

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, 2022

IMPEL NEUROPHARMA, 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, 2022, Impel NeuroPharma, Inc. issued a press release announcing its financial results for the quarter ended December 31, 2021. 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	Press release issued by Impel NeuroPharma, Inc. regarding its financial results for the fourth quarter and year ended December 31, 2021, dated March 24, 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 NEUROPHARMA, INC.

Date: March 24, 2022

By: /s/ John Leaman

John Leaman

Chief Financial Officer

IMPEL NEUROPHARMA ANNOUNCES FOURTH QUARTER AND FULL YEAR 2021 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

Trudhesa™ Exceeds Fourth Quarter 2021 Prescription Guidance; Strong Launch Continues Into 2022 Demonstrated by 157% Growth Since December 31, 2021

Planned Initiation of INP105 Proof-Of-Concept Study for Autism Spectrum Disorder in First Half of 2022

Recent \$100 million Royalty and Debt agreement provides a projected cash runway into 2024

Impel To Host Investor Conference Call Today At 8:30 A.M. ET

SEATTLE, March 24, 2022 — Impel NeuroPharma (NASDAQ: IMPL), a commercial-stage pharmaceutical company developing transformative therapies for people suffering from diseases with high unmet medical needs, with an initial focus on the central nervous system, today reported financial results for the fourth quarter and full year ended December 31, 2021, and a corporate update.

“We are pleased to see that our targeted and disciplined commercial approach to the Trudhesa™ launch is effective, as evident by our strong growth trajectory thus far in the first quarter of 2022. Given this substantial progress, we remain confident in our ability to meet the current overall expectations for 2022,” said Adrian Adams, chairman and chief executive officer of Impel NeuroPharma. “Following our non-dilutive royalty and debt agreements with Oaktree Capital, we have sufficient capital to take us into 2024, thus enabling us to continue executing on the strong Trudhesa launch.”

Recent Corporate Highlights

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

- Following the October 2021 commercial launch, the performance of Trudhesa exceeded expectations for 2021 with over 4,200 (TRx) prescriptions generated, surpassing the Company’s fourth quarter 2021 guidance of 3,000-4,000 prescriptions.
 - To date, Trudhesa continues a strong trajectory with approximately 11,000 prescriptions generated since launch, through the week of March 11th (157 percent growth from December 31, 2021, through March to date). To-date, based on third party data, we believe Trudhesa accounts for approximately 3.1 percent of new branded acute migraine prescriptions (NBRx) among Impel’s 2,000 Super Target prescribers.
 - Through the end of 2021 the Company has secured broad and favorable Trudhesa contracts and payer coverage with several leading pharmacy benefit managers which together, cover approximately 80 percent of U.S. commercial lives.
 - To date prescribers are using Trudhesa in a broad mix of patients with approximately 26 percent of situations being in patients new to migraine therapy, 32 percent in situations where Trudhesa is added
-

to other migraine therapy, and 42 percent in situations where patients are switched to Trudhesa from other migraine therapy.

- Company to present data highlighting additional data on the safety and efficacy of Trudhesa from the pivotal, Phase 3 STOP-301 trial, at the upcoming American Academy of Neurology annual meeting, to be held April 2 – 7, 2022 in Seattle, Washington.

Clinical Development

- Impel continues 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 (ASD) via Impel's POD® technology. The company anticipates, subject to FDA agreement, that the Phase 2a proof-of-concept study (the CALM 201 Study) will start in the first half of 2022.

Corporate

- On March 17, the Company announced two separate transactions with funds managed by Oaktree Capital Management, L.P. totaling \$100 million in gross funding. The transactions include a \$50 million royalty agreement on net sales of Trudhesa and \$50 million of senior secured debt. Based on current projections, these funds provide Impel with a projected cash runway into 2024.

