Imara Reports Third Quarter 2021 Financial Results and Business Highlights

November 9, 2021

Interim analysis data for Phase 2b clinical trials of tovinontrine (IMR-687) in patients with beta-thalassemia and sickle cell disease expected in fourth quarter of 2021

Introduction of pipeline program IMR-261, a novel oral clinic-ready Nrf2 activator shown to reactivate fetal hemoglobin and reduce VOCs in preclinical models of sickle cell disease

Building team for planned HFpEF Phase 2 trial, led by hiring of Dr. Toni Bransford, a seasoned cardiologist and heart failure clinical developer

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

BOSTON, Nov. 09, 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 third quarter ending September 30, 2021 and reviewed recent business highlights.

“Following the completion of enrollment in both our Ardent trial of tovinontrine (IMR-687) for sickle cell disease (SCD) and in the transfusion-dependent thalassemia (TDT) cohort of our Forte trial of tovinontrine for beta-thalassemia, we remain on track to report interim analysis data from these higher dose trials in the fourth quarter of 2021. Furthermore, we expect to report data from the primary analysis of the Ardent trial and to conduct a key efficacy analysis in TDT patients in the Forte trial in the first quarter of 2022,” said Rahul Ballal, Ph.D., President and Chief Executive Officer of Imara. “We also expect to present 12-month VOC data from our ongoing Phase 2a open label extension study of tovinontrine in patients with sickle cell disease at the American Society of Hematology (ASH) Annual Meeting to be held December 11-14, 2021.”

Dr. Ballal continued, “I also am pleased to introduce our newest pipeline asset, IMR-261, a clinic-ready oral activator of nuclear factor erythroid 2–related factor 2, or Nrf2. We are excited about the potential for this compound, which the medical literature suggests has promise in a broad array of red blood cell diseases, including disorders of hemoglobin. We are also looking forward to presenting key preclinical data on IMR-261 in an oral presentation at the ASH Annual Meeting.

Finally, we are excited about the potential for tovinontrine’s application in heart failure with preserved ejection fraction (HFpEF) and will be presenting preclinical data for this indication at the American Heart Association (AHA) Scientific Sessions to be held November 13-15, 2021. Importantly, we have been building the team that will lead our HFpEF clinical development program, including our recent appointment of seasoned cardiologist Toni Bransford, M.D., as our Vice President, Clinical Development. Toni brings significant experience to our team in the strategy, design and conduct of heart failure trials, and specifically HFpEF trials. We expect to commence a Phase 2 clinical trial of tovinontrine in HFpEF in 2022.”

Recent Corporate Highlights

Completion of Patient Enrollment in Ardent Phase 2b Clinical Trial
In August, Imara announced the completion of patient enrollment in the Ardent Phase 2b clinical trial of tovinontrine for SCD. The Ardent trial is a randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of tovinontrine administered once daily in adult patients with SCD. Approximately 115 patients have been randomized to the tovinontrine higher dose arm (once daily dose of 300 mg or 400 mg based on patient weight), tovinontrine lower dose arm (once daily dose of 200 mg or 300 mg based on patient weight), or placebo. The trial is being conducted at approximately 50 sites in 13 different countries. Imara expects to report interim data from the Ardent trial in the fourth quarter of 2021, primary efficacy analysis data in the first quarter of 2022 and final analysis data in the second half of 2022.

Completion of TDT Patient Enrollment in Forte Phase 2b Clinical Trial
In August, Imara announced the completion of patient enrollment in the transfusion dependent thalassemia (TDT) cohort and increased enrollment in the non-transfusion dependent thalassemia (NTDT) cohort of the Forte Phase 2b clinical trial of tovinontrine for beta-thalassemia. The Forte trial is a randomized, double-blind, placebo-controlled Phase 2b clinical trial designed to evaluate the safety and tolerability of tovinontrine administered once daily in adult patients with beta-thalassemia. Imara expects to report interim data from the TDT cohort in the fourth quarter of 2021 and to conduct a key efficacy analysis of the full TDT cohort in the first quarter of 2022. Data from the final analysis is expected in the second half of 2022. In addition, Imara expects to report interim data from the NTDT cohort of the Forte trial in the first half of 2022.

