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): July 26, 2023

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

(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:

☐ 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 July 26, 2023, Inozyme Pharma, Inc. (the "Company") disclosed in a press release that it expects to report cash, cash equivalents, and short-term investments of approximately $140.2 million as of June 30, 2023. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The estimated cash, cash equivalents, and short-term investments amount as of June 30, 2023 includes: (1) $16.1 million in net proceeds received by the Company during the three months ended June 30, 2023 for the issuance and sale of an aggregate of 2,591,995 shares of the Company's common stock, $0.0001 par value per share (the "Common Stock"), pursuant to the Company's Open Market Sale Agreement℠ (the "Sales Agreement"), with Jefferies, LLC ("Jefferies"), and (2) $7.5 million in principal that the Company elected to draw down in June 2023 under its Loan and Security Agreement (the "Loan Agreement"), dated July 25, 2022, with K2 HealthVentures LLC.

The financial statements for the Company for the three and six months ended June 30, 2023 are not yet available. The estimated cash, cash equivalents, and short-term investments amount as of June 30, 2023 is preliminary and unaudited, represents management's estimate as of the date of this report, is subject to completion of the Company's financial closing procedures for the three and six months ended June 30, 2023, and does not present all necessary information for a complete understanding of the Company's financial condition as of June 30, 2023, or the Company's results of operations for the three and six months ended June 30, 2023. The actual financial results may differ materially from the preliminary estimated financial information.

The information in this Item 2.02, including Exhibit 99.1, 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 under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01. Regulation FD Disclosure.

On July 26, 2023, the Company issued a press release announcing a regulatory update for its global development strategy of INZ-701 for the treatment of ENPP1 Deficiency following recent meetings with the U.S. Food and Drug Administration (the "FDA") and the Paediatric Committee (the "PDCO") of the European Medicines Agency (the "EMA"). A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

Cash Updates; Cash Runway

As previously disclosed, the Company is party to a Loan Agreement with K2 HealthVentures LLC. The Loan Agreement provides for up to $70.0 million aggregate principal amount in term loans, subject to certain customary conditions. In June 2023, the Company elected to draw down $7.5 million in principal under the Loan Agreement. Immediately following this drawdown, $37.5 million of borrowing capacity remained available under the Loan Agreement, subject to the terms and conditions set forth therein.

During the three months ended June 30, 2023, the Company issued and sold an aggregate of 2,591,995 shares of Common Stock pursuant to its Sales Agreement with Jefferies for aggregate net proceeds of $16.1 million. From July 1, 2023 through the date of this report, the Company issued and sold an aggregate of 962,000 additional shares of Common Stock pursuant to its Sales Agreement with Jefferies, for aggregate net proceeds of $5.1 million.

The Company expects that its cash, cash equivalents, and short-term investments as of June 30, 2023, will enable the Company to fund its cash flow requirements into the first quarter of 2025. The Company has based this estimate on assumptions that may prove to be wrong, and the Company could use its available capital resources sooner than it currently expects.

Global Development Strategy of INZ-701 for the Treatment of ENPP1 Deficiency

On July 26, 2023, the Company announced a regulatory update for its global development strategy of INZ-701 for the treatment of ENPP1 Deficiency following recent meetings with the FDA and the PDCO of the EMA.

ENERGY-3 Trial Design – Planned Pivotal Trial in Pediatric Patients with ENPP1 Deficiency

The Company plans to initiate the ENERGY-3 pivotal trial (the "ENERGY-3 trial"), a multicenter, randomized, open label trial in pediatric patients with ENPP1 Deficiency in October 2023. The ENERGY-3 trial is expected to enroll up to 33 patients between the ages of one and less than 13 years across multiple sites globally and is designed primarily to assess the efficacy and safety of INZ-701 in pediatric patients with ENPP1 Deficiency. Enrollment criteria for the trial include a confirmed genetic diagnosis of ENPP1 Deficiency, radiographic evidence of skeletal abnormalities and low plasma pyrophosphate ("PPi"). Patients will be randomized in a 2:1 ratio to an INZ-701 arm or a control arm (conventional therapy, which is oral phosphate and active vitamin D) for 52 weeks, followed by an open label extension period during which all patients may receive INZ-701. INZ-701 will be administered at a 2.4 mg/kg once weekly dose via subcutaneous injection.

