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): March 25, 2021

Inozyme Pharma, Inc.
(Exact Name of Registrant as Specified in 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** **(Address of Principal Executive Offices)**	**02210** **(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 March 25, 2021, Inozyme Pharma, Inc. (the "Company") announced its financial results for the year ended December 31, 2020. 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 No.	Description
99.1	Press Release issued by the Company on March 25, 2021

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INOZYME PHARMA, INC.

Date: March 25, 2021

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

Inozyme Pharma Reports Full Year 2020 Financial Results and Provides Business Highlights

– Received Orphan Drug Designation by the U.S. Food and Drug Administration for INZ-701 for treatment of ABCC6 deficiency –

– Expect to initiate Phase 1/2 trials of INZ-701 for ENPP1 deficiency in the first half of the year and ABCC6 deficiency by mid-2021 –

– Cash, cash equivalents, and investments expected to enable continued operations into second half of 2022 –

BOSTON, March 25, 2021 [GLOBE NEWSWIRE] – Inozyme Pharma, Inc. (Nasdaq: INZY), a rare disease biopharmaceutical company developing novel therapeutics for the treatment of diseases of abnormal mineralization, today reported financial results for the full year ended December 31, 2020 and provided recent business highlights.

"2020 was a foundational year for Inozyme as we laid the groundwork to become a clinical stage company focused on the biology of mineralization. We have significantly expanded our team and operational footprint, ensuring we have the resources required to bring INZ-701—our lead product candidate—into two planned first-in-human clinical studies in patients with ENPP1 deficiency and ABCC6 deficiency," said Axel Bolte, MSc, MBA, co-founder, president, and chief executive officer of Inozyme Pharma. "ENPP1 deficiency is a systemic, progressive, and chronic disease that occurs over a patient's lifetime, starting as early as fetal development, and spanning into adulthood, with devastating and often fatal effect. ABCC6 deficiency is a calcification disorder with an onset in adolescence and progressive worsening and high morbidity."

Mr. Bolte continued, "Based on discussions with U.S. and European regulatory authorities, we plan to initiate our Phase 1/2 clinical trial in ENPP1 deficiency in the first half of 2021 and our Phase 1/2 clinical trial in ABCC6 deficiency by mid-2021."

Recent Business Highlights

- **Granted Orphan Drug Designation for INZ-701 for ABCC6 Deficiency** – Inozyme recently received orphan drug designation by the U.S. Food and Drug Administration for INZ-701 for the treatment of patients with ABCC6 deficiency.

- **Received Clearance to Proceed in U.S. and U.K. with Phase 1/2 Clinical Trial of INZ-701 for the Treatment of ENPP1 Deficiency –** the Company expects to initiate the Phase 1/2 trial in the first half of 2021 and to provide preliminary safety and biomarker data in the second half of 2021.
- **Completed the Burden of Disease Patient Study** – this study provides an overview of the burden of disease in patients with ENPP1 deficiency and ABCC6 deficiency. The study has been accepted as poster presentations at three scientific conferences in the second quarter of 2021.
- **Completed the Healthy Volunteer Pyrophosphate (PPi) Study** – this study validates the highly sensitive assay that will be used to evaluate INZ-701 in clinical trials. The results of this study will be presented at medical conferences later in the year.
- **Advanced Gene Therapy Research and Development** – Inozyme progressed research and preclinical proof-of-concept work in demonstrating the ability to raise PPi levels using a gene therapy approach in animal models.

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**
  - **H1 2021:** Initiate prospective natural history study
  - **H1 2021:** Initiate Phase 1/2 clinical trial
  - **H2 2021:** Report preliminary safety and biomarker data from Phase 1/2 clinical trial
- **ABCC6 Deficiency**
  - **H1 2021**: File Clinical Trial Applications
  - **Mid-2021:** Initiate 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 Year Ended December 31, 2020

- **Cash Position and Financial Guidance –** Cash, cash equivalents, and investments were $159.9 million as of December 31, 2020. 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 second half of 2022.

- **Research and Development (R&D) Expenses –** R&D expenses were $46.5 million for the year ended December 31, 2020, compared to $16.2 million for the year ended December 31, 2019. The increase was primarily due to an increase of $17.8 million resulting from the non-recurring, non-cash purchase of in-process research and development intellectual property assets from Alexion Pharmaceuticals in exchange for stock of the Company in July 2020; costs associated with preclinical studies and clinical preparation activities with the Company's contract research organization; and growth in the number of R&D employees.
- **General and Administrative (G&A) Expenses –** G&A expenses were $10.5 million for the year ended December 31, 2020, compared to $4.6 million for the year ended December 31, 2019. The increase was primarily due to the growth in the number of G&A employees; an increase in legal fees related to patents, 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 $56.4 million, or $5.11 loss per share, for the year ended December 31, 2020, compared to $19.7 million, or $16.67 loss per share, for the year ended December 31, 2019.

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 future clinical trials, 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, 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)

	December 31, 2020	December 31, 2019
Cash, cash equivalents, and investments	$ 159,896	$ 47,132
Total assets	169,363	47,944
Total liabilities	11,260	3,236
Convertible preferred stock	—	77,927
Additional paid-in-capital	249,175	1,428
Accumulated deficit	(91,076)	(34,652)
Total stockholders' equity (deficit)	158,103	(33,219)

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Year Ended December 31,	
	2020	2019
Operating expenses:		
Research and development	$ 46,493	$ 16,220
General and administrative	10,548	4,586
Total operating expenses	57,041	20,806
Loss from operations	(57,041)	(20,806)
Other income (expense):		
Interest income	370	1,106
Other income (expense), net	247	(24)
Other income (expense), net	617	1,082
Net loss	$ (56,424)	$ (19,724)
Other comprehensive (loss) income:		
Unrealized (losses) gains on available-for-sale securities	(3)	7
Total other comprehensive (loss) income	(3)	7
Comprehensive loss	$ (56,427)	$ (19,717)
Net loss attributable to common stockholders—basic and diluted	$ (56,424)	$ (19,724)
Net loss per share attributable to common stockholders—basic and diluted	$ (5.11)	$ (16.67)
Weighted-average common shares outstanding—basic and diluted	11,036,500	1,183,147

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Investors:

Inozyme Pharma
Axel Bolte, co-founder, president, and chief executive officer
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