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 11, 2021



(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-39247 (Commission File Number) 81-1523849 (IRS Employer Identification No.)

116 Huntington Avenue, 6th Floor Boston, MA (Address of Principal Executive Offices)

02116 (Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 206-2020

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:

□ 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)

Dere-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 \$0.001 per share	IMRA	The Nasdaq Stock Market LLC

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 \boxtimes

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 11, 2021, IMARA Inc. (the "Company") announced its financial results for the quarter ended March 31, 2021 and other business highlights. 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 (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, 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

Exhibit Number	Description	
99.1	Press Release issued by the Company on May 11, 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.

IMARA INC.

Date: May 11, 2021

By: /s/ Rahul D. Ballal

Name: Rahul D. Ballal Title: President and Chief Executive Officer



Imara Reports First Quarter 2021 Financial Results and Business Highlights

On-track to report interim analyses for both Ardent sickle cell disease and Forte beta-thalassemia Phase 2b clinical trials in the second half of 2021

Completed enrollment in the transfusion-dependent beta-thalassemia arm of the Forte Phase 2b trial

Higher dose arms open in both the Ardent and Forte Phase 2b clinical trials

Applications now being accepted for 2021 Real Impact grant program

Company to host conference call and live webcast today at 8:30 AM ET

BOSTON—May 11, 2021 (GLOBE NEWSWIRE) — Imara Inc. (Nasdaq: IMRA), a clinical-stage biopharmaceutical company dedicated to developing and commercializing novel therapeutics to treat patients suffering from rare inherited genetic disorders of hemoglobin, today reported financial results for the first quarter ended March 31, 2021 and reviewed recent business highlights.

"We have made substantial enrollment progress in our higher dose Phase 2b clinical trials for patients with sickle cell disease and beta-thalassemia, which are designed to test higher doses of IMR-687," said Rahul Ballal, Ph.D., President and Chief Executive Officer of Imara. "We are now conducting these studies at approximately 75 clinical trial sites across 20 countries and have fully enrolled the transfusion-dependent beta-thalassemia arm of the Forte trial. We remain on track to complete the respective protocol-driven interim analyses for the Ardent and Forte trials and to report interim data in the second half of 2021 for both programs. Furthermore, following the recommendation of independent data monitoring committees, we opened the higher dose treatment arms in both Phase 2b clinical trials and are currently testing IMR-687 at daily dose levels of up to 400 mg."

Dr. Ballal continued, "In addition to our progress in the Phase 2b clinical trials, we reported topline data from our Phase 2a clinical trial of IMR-687 in sickle cell disease, in which IMR-687 was well tolerated, and promising reductions in rates of vaso-occlusive crises (VOCs) were observed with variable changes in certain biomarkers, including HbF and F-cells. We also reported preliminary data from our Phase 2a open label extension trial, which showed that IMR-687 was well tolerated and in which increases in fetal hemoglobin and F-cells were observed. We plan to present comprehensive VOC data from the completed, 93-patient, placebo-controlled Phase 2a clinical trial, as well as additional data from the ongoing open label extension trial, at the European Hematology Association (EHA) 2021 Virtual Congress in June 2021."

"We have also been working to explore the therapeutic potential of IMR-687 in additional indications. We are pleased to have successfully completed pre-clinical studies of IMR-687 in heart failure with preserved ejection fraction, or HFpEF, and we plan to present these encouraging data at an upcoming cardiovascular medical meeting later in 2021," said Dr. Ballal.

"Finally, we are proud to continue with our Real Impact community support program, which provides needed resources to community-based organizations around the country that serve patients and families with sickle cell disease and beta-thalassemia," Dr. Ballal stated. "We have now opened the application process for the Real Impact grant program and expect to award up to \$150,000 in funding in 2021 to deserving community-based organizations. We are committed to the sickle cell and beta-thalassemia patient community and supporting these groups are core to the Imara mission."

Recent Corporate Highlights and Updates

Higher Dose Arms Opened in Global Phase 2b Clinical Trials of IMR-687

Following recommendations from separate independent data monitoring committees for the Ardent and Forte Phase 2b clinical trials of IMR-687 for sickle cell disease and beta-thalassemia, respectively, Imara has opened the higher dose IMR-687 treatment arms. Enrollment is proceeding in each study at either the IMR-687 higher dose (once daily dose of 300 mg or 400 mg based on patient weight), IMR-687 lower dose (once daily dose of 200 mg or 300 mg based on patient weight), or placebo. Imara expects to report interim data from the Ardent and Forte Phase 2b clinical trials in the second half of 2021, data from the primary analysis from each of these trials in the first half of 2022 and data from the final analysis from each of these trials in the second half of 2022.

Opening of Applications Process for 2021 Real Impact Grants

Imara's Real Impact grant program moves into its second year after distributing \$125,000 in funding in 2020 to community-based organizations dedicated to raising awareness for and support of the sickle cell and beta-thalassemia patient communities. Imara expects to increase total grant funding to \$150,000 for 2021, which will be distributed according to three key areas of need: social determinants of health (including COVID-19 relief), virtual support programs and community-based organization capacity. The application window is open until May 14th and organizations are encouraged to apply at the following link: https://webportalapp.com/sp/login/real_impact_grants

Completed Preclinical Studies in Heart Failure Indication

Imara completed preclinical studies of IMR-687 in heart failure with preserved ejection fraction, or HFpEF, during the first quarter. The results of these studies continue to support the further development of IMR-687 in HFpEF and Imara is formulating a clinical development plan for IMR-687 in this indication.

