# 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): November 09, 2021**

# INOZYME PHARMA, INC.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-39397** | **38-4024528** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **321 Summer Street**<br>**Suite 400**<br>**Boston, Massachusetts** | **02210** |
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: (857) 330-4340**

**Not applicable**
**(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 (see General Instruction A.2. below):

☐ 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, par value $0.0001 per share | INZY | NASDAQ Global Select Market |

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 November 9, 2021, Inozyme Pharma, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2021. The full text of the press release issued in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "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, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits:
The following exhibit is furnished herewith:

| Exhibit | Description |
|---|---|
| 99.1 | Press Release issued by the Company on November 9, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

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.

INOZYME PHARMA, INC.

Date: November 9, 2021

By: /s/ Axel Bolte
Name: Axel Bolte
Title: President and Chief Executive Officer

**Exhibit 99.1**

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

*– 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, November 9, 2021** – 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
- **ACBB6 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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**Contacts**

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