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): May 12, 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, Suite 400 **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 May 12, 2021, Inozyme Pharma, Inc. (the "Company") announced its financial results for the quarter ended March 31, 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 Number	Description
99.1	Press Release issued by the Company on May 12, 2021

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: May 12, 2021

By: /s/ Axel Bolte

Name: Axel Bolte

Title: President and Chief Executive Officer

Exhibit 99.1

Inozyme Pharma Reports Q1 2021 Financial Results and Provides Business Highlights

– Filed Clinical Trial Application for INZ-701 for ABCC6 Deficiency in Europe; on track to initiate Phase 1/2 clinical trial in mid-2021 –

– Published peer-reviewed preclinical data supporting INZ-701 as a potential treatment for ENPP1 Deficiency in Journal of Bone and Mineral Research –

– Presented data from first-ever Burden of Illness Study for ENPP1 and ABCC6 Deficiencies at multiple medical conferences –

– Cash, cash equivalents, and investments expected to enable continued operations into the fourth quarter of 2022 –

BOSTON, May 12, 2021 [GLOBE NEWSWIRE] – Inozyme Pharma, Inc. (Nasdaq: INZY), a rare disease biopharmaceutical company developing novel therapeutics for the treatment of abnormal mineralization, today reported financial results for the first quarter ended March 31, 2021 and provided recent business highlights.

"We closed 2020 with the clearance of our IND for INZ-701 by the FDA and our CTA by the MHRA of the UK, both for ENPP1 Deficiency. Since then, we have continued to execute on our plan to deliver a potential therapeutic option for patients with ENPP1 and ABCC6 Deficiencies," said Axel Bolte, MBA, co-founder, president, and chief executive officer of Inozyme Pharma. "We recently reported key findings from the Burden of Illness Study in patients with both ENPP1 Deficiency and ABCC6 Deficiency. Notably, we found patients in different age groups are impacted by these deficiencies in distinct ways, illuminating an age-based shift that reflects the progression of these debilitating genetic diseases. We expect site activation in the United States for our Phase 1/2 clinical trial site for ENPP1 Deficiency in June 2021 and enrollment of the first patient shortly thereafter. Subject to receiving regulatory clearance, we also expect to intiate our planned Phase 1/2 clincial trial of INZ-701 for ABCC6 Deficiency in mid-2021."

Mr. Bolte continued, "Our current cash position allows us to appropriately resource each of the key functions necessary to execute on our goals, and is expected to enable our operations into the fourth quarter of 2022."

Recent Business Highlights

- **Filed Clinical Trial Application for INZ-701 for ABCC6 Deficiency in Europe –** The Company expects to initiate a Phase 1/2 clinical trial in mid-2021 and to provide preliminary safety and biomarker data by the end of 2021.
- **Published data supporting INZ-701 as a potential treatment for ENPP1 Deficiency –** Peer-reviewed article in the *Journal of Bone and Mineral Research* shows INZ-701 increased plasma pyrophosphate (PPi) levels, improved disease markers, and decreased mortality in an Enpp1-deficient mouse model. Preclinical findings support increase of PPi levels as a predictive marker of therapeutic benefit.
- **Data presented on utility of INZ-701 as a potential treatment for ABCC6 Deficiency –** The Company and research collaborators from Thomas Jefferson University presented data from a preclinical study examining INZ-701 for the potential treatment for ABCC6 Deficiency/Pseudoxanthoma elasticum (PXE) at multiple medical conferences.
- **Data presented from Burden of Illness Study for ENPP1 and ABCC6 Deficiencies –** The Company presented data from the first-ever burden of illness study in patients with ENPP1 and ABCC6 Deficiencies at multiple medical conferences.

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**
  - **June 2021:** Site activation for Phase 1/2 clinical trial
  - **Mid-2021:** Enrollment for Phase 1/2 clinical trial
  - **Mid-2021:** Initiate prospective natural history study
  - **H2 2021:** Report preliminary safety and biomarker data from Phase 1/2 clinical trial
- **ABCC6 Deficiency**
  - **Mid-2021:** Site activation and enrollment for Phase 1/2 clinical trial
  - **By the End of 2021:** Report preliminary safety and biomarker data from Phase 1/2 clinical trial

Financial Results for the Quarter Ended March 31, 2021

- **Cash Position and Financial Guidance –** Cash, cash equivalents, and investments were $147.6 million as of March 31, 2021. Based on its current plans, 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 fourth quarter of 2022.
- **Research and Development (R&D) Expenses –** R&D expenses were $6.6 million for the quarter ended March 31, 2021, compared to $6.4 million for the quarter ended March 31, 2020. The increase was primarily due to costs associated with preclinical studies and

clinical preparation activities with the Company's contract research organization and increased salaries and employee-related costs due to the growth in the number of R&D employees.

- **General and Administrative (G&A) Expenses –** G&A expenses were $4.4 million for the quarter ended March 31, 2021, compared to $1.5 million for the quarter ended March 31, 2020. 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 $11.1 million, or $0.47 loss per share, for the quarter ended March 31, 2021, compared to $7.7 million, or $6.42 loss per share, for the quarter ended March 31, 2020.

About Inozyme Pharma

Inozyme Pharma, Inc. (Nasdaq: INZY), is a 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 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 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)

	March 31, 2021	December
Cash, cash equivalents and investments	$ 147,634	$
Total assets	158,915	
Total liabilities	10,026	
Additional paid-in-capital	251,001	
Accumulated deficit	(102,126)	
Total stockholders' equity	148,889	

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended March 3	
	2021	20
Operating expenses:		
Research and development	$ 6,603	$
General and administrative	4,369	
Total operating expenses	10,972	
Loss from operations	(10,972)	
Other income (expense):		
Interest income	63	
Other expenses	(141)	
Other income (expense), net	(78)	
Net loss	$ (11,050)	$
Other comprehensive income:		
Unrealized gains on available-for-sale securities	10	
Total other comprehensive income	10	
Comprehensive loss	$ (11,040)	$
Net loss attributable to common stockholders—basic and diluted	$ (11,050)	$
Net loss per share attributable to common stockholders—basic and diluted	$ (0.47)	$
Weighted-average common shares outstanding—basic and diluted	23,429,507	1

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Contacts

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