

**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): August 16, 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 August 16, 2021, Impel NeuroPharma, Inc. issued a press release announcing its financial results for the quarter ended June 30, 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 June 30, 2021, dated August 16, 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: August 16, 2021

By: /s/ John Leaman

John Leaman

Chief Financial Officer



EXHIBIT 99.1

IMPEL NEUROPHARMA ANNOUNCES SECOND QUARTER 2021 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

TRUDHESA™ New Drug Application (NDA) Under Review by U.S. Food & Drug Administration (FDA) with PDUFA Target Action Date of September 6, 2021

Preparations On Track for Potential TRUDHESA Launch in the Fourth Quarter of 2021

Increased Cash Position and Extended Runway through 2022 Following \$50 Million Debt Facility Agreement with Oxford Finance LLC and Silicon Valley Bank

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

SEATTLE, August 16, 2021 — Impel NeuroPharma (NASDAQ: IMPL), 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, today reported financial results for the second quarter ended June 30, 2021 and provided a corporate update.

“The first half of 2021 has been marked by significant milestones which we believe have positioned Impel well for a successful commercial launch of TRUDHESA™ in the fourth quarter, subject to regulatory approval. In addition, our pre-launch activities together with ongoing interactions with patients and healthcare providers continue to reinforce our view that significant unmet needs remain in the treatment of acute migraine,” said Adrian Adams, chairman and chief executive officer of Impel NeuroPharma. “Following the recent closing of our debt financing agreement, we are confident that Impel’s strengthened balance sheet will provide us not only with the resources for a successful launch of TRUDHESA, but also the continued development of INP105 for the potential treatment of agitation and aggression in autism.”

Recent Corporate Highlights:

- On August 6, the Company hosted a virtual key opinion leader (KOL) event to review the evolving role of DHE in the treatment of acute migraine. The event featured presentations from guest speakers Dr. Nada Hindiyeh, Assistant Professor of neurology and neurological systems at Stanford Medical School, Dr. Wade Cooper, Director of Headache and Neuropathic Pain at the University of Michigan School of Medicine, Dr. Stewart Tepper, Director of Dartmouth Headache Center at the Geisel School of Medicine and Impel NeuroPharma management. The event presentation and webcast recording can be accessed [here](#).
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- In July, the Company announced the closing of a \$50 million debt facility with Oxford Finance LLC and Silicon Valley Bank, of which the first \$20 million was funded at closing. The initial \$20 million tranche extends Impel's expected cash runway through 2022.
- The Company's 505(b)(2) New Drug Application (NDA) for TRUDHESA for the treatment of acute migraine headaches with or without aura in adults is under review by the FDA with a PDUFA target action date of September 6, 2021.
- 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, were presented at the 63RD American Headache Society Annual Scientific Meeting (AHS) and published in *Headache: The Journal of Head and Face Pain*.

Second Quarter 2021 Financial Results:

- **Research and Development (R&D) Expenses:** Research and development expenses for the second quarter of 2021 were \$6.1 million, which compares with \$6.8 million for the second 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 second quarter of 2021 were \$8.9 million, which compares with \$6.1 million for the second quarter of 2020. The increase in G&A was due primarily to the ramp up in commercial expenses related to pre-launch activities ahead of the TRUDHESA launch.
 - **Net Loss:** For the second quarter of 2021, Impel reported a net loss of \$15.5 million, compared to a net loss of \$13.1 million for the same period in 2020.
 - **GAAP Net Loss Per Share:** GAAP Net Loss Per Share totaled \$1.10 per share in the second quarter of 2021 and \$35.88 in the second quarter of 2020. The weighted average share count used in our GAAP net loss per share calculation for second quarter 2020 does not reflect the issuance of 5.3 million shares of common stock in our IPO, 0.06 million shares upon conversion of our convertible preferred stock warrants, and 12.6 million shares upon the April 2021 conversion of our convertible preferred stock.
 - **Non-GAAP Net Loss Per Share:** Non-GAAP Net Loss Per Share was \$0.79 for the second quarter of 2021, and \$0.71 for the second 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, the conversion of our convertible preferred stock, the conversion of our convertible
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preferred stock warrants 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 Position:** As of June 30, 2021, the Company had cash and cash equivalents of \$60.9 million and this cash position, coupled with the Company's July 2nd debt financing provide the Company with a cash runway through 2022.

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 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 INP104 for the acute treatment of migraine, INP105 for the acute treatment of agitation in patients with autism, and INP107 for OFF episodes in Parkinson's disease.



About TRUDHESA™:

Impel NeuroPharma is developing TRUDHESA with the goal to be a transformative new therapy for the acute treatment of migraine headaches. TRUDHESA 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 deep into the vascular rich upper nasal space, an ideal target for efficient drug administration. This may be particularly important for the majority of 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.

