

**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 14, 2020

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 14, 2020, IMARA Inc. (the “Company”) announced its financial results for the quarter ended June 30, 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 (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 14, 2020

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 14, 2020

By: /s/ Rahul D. Ballal

Name: Rahul D. Ballal

Title: President and Chief Executive Officer



Imara Reports Second Quarter 2020 Financial Results and Business Highlights

Initiated Phase 2b clinical trials of IMR-687 in sickle cell disease and beta-thalassemia; First patient dosed in Ardent Phase 2b sickle cell clinical trial

Reported Phase 2a interim safety and efficacy data at the European Hematology Association Annual Congress and promising clinical outcomes in an Open Label Extension Study that tests IMR-687 for longer duration

IMR-687 granted Orphan Drug, Fast Track and Rare Pediatric designations by the FDA for beta-thalassemia

Company to host conference call and live webcast today at 8:30 a.m. ET

BOSTON, Mass., August 14, 2020 – 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 second quarter ended June 30, 2020 and reviewed recent business highlights.

“As we head into the second half of 2020, we are encouraged by several advancements across our programs that bring us closer to providing oral treatment options to patients with rare blood disorders,” said Rahul Ballal, Ph.D., President and Chief Executive Officer of Imara. “We initiated our Phase 2b clinical trials for IMR-687 in both sickle cell disease and beta-thalassemia and dosed the first patient in our Ardent Phase 2b clinical trial for adult patients with sickle cell disease. We also reported encouraging Phase 2a interim clinical trial results with IMR-687 at the European Hematology Association Annual Congress and more recently observed promising clinical outcomes with longer duration IMR-687 treatment as part of our Phase 2a open label extension trial. In addition, we made important progress on the regulatory front as we were granted Orphan Drug, Fast Track and Rare Pediatric designations by the FDA for the treatment of patients with beta-thalassemia. Finally, we are leveraging IMR-687’s differentiated mechanism of action and began preclinical studies to explore its potential for the treatment of heart failure with preserved ejection fraction, or HFpEF.”

Dr. Ballal continued, “We look forward to further advancing patient recruitment activities for our Phase 2b clinical trials and expect to report top-line data from our ongoing Phase 2a clinical trial in sickle cell disease during the fourth quarter of 2020.”

Recent Corporate Highlights and Updates

- **Presented Clinical Data from Phase 2a and Phase 2a Open Label Extension Clinical Trials:** Imara presented interim Phase 2a clinical trial results for IMR-687 in adult patients with sickle cell disease (SCD) at the virtual 25th European Hematology Association (EHA) Annual Congress in June 2020. The data from this ongoing clinical trial demonstrated that IMR-687 was well tolerated as a monotherapy and in combination with hydroxyurea (HU). In the higher dose cohort, IMR-687 monotherapy showed a statistically significant ($p=0.022$) increase in the number of F-cells, which are red blood cells containing fetal hemoglobin (HbF), as well as a dose-dependent increase in HbF levels in adult patients with SCD.

In addition, two adult patients with SCD have passed six-months of treatment in the Company's ongoing Phase 2a open label extension (OLE) clinical trial (one at six months and one at twelve months). A review of outcomes for these two patients indicate potential benefits of IMR-687 with respect to reported vaso-occlusive crises (VOCs) trends, healthcare facility use, and SCD associated biomarkers. Enrollment in the OLE has also recently increased as the Phase 2a trial is completing, with six of eight patients entering this four-year safety study since the beginning June 2020.

- **Initiated Clinical Trials:** Imara initiated Phase 2b clinical trials of IMR-687 in SCD and adult patients with beta-thalassemia. Patient screening is underway in both trials, and the Company dosed the first patient in its Ardent Phase 2b SCD clinical trial and expects to begin dosing in the beta-thalassemia trial in the near-term.
 - **IMR-687 Granted Multiple Regulatory Designations:** The FDA granted IMR-687 Orphan, Fast Track and Rare Pediatric Disease designations for the treatment of patients with beta-thalassemia.
 - **Established Advisory Board for Clinical Studies in Africa:** Imara established a regional advisory board to guide the execution of IMR-687 clinical studies in Africa, which includes key opinion leaders with expertise treating patients and conducting clinical studies in the region.
 - **Expanded Pipeline:** Imara is conducting preclinical research to evaluate the potential of IMR-687 in heart failure with preserved ejection fraction (HFpEF), also referred to as diastolic heart failure. Published literature suggests that inhibition of PDE9, and resulting increases in cyclic guanosine monophosphate (cyclic GMP) through natriuretic peptide modulation, can serve as an attractive target for the prevention and treatment of vascular disease, including HFpEF. Imara has formed an advisory board comprised of key heart failure opinion leaders to further advise on potential development of IMR-687 in this indication.
 - **Initiated Real Impact Program and Funded Community Support Grants:** Imara announced the grant recipients of its 'Real Impact' community support initiative. This program, which includes grant funding to support nonprofit, community-based
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organizations serving patients and families impacted by SCD and beta-thalassemia, awarded 25 grants of approximately \$5,000 each to community-based organizations in 13 states. The grant funding was increased by 25% from original plans due to the strong demand for COVID-19 related relief programs.

