

Theseus Pharmaceuticals Announces Business Highlights and Reports Fourth Quarter and Full Year 2021 Financial Results

Patient enrollment underway in Phase 1/2 clinical trial in patients with advanced gastrointestinal stromal tumors (GIST)

Nomination of development candidate for fourth-generation epidermal growth factor receptor (EGFR) program targeting non-small cell lung cancer (NSCLC) expected in Q3 2022; IND expected in 2023

Continue to advance additional preclinical programs with one or more targets expected to be nominated in 2022

\$244.7 million in cash and cash equivalents, expected to fund operations into the second half of 2024

CAMBRIDGE, Mass., March 10, 2022 /PRNewswire/ -- Theseus Pharmaceuticals, Inc. (NASDAQ: THRX) (Theseus or the Company), a clinical-stage biopharmaceutical company focused on improving the lives of cancer patients through the discovery, development and commercialization of transformative targeted therapies, today announced business highlights and reported financial results for the fourth quarter and full year ended December 31, 2021.

"2021 was a transformative year for Theseus—we evolved into a clinical stage company, strengthened our team, and completed a successful IPO," said Tim Clackson, Ph.D., President and Chief Executive Officer of Theseus. "In January 2022 we initiated a Phase 1/2 clinical trial to evaluate our lead candidate, THE-630, in patients with advanced GIST and continue to drive towards development candidate nomination for our fourth-generation EGFR program in non-small cell lung cancer. Over the course of this year, we look forward to executing across our pipeline, which includes advancing THE-630 in the clinic, initiating IND-enabling studies of our second development candidate targeting EGFR, and expanding our pipeline with one or more additional kinase targets."

Recent Business Highlights and Anticipated Milestones:

- **Initiated Phase 1/2 clinical trial to evaluate THE-630 in patients with GIST.** First patient treated in January 2022 in a Phase 1/2 dose escalation and expansion clinical trial of THE-630 in patients with advanced GIST. THE-630 is a pan-variant inhibitor of the receptor tyrosine kinase KIT designed for patients with advanced GIST whose cancer has developed resistance to earlier lines of therapy. Initial data from the Phase 1 portion of the clinical trial is expected to be presented at a scientific meeting in the first half of 2023.
- **Nomination of development candidate for fourth-generation EGFR program expected in the third quarter of 2022.** Theseus expects to nominate an EGFR candidate designed to inhibit the full range of single-, double-, and triple-mutant EGFR variants found in the tumors of patients with EGFR-mutant NSCLC that have developed resistance to osimertinib, including the C797S mutation. Preclinical data is expected to be presented at the American Association for Cancer Research (AACR) Annual Meeting in April and at a scientific conference in the second half of 2022. IND submission is expected in 2023.
- **One or more additional kinase targets expected to be nominated by the end of 2022.**
- **Successfully completed initial public offering (IPO).** In October 2021, the Company completed a successful IPO, raising \$178.8 million in aggregate gross proceeds, and listed on the Nasdaq Global Select Market.

Fourth Quarter and Full Year Financial Results:

- **Cash Position:** As of December 31, 2021, Theseus had cash and cash equivalents of \$244.7 million. Theseus expects its cash and cash equivalents, including proceeds from the IPO, to fund operations and capital expenditures into the second half of 2024 based on its current operating plan.
- **R&D Expenses:** Research and development expenses were \$5.0 million for the fourth quarter of 2021, as compared to \$2.5 million for the fourth quarter of 2020. This increase was primarily due to \$1.6 million of increased employee-related costs, and \$0.9 million in increased expenses for clinical and preclinical studies. Research and development expenses were \$18.3 million for the full year 2021, as compared to \$6.0 million for the full year 2020.
- **G&A Expenses:** General and administrative expenses were \$3.6 million for the fourth quarter of 2021, as compared to \$0.4 million for the fourth quarter of 2020. This increase was primarily due to \$1.6 million of increased employee-related costs, primarily due to increases in our headcount, as well as \$1.7 million of increased general expenses, primarily driven by public company-related costs. General and administrative expenses were \$9.0 million for the full year 2021, as compared to \$0.9 million for the full year 2020.