Financial Results for Fourth Quarter and Full Year 2021

- **Product Revenue, Net:** The Company's net revenues from sales of Trudhesa was \$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 commercial launch.
 - **Research and Development (R&D) Expenses:** R&D expenses were \$4.5 million and \$20.6 million, respectively for the fourth quarter and full year 2021, respectively, compared with \$8.8 million and \$28.3 million for the same periods of 2020, respectively. The decrease in R&D spending was primarily due to the reduction in Trudhesa clinical expenses as the Phase 3 study was concluded.
 - **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses were \$19.9 million and \$50.9 million for the fourth quarter and full year 2021, respectively, compared with \$4.8 million and \$17.0 million for the same periods of 2020, respectively. The increase in SG&A spending was due primarily to the ramp up in spending to support the commercial and marketing activity for the Trudhesa launch.
 - **GAAP Net Loss:** Net losses for the fourth quarter and full year 2021 were \$24.7 million and \$76.7 million, respectively, or \$1.07 and \$5.25 per common share, respectively. This compared to net losses of \$14.2 million and \$46.3 million, respectively, or \$19.81 and \$91.05 per common share, respectively for the same periods in 2020.
 - **Non-GAAP Net Loss Per Share:** Non-GAAP Net Loss Per Share for the fourth quarter and full year 2021 were \$1.07 and \$3.68, respectively. This compared to a Non-GAAP Net Loss Per Share of \$0.74 and \$2.47, respectively for the same periods in 2020. Non-GAAP Pro Forma Net Loss Per Share gives effect to our reverse stock split, the shares of common stock issued in our IPO, 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 effect of accretion on our redeemable convertible preferred stock and interest expense on our convertible notes, 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.

- **Trudhesa Guidance for 2022**

Based on year-to-date prescription performance the Company projects that Trudhesa will deliver prescriptions within the range of 70,000 – 85,000 for full year 2022.

- **Cash runway into 2024**

As of December 31, 2021, Impel had \$88.2 million in combined cash, cash equivalents and marketable securities. The Company subsequently closed on a \$100 million Royalty and Debt agreement with Oaktree Capital on March 17, 2022. Following closing of this transaction, the Company believes, based on its current operating plan, that it has sufficient capital to fund operations into 2024.

Conference Call Information

Impel NeuroPharma's Executive Management will host a live conference call and webcast at 8:30 a.m. ET today to discuss the fourth quarter and year end 2021 financial results and provide a corporate update. The conference call may be accessed by dialing 877-295-2648 (domestic) or 470-495-9487 (international) and referring to conference ID 5542868. A live webcast of the event will be available on the Investors section of the Impel NeuroPharma website at <https://investors.impelnp.com/>. A replay of the webcast and accompanying slides will be available on the Impel NeuroPharma 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 NeuroPharma

Impel NeuroPharma, Inc. is a commercial-stage biopharmaceutical 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 Precision Olfactory Delivery (POD®) technology with well-established therapeutics. In addition to Trudhesa™ (dihydroergotamine mesylate) nasal spray, which is approved in the United States 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, and INP107 for OFF episodes in Parkinson's disease.

Trudhesa™ Indication and Important Safety Information

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 1 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 Precision Olfactory Delivery, or POD[®], technology and being developed for the potential treatment of agitation and aggression associated with autism spectrum disorder (ASD). 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 offering 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, including expectations regarding the amount of Trudhesa prescriptions in 2022, and the timing of announcements of clinical results, the Company's projected cash runway and clinical development activities of Impel's product candidates. 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.

Impel, POD and the Impel logo are trademarks of Impel NeuroPharma, Inc. To learn more about Impel NeuroPharma, please visit our website at <https://impelnp.com/>.

###

Contact:

Investor Relations:

Christina Tartaglia
Stern Investor Relations
Phone: (1) 212-362-1200
Email: christina.tartaglia@sternir.com

Media Relations:

Melyssa Weible
Elixir Health Public Relations
Phone: (1) 201-723-5805
Email: mweible@elixirhealthpr.com