First Quarter 2021 Financial Results

- **Cash Position:** Cash, cash equivalents and investments were \$75.6 million as of March 31, 2021, as compared to cash, cash equivalents and investments of \$88.2 million as of December 31, 2020.
- **Research and Development Expenses:** Research and development expenses were \$7.1 million for the first quarter of 2021, as compared to \$5.8 million for the first quarter of 2020. The increase of \$1.3 million was primarily related to the development and manufacturing of clinical materials, clinical research and oversight of the Company's clinical trials and investigative fees related to the development of IMR-687, as well as increased personnel-related and other research and development operational costs.
- **General and Administrative Expenses:** General and administrative expenses were \$3.2 million for the first quarter of 2021, as compared to \$1.6 million for the first quarter of 2020. The increase of \$1.6 million was primarily due to increased personnel-related and other general and administrative operational costs as a result of operating as a public company.
- **Net Loss Attributable to Common Stockholders:** Net loss attributable to common stockholders was \$10.3 million, or \$0.58 per share, for the first quarter of 2021, as compared to a net loss of \$15.1 million, or \$4.31 per share, for the first quarter of 2020.

Financial Guidance

The Company currently expects that its full-year 2021 research and development expenses will range between \$50 million and \$55 million and that its full-year 2021 general and administrative expenses will range between \$12 million and \$14 million. The Company expects that its cash, cash equivalents and investments as of March 31, 2021, will be sufficient to enable it to fund its planned operations into mid-2022.

Conference Call and Webcast Information

Imara will host a conference call and live webcast today at 8:30 a.m. ET to discuss its first quarter 2021 financial results and other business updates. The live webcast will be available under "Events and Presentations" in the Investors section of the Company's website at <u>imaratx.com</u>. The conference call can be accessed by dialing 1 (833) 519-1307 (U.S. domestic) or +1 (914) 800-3873 (international) and referring to conference ID 7598753. A replay of the webcast will be archived on the Imara website following the presentation.

About Imara

Imara Inc. is a clinical-stage biotechnology company dedicated to developing and commercializing novel therapeutics to treat patients suffering from rare inherited genetic disorders of hemoglobin. Imara is currently advancing IMR-687, a highly selective, potent small molecule inhibitor of PDE9 that is an oral, once-a-day, potentially disease-modifying treatment

for sickle cell disease and beta-thalassemia. IMR-687 is being designed to have a multimodal mechanism of action that acts on red blood cells, white blood cells, adhesion mediators and other cell types. For more information, please visit <u>www.imaratx.com</u>.

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 (i) the timing for reporting of data from the Company's ongoing Phase 2b clinical trials in patients with sickle cell disease and beta-thalassemia, (ii) the plan for reporting of comprehensive data on the completed Phase 2a clinical trial in sickle cell disease and additional data from the open label extension clinical trial in sickle cell disease, (iii) the plan for reporting of preclinical data in HFpEF (iv) the Company's beliefs regarding the strength of its clinical data, the therapeutic potential of IMR-687 and advancement of its clinical program, and (v) financial guidance regarding the Company's projected operating expenses and sufficiency of the Company's capital resources to fund its operations into mid-2022. 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. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the impact of extraordinary external events, such as the risks and uncertainties resulting from the impact of the COVID-19 pandemic on the Company's business, operations, strategy, goals and anticipated milestones, including its ongoing and planned research activities and ability to enroll, dose and readout data from its open label extension clinical trial of IMR-687 in sickle cell disease and its Phase 2b clinical trials of IMR-687 in sickle cell disease and beta-thalassemia; the Company's ability to advance the development of IMR-687 under the timelines it projects in current and future clinical trials, demonstrate in any current and future clinical trials the requisite safety and efficacy of IMR-687; and other factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K, which is on file with the Securities and Exchange Commission and in other filings that the Company makes with the Securities and Exchange Commission in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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IMARA INC.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands) (Unaudited)

	March 31, 2021		December 31, 2020	
Cash, cash equivalents and investments	\$	75,592	\$	88,222
Working capital ⁽¹⁾		74,858		84,158
Total assets		81,687		90,842
Total liabilities		6,093		6,407
Accumulated deficit		(106,370)		(96,113)
Total stockholders' equity		75,594		84,435

(1) Working capital is defined as current assets less current liabilities.

IMARA INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share data) (Unaudited)

	Three Months Ended March 31,				
		2021		2020	
Operating expenses:					
Research and development	\$	7,115	\$	5,793	
General and administrative		3,165		1,559	
Total operating expenses		10,280		7,352	
Loss from operations		(10,280)		(7,352)	
Total other income:					
Interest income		83		132	
Other income (expense)		(60)		5	
Total other income, net		23		137	
Net loss	\$	(10,257)	\$	(7,215)	
Accretion of Series B convertible preferred stock		_		(7,858)	
Net loss attributable to common stockholders—basic and diluted	\$	(10,257)	\$	(15,073)	
Weighted-average common shares outstanding—basic and diluted		17,577,454		3,493,359	
Net loss per share attributable to common stockholders—basic and diluted	\$	(0.58)	\$	(4.31)	