- **Added to Russell 2000® Index:** Imara was added as a member of the U.S. small-cap Russell 2000® Index. Russell U.S. Indexes are widely used by investment managers and institutional investors for passive funds and investment products and as benchmarks for active investment strategies.

Second Quarter 2020 Financial Results

- **Cash Position:** Cash, cash equivalents and investments were \$106.3 million as of June 30, 2020, as compared to cash, cash equivalents and investments of \$28.9 million as of December 31, 2019.
- **Research and Development Expenses:** Research and development expenses were \$7.9 million for the second quarter of 2020, as compared to \$4.4 million for the second quarter of 2019. The increase of \$3.5 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 \$2.4 million for the second quarter of 2020, as compared to \$1.2 million for the second quarter of 2019. The increase of \$1.2 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 \$10.2 million, or \$0.59 per share, for the second quarter of 2020, as compared to a net loss of \$5.4 million, or \$7.68 per share, for the second quarter of 2019.

Financial Guidance

The Company currently expects that its full-year 2020 research and development expenses will range between \$35 million and \$40 million and that its full-year 2020 general and administrative expenses will range between \$8 million and \$10 million. The Company expects that its cash, cash equivalents and investments as of June 30, 2020 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 second quarter 2020 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 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 9775635. 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 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 made by Dr. Ballal in this press release and statements relating to (i) the timing for reporting and the quality of data from the ongoing Phase 2a clinical trial evaluating IMR-687 in patients with sickle cell disease, (ii) the design and timing of the Company's clinical development program for IMR-687, including the open label extension clinical trial of IMR-687 in sickle cell disease and the recently initiated Phase 2b clinical trials in patients with sickle cell disease and beta-thalassemia, (iii) the Company's development plans and preclinical studies of IMR-687 in heart failure with preserved ejection fraction; (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 conduct and readout data from its ongoing Phase 2a clinical trial of IMR-687 in sickle cell disease and its 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, replicate scientific and non-clinical data in clinical trials, obtain and

maintain necessary regulatory approvals, obtain, maintain and enforce necessary patent and other intellectual property protection, identify, enter into and maintain collaboration agreements with third parties, manage competition, manage expenses, raise the substantial additional capital needed to achieve its business objectives, attract and retain qualified personnel, and successfully execute on its business strategies; 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, 2020	December 31, 2019
Cash, cash equivalents and investments	\$ 106,275	\$ 28,907
Working capital ⁽¹⁾	105,745	26,426
Total assets	111,317	33,298
Total liabilities	5,021	4,382
Convertible preferred stock	—	77,764
Accumulated deficit	(72,172)	(54,753)
Total stockholders' equity (deficit)	106,296	(48,848)

(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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 7,869	\$ 4,366	\$ 13,662	\$ 7,926
General and administrative	2,433	1,191	3,992	1,825
Total operating expenses	<u>10,302</u>	<u>5,557</u>	<u>17,654</u>	<u>9,751</u>
Loss from operations	<u>(10,302)</u>	<u>(5,557)</u>	<u>(17,654)</u>	<u>(9,751)</u>
Total other income:				
Interest income	110	160	242	160
Other expense	(12)	—	(7)	—
Total other income (net)	<u>98</u>	<u>160</u>	<u>235</u>	<u>160</u>
Net loss	<u>\$ (10,204)</u>	<u>\$ (5,397)</u>	<u>\$ (17,419)</u>	<u>\$ (9,591)</u>
Accretion of Series B convertible preferred stock	—	—	(7,858)	—
Net loss attributable to common stockholders—basic and diluted	<u>\$ (10,204)</u>	<u>\$ (5,397)</u>	<u>\$ (25,277)</u>	<u>\$ (9,591)</u>
Weighted-average common shares outstanding—basic and diluted	<u>17,194,795</u>	<u>702,510</u>	<u>10,344,077</u>	<u>702,510</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.59)</u>	<u>\$ (7.68)</u>	<u>\$ (2.44)</u>	<u>\$ (13.65)</u>