (benefit) for income taxes	—	—
Net loss and comprehensive loss	$ (30,067)	$ (26,970)
Net loss per share, basic and diluted	$ (1.27)	$ (1.17)
Weighted-average shares used in computing net loss per share — basic and diluted	23,745,871	23,143,773

IMPEL PHARMACEUTICALS INC.
Condensed Consolidated Balance Sheet
(In thousands, except share and per share data)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 35,465	$ 60,654
Trade receivables, net	6,280	7,444
Inventory	8,014	8,427
Prepaid expenses and other current assets	2,125	3,284
Total current assets	51,884	79,809
Property and equipment, net	4,081	3,863
Operating lease right-of-use assets	4,833	3,132
Other assets	3,931	1,746
Total assets	**$ 64,729**	**$ 88,550**
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 6,133	$ 6,092
Accrued liabilities and other liabilities	11,723	12,503
Current portion of deferred royalty obligation	2,690	2,027
Current portion of operating lease liability	1,736	1,541
Total current liabilities	22,282	22,163
Operating lease liability, net of current portion	3,074	1,573
Deferred royalty obligation, net of current portion	64,183	60,899
Long-term debt	48,095	48,072
Total liabilities	**137,634**	**132,707**
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized: none issued	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized; 23,746,257 and 23,739,313 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	24	24
Additional paid-in capital	278,248	276,929
Accumulated deficit	(351,177)	(321,110)
Total stockholders' (deficit) equity	(72,905)	(44,157)
Total liabilities and stockholders' (deficit) equity	**$ 64,729**	**$ 88,550**

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