

**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): August 6, 2021

IMARA INC.

(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)
- 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 \$0.001 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

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 August 6, 2021, IMARA Inc. (the “Company”) announced its financial results for the quarter ended June 30, 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 August 6, 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: August 6, 2021

By: /s/ Rahul D. Ballal, Ph.D.

Name: Rahul D. Ballal

Title: President and Chief Executive Officer



Imara Reports Second Quarter 2021 Financial Results and Business Highlights

Accelerated enrollment in Phase 2b trials in sickle cell disease and beta-thalassemia; interim analyses expected in fourth quarter of 2021

Positive IMR-687 data in sickle cell disease presented at the European Hematology Association (EHA) Annual Congress

HFpEF Phase 2 proof-of-concept study under development; FDA interaction planned in fourth quarter of 2021

\$50 million July follow-on offering extends cash runway through 2022

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

BOSTON, August 6, 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 and other serious diseases, today reported financial results for the second quarter ending June 30, 2021, and reviewed recent business highlights.

“We are pleased with the progress of IMR-687 (tovinontrine), including accelerated study enrollment in our Ardent Phase 2b clinical trial in sickle cell disease (SCD),” said Rahul Ballal, Ph.D., President and Chief Executive Officer of Imara. “We have completed patient enrollment in the trial and as a result are refining our prior guidance and now expect to report data from the primary analysis in the first quarter of 2022. We continue to expect to report an interim analysis during the fourth quarter of 2021.”

Dr. Ballal continued, “Similarly, we have seen accelerated enrollment in our Forte Phase 2b clinical trial in beta-thalassemia, having reached full enrollment in the transfusion-dependent thalassemia (TDT) cohort, while also seeing increased enrollment in the non-transfusion-dependent thalassemia (NTDT) cohort, where we have enrolled approximately half of the study patients. We expect to report interim data from the TDT cohort in the fourth quarter of 2021 and conduct an additional efficacy analysis of the full TDT cohort at 24 weeks in the first quarter of 2022.”

“We are also selectively expanding our indication footprint to areas where PDE9 over-expression is implicated in serious diseases with high unmet needs,” Dr. Ballal added. “To that end, we are developing a protocol for a Phase 2 proof-of-concept study in heart failure with preserved ejection fraction (HFpEF) with help from our experienced cardiology clinical advisory board and

expect to interact with the FDA in late 2021. We also submitted our recent pre-clinical work in HFpEF to a cardiology focused medical meeting and hope to present this data later this year.”

Recent Corporate Highlights

IMR-687 in SCD: Enrollment Complete in Ardent Phase 2b Clinical Trial; Phase 2a and Open Label Extension Clinical Trial Data Reported

Imara has completed patient enrollment in the Ardent Phase 2b clinical trial of IMR-687 for SCD. Imara expects to report interim data from the Ardent trial in the fourth quarter of 2021, data from the primary efficacy analysis in the in the first quarter of 2022 and data from the final analysis in the second half of 2022.

Imara also presented data from the Phase 2a clinical trial and its OLE trial of IMR-687 in adults with SCD at the EHA Annual Congress in June 2021. Final data from the 93-patient Phase 2a trial showed a well-tolerated safety profile along with a decrease in annualized vaso-occlusive crisis (VOC) rates, fewer VOC-related hospitalizations, increased time to first VOC, and improvements in patient-reported VOC pain severity scores. Changes in SCD-related biomarkers were variable and included directional increases in HbF.

Updated interim data through eight months from the ongoing OLE clinical trial show maintenance of the lower VOC rate on IMR-687 observed in the Phase 2a parent trial. An increased HbF response was also observed in the OLE, with 4 of 11, or 36%, of patients having absolute fetal hemoglobin (HbF) increases of more than 3% at the eight-month timepoint while receiving a 200 mg daily dose of IMR-687.

IMR-687 in Beta-Thalassemia: Patient Enrollment Accelerated in Forte Phase 2b Clinical Trial

In the Forte Phase 2b clinical trial, Imara reached full enrollment in the TDT cohort and saw increased enrollment in the NTDT cohort. Imara expects to report interim data from the TDT cohort in the fourth quarter of 2021 and conduct an additional efficacy analysis of the full TDT cohort at 24 weeks in the first quarter of 2022. Data from the final analysis is expected in the second half of 2022.

Tovinontrine adopted as generic name for IMR-687

On June 30, 2021 the United States Adopted Names (USAN) Council adopted “*tovinontrine*” (pronounced toe” vi non’ treen) as the generic name for IMR-687.

