

**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 24, 2023**

**IMPEL PHARMACEUTICALS INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-40353**  
(Commission  
File Number)

**26-3058238**  
(IRS Employer  
Identification No.)

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

**98119**  
(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 March 24, 2023, Impel Pharmaceuticals Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2022. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release issued by Impel Pharmaceuticals Inc. regarding its financial results for the fourth quarter and full year ended December 31, 2022, dated March 24, 2023.</a>
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: March 24, 2023

By: /s/ Rajiv Amin

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Rajiv Amin

Vice President, Controller & Interim Chief Financial  
Officer

## IMPEL PHARMACEUTICALS ANNOUNCES FOURTH QUARTER AND FULL YEAR 2022 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

*Trudhesa® Achieved nTRx of Over 58.4K in 2022; nTRx Increased by 19.4% in Q4 vs. Q3 2022*

*Net Product Revenue Finished Year at \$12.7 Million; Increased 62% in Q4 vs. Q3 2022 to \$5 Million*

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

**SEATTLE, March 24, 2023 — Impel Pharmaceuticals Inc. (NASDAQ: IMPL),** a commercial-stage pharmaceutical company with a mission to develop transformative therapies for people suffering from diseases with high unmet medical needs, today reported financial results for the fourth quarter and full year ended December 31, 2022 and provided a business update.

“We continued to see strong growth in Trudhesa® prescriptions as we moved into 2023. The Company’s priority objective is to maximize the growth potential of Trudhesa in a market where we already hold 4.3 percent of total branded acute migraine prescriptions among Trudhesa prescribers,” said Adrian Adams, Chairman of the Board and Chief Executive Officer of Impel Pharmaceuticals. “Additionally, we continue to see increased productivity and efficiency from the field force expansion we completed in July 2022. This, together with the increased number of prescriptions reimbursed and resultant positive impact on revenue growth, points to the value creation opportunity with Impel.”

### Recent Corporate Highlights

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

- To-date, Trudhesa continues a strong trajectory with more than 58,400 prescriptions generated in 2022. Based on third-party data, it is estimated that at the end of December Trudhesa accounted for 4.3 percent of branded acute migraine prescriptions (nTRx) among prescribers.
- We continue to see the benefits of the increased sales force from last July. New Trudhesa prescriptions increased by 24 percent from Q3 to Q4 2022 driven by an expanded, more efficient salesforce. Additionally, the existing (n=60) and new (n=30) sales representatives increased monthly new patients starts by 29.7 percent and 45.8 percent, respectively, from October through December 2022, for a total increase in monthly new patient starts of more than 35 percent during this time period.
- Reimbursement of all shipments is 60 percent for the fourth quarter 2022. Refill rates have remained consistently high with 63 percent at the end of 2022.



- Impel will have a presence at the American Academy of Neurology (AAN) Annual Meeting taking place in Boston, April 22-27, 2023 and at the American Headache Society (AHS) Annual Scientific Meeting taking place in Austin, Texas, June 15-18, 2023.

### **Clinical Developments**

- In November 2022, Impel published a manuscript in *The Journal of Headache and Pain* which detailed results from a review developed to illustrate the variability of recurrence rates depending on the definition of “recurrence” for widely used acute treatments for migraine.
- Also in November 2022, Impel published a manuscript in the *Journal of Aerosol Medicine and Pulmonary Drug Delivery* which showed that clinical studies of Trudhesa demonstrated a favorable pharmacokinetic profile, consistent and predictable dosing, rapid systemic levels known to be effective (similar to other DHE mesylate clinical programs), safety and tolerability on the upper nasal mucosa, and high patient acceptance. Additionally, the Precision Olfactory Delivery (POD<sup>®</sup>) technology may have the potential to overcome the limitations of traditional nasal delivery systems, while utilizing the nasal delivery benefits of gastrointestinal tract avoidance, rapid onset, patient convenience, and ease of use.
- In October 2022, Impel published a manuscript in the *Annals of Otolaryngology and Rhinology Outreach* detailing results from first-of-their-kind safety assessments designed for and used in the pivotal STOP 301 study of Trudhesa.