ENERGY-3 is a single, multicenter, clinical trial with differences in the statistical treatment of endpoints, based on guidance from the FDA and PDCO, as follows:

United States	European Union
Primary Endpoint – Change in plasma PPi from baseline	**Co-Primary Endpoints –** Change in plasma PPi from baseline and Radiographic Global Impression of Change ("RGI-C") score ($p<0.2$)
Secondary Endpoints - RGI-C score, Rickets Severity Score ("RSS"), Growth Z-score and pharmacokinetics ("PK")	**Secondary Endpoints –** RSS, Growth Z-score and PK

Based on recommendations from the FDA, the primary endpoint of plasma PPi should be supported by consistent trends in appropriate secondary endpoints. Based on the agreed Paediatric Investigational Plan ("PIP") with PDCO, plasma PPi and RGI-C are co-primary endpoints, with a relaxed p-value of <0.2 for RGI-C.

Planned Pivotal Trials in Infants and Adolescent/Adult Patients with ENPP1 Deficiency

The Company plans to conduct the ENERGY-2 pivotal trial (the "ENERGY-2 trial"), an open label, single arm trial in infants with ENPP1 Deficiency, based on the PIP agreed upon by PDCO. The trial is expected to be initiated outside of the United States. The trial's co-primary endpoints will be change in plasma PPi from baseline and survival. The trial is expected to enroll up to 12 infants between birth and up to 12 months of age. Primary endpoint data from this trial will be compared to a natural history control group with patients matched on covariates associated with mortality. Discussions are ongoing with the FDA regarding the design of a potential pivotal trial of INZ-701 in infants with ENPP1 Deficiency in the United States.

Pending regulatory discussions and appropriate financial resources, the Company also plans to conduct the ENERGY-4 pivotal trial (the "ENERGY-4 trial"), a multicenter, randomized, controlled trial in adolescents and adults with ENPP1 Deficiency. In the United States, the trial's sole primary endpoint is expected to be change in plasma PPi from baseline, supported by trends in appropriate secondary endpoints, and in the European Union, the trial's co-primary endpoints are expected to be change in plasma PPi from baseline and bone mineral content/density. Subject to regulatory review, the trial is expected to enroll up to 30 patients 13 years and older, and patients will be randomized in a 2:1 ratio to an INZ-701 arm or a control arm (conventional therapy, which is oral phosphate and active vitamin D).

Basis for Planned Marketing Applications

Based on regulatory feedback from the FDA and EMA, positive data from the ongoing and planned clinical trials of INZ-701 in patients with ENPP1 Deficiency, including comprehensive data demonstrating clinical impact of plasma PPi, could provide the basis for the Company's submission of marketing applications in both the United States and the European Union. These data will include final results from the Company's ongoing Phase 1/2 trial in adults with ENPP1 Deficiency, available results from the Company's ongoing ENERGY-1 trial (the "ENERGY-1 trial"), a Phase 1b clinical trial of INZ-701 in infants with ENPP1 Deficiency, available results from the planned pivotal ENERGY-2 trial in infants to be initiated outside of the United States, and final results from the planned pivotal ENERGY-3 trial in pediatric patients.

If these marketing applications are approved, the Company expects to commercially launch INZ-701 for infants and pediatric patients as early as the second half of 2026. Data from the planned ENERGY-4 trial in adolescent and adult patients with ENPP1 Deficiency may provide a basis for a supplemental marketing application.

Anticipated Milestones for ENPP1 Deficiency Program

- The Company expects to report interim data from the first three cohorts of the ongoing Phase 2 portion of the Phase 1/2 clinical trial of INZ-701 in adults with ENPP1 Deficiency in September 2023.
- The Company anticipates initiating the ENERGY-3 trial, a pivotal trial of INZ-701 in pediatric patients with ENPP1 Deficiency in October 2023.
- The Company expects to report topline data from the first three cohorts of the ongoing Phase 2 portion of the ongoing Phase 1/2 clinical trial of INZ-701 in adults with ENPP1 Deficiency in the first quarter of 2024.
- The Company anticipates initiating the ENERGY-2 trial, a pivotal trial of INZ-701 in infants with ENPP1 Deficiency, outside of the United States in the second quarter of 2024.
- The Company expects to report interim data from the ongoing ENERGY-1 trial, a Phase 1b clinical trial of INZ-701 in infants with ENPP1 Deficiency in the second half of 2024.
- The Company anticipates reporting topline data from the ENERGY-3 trial in mid-2025.

