

Theseus Pharmaceuticals Announces Business and Program Highlights and Reports Third Quarter 2021 Financial Results

IND application for lead program candidate, THE-630, cleared by U.S. Food and Drug Administration; initiation of Phase 1/2 clinical trial expected between late fourth quarter 2021 and mid-first quarter 2022

\$178.8 million upsized IPO completed to fund continued development of pan-variant kinase inhibitors

Strengthened leadership with key appointments to senior scientific team

CAMBRIDGE, Mass., Nov. 15, 2021 /PRNewswire/ -- Theseus Pharmaceuticals, Inc. (NASDAQ: THRX), a biopharmaceutical company focused on improving the lives of cancer patients through the discovery, development and commercialization of transformative targeted therapies, today announced business and program highlights and reported financial results for the third quarter ended September 30, 2021.

"At Theseus, we are leveraging our deep expertise in the development of targeted therapies to address the problem of drug resistance mutations in cancer," said Tim Clackson, Ph.D., President and Chief Executive Officer of Theseus Pharmaceuticals. "The third quarter marked two significant milestones for Theseus: our entrance into the public markets and the start of our transition into a clinical-stage company. The recent IND clearance for our lead candidate, THE-630, a pan-variant KIT inhibitor with the potential to address unmet need in patients with previously treated gastrointestinal stromal tumors (GIST), and the completion of our successful IPO position Theseus well to advance both the Phase 1/2 clinical trial of THE-630 and our pipeline of novel pan-variant inhibitors specifically designed to overcome the full range of drug resistance mutations."

Third Quarter Highlights and Upcoming Milestones:

- **Received FDA clearance of an investigational new drug (IND) application to evaluate THE-630 in patients with GIST.** Theseus plans to initiate a Phase 1/2 dose escalation and expansion clinical trial of THE-630, its lead development program, in patients with previously treated advanced GIST between late fourth quarter 2021 and mid-first quarter 2022. 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.
- **Completed \$178.8 million upsized initial public offering.** In October 2021, Theseus sold 11,172,190 shares of common stock at a price to the public of \$16.00 per share. The gross proceeds from the offering were approximately \$178.8 million, before deducting underwriting discounts and commissions and other estimated offering expenses.
- **Leadership strengthened through appointments to senior scientific team.** Theseus recently appointed Nachu Narasimhan, Ph.D., as Senior Vice President, Drug Metabolism and Preclinical Safety, and Len Rozamus as Senior Vice President, Technical Operations. Together, their deep experience in targeted oncology research and development will help to further advance Theseus' pipeline.
 - Dr. Narasimhan brings over 30 years of experience in drug metabolism and bioanalytical disciplines and over 10 years' experience in preclinical safety and clinical pharmacology. Dr. Narasimhan was most recently Vice President of Drug Metabolism and Clinical Pharmacology at Verastem Oncology. Previously, he contributed to the development and approval of several drugs while working at Merck, ARIAD Pharmaceuticals, and Bristol-Myers-Squibb.
 - Mr. Rozamus brings over 30 years of experience in pharmaceutical discovery and development, from pre-clinical programs through commercial products. Most recently, Mr. Rozamus served as Founder and President of Rozamus and Associates, Inc. Previously, his work while Senior Director of Manufacturing Operations at ARIAD Pharmaceuticals contributed to the approval of three oncology drugs.
- **Advanced fourth-generation epidermal growth factor receptor (EGFR) program towards development candidate nomination in the first half of 2022, and thereafter initiate IND-enabling studies.** For its second development program, 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 non-small cell lung cancer (NSCLC) that have developed resistance to osimertinib, including the C797S mutation.

- **One or more additional kinase targets expected to be nominated by the end of 2022.**

Third Quarter Financial Results:

- As of September 30, 2021, Theseus had cash and cash equivalents of \$90.4 million, which does not include net proceeds from its IPO, which was completed in October 2021.
 - Theseus expects its cash and cash equivalents, including proceeds from the IPO, to fund operations and capital expenditures into the second half of 2024.
- Research & Development expenses for the third quarter of 2021 were \$5.0 million.
- General & Administrative expenses for the third quarter of 2021 were \$2.4 million.
- Net Loss for the third quarter 2021 was \$7.4 million, or \$5.16 per share.

About Theseus Pharmaceuticals, Inc.

Theseus is a biopharmaceutical company focused on improving the lives of cancer patients through the discovery, development and commercialization of transformative targeted therapies. Theseus is developing next-generation tyrosine kinase inhibitors (TKIs): "pan-variant" targeted therapies that address all major drug resistance mutations. 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 clinical trial, expected milestones, market opportunity and sizing and objectives of management, including in relation to THE-630 and the planned Phase 1/2 dose escalation and expansion clinical trial and its EGFR 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. 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.

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Theseus Pharmaceuticals, Inc.

Condensed Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

(Unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 4,996	\$ 1,275	\$ 13,306	\$ 3,470
General and administrative	2,378	154	5,371	478
Total operating expenses	7,374	1,429	18,677	3,948
Loss from operations	(7,374)	(1,429)	(18,677)	(3,948)
Other income (expense), net	2	—	25	(5,159)
Net loss	\$ (7,372)	\$ (1,429)	\$ (18,652)	\$ (9,107)
Net loss per share attributable to common stockholders—basic and diluted	\$ (5.16)	\$ (2.12)	\$ (18.69)	\$ (18.11)
Weighted-average common stock outstanding—basic and diluted	1,428,054	672,911	997,949	502,804

Theseus Pharmaceuticals, Inc.

Condensed Balance Sheets

(in thousands, except share and per share data)

(Unaudited)

	NINE MONTHS ENDED SEPTEMBER 30, 2021	YEAR ENDED DECEMBER 31, 2020
Assets		
Cash and cash equivalents	\$ 90,404	\$ 8,457
Other assets	7,215	157
Total assets	\$ 97,619	\$ 8,614
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Liabilities	6,583	1,595
Redeemable convertible preferred stock	141,181	41,289
Stockholders' deficit	(50,145)	(34,270)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	\$ 97,619	\$ 8,614

<https://ir.theseusrx.com/2021-11-15-Theseus-Pharmaceuticals-Announces-Business-and-Program-Highlights-and-Reports-Third-Quarter-2021-Financial-Results>