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 14, 2022

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 November 14, 2022, Impel Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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

Exhibit No.	Description
99.1	Press release issued by Impel Pharmaceuticals Inc. regarding its financial results for the quarter ended September 30, 2022, dated November 14, 2022.
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: November 14, 2022

By: /s/ John Leaman

John Leaman

Chief Financial and Business Officer

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Exhibit 99.1

EXHIBIT 99.1

IMPEL PHARMACEUTICALS ANNOUNCES THIRD QUARTER 2022 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

Trudhesa® nTRx Increased by 27% in Q3 2022 vs. Q2 2022 to 16.7K: Net Product Revenue Increased to $3.1 Million

Trudhesa surpasses 5% of Acute Branded Prescriptions among prescribers in Q3 One Year After Launch

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

SEATTLE, November 14, 2022 — Impel Pharmaceuticals (NASDAQ: IMPL),a commercial-stage pharmaceutical company developing transformative therapies for people suffering from diseases with high unmet medical needs, today reported financial results for the third quarter ended September 30, 2022 and provided a corporate update.

"This quarter represents a milestone for Impel as we completed the first full year of Trudhesa® marketing and sales, generating over 42,000 prescriptions at the end of September," said Adrian Adams, Chairman of the Board and Chief Executive Officer of Impel Pharmaceuticals. "Trudhesa continues to show robust growth and momentum and has captured approximately a 5 percent market share of acute branded prescriptions among prescribers after only one year in the market."

Adams added, "We are also encouraged with the results that we've seen from the additional sales force added towards the end of July of this year. As expected, the expansion has led to efficiencies among both new and existing sales representatives and has already had a positive impact on all leading performance indicators. We have increased Trudhesa prescribers by 30 percent and increased new patients by 58 percent since Q2 and will continue to have a strong focus on disciplined execution. At the same time, we are actively assessing both financing and strategic opportunities."

Recent Corporate Highlights

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

- To-date, Trudhesa continues a strong trajectory with more than 48,600 prescriptions generated since launch. Based on third-party data, it is estimated that at the end of September Trudhesa accounts for 5.2 percent of branded acute migraine prescriptions (nTRx) among prescribers.
- In July of this year, Impel expanded its sales force by 50 percent, from 60 to 90 sales professionals, to further capitalize on prescription momentum and the large business opportunity. New Trudhesa prescriptions increased by 45 percent from Q2 to Q3 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 56 percent and 74 percent, respectively, from July 2022 to October 2022 for a total increase in monthly new patient starts of 58 percent during this time period.

- Reimbursement of all shipments is over 50 percent for the entire year and 58 percent for the third quarter 2022. Refill rates have remained consistently high with 63 percent at the end of the third quarter 2022.
- Company will have a presence at the American Headache Society (AHS) Scottsdale Headache Symposium® taking place in Scottsdale, Arizona, November 17-20, 2022.

Clinical Developments

- In July 2022, the first patient was dosed in a Phase 2a proof-of-concept study (the CALM 201 Study) to advance its combination product candidate, INP105, an intranasal olanzapine product (a widely used atypical, second-generation antipsychotic) being developed as an acute treatment for agitation in persons with autism spectrum disorder using Impel's POD technology. Results from this trial are expected in Q2 2023.
- In September 2022, Impel published a manuscript in the *Journal of Aerosol Medicine and Pulmonary Drug Delivery*, that showed the upper nasal space is an attractive alternative route (to oral medications) of drug delivery. The paper evaluated the safety of the novel technology powering Trudhesa, Precision Olfactory Delivery (POD®), a device that delivers drug specifically to the upper nasal space. Results from clinical studies of Trudhesa demonstrated that the POD 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 comprehensive review of both published and previously unpublished preclinical data outlining the development and optimization of INP105 using Impel's POD® technology. These findings have been published in the October issue of the *Medical Research Archives*, an international scientific peer-reviewed journal publishing articles in all disciplines of medicine.