### **Financial Results for Fourth Quarter and Year End 2022**

- **Net Product Revenue:** The Company’s net revenue from sales of Trudhesa was \$5.0 million and \$12.7 million for the fourth quarter and full year 2022, respectively. This compared to net revenues of \$0.6 million and \$0.7 million for the fourth quarter and full year 2021, respectively. Shipments of Trudhesa were initiated to specialty pharmacies in late September 2021 ahead of the October 2021 commercial launch.
- **Research and Development (R&D) Expenses:** R&D expenses were \$0.7 million and \$11.5 million for the fourth quarter and full year 2022, respectively, compared with \$4.5 million and \$20.6 million for the same periods of 2021, respectively. The decrease in R&D expense was due to the return of the \$2.9 million new drug application fee from the U.S. Food and Drug Administration (FDA) received in the fourth quarter of 2022 and a reduction in Trudhesa clinical expenses as the Phase 3 STOP 301 study was closed. This was partially offset by an increase in spending for the clinical development of INP105.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses were \$20.3 million and \$77.9 million for the fourth quarter and full year 2022, respectively, compared with \$19.9 million and \$50.9 million for the same periods of 2021, respectively. 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 the Trudhesa launch.
- **GAAP Net Loss:** Net losses for the fourth quarter and full year 2022 were \$23.0 million and \$106.3 million, respectively, or \$0.97 and \$4.53 per common share, respectively. This compared to net losses of \$24.7 million and \$76.7 million, respectively, or \$1.07 and \$5.25 per common share, respectively, for the same periods in 2021.



- **Non-GAAP Net Loss Per Share:** Non-GAAP Net Loss Per Share for the fourth quarter and full year 2022 were \$0.97 and \$4.53, respectively, compared to a Non-GAAP Net Loss Per Share of \$1.07 and \$3.68, respectively, for the same periods in 2021. Non-GAAP Pro Forma Net Loss Per Share gives effect to the Company's reverse stock split, the shares of common stock issued in its April 2021 IPO, shares exchanged for previously issued and outstanding stock warrants of Impel, and the conversion of the Company's convertible preferred stock and its convertible notes into shares of common stock as if such conversions occurred at the beginning of each period presented. Non-GAAP Net Loss Per Share excludes the change in fair value of the convertible notes and interest expense on Impel's convertible notes, the effect of accretion on its redeemable convertible preferred stock and the change in fair value of its redeemable convertible preferred stock warrants, all of which converted to shares of common stock in the Company's April 2021 IPO. Please refer to the section in this press release titled "Reconciliation of GAAP and Non-GAAP Results" for details.
- **Cash on Hand/Cash Runway:** As of December 31, 2022, Impel had approximately \$60.7 million in cash and cash equivalents. The Company believes, based on its current operating plan, that it has sufficient capital to fund operations into the third quarter of 2023.

### Trudhesa Guidance for 2023

- The Company projects 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 fourth quarter and full year 2022 financial results and provide a corporate and business update. To access the live conference call, please register using the conference link: [Conference Registration \(vevent.com\)](https://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.

### Non-GAAP Financial Measures

We have provided in this press release certain financial information that has not been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). Our management uses these non-GAAP financial measures internally in analyzing our financial results and believes that use of these non-GAAP financial measures is useful to investors as an additional tool to evaluate ongoing operating results and trends and in comparing our financial results with other companies in our industry, many of which present similar non-GAAP financial measures. Non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable financial measures prepared in accordance with GAAP and should be read only in conjunction with our consolidated financial statements prepared in accordance with GAAP. A reconciliation of our historical non-GAAP financial measures to the most directly comparable GAAP measures has been provided in the financial statement tables included in this press release, and investors are encouraged to review these reconciliations.

### 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<sup>®</sup> technology with well-established therapeutics. In September 2021, Impel received U.S. FDA approval for its first product, Trudhesa<sup>®</sup> 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<sup>®</sup>) Technology:

Impel's proprietary POD<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>

##### Indication

Trudhesa<sup>®</sup> 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](http://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, our expected full year 2023 reported TRx guidance, 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 general market and 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, POD, Trudhesa and the Impel logo are registered trademarks of Impel Pharmaceuticals Inc. To learn more about Impel Pharmaceuticals, please visit our website at <https://impelpharma.com>.



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

	December 31, 2022	December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 60,654	\$ 88,212
Trade receivables, net	7,444	1,352
Inventory	8,427	2,824
Prepaid expenses and other current assets	3,284	2,188
<b>Total current assets</b>	<b>79,809</b>	<b>94,576</b>
Property and equipment, net	3,863	3,149
Operating lease right-of-use assets	3,132	—
Other assets	1,746	187
<b>Total assets</b>	<b>\$ 88,550</b>	<b>\$ 97,912</b>
<b>Liabilities and stockholders' (deficit) equity</b>		
Current liabilities:		
Accounts payable	\$ 6,092	\$ 6,367
Accrued liabilities	12,242	8,950
Current portion of deferred royalty obligation	2,027	—
Current portion of operating lease liability	1,541	—
Common stock warrant liability	261	637
<b>Total current liabilities</b>	<b>22,163</b>	<b>15,954</b>
Operating lease liability, net of current portion	1,573	—
Deferred royalty obligation, net of current portion	60,899	—
Long-term debt	48,072	29,450
<b>Total liabilities</b>	<b>132,707</b>	<b>45,404</b>
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; 23,739,313 and 23,123,062 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	24	23
Additional paid-in capital	276,929	267,283
Accumulated deficit	(321,110)	(214,798)
<b>Total stockholders' (deficit) equity</b>	<b>(44,157)</b>	<b>52,508</b>
<b>Total liabilities and stockholders' (deficit) equity</b>	<b>\$ 88,550</b>	<b>\$ 97,912</b>



