



Inozyme Pharma Reports Third Quarter 2021 Financial Results and Provides Business Highlights

November 9, 2021

– On track to enroll patients in Phase 1/2 clinical trials in ENPP1 Deficiency and ABCC6 Deficiency in Q4 2021 and report preliminary biomarker and safety data in the first half of 2022 –

– Cash, cash equivalents, and investments expected to support continued operations into the first quarter of 2023 –

BOSTON, Nov. 09, 2021 (GLOBE NEWSWIRE) -- Inozyme Pharma, Inc. (Nasdaq: INZY), a clinical-stage rare disease biopharmaceutical company developing novel therapeutics for the treatment of abnormal mineralization, today reported financial results for the third quarter ended September 30, 2021, and provided recent business highlights.

"The third quarter was marked by continued progress advancing our INZ-701 program for ENPP1 Deficiency and ABCC6 Deficiency," said Axel Bolte, MSc, MBA, Inozyme's co-founder, president, and chief executive officer. "We remain on track to enroll patients in both Phase 1/2 trials imminently, with preliminary biomarker and safety data expected in the first half of 2022. We are steadfast in our mission to bring an effective therapeutic option to patients with ENPP1 Deficiency and ABCC6 Deficiency and look forward to sharing our progress in the coming months."

Recent Updates

- **On Track to Commence Phase 1/2 Trials in ENPP1 Deficiency and in ABCC6 Deficiency in Q4 2021:** The Company remains on track to enroll patients in its Phase 1/2 clinical trials of INZ-701, its enzyme replacement therapy (ERT) in development for the treatment of mineralization disorders in Q4 2021, with preliminary biomarker and safety data expected from both trials in the first half of 2022.
- **Presented Data on ENPP1 Program at the American Society for Bone and Mineral Research (ASBMR) 2021 Annual Meeting:** The Company [presented data](#) from its ENPP1 Deficiency Natural History Study and gene therapy program supporting the urgent need for novel interventions for ENPP1 Deficiency.

Upcoming Anticipated Milestones

The Company also announced the following anticipated milestones for the INZ-701 clinical development program, subject to COVID-19-related restrictions:

- **ENPP1 Deficiency**
 - **Q4 2021:** Start enrollment for Phase 1/2 clinical trial
 - **Q1 2022:** Initiate prospective natural history study
 - **H1 2022:** Report preliminary safety and biomarker data from Phase 1/2 clinical trial
- **ABCC6 Deficiency**
 - **Q4 2021:** Start enrollment for Phase 1/2 clinical trial
 - **H1 2022:** Report preliminary safety and biomarker data from Phase 1/2 clinical trial

Third Quarter 2021 Financial Results

- **Cash Position and Financial Guidance** – Cash, cash equivalents, and investments were \$125.3 million as of September 30, 2021. Based on its current plans and considering the impact of COVID-19-related clinical trial delays, the Company expects that its existing cash, cash equivalents, and investments will be sufficient to enable funding of its operating expenses and capital expenditure requirements into the first quarter of 2023.
- **Research and Development (R&D) Expenses** – R&D expenses were \$9.3 million for the quarter ended September 30, 2021, compared to \$25.2 million for the prior-year period. This decrease was primarily due to the non-recurring, non-cash purchase of in-process research and development intellectual property assets from Alexion Pharmaceuticals, Inc. in exchange for our stock in July 2020, as well as decreases in manufacturing operations based on the timing of production runs. These decreases were partially offset by increases in clinical trials costs to support the preparation for clinical trials and increased salaries and other employee-related costs to support the growth of the business.
- **General and Administrative (G&A) Expenses** – G&A expenses were \$4.9 million for the quarter ended September 30, 2021, compared to \$3.1 million for the prior-year period. The increase was primarily due to the growth in the number of G&A employees, an increase in legal fees related to new contracts and operations as a public company, and generally higher fees in areas such as audit, tax, and information technology to support the Company's growth.

- **Net Loss** – Net loss was \$14.3 million, or \$0.60 loss per share, for the quarter ended September 30, 2021, compared to \$28.1 million, or \$1.55 loss per share, for the prior-year period.

