Impel NeuroPharma Announces Third Quarter 2021 Financial Results and Provides Corporate Update

November 15, 2021

Launched Trudhesa™ (dihydroergotamine mesylate) Nasal Spray (0.725 mg per spray) for the Acute Treatment of Migraine with and without Aura in Adults

Mobilized 60-Person Salesforce with a Targeted Focus on High-Prescribing Neurologists, Headache Specialists and Primary Care Physicians

Increased Cash Position and Extended Runway into 2023 with Follow-on Equity Offering of 3.45 Million Shares Valued at $51.8 Million

Company Plans to Initiate Phase 2a Proof-of-Concept Trial Evaluating INP105 in Agitation and Aggression in Autism in Late Q4 2021

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

SEATTLE, Nov. 15, 2021 (GLOBE NEWSWIRE) -- 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 third quarter ended September 30, 2021 and provided a corporate update.

“With the approval and timely launch of Trudhesa, the third quarter was truly transformational for Impel. We are delighted by the early uptake and prescription trends we are seeing in the marketplace since our commercial launch in early October,” said Adrian Adams, chairman and chief executive officer of Impel NeuroPharma. “Following the recent follow-on equity offering, we are confident that Impel’s strengthened balance sheet will provide us not only with the resources to continue our successful commercialization of Trudhesa, but also the continued development of INP105 for the potential treatment of agitation and aggression in autism.”

Recent Corporate Highlights

- On September 3, the company announced that the U.S. Food and Drug Administration (FDA) approved Trudhesa (dihydroergotamine mesylate) nasal spray (0.725 mg per spray) for the acute treatment of migraine with or without aura in adults. Trudhesa was previously known as INP104. The IR call webcast recording can be accessed here.

- On September 9, the company closed a public offering of 3,450,000 shares of its common stock at a price to the public of $15.00 per share. All of the shares of common stock were offered by Impel. The gross proceeds from the offering, before deducting underwriting discounts and commissions, and other offering expenses payable by Impel, were $51.8 million. Cowen and Guggenheim Securities acted as joint bookrunning managers for the proposed offering. Wedbush PacGrow was a lead manager.

- Key endpoint results from the pivotal Phase 3 STOP 301 study of Trudhesa were presented at the 2021 PainWEEK Conference and the International Headache Congress IHS and EHF Joint Congress 2021, underscoring the need for a non-oral treatment option for acute migraine. The presentations also looked at the exploratory efficacy data from STOP 301 suggesting improvements in migraine-related disability as assessed by the MIDAS questionnaire.

- On September 23, the company announced Trudhesa’s availability through Trudhesa Direct™, a streamlined, customized, end-to-end process that provides hassle-free prescribing, savings, and home delivery. The digital pharmacy partners, Carepoint Pharmacy and Phil Inc., facilitate the process beginning with e-prescribing and automatic enrollment of eligible, commercially insured patients in the Trudhesa Direct™ Savings Program to obtain Trudhesa.

- The clinical development program evaluating INP105 in agitation and aggression in autism is progressing on track; the company plans to initiate a Phase 2a proof-of-concept trial, known as the CALM 201 Study, in late Q4 2021.

Third Quarter 2021 Financial Results

- **Product Revenue, Net:** We recorded net product revenues in the third quarter of 2021 following the approval of Trudhesa on September 2, 2021. Although the product was not commercially launched in the U.S. until October 4, 2021, we recognized $0.1 million of product revenue, net of sales allowances and rebates, related to sales of Trudhesa during the three months ending September 31, 2021.

- **Research and Development (R&D) Expenses:** R&D expenses for the third quarter of 2021 were $5.9 million, which compares with $6.1 million for the third quarter of 2020. The decrease in R&D spending was due primarily to the decrease in Trudhesa clinical expenses as the Phase 3 study was closed.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the third quarter of 2021 were $16.3 million, which compares with $2.9 million for the third quarter of 2020. The increase in SG&A was primarily due to the ramp up in spending to support the commercial and marketing preparation for the Trudhesa launch.

- **GAAP Net Loss:** For the third quarter of 2021, Impel reported a net loss of $25.0 million, compared to a net loss of $9.2 million for same period in 2020.

- **GAAP Net Loss Per Share:** GAAP Net Loss Per Share totaled $1.24 per share in the third quarter of 2021 and $15.56 in the third quarter of 2020. The weighted average share count used in our GAAP net loss per share calculation in the third quarter of 2020 does not reflect the issuance of 5.3 million shares of common stock in our IPO, 0.07 million shares upon conversion of our convertible preferred stock warrants, and 12.6 million shares upon the April 2021 conversion of our preferred stock.