Clinical Trial of INZ-701 in Patients with ABCC6 Deficiency

The Company is currently conducting a Phase 1/2 clinical trial of INZ-701 in adults with ABCC6 Deficiency at sites in the United States and Europe. The trial is designed to primarily assess the safety and tolerability of INZ-701 in adults with ABCC6 Deficiency, as well as characterize the pharmacokinetic and pharmacodynamic profile of INZ-701, including the evaluation of levels of plasma PPi and other biomarkers. The Company plans to report interim data from the ongoing Phase 2 portion of this trial in September 2023 and topline data from the ongoing Phase 2 portion of this trial in the first quarter of 2024. Subject to regulatory review and sufficient funding, the Company plans to initiate a Phase 2 clinical trial of INZ-701 in adults with ABCC6 Deficiency in the fourth quarter of 2024.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

The following exhibit is furnished herewith:

Exhibit No.	Description
99.1	Press Release dated July 26, 2023
104	Cover Page Interactive Data File (formatted as Inline XBRL)

Cautionary Note Regarding Forward-Looking Statements

Statements in this Current Report on Form 8-K 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 timing and design of the Company's ongoing and planned clinical trials, the potential benefits of INZ-701, and the timing and contents of the Company's planned global development strategy, the availability and timing of clinical trial data, planned regulatory filings and the basis for such filings, the timing of the planned commercial launch of INZ-701, if approved, and the period over which the Company believes that its existing cash, cash equivalents, and short term investments will be sufficient to fund its cash flow requirements. 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 conduct its ongoing clinical trials of INZ-701 for ENPP1 Deficiency and ABCC6 Deficiency; enroll patients in ongoing and planned trials; obtain and maintain necessary approvals from the FDA, EMA 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; obtain clinically meaningful results with respect to novel endpoints; 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; comply with the covenants under its outstanding loan agreement; 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 Current Report on Form 8-K 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.

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: July 26, 2023

By: /s/ Douglas A. Treco
Name: Douglas A. Treco
Title: Chief Executive Officer

Exhibit 99.1

Inozyme Pharma Announces Updates on Global Development Strategy of INZ-701 for the Treatment of ENPP1 Deficiency

- Change in plasma pyrophosphate (PPi) as primary endpoint in the U.S. and co-primary endpoint in the EU for planned ENERGY-3 pivotal trial in pediatric patients -

- ENERGY-3 pivotal trial in pediatric patients expected to initiate in October 2023, topline data expected to be reported in mid-2025 -

- Updated cash runway expected to fund cash flow requirements into Q1 2025 -

- Company to host conference call today at 8am ET -

BOSTON, July 26, 2023 — **Inozyme Pharma, Inc.** (Nasdaq: INZY) ("Inozyme" or the "Company"), a clinical-stage rare disease biopharmaceutical company developing novel therapeutics for the treatment of pathologic mineralization and intimal proliferation, today announced a regulatory update for its global development strategy of INZ-701 for the treatment of ENPP1 Deficiency following recent meetings with the United States (U.S.) Food and Drug Administration (FDA) and the Paediatric Committee (PDCO) of the European Medicines Agency (EMA).

"We are pleased to have finalized our pediatric pivotal trial design with PPi, a well-established natural inhibitor of mineralization, as a primary endpoint in the U.S. and a co-primary endpoint in the EU. We have already observed that INZ-701 meaningfully increased PPi levels in our ongoing trial of INZ-701 in adults with ENPP1 Deficiency and, based on our discussions with regulators in the U.S. and EU, we believe we have a clear path forward in our clinical development program for the treatment of ENPP1 Deficiency," said Douglas A. Treco, Ph.D., CEO of Inozyme Pharma.

ENERGY-3 Trial Design – Planned Pivotal Trial in Pediatric Patients with ENPP1 Deficiency

The Company plans to initiate the ENERGY-3 pivotal trial, a multicenter, randomized, open label trial in pediatric patients with ENPP1 Deficiency in October 2023. The ENERGY-3 trial is expected to enroll up to 33 patients between the ages of one and less than 13 years across multiple sites globally and is designed primarily to assess the efficacy and safety of INZ-701 in pediatric patients with ENPP1 Deficiency. Enrollment criteria for the trial include a confirmed genetic diagnosis of ENPP1 Deficiency, radiographic evidence of skeletal abnormalities and low plasma PPi. Patients will be randomized in a 2:1 ratio to an INZ-701 arm or a control arm (conventional therapy, i.e., oral phosphate and active vitamin D) for 52 weeks, followed by an open label extension period during which all patients may receive INZ-701. INZ-701 will be administered at a 2.4 mg/kg once weekly dose via subcutaneous (SC) injection.