About Inozyme Pharma

Inozyme Pharma, Inc. (Nasdaq: INZY) is a clinical-stage rare disease biopharmaceutical company developing novel therapeutics for the treatment of diseases of abnormal mineralization impacting the vasculature, soft tissue, and skeleton. Through our in-depth understanding of the biological pathways involved in mineralization, we are pursuing the development of therapeutics to address the underlying causes of these debilitating diseases. It is well established that two genes, *ENPP1* and *ABCC6*, play key roles in a critical mineralization pathway and that defects in these genes lead to abnormal mineralization. We are initially focused on developing a novel therapy, INZ-701, to treat the rare genetic diseases of *ENPP1* and *ABCC6* Deficiencies.

Inozyme Pharma was founded in 2017 by Joseph Schlessinger, Ph.D., Demetrios Braddock, M.D., Ph.D., and Axel Bolte, MSc, MBA, with technology developed by Dr. Braddock and licensed from Yale University. For more information, please visit www.inozyme.com.

Cautionary Note Regarding Forward-Looking Statements

Statements in this press release about future expectations, plans, and prospects, as well as any other statements regarding matters that are not historical facts, may constitute “forward-looking statements” within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to the initiation and timing of our clinical trials, the initiation and timing of our natural history study, our research and development programs, the availability of preclinical study and clinical trial data, the timing of our regulatory applications and the period over which we believe that our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with the Company’s ability to initiate and conduct its planned Phase 1/2 clinical trials of INZ-701 for *ENPP1* Deficiency and *ABCC6* Deficiency; obtain and maintain necessary approvals from the FDA and other regulatory authorities; continue to advance its product candidates in preclinical studies and clinical trials; replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; advance the development of its product candidates under the timelines it anticipates in planned and future clinical trials; obtain, maintain and protect intellectual property rights related to its product candidates; manage expenses; and raise the substantial additional capital needed to achieve its business objectives. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company’s actual results to differ from those contained in the forward-looking statements, see the “Risk Factors” section in the Company’s most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties and other important factors, in the Company’s most recent filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company’s views as of the date hereof and should not be relied upon as representing the Company’s views as of any date subsequent to the date hereof. The Company anticipates that subsequent events and developments will cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so.

Condensed Consolidated Balance Sheet Data (Unaudited)

(in thousands)

	September 30, 2021	December 31, 2020
Cash, cash equivalents and investments	\$ 125,283	159,896
Total Assets	137,746	169,363
Total Liabilities	11,772	11,260
Additional paid-in-capital	254,915	249,175
Accumulated deficit	(128,946)	(91,076)
Total stockholders' equity	125,974	158,103

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,	
	2021	2020
Operating expenses:		
Research and development	\$ 9,346	\$ 25,174
General and administrative	4,916	3,142
Total operating expenses	14,262	28,316
Loss from operations	(14,262)	(28,316)
Other income (expense):	—	—
Interest income	47	64
Other income (expenses)	(65)	157

Other income (expense), net	(18)	221
Net loss	\$ (14,280)	\$ (28,095)
Other comprehensive income (loss):		
Unrealized gains (losses) on available-for-sale securities	(6)	(13)
Foreign currency translation adjustment	(9)	—
Total other comprehensive income (loss)	(15)	(13)
Comprehensive loss	\$ (14,295)	\$ (28,108)
Net loss attributable to common stockholders—basic and diluted	\$ (14,280)	\$ (28,095)
Net loss per share attributable to common stockholders—basic and diluted	\$ (0.60)	\$ (1.55)
Weighted-average common shares outstanding—basic and diluted	23,643,494	18,101,496

	Nine Months Ended September 30,	
	2021	2020
Operating expenses:		
Research and development	\$ 24,169	\$ 39,457
General and administrative	13,720	6,313
Total operating expenses	37,889	45,770
Loss from operations	(37,889)	(45,770)
Other income (expense):	—	—
Interest income	168	306
Other income (expenses)	(149)	158
Other income (expense), net	19	464
Net loss	\$ (37,870)	\$ (45,306)
Other comprehensive income (loss):		
Unrealized gains (losses) on available-for-sale securities	10	(5)
Foreign currency translation adjustment	(9)	—
Total other comprehensive income (loss)	1	(5)
Comprehensive loss	\$ (37,869)	\$ (45,311)
Net loss attributable to common stockholders—basic and diluted	\$ (37,870)	\$ (45,306)
Net loss per share attributable to common stockholders—basic and diluted	\$ (1.61)	\$ (6.57)
Weighted-average common shares outstanding—basic and diluted	23,521,981	6,893,745

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