

**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): June 7, 2021

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 June 7, 2021, Impel NeuroPharma, Inc. issued a press release announcing its financial results for the quarter ended March 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 quarter ended March 31, 2021, dated June 7, 2021.
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: June 7, 2021

By: /s/ John Leaman

John Leaman

Chief Financial Officer

Impel NeuroPharma Announces First Quarter 2021 Financial Results and Provides Business Update

- *Completed successful IPO raising approximately \$80.0 million in gross proceeds –*
- *NDA for TRUDHESA for treatment of acute migraine accepted for review by FDA; PDUFA date of September 6, 2021 –*
- *Strengthened commercial capabilities with expanded management team and strategic collaboration with Veeva Systems –*

SEATTLE, June 7, 2021 -- Impel NeuroPharma, Inc. (NASDAQ: IMPL), a late-stage pharmaceutical company focused on utilizing its proprietary POD® technology to develop and commercialize transformative therapies for patients suffering from diseases with high unmet medical needs, today reported financial results for the first quarter ended March 31, 2021 and produced a recent business update.

“The past quarter and recent months were marked by significant financial and clinical milestones for Impel as we execute on what we believe will be a transformational year for the Company. With the completion of a successful IPO, we are well-financed as we approach the potential launch of TRUDHESA, a treatment option for patients with migraines, later this year,” said Adrian Adams, chairman and chief executive officer of Impel NeuroPharma. “Additionally, we have continued the disciplined build-out of our commercial infrastructure, by the addition of key, experienced hires with considerable track records of success, in addition to engaging in a strategic collaboration with Veeva to broaden our commercial capabilities.”

First Quarter and Recent Business Highlights

- **Completed initial public offering (IPO), raising approximately \$80.0 million in gross proceeds.** In April, Impel announced it had closed its initial public offering of 5,333,334 common shares at a price to the public of \$15.00 per share. With completion of the IPO, the Company believes it has sufficient financial resources to fund operations through mid-2022.
 - **FDA PDUFA date set for September 6, 2021.** In January 2021, U.S. Food and Drug Administration (FDA) accepted for review the Company’s 505(b)(2) New Drug Application (NDA) for TRUDHESA for the acute treatment of migraine headaches with or without aura in adults. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of September 6, 2021. The NDA submission for TRUDHESA is supported by safety results from the pivotal Phase 3 STOP 301 study, which met its primary objectives, with no new safety signals or concerning trends in nasal safety findings observed for TRUDHESA. TRUDHESA, if approved by the FDA, will become the first and only therapy to utilize the POD technology, a novel delivery system that specifically targets the vascular-rich upper nasal space.
 - **Expanded management team with key, experienced hires to further enhance commercial execution, infrastructure, and market access capabilities as Company advances toward**
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commercialization. In March 2021, the Company appointed Leonard S. Paolillo as Chief Commercial Officer, and Gerald F. Penn as Vice President, Market Access and Trade. Mr. Paolillo and Mr. Penn bring a wealth of commercial strategy and product launch experience in competitive and complex markets.

- **Engaged in strategic collaboration with Veeva to build integrated, digital-first commercial foundation.** In February 2021, Impel announced a collaboration on key pre-launch preparations for TRUDHESA with Veeva Commercial Cloud, which will provide a complete commercial suite of data, software, and consulting services to drive its strategy and accelerate field engagement. This collaboration will help design and implement customer-centric strategies that will enable Impel sales professionals to increase the value of their targeted interactions with healthcare professionals.

First Quarter 2021 Financial Results:

- **Research and Development (R&D) Expenses:** Research and development expenses for the first quarter of 2021 were \$4.1 million, which compares with \$6.4 million for the first quarter of 2020. The decrease in R&D spending was due primarily to a decrease in clinical costs post the completion of the TRUDHESA Phase 3 trial.
 - **General and Administrative (G&A) Expenses:** General and administrative expenses for the first quarter of 2021 were \$5.8 million, which compares with \$3.5 million for the first quarter of 2020. The increase in G&A was due primarily to the ramp up of commercial related activity in preparation for the potential approval (and subsequent launch) of TRUDHESA.
 - **Net Loss:** For the first quarter of 2021, Impel reported a net loss of \$11.4 million, compared to a net loss of \$9.9 million for the same period in 2020.
 - **Non-GAAP Net Loss Per Share:** Non-GAAP Net Loss Per Share was \$0.54 for the first quarter of 2021, and \$0.54 for the first quarter of 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.
 - **GAAP Net Loss Per Share:** GAAP Net loss per share totaled \$15.09 per share in the first quarter of 2021 and \$27.40 in the first quarter of 2020. The weighted average share count used in our GAAP net loss per share calculations does not reflect the issuance of 5.3 million shares of common stock in our IPO, 0.6 million shares upon the April 2021 conversion of our convertible notes, 0.05 million shares upon conversion of net exercised warrants, and 12.6 million shares upon the April 2021 conversion of our preferred stock.
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- **Cash Balance:** As of March 31, 2021, the Company had cash and cash equivalents of \$4.4 million, and the Company had cash and cash equivalents of \$71.1m as of April 30, 2021, post the April IPO.

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 TRUDHESA™:

TRUDHESA™, the Company’s lead product candidate, aims to optimize dihydroergotamine mesylate (DHE) for fast and lasting whole migraine relief, regardless of when in the migraine attack it is administered, without an injection. Importantly, TRUDHESA™ is designed to deliver a lower dose of DHE compared to other nasally administered, FDA-approved and investigational products. This may enable patients to benefit from the established efficacy of DHE, without the undesired side effects that may be experienced with delivery to the lower nasal space.