Financial Results for Third Quarter 2022

- **Net Product Revenue:** The Company's net revenue from sales of Trudhesa was $3.1 million for the third quarter 2022. As initial shipments of Trudhesa were sent to specialty pharmacies in late September 2021 ahead of the October commercial launch, there were $0.1 million in revenues for the same period of 2021.

- **Research and Development (R&D) Expenses:** R&D expenses were $3.2 million for the third quarter 2022 compared with $5.9 million for the same period of 2021. The decrease in R&D spending was primarily due to a reduction in Trudhesa clinical expenses as the Phase 3 STOP 301 study was closed, and partially offset by an increase in spend for the clinical development of INP105.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses were $19.7 million for the third quarter 2022, compared with $16.3 million for the same period of 2021. The increase in SG&A spending was due 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 third quarter 2022 were $31.1 million or $1.31 per common share. This is compared to net losses of $25 million or $1.24 per common share for the same period in 2021.

- **Non-GAAP Net Loss Per Share:** Non-GAAP Net Loss Per Share for the third quarter 2022 were $1.31 compared to a Non-GAAP Net Loss Per Share of $1.24 for the same periods in 2021. Non-GAAP Pro Forma Net Loss Per Share gives effect to our reverse stock split, the shares of common stock issued in our April 2021 IPO, shares exchanged for previously issued and outstanding stock warrants of Impel, and the conversion of our convertible preferred stock and our 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 our convertible notes, the effect of accretion on our redeemable convertible preferred stock and the change in fair value of our redeemable convertible preferred stock warrants, all of which converted to shares of common stock in our 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:** As of September 30, 2022, Impel had approximately $79.7 million in cash and cash equivalents.

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 third quarter 2022 financial results and provide a corporate 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

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, with an initial focus on diseases of the central nervous system. Impel offers and is developing treatments that pair its proprietary POD® technology with well-established therapeutics. In addition to Trudhesa® nasal spray, which is approved in the U.S. for the acute treatment of migraine with or without aura in adults, Impel is also developing INP105 for the acute treatment of agitation and aggression in patients with autism.

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 central nervous system (CNS) and other 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.

About INP105:

INP105 is an upper nasal formulation of olanzapine administered using Impel's novel POD® technology and being developed for the potential treatment of agitation and aggression associated with autism spectrum disorder. The POD® is a novel, simple-to-use device designed to deliver consistent and predictable doses of drug. INP105 delivers olanzapine to the richly vascularized upper nasal space to offer rapid, consistent, and optimized bioavailability that can be administered by the patient or a caregiver. Olanzapine is the most used treatment for acute agitation, but its use is limited to intramuscular injection and in a hospital setting. INP105 is intended to be a preferred choice for the safe and rapid treatment of acute agitation and because it is designed to be non-invasive, it has the potential to expand the treatment setting beyond the emergency room, such as inpatient treatment or community care facilities and the patient's home.

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, the timing of announcements of clinical results and clinical development activities of Impel's product candidates, 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 its other product candidates including plans for future development of its POD® devices and plans to address additional indications for which Impel may pursue regulatory approval, whether results of preclinical studies or clinical trials will be indicative of the results of future trials, and the effects of COVID-19 on its clinical programs and business operations. 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.

 To learn more about Impel Pharmaceuticals, please visit our website at https://impelpharma.com.