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

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 88,212	\$ 7,095
Trade receivables, net	1,352	—
Inventory	2,824	—
Prepaid expenses and other current assets	2,188	1,077
Total current assets	94,576	8,172
Property and equipment, net	3,149	3,700
Other assets	187	187
Total assets	\$ 97,912	\$ 12,059
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 6,367	\$ 4,314
Accrued liabilities	8,950	3,173
Current portion of term debt	—	417
Common stock warrant liabilities	637	—
Redeemable convertible preferred stock warrant liabilities	—	2,622
Total current liabilities	15,954	10,526
Long-term debt	29,450	7,994
Total liabilities	45,404	18,520
Commitments and contingencies (Note 5)		
Redeemable convertible preferred stock, \$0.001 par value; 204,198,489 shares authorized at December 31, 2020; 202,009,981 shares issued and outstanding at December 31, 2020; aggregate liquidation preference of \$128,922 at December 31, 2020	—	127,039
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 10,000,000 and — shares authorized at December 31, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.001 par value; 300,000,000 and 266,833,885 shares authorized at December 31, 2021 and December 31, 2020, respectively; 23,123,062 and 755,478 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	23	-
Additional paid-in capital	267,283	4,762
Accumulated deficit	(214,798)	(138,262)
Total stockholders' equity (deficit)	52,508	(133,500)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 97,912	\$ 12,059

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

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2021	2020	2021	2020
Product revenue, net	\$ 577	\$ —	\$ 668	\$ —
Cost of goods sold	441	—	691	—
Gross profit	136	—	(23)	—
Operating expenses:				
Research and development	4,460	8,774	20,563	28,298
Selling, general and administrative	19,929	4,796	50,900	17,036
Total operating expenses	24,389	13,570	71,463	45,334
Loss from operations	(24,253)	(13,570)	(71,486)	(45,334)
Other (expense) income, net	(487)	(454)	(5,048)	(463)
Loss before income taxes	(24,740)	(14,024)	(76,534)	(45,797)
Provision for income taxes	2	—	2	1
Net loss and comprehensive loss	\$ (24,742)	\$ (14,024)	\$ (76,536)	\$ (45,798)
Accretion on redeemable convertible preferred stock	—	(132)	(129)	(518)
Net loss attributable to common stockholders	\$ (24,742)	\$ (14,156)	\$ (76,665)	\$ (46,316)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.07)	\$ (19.81)	\$ (5.25)	\$ (91.05)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	23,067,570	714,448	14,600,346	508,668

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

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2021	2020	2021	2020
GAAP Basic and Diluted EPS				
Numerator:				
Net loss and comprehensive loss	\$ (24,742)	\$ (14,024)	\$ (76,536)	\$ (45,798)
Add: Accretion of preferred stock to redemption value	-	(132)	(129)	(518)
Net loss attributable to common shareholders	<u>\$ (24,742)</u>	<u>\$ (14,156)</u>	<u>\$ (76,665)</u>	<u>\$ (46,316)</u>
Denominator:				
Weighted-average common shares shares outstanding, basic and diluted	<u>23,067,570</u>	<u>714,448</u>	<u>14,600,346</u>	<u>508,668</u>
Net loss per share attributable to common shareholders, basic and diluted	<u>\$ (1.07)</u>	<u>\$ (19.81)</u>	<u>\$ (5.25)</u>	<u>\$ (91.05)</u>
	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2021	2020	2021	2020
Non-GAAP loss per share information:				
Numerator:				
Historical net loss attributable to common shareholders	\$ (24,742)	\$ (14,156)	\$ (76,665)	\$ (46,316)
Accretion of preferred stock to redemption value	-	132	129	518
Change in fair value of convertible notes	-	-	839	-
Change in fair value of redeemable convertible preferred stock warrant liabilities	-	233	55	153
Interest expense on convertible notes	-	-	55	-
Non-GAAP pro forma net loss attributable to common stockholders	<u>\$ (24,742)</u>	<u>\$ (13,791)</u>	<u>\$ (75,587)</u>	<u>\$ (45,645)</u>
Denominator:				
Common shares outstanding:				
Weighted average common shares outstanding	23,067,570	714,448	14,600,346	508,668
Shares issued in IPO	-	5,333,334	1,694,977	5,333,334
Common shares issued upon conversion of preferred stock	-	12,605,800	4,006,227	12,605,800
Automatic exchange of Avenue warrant	-	-	34,216	-
Issuance of shares of common stock pursuant to the cash and net exercise of warrants	-	9,318	19,550	66,711
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>23,067,570</u>	<u>18,662,900</u>	<u>20,533,157</u>	<u>18,514,513</u>
Pro forma net loss per share attributable to common shareholders, basic and diluted	<u>\$ (1.07)</u>	<u>\$ (0.74)</u>	<u>\$ (3.68)</u>	<u>\$ (2.47)</u>