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

	For the Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Product revenue, net	\$ 5,008	\$ 577	\$ 12,652	\$ 668
Cost of goods sold	2,217	441	6,495	691
Gross profit	2,791	136	6,157	(23)
Operating expenses:				
Research and development	700	4,460	11,456	20,563
Selling, general and administrative	20,332	19,929	77,885	50,900
Total operating expenses	21,032	24,389	89,341	71,463
Loss from operations	(18,241)	(24,253)	(83,184)	(71,486)
Other income (expense), net :				
Interest income (expense), net	(2,766)	(772)	(13,835)	(4,243)
Other income (expense), net	(2,034)	285	(9,293)	(805)
Total other income (expense), net	(4,800)	(487)	(23,128)	(5,048)
Loss before income taxes	(23,041)	(24,740)	(106,312)	(76,534)
Provision for income taxes	—	2	—	2
Net loss and comprehensive loss	\$ (23,041)	\$ (24,742)	\$ (106,312)	\$ (76,536)
Accretion on redeemable convertible preferred stock	—	—	—	129
Net loss attributable to common stockholders	\$ (23,041)	\$ (24,742)	\$ (106,312)	\$ (76,665)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.97)	\$ (1.07)	\$ (4.53)	\$ (5.25)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	23,739,312	23,067,570	23,445,096	14,600,346



**Impel Pharmaceuticals Inc.**  
**Earnings Per Share**  
(in thousands, except share and per share amounts)

	For the Three Months Ended December 31,		For the Years Ended, December 31,	
	2022	2021	2022	2021
<b>GAAP Basic and Diluted EPS</b>				
Numerator:				
Net loss and comprehensive loss	\$ (23,041)	\$ (24,742)	\$ (106,312)	\$ (76,536)
Add: Accretion of preferred stock to redemption value	—	—	—	(129)
Net loss attributable to common shareholders	<u>\$ (23,041)</u>	<u>\$ (24,742)</u>	<u>\$ (106,312)</u>	<u>\$ (76,665)</u>
Denominator:				
Weighted-average common shares outstanding, basic and diluted	<u>23,739,312</u>	<u>23,067,570</u>	<u>23,445,096</u>	<u>14,600,346</u>
Net loss per share attributable to common shareholders, basic and diluted	<u>\$ (0.97)</u>	<u>\$ (1.07)</u>	<u>\$ (4.53)</u>	<u>\$ (5.25)</u>
	2022	2021	2022	2021
<b>Non-GAAP loss per share information:</b>				
Numerator:				
Historical net loss attributable to common shareholders	\$ (23,041)	\$ (24,742)	\$ (106,312)	\$ (76,665)
Accretion of preferred stock to redemption value	—	—	—	129
Change in fair value of convertible notes	—	—	—	839
Change in fair value of redeemable convertible preferred stock warrant liabilities	—	—	—	55
Interest expense on convertible notes	—	—	—	55
Non-GAAP pro forma net loss attributable to common stockholders	<u>\$ (23,041)</u>	<u>\$ (24,742)</u>	<u>\$ (106,312)</u>	<u>\$ (75,587)</u>
Denominator:				
Common shares outstanding:				
Weighted average common shares outstanding	23,739,312	23,067,570	23,445,096	14,600,346
Shares issued in IPO	—	—	—	1,694,977
Common shares issued upon conversion of preferred stock	—	—	—	4,006,227
Automatic exchange of Avenue warrant	—	—	—	34,216
Issuance of shares of common stock pursuant to the cash and net exercise of warrants	—	—	—	19,550
Shares issued upon conversion of convertible notes	—	—	—	177,841
Weighted-average number of common shares outstanding used to compute pro forma net loss per share, as adjusted, basic and diluted	<u>23,739,312</u>	<u>23,067,570</u>	<u>23,445,096</u>	<u>20,533,157</u>
Pro forma net loss per share attributable to common shareholders, basic and diluted	<u>\$ (0.97)</u>	<u>\$ (1.07)</u>	<u>\$ (4.53)</u>	<u>\$ (3.68)</u>





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Seattle, WA 98119 | 206.568.1466  
[www.impelpharma.com](http://www.impelpharma.com)

**Exhibit 99.1**

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