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 approximately $50 million before underwriting discounts and commissions and offering expenses.

Announcement of Acquisition of IMR-261
IMR-261, formerly known as CXA-10, was acquired by Imara and was previously evaluated by Complexa, Inc. in Phase 2 clinical trials in focal segmental glomerulosclerosis (FSGS) and pulmonary arterial hypertension (PAH). IMR-261 is an activator of nuclear factor erythroid 2–related factor 2, or Nrf2. In-vitro and in-vivo studies show that Nrf2 coordinates the expression of antioxidant genes in response to oxidative stress, regulates inflammation, inhibits the NF-kB pathway, and reactivates fetal hemoglobin, or HbF. In preclinical sickle cell disease models, IMR-261 significantly increased HbF and F-cells, improved hemolytic markers and decreased vaso-occlusive crises. In a preclinical beta-thalassemia model, IMR-261 increased hemoglobin and enabled RBC maturation. In addition, independent medical literature suggests potential promise in a broad array of red blood cell diseases, including disorders of hemoglobin. Imara has initiated work on drug product manufacturing for IMR-261, as it explores potential clinical development paths.

Participation in Investor Conferences

Imara presented or participated in multiple investor conferences during the third quarter, including the Citi 16th Annual BioPharma Virtual Conference, H.C. Wainwright 23rd Annual Global Investment Conference, Morgan Stanley 19th Annual Global Healthcare Conference, SCB Leerink CybeRx Series and 2021 Cantor Virtual Global Healthcare Conference.

Third Quarter 2021 Financial Results

- **Cash Position:** Cash, cash equivalents and investments were $102.8 million as of September 30, 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 $10.4 million for the third quarter of 2021, as compared to $9.5 million for the third quarter of 2020. The increase of $0.9 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 tovinontrine (IMR-687), as well as increased personnel-related and other research and development operating costs.
- **General and Administrative Expenses:** General and administrative expenses were $3.3 million for the third quarter of 2021, as compared to $3.0 million for the third quarter of 2020. The increase of $0.3 million was primarily due to increased personnel-related and other general and administrative operating costs.
- **Net Loss Attributable to Common Stockholders:** Net loss attributable to common stockholders was $13.6 million, or $0.55 per share, for the third quarter of 2021, as compared to a net loss of $12.4 million, or $0.72 per share, for the third quarter of 2020.

Financial Guidance

The Company currently expects that its full-year 2021 research and development expenses will range between $40 million and $45 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 September 30, 2021 will be sufficient to enable it to fund its planned operations into the first quarter of 2023.

Conference Call and Webcast Information

Imara will host a conference call and live webcast today at 8:30 a.m. ET to discuss its third 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 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 1235955. 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 advancing tovinontrine (IMR-687), a highly selective, potent small molecule inhibitor of PDE9 that is an oral, potentially disease-modifying treatment currently in clinical development for sickle cell disease and beta-thalassemia and preclinical development for HFpEF. Imara is also advancing IMR-261, an oral activator of nuclear factor erythroid 2–related factor 2 (Nrf2). 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 of tovinontrine (IMR-687) in patients with sickle cell disease and beta-thalassemia and preclinical data for tovinontrine in HFpEF, (ii) the Company's timing and clinical development plans for tovinontrine in HFpEF, (iii) the Company's clinical development plans for the potential development of IMR-261 (iv) the Company's beliefs regarding the strength of its clinical data, the therapeutic potential of tovinontrine and IMR-261 and advancement of its preclinical and 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 the first quarter of 2023. 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 readout data from its open label extension clinical trial of tovinontrine in sickle cell disease and its Phase 2b clinical trials of tovinontrine in sickle cell disease and beta-thalassemia; the Company's ability to advance the development of tovinontrine 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 tovinontrine; 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.

Media Contact:
Marin Bergman
Ten Bridge Communications
818-516-2746
marin@tenbridgecommunications.com

Investor Contact:
Michael Gray
617-835-4061
mgray@imaratx.com

IMARA INC.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)