- **Non-GAAP Net Loss Per Share:** Non-GAAP Net Loss Per Share was $1.23 for the third quarter of 2021, and $0.49 for the third 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.

- **Cash Balance:** As of September 30, 2021, the company had cash and cash equivalents of $111.3 million.

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 third quarter 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 8366131. 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, and the timing of announcements of clinical results 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.

 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)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 111,289	$ 7,095
Trade receivables, net	981	—
Inventory	1,548	—
Prepaid expenses and other current assets	4,385	1,077
Total current assets	118,203	8,172
Property and equipment, net	3,278	3,700
Other assets	—	187
Total assets	**$ 121,481**	**$ 12,059**
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 8,700	$ 4,314
Accrued liabilities	6,692	3,173
Current portion of term debt	—	417
Common stock warrant liabilities	918	—
Redeemable convertible preferred stock warrant liabilities	—	2,622
Total current liabilities	16,310	10,526
Long-term debt	29,285	7,994
Total liabilities	**45,595**	**18,520**
Commitments and contingencies (Note 5)		
Redeemable convertible preferred stock, $0.001 par value; — and 204,198,489 shares authorized at September 30, 2021 and December 31, 2020 respectively; — and 202,009,981 shares issued and outstanding at September 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 September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.001 par value; 300,000,000 and 266,833,885 shares authorized at September 30, 2021 and December 31, 2020, respectively; 23,037,298 and 755,478 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	23	-
Additional paid-in capital	265,919	4,762
Accumulated deficit	(190,056)	(138,262)
Total stockholders' equity (deficit)	75,886	(133,500)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	**$ 121,481**	**$ 12,059**

Impel NeuroPharma 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,	
	2021	2020	2021	2020
Product revenue, net	$ 91	$ —	$ 91	$ —
Cost of goods sold	250	—	250	—
Gross profit	(159)	—	(159)	—
Operating expenses:				
Research and development	5,929	6,133	16,103	19,524
Selling, general and administrative	16,338	2,866	30,971	12,240
Total operating expenses	22,267	8,999	47,074	31,764
Loss from operations	(22,426)	(8,999)	(47,233)	(31,764)
Other (expense) income, net	(2,595)	(93)	(4,561)	(9)
Loss before income taxes	(25,021)	(9,092)	(51,794)	(31,773)
Provision (benefit) for income taxes	—	1	—	1
Net loss and comprehensive loss	$ (25,021)	$ (9,093)	$ (51,794)	$ (31,774)
Accretion on redeemable convertible preferred stock	—	130	129	386

Net loss attributable to common stockholders	$ (25,021)	$ (9,223)	$ (51,923)	$ (32,160)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.24)	$ (15.56)	$ (4.42)	$ (73.16)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	20,150,990	592,550	11,746,923	439,575

Impel Neuropharma, 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,	
	2021	**2020**	**2021**	**2020**
GAAP Basic and Diluted EPS				
Numerator:				
Net loss and comprehensive loss	$ (25,021)	$ (9,093)	$ (51,794)	$ (31,774)
Add: Accretion of preferred stock to redemption value	-	130	129	386
Net loss attributable to common shareholders	$ (25,021)	$ (9,223)	$ (51,923)	$ (32,160)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	20,150,990	592,550	11,746,923	439,575
Net loss per share attributable to common shareholders, basic and diluted	**$ (1.24)**	**$ (15.56)**	**$ (4.42)**	**$ (73.16)**

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Non-GAAP loss per share information:				
Numerator:				
Historical net loss attributable to common shareholders	$ (25,021)	$ (9,223)	$ (51,923)	$ (32,160)
Accretion of preferred stock to redemption value	-	130	129	386
Change in fair value of convertible notes	-	-	839	0
Change in fair value of redeemable convertible preferred stock warrant liabilities	-	(35)	222	(80)
Interest expense on convertible notes	-	-	55	-
Non-GAAP pro forma net loss attributable to common stockholders	$ (25,021)	$ (9,128)	$ (50,678)	$ (31,854)
Denominator:				
Common shares outstanding:				
Weighted average common shares outstanding	20,150,990	592,550	11,746,923	439,575
Shares issued in IPO	-	5,333,334	2,266,179	5,333,334
Common shares issued upon conversion of preferred stock	-	12,592,799	5,356,311	12,592,799
Automatic exchange of Avenue warrant	-	-	45,747	-
Issuance of shares of common stock pursuant to the cash and net exercise of warrants	-	67,897	26,138	68,175
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	20,150,990	18,586,580	19,679,070	18,433,883
Pro forma net loss per share attributable to common shareholders, basic and diluted	**$ (1.24)**	**$ (0.49)**	**$ (2.58)**	**$ (1.73)**

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