ENERGY-3 is a single, multicenter, clinical trial with differences in the statistical treatment of endpoints, based on guidance from the FDA and PDCO, as follows:

U.S.	EU
Primary Endpoint – Change in plasma PPi from baseline	**Co-Primary Endpoints –** Change in plasma PPi from baseline and Radiographic Global Impression of Change (RGI-C) score ($p<0.2$)
Secondary Endpoints – RGI-C score, Rickets Severity Score (RSS), Growth Z-score and pharmacokinetics (PK)	**Secondary Endpoints –** RSS, Growth Z-score and PK

Based on recommendations from the FDA, the primary endpoint of plasma PPi should be supported by consistent trends in appropriate secondary endpoints. Based on the agreed Paediatric Investigational Plan (PIP) with PDCO, plasma PPi and RGI-C are co-primary endpoints, with a relaxed p-value of <0.2 for RGI-C.

Planned Pivotal Trials in Infants and Adolescent/Adult Patients with ENPP1 Deficiency

The Company plans to conduct the ENERGY-2 pivotal trial, an open label, single arm trial in infants with ENPP1 Deficiency, based on the Paediatric Investigational Plan (PIP) agreed upon by PDCO. The trial is expected to be initiated outside of the U.S. The trial's co-primary endpoints will be change in plasma PPi from baseline and survival. The trial is expected to enroll up to 12 infants between birth and up to 12 months of age. Primary endpoint data from this trial will be compared to a natural history control group with patients matched on covariates associated with mortality. Discussions are ongoing with the FDA regarding the design of a potential pivotal trial of INZ-701 in infants with ENPP1 Deficiency in the U.S.

Pending regulatory discussions and appropriate financial resources, the Company also plans to conduct the ENERGY-4 pivotal trial, multicenter, randomized, controlled trial in adolescents and adults with ENPP1 Deficiency. In the U.S., the trial's sole primary endpoint is expected to be change in plasma PPi from baseline, supported by trends in appropriate secondary endpoints, and in the EU, the trial's co-primary endpoints are expected to be change in plasma PPi from baseline and bone mineral content/density. Subject to regulatory review, the trial is expected to enroll up to 30 patients 13 years and older, and patients will be randomized in a 2:1 ratio to an INZ-701 arm or a control arm (conventional therapy, i.e., oral phosphate and active vitamin D).

Basis for Planned Marketing Applications

Based on regulatory feedback from the FDA and EMA, positive data from the ongoing and planned clinical trials of INZ-701 in patients with ENPP1 Deficiency, including comprehensive data demonstrating clinical impact of plasma PPi, could provide the basis for the Company's submission of marketing applications in both the U.S. and EU. These data will include final results from the Company's ongoing Phase 1/2 trial in adult patients with ENPP1 Deficiency, available results from the Company's ongoing ENERGY-1 trial, a Phase 1b trial of INZ-701 in infants with ENPP1 Deficiency, available results from the planned pivotal ENERGY-2 trial in infants to be initiated ex-U.S., and final results from the planned pivotal ENERGY-3 trial in pediatric patients.

If these marketing applications are approved, the Company expects to commercially launch INZ-701 for infant and pediatric patients as early as the second half of 2026. Data from the planned ENERGY-4 trial in adolescent and adult patients with ENPP1 Deficiency may provide a basis for a supplemental marketing application.

Anticipated Milestones for ENPP1 Deficiency Program

- Interim data from Cohorts 1-3 in the Phase 2 portion of the ongoing Phase 1/2 trial in adults – September 2023
- Initiation of ENERGY-3 trial, a pivotal trial in pediatric patients – October 2023
- Topline data from Cohorts 1-3 in the Phase 2 portion of the ongoing Phase 1/2 trial in adults – Q1 2024
- Initiation of ENERGY-2 trial, a pivotal trial in infants, ex U.S. – Q2 2024
- Interim data from ENERGY-1 trial, a Phase 1b trial in infants – 2H 2024
- Topline data from ENERGY-3 trial, a pivotal trial in pediatric patients – Mid-2025

Cash Runway Guidance

The Company expects to report cash, cash equivalents, and short-term investments of approximately $140.2 million as of June 30, 2023. The estimated cash, cash equivalents, and short-term investments amount is preliminary and unaudited, represents management's estimate as of the date of this press release, is subject to completion of the Company's financial closing procedures for the quarter ended June 30, 2023 and does not present all necessary information for a complete understanding of the Company's financial condition as of June 30, 2023, or the Company's results of operations for the quarter ended June 30, 2023. The actual financial results may differ materially from the preliminary estimated financial information.