TRUDHESA™ utilizes Impel’s propellant-enabled POD technology to conveniently and consistently deliver optimal doses of DHE directly into the vascular rich upper nasal space, an ideal target for efficient drug administration. This may be particularly important for many patients with migraine who experience nausea and/or vomiting during an attack, which presents limitations for the use of oral therapies, including triptans, CGRP inhibitors and ditans as well as other non-specific medications used for the acute treatment of migraine.

About Impel NeuroPharma:

Impel NeuroPharma, Inc. is a late-stage pharmaceutical company focused on utilizing its proprietary



technology to develop and commercialize transformative therapies for people suffering from diseases with high unmet needs, with an initial focus on diseases of the CNS. The Company's strategy is to rapidly advance its product candidate pipeline that pairs its proprietary Precision Olfactory Delivery (POD®) system with well-established therapeutics, including TRUDHESA™ for the acute treatment of migraine, INP105 for the acute treatment of agitation and aggression in patients with autism, and INP107 for OFF episodes in Parkinson's disease.

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, timing of approval of Impel's NDA for TRUDHESA™ and of Impel's other regulatory submissions, timing of announcements of clinical results and clinical development activities of its product candidates, potential benefits and market opportunities of TRUDHESA™ and its other product candidates and its 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 obtain and maintain regulatory approval of TRUDHESA™ and its other product candidates, its ability to execute its commercialization strategy for TRUDHESA™, its ability to develop, manufacture and commercialize its 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 Neuropharma, Inc.
Condensed Consolidated Statement of Operations and Comprehensive Loss
(in thousands)

	For the three months ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 4,098	\$ 6,354
General and administrative	5,771	3,452
Total operating expenses	9,869	9,805
Loss from operations	(9,869)	(9,805)
Interest income (expense), net	(298)	33
Other expense, net	(1,124)	14
Loss before income taxes	(11,291)	(9,758)
Provision for income taxes	—	1
Net loss and comprehensive loss	(11,291)	(9,759)
Accretion on redeemable convertible preferred stock	129	128
Net loss attributable to common stockholders	\$ (11,420)	\$ (9,887)

Impel Neuropharma, Inc.
Condensed Consolidated Balance Sheet
(in thousands)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash	\$ 4,467	\$ 7,095
Prepaid expenses and other current assets	1,792	1,077
Total current assets	6,259	8,172
Property and equipment, net	3,512	3,700
Other assets	1,711	187
Total assets	\$ 11,482	\$ 12,059
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 6,425	\$ 4,314
Accrued liabilities	2,625	3,173
Current portion of term debt	1,667	417
Redeemable convertible preferred stock warrant liabilities	2,677	2,622
Total current liabilities	13,394	10,526
Convertible notes at fair value	8,366	-
Long-term debt	6,963	7,994
Total liabilities	\$ 28,723	\$ 18,520
Commitments and contingencies (Note 5)		
Redeemable convertible preferred stock, \$0.001 par value; 204,198,489 shares authorized at March 31, 2021 and December 31, 2020; 202,009,981 shares issued and outstanding at March 31, 2021 and December 31, 2020; aggregate liquidation preference of \$128,922 at March 31, 2021 and December 31, 2020	127,168	127,039
Stockholders' deficit:		
Common stock, \$0.001 par value; 266,833,885 shares authorized at March 31, 2021 and December 31, 2020; 763,573 and 755,478 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	—	-
Additional paid-in capital	5,144	4,762
Accumulated deficit	(149,553)	(138,262)
Total stockholders' deficit	(144,409)	(133,500)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	\$ 11,482	\$ 12,059

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

	For the three months ended March 31,	
	2021	2020
GAAP Basic and Diluted EPS		
Numerator:		
Net loss and comprehensive loss	\$ (11,291)	\$ (9,758)
Add: Accretion of preferred stock to redemption value	129	128
Net loss attributable to common shareholders	\$ (11,420)	\$ (9,886)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	756,986	360,808
Net loss per share attributable to common shareholders, basic and diluted	\$ (15.09)	\$ (27.40)

	For the three months ended March 31,	
	2021	2020
Non-GAAP loss per share information:		
Numerator:		
Historical net loss attributable to common shareholders	\$ (11,420)	\$ (9,886)
Accretion of preferred stock to redemption value	129	128
Change in fair value of convertible notes	839	-
Change in fair value of redeemable convertible preferred stock warrant liabilities	55	(44)
Interest expense on convertible notes	27	-
Non-GAAP pro forma net loss attributable to common stockholders	\$ (10,370)	\$ (9,802)
Denominator:		
Common shares outstanding:		
Weighted average common shares outstanding	756,986	360,808
Shares issued in IPO	5,333,334	5,333,334
Common shares issued upon conversion of preferred stock	12,605,800	12,539,109
Automatic exchange of Avenue warrant	16,518	-
Issuance of shares of common stock pursuant to the net exercise of warrants	52,974	68,730
Shares issued upon conversion of convertible notes	559,585	-
Total Non-GAAP Pro Forma Loss per share attributable to common shareholders	19,325,197	18,301,981
Pro forma net loss per share attributable to common shareholders, basic and diluted	\$ (0.54)	\$ (0.54)

Contact

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