- **Net Loss:** Net loss was \$8.7 million for the fourth quarter of 2021, as compared to a net loss of \$2.9 million for the fourth quarter of 2020. Net loss was \$27.3 million for the full year 2021, or a net loss per share of \$2.84, as compared to a net loss of \$12.0 million for the full year 2020, or a net loss per share of \$21.10.

About Theseus Pharmaceuticals, Inc.

Theseus is a clinical-stage biopharmaceutical company focused on improving the lives of cancer patients through the discovery, development and commercialization of transformative targeted therapies. Theseus is working to outsmart cancer resistance by developing pan-variant tyrosine kinase inhibitors (TKIs) to target all known classes of cancer-causing and resistance mutations that lead to variants in a particular protein in a given type of cancer. Theseus' lead product candidate, THE-630, is a pan-variant KIT inhibitor for the treatment of patients with advanced gastrointestinal stromal tumors (GIST), whose cancer has developed resistance to earlier lines of kinase inhibitor therapy. Theseus is also developing a fourth-generation, selective epidermal growth factor receptor (EGFR) inhibitor for C797S-mediated resistance to first- or later-line osimertinib treatment in patients with non-small cell lung cancer (NSCLC). For more information, visit www.theseusrx.com.

Cautionary Statement Regarding Forward Looking Statements

Certain statements included in this press release are not historical facts but are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "would," "plan," "predict," "potential," "seem," "seek," "future," "outlook," and similar expressions that predict or indicate future events or trends or that are not statements of historical matters, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements include, but are not limited to, statements regarding Theseus' strategy, future operations, prospects and plans, the structure and timing of its planned preclinical studies and clinical trials, expected milestones, market opportunity and sizing and objectives of management, including in relation to the Phase 1/2 dose escalation and expansion clinical trial for THE-630, EGFR inhibitor program and other programs.

Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, such as those described from time to time in the reports Theseus files with the Securities and Exchange Commission (SEC), including Theseus' Form 10-Q for the quarter ended September 30, 2021 filed with the SEC on November 15, 2021 and Theseus' Form 10-K for the year ended December 31, 2021 expected to be filed with the SEC in the first quarter of 2022. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statements contained in this press release are based on the current expectations of Theseus' management team and speak only as of the date hereof, and Theseus specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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Theseus Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 5,022	\$ 2,488	\$ 18,328	\$ 5,958
General and administrative	3,637	400	9,008	878
Total operating expenses	<u>8,659</u>	<u>2,888</u>	<u>27,336</u>	<u>6,836</u>
Loss from operations	(8,659)	(2,888)	(27,336)	(6,836)

Other income (expense), net	3	(2)	28	(5,161)
Net loss	<u>\$ (8,656)</u>	<u>\$ (2,890)</u>	<u>\$ (27,308)</u>	<u>\$ (11,997)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.24)</u>	<u>\$ (3.78)</u>	<u>\$ (2.84)</u>	<u>\$ (21.10)</u>
Weighted-average common stock outstanding—basic and diluted	<u>35,877,802</u>	<u>763,746</u>	<u>9,631,818</u>	<u>568,467</u>

Theseus Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	December 31,	
	2021	2020
Assets		
Cash and cash equivalents	\$ 244,662	\$ 8,457
Other assets	6,267	157
Total assets	<u>250,929</u>	<u>8,614</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Liabilities	4,495	1,595
Redeemable convertible preferred stock	-	41,289
Stockholders' equity (deficit)	246,434	(34,270)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 250,929</u>	<u>\$ 8,614</u>

SOURCE Theseus Pharmaceuticals

<https://ir.theseusrx.com/2022-03-10-Theseus-Pharmaceuticals-Announces-Business-Highlights-and-Reports-Fourth-Quarter-and-Full-Year-2021-Financial-Results>