Based on its current plans, the Company anticipates its cash, cash equivalents, and short-term investments as of June 30, 2023, will enable the Company to fund cash flow requirements into the first quarter of 2025.

Conference Call

Inozyme will host a conference call and webcast to discuss its global development strategy for INZ-701 in patients with ENPP1 Deficiency today, July 26, 2023, at 8am ET. The live webcast will be accessible through the Investor Relations section of Inozyme's website under News & Events. To access the live call by phone, dial 1-877-270-2148 (domestic) or 1-412-902-6510 (international) and ask to be connected to the Inozyme Pharma call. For those unable to participate live, a replay will be available in the Investor Relations section of Inozyme's website for a limited time following the event.

About ENPP1 Deficiency

ENPP1 Deficiency is a progressive condition that manifests as a spectrum of diseases. The estimated genetic prevalence of ENPP1 Deficiency is approximately 1 in 64,000 pregnancies worldwide. Individuals who present in utero or in infancy are typically diagnosed with generalized arterial calcification of infancy (GACI), which is characterized by extensive vascular calcification and intimal proliferation (overgrowth of smooth muscle cells inside blood vessels), resulting in myocardial infarction, stroke, or cardiac or multiorgan failure. Approximately 50% of infants with ENPP1 Deficiency die within six months of birth. Children with ENPP1 Deficiency typically develop rickets, a condition diagnosed as autosomal-recessive hypophosphatemic rickets type 2 (ARHR2), while adults can develop osteomalacia (softened bones). ARHR2 and osteomalacia lead to pain and mobility issues. Patients can also exhibit signs and symptoms of hearing loss, arterial and joint calcification, and cardiovascular complications. There are no approved therapies for ENPP1 Deficiency.

About INZ-701

INZ-701, a recombinant Fc fusion protein, is an ENPP1 enzyme replacement therapy in development for the treatment of rare disorders of the vasculature, soft tissue, and skeleton. In preclinical studies, the experimental therapy has shown potential to prevent pathologic mineralization and intimal proliferation (the overgrowth of smooth muscle cells inside blood vessels), which can drive morbidity and mortality in devastating genetic disorders such as ENPP1 Deficiency and ABCC6 Deficiency. INZ-701 is currently in clinical trials for the treatment of ENPP1 Deficiency and ABCC6 Deficiency.

About Inozyme Pharma

Inozyme Pharma, Inc. (Nasdaq: INZY) is a clinical-stage rare disease biopharmaceutical company developing novel therapeutics for the treatment of diseases impacting the vasculature, soft tissue, and skeleton. We are developing INZ-701, an enzyme replacement therapy, to address pathologic mineralization and intimal proliferation which can drive morbidity and mortality in these severe diseases. INZ-701 is currently in clinical trials for the treatment of ENPP1 Deficiency and ABCC6 Deficiency.

For more information, please visit **www.inozyme.com** and follow us on **LinkedIn**, **Twitter**, and **Facebook**.

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 timing and design of our clinical trials, the potential benefits of INZ-701, the timing and contents of our planned global development strategy, the availability and timing of clinical trial data, planned regulatory filings and the basis for such filings, the timing of the planned commercial launch of INZ-701, if approved, and the period over which we believe that our existing cash, cash equivalents and short term investments will be sufficient to fund our cash flow requirements. 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 conduct its ongoing clinical trials of INZ-701 for ENPP1 Deficiency and ABCC6 Deficiency; enroll patients in ongoing and planned trials; obtain and maintain necessary approvals from the FDA, EMA, 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; obtain clinically meaningful results with respect to novel endpoints; 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; comply with the covenants under its outstanding loan agreement; 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 (SEC), as well as discussions of

potential risks, uncertainties, and other important factors, in the Company's most recent filings with the SEC. 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.

Contacts

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