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Exhibit 99.1

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 79,731	$ 88,212
Trade receivables, net	6,129	1,352
Inventory	8,622	2,824
Prepaid expenses and other current assets	4,794	2,188
Total current assets	99,276	94,576
Property and equipment, net	2,776	3,149
Operating lease right-of-use assets	2,933	—
Other assets	187	187
Total assets	**$ 105,172**	**$ 97,912**
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 4,751	$ 6,367
Accrued liabilities	11,743	8,950
Current portion of deferred royalty obligation	1,765	—
Current portion of operating lease liability	1,346	—
Common stock warrant liability	358	637
Total current liabilities	19,963	15,954
Operating lease liability, net of current portion	1,584	—
Derivative liability	1,890	—
Deferred royalty obligation, net of current portion	56,662	—
Long-term debt	47,362	29,450
Total liabilities	**127,461**	**45,404**
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized: none issued	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized; 23,739,313 and 23,037,298 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	24	23
Additional paid-in capital	275,756	267,283
Accumulated deficit	(298,069)	(214,798)
Total stockholders' (deficit) equity	(22,289)	52,508
Total liabilities and stockholders' (deficit) equity	**$ 105,172**	**$ 97,912**

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Product revenue, net	$ 3,082	$ 91	$ 7,644	$ 91
Cost of goods sold	1,508	250	4,277	250
Gross profit	1,574	(159)	3,367	(159)
Operating expenses:				
Research and development	3,155	5,929	10,756	16,103
Selling, general and administrative	19,659	16,338	57,553	30,971
Total operating expenses	22,814	22,267	68,309	47,074
Loss from operations	(21,240)	(22,426)	(64,942)	(47,233)
Other income (expense), net :				
Interest income (expense), net	(3,192)	(2,420)	(11,069)	(3,471)
Other income (expense), net	(6,665)	(175)	(7,260)	(1,090)
Total other income (expense), net	(9,857)	(2,595)	(18,329)	(4,561)
Loss before income taxes	(31,097)	(25,021)	(83,271)	(51,794)
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	$ (31,097)	$ (25,021)	$ (83,271)	$ (51,794)
Accretion on redeemable convertible preferred stock	—	—	—	129
Net loss attributable to common stockholders	$ (31,097)	$ (25,021)	$ (83,271)	$ (51,923)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.31)	$ (1.24)	$ (3.57)	$ (4.42)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	23,709,546	20,150,990	23,345,946	11,746,923

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
GAAP Basic and Diluted EPS				
Numerator:				
Net loss and comprehensive loss	$ (31,097)	$ (25,021)	$ (83,271)	$ (51,794)
Add: Accretion of preferred stock to redemption value	—	—	—	(129)
Net loss attributable to common shareholders	$ (31,097)	$ (25,021)	$ (83,271)	$ (51,923)
Denominator:				
Weighted-average common shares shares outstanding, basic and diluted	23,709,546	20,150,990	23,345,946	11,746,923
Net loss per share attributable to common shareholders, basic and diluted	**$ (1.31)**	**$ (1.24)**	**$ (3.57)**	**$ (4.42)**

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Non-GAAP loss per share information:				
Numerator:				
Historical net loss attributable to common shareholders	$ (31,097)	$ (25,021)	$ (83,271)	$ (51,923)
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	—	—	—	222
Interest expense on convertible notes	—	—	—	55
Non-GAAP pro forma net loss attributable to common stockholders	$ (31,097)	$ (25,021)	$ (83,271)	$ (50,678)
Denominator:				
Common shares outstanding:				
Weighted average common shares outstanding	23,709,546	20,150,990	23,345,946	11,746,923
Shares issued in IPO	—	—	—	2,266,179
Common shares issued upon conversion of preferred stock	—	—	—	5,356,311
Automatic exchange of Avenue warrant	—	—	—	45,747
Issuance of shares of common stock pursuant to the cash and net exercise of warrants	—	—	—	26,138
Shares issued upon conversion of convertible notes	—	—	—	237,772
Weighted-average number of common shares outstanding used to compute pro forma net loss per share, as adjusted, basic and diluted	23,709,546	20,150,990	23,345,946	19,679,070
Pro forma net loss per share attributable to common shareholders, basic and diluted	**$ (1.31)**	**$ (1.24)**	**$ (3.57)**	**$ (2.58)**

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Exhibit 99.1

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