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, 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 INP104 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, 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/>.



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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 60,948	\$ 7,095
Prepaid expenses and other current assets	4,619	1,077
Total current assets	65,567	8,172
Property and equipment, net	3,408	3,700
Other assets	187	187
Total assets	\$ 69,162	\$ 12,059
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	\$ 5,461	\$ 4,314
Accrued liabilities	3,546	3,173
Current portion of term debt	-	417
Convertible preferred stock warrant liabilities	-	2,622
Total Current Liabilities	\$ 9,007	\$ 10,526
Long-term debt	8,857	7,994
Total liabilities	\$ 17,864	\$ 18,520
Commitments and contingencies		
Redeemable convertible preferred stock, \$0.001 par value; — and 204,198,489 shares authorized at June 30, 2021 and December 31, 2020 respectively; — and 202,009,981 shares issued and outstanding at June 30, 2021 and December 31, 2020 respectively; 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 June 30, 2021, and December 31, 2020, respectively	-	-
Common stock, \$0.001 par value; 300,000,000 and 266,833,885 shares authorized at June 30, 2021, and December 31, 2020, respectively; 19,470,914 and 755,478 shares issued and outstanding at June 30, 2021, and December 31, 2020, respectively	19	-
Additional paid-in-capital	216,314	4,762
Accumulated Deficit	(165,035)	(138,262)
Total stockholders' equity (deficit)	\$ 51,298	\$ (133,500)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	\$ 69,162	\$ 12,059



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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 6,076	\$ 6,832	\$ 10,174	\$ 13,391
General and administrative	8,862	6,127	14,633	9,374
Total operating expenses	14,938	12,959	24,807	22,765
Loss from operations	(14,938)	(12,959)	(24,807)	(22,765)
Other income (expense)	(544)	36	(1,966)	84
Loss before income taxes	(15,482)	(12,923)	(26,773)	(22,681)
Provision for (Benefit from) income taxes	-	(1)	-	-
Net loss and comprehensive loss	(15,482)	(12,922)	(26,773)	(22,681)
Accretion on redeemable convertible preferred stock		128	129	256
Net loss attributable to common stockholders	\$ (15,482)	\$ (13,050)	\$ (26,902)	\$ (22,937)



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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
GAAP Basic and Diluted EPS				
Numerator:				
Net loss and comprehensive loss	\$ (15,482)	\$ (12,922)	\$ (26,773)	\$ (22,681)
Add: Accretion of preferred stock to redemption value	-	128	129	256
Net loss attributable to common shareholders	<u>\$ (15,482)</u>	<u>\$ (13,050)</u>	<u>\$ (26,902)</u>	<u>\$ (22,937)</u>
Denominator:				
Weighted-average common shares outstanding, basic and diluted	14,119,672	363,684	7,475,242	362,246
Net loss per share attributable to common shareholders, basic and diluted	<u>\$ (1.10)</u>	<u>\$ (35.88)</u>	<u>\$ (3.60)</u>	<u>\$ (63.32)</u>

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Non-GAAP loss per share information:				
Numerator:				
Historical net loss attributable to common shareholders	\$ (15,482)	\$ (13,050)	\$ (26,902)	\$ (22,937)
Accretion of preferred stock to redemption value	-	128	129	256
Change in fair value of convertible notes	-	-	839	-
Change in fair value of redeemable convertible preferred stock warrant liabilities	-	(35)	54	(80)
Interest expense on convertible notes	28	-	55	-
Non-GAAP pro forma net loss attributable to common stockholders	<u>\$ (15,454)</u>	<u>\$ (12,957)</u>	<u>\$ (25,825)</u>	<u>\$ (22,761)</u>
Denominator:				
Common shares outstanding:				
Weighted average common shares outstanding	14,119,672	363,684	7,475,242	362,246
Shares issued in IPO	1,523,810	5,333,334	3,418,048	5,333,334
Common shares issued upon conversion of preferred stock	3,601,657	12,541,340	8,078,855	12,541,340
Automatic exchange of Avenue warrant	30,761	-	68,999	-
Issuance of shares of common stock pursuant to the cash and net exercise of warrants	17,576	67,333	46,132	67,333
Shares issued upon conversion of convertible notes	159,881	-	358,629	-
Weighted-average number of common shares outstanding used to compute pro forma net loss per share, as adjusted, basic and diluted	<u>19,453,357</u>	<u>18,305,691</u>	<u>19,445,905</u>	<u>18,304,253</u>
Pro forma net loss per share attributable to common shareholders, basic and diluted	<u>\$ (0.79)</u>	<u>\$ (0.71)</u>	<u>\$ (1.33)</u>	<u>\$ (1.24)</u>

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