Recipients of the Second Annual Real Impact Grants Program

Imara continued and expanded the Real Impact program by awarding 30 grants totaling \$150,000 to fund nonprofit, community-based organizations (CBOs) supporting individuals with sickle cell disease and beta-thalassemia. The grant funding was increased by \$25,000 from 2020, the program’s inaugural year.

Closed \$50 Million Public Offering

On July 16, 2021, Imara closed an underwritten public offering of shares of its common stock at a public offering price of \$6.00 per share, for gross proceeds of \$50 million, before underwriting discounts and commissions and offering expenses.

Laura A. Williams, M.D., MPH Appointed to Board of Directors

Dr. Williams has served as Senior Vice President of Global Therapeutic Strategies and Patient Advocacy at Ardelyx since November 2020, where she is also a member of the Executive Leadership Team. Dr. Williams brings 25 years of early-to-late-stage drug development experience across multiple therapeutic areas, as well as expertise in patient advocacy to Imara.

Second Quarter 2021 Financial Results

- **Cash Position:** Cash, cash equivalents and investments were \$66.8 million as of June 30, 2021, 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 \$10.1 million for the second quarter of 2021, as compared to \$7.9 million for the second quarter of 2020. The increase of \$2.2 million was primarily related to the development and manufacturing of clinical materials, clinical research and oversight of the Company's clinical trials and investigator fees related to the development of IMR-687, as well as increased personnel-related and other research and development operating costs.
- **General and Administrative Expenses:** General and administrative expenses were \$3.1 million for the second quarter of 2021, as compared to \$2.4 million for the second quarter of 2020. The increase of \$0.7 million was primarily due to increased personnel-related and other general and administrative operating costs as a result of operating as a public company.
- **Net Loss Attributable to Common Stockholders:** Net loss attributable to common stockholders was \$13.2 million, or \$0.74 per share, for the second quarter of 2021, as compared to a net loss of \$10.2 million, or \$0.59 per share, for the second quarter of 2020.

Financial Guidance

The Company currently expects that its full-year 2021 research and development expenses will range between \$42.5 million and \$47.5 million and that its full-year 2021 general and administrative expenses will range between \$12 million and \$13 million. The Company expects that its cash, cash equivalents and investments as of June 30, 2021, together with the net proceeds from its July 2021 public offering of shares of common stock, will be sufficient to enable it to fund its planned operations through the end of 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 second 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 www.imaratx.com. 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 6499377. 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 and other serious diseases. 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 www.imaratx.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 (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 Company's clinical development plans and expected regulatory interactions for the potential development of IMR-687 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 through the end of 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 Quarterly Report on Form 10-Q, 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)

	June 30, 2021	December 31, 2020
Cash, cash equivalents and investments	\$ 66,768	\$ 88,222
Working capital ⁽¹⁾	64,384	84,158
Total assets	72,468	90,842
Total liabilities	7,501	6,407
Accumulated deficit	(119,531)	(96,113)
Total stockholders' equity	64,967	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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 10,074	\$ 7,869	\$ 17,189	\$ 13,662
General and administrative	3,095	2,433	6,260	3,992
Total operating expenses	<u>13,169</u>	<u>10,302</u>	<u>23,449</u>	<u>17,654</u>
Loss from operations	<u>(13,169)</u>	<u>(10,302)</u>	<u>(23,449)</u>	<u>(17,654)</u>
Total other income, (net):				
Interest income	48	110	131	242
Other expense	(40)	(12)	(100)	(7)
Total other income, (net)	<u>8</u>	<u>98</u>	<u>31</u>	<u>235</u>
Net loss	<u>\$ (13,161)</u>	<u>\$ (10,204)</u>	<u>\$ (23,418)</u>	<u>\$ (17,419)</u>
Accretion of Series B convertible preferred stock	—	—	—	(7,858)
Net loss attributable to common stockholders—basic and diluted	<u>\$ (13,161)</u>	<u>\$ (10,204)</u>	<u>\$ (23,418)</u>	<u>\$ (25,277)</u>
Weighted-average common shares outstanding—basic and diluted	<u>17,715,474</u>	<u>17,194,795</u>	<u>17,647,476</u>	<u>10,344,077</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.74)</u>	<u>\$ (0.59)</u>	<u>\$ (1.33)</u>	<u>\$ (2.44)</u>
Comprehensive loss:				
Net loss	\$ (13,161)	\$ (10,204)	\$ (23,418)	\$ (17,419)
Other comprehensive income:				
Unrealized gain (loss) on investments (net)	(1)	64	(4)	16
Comprehensive loss	<u>\$ (13,162)</u>	<u>\$ (10,140)</u>	<u>\$ (23,422)</u>	<u>\$ (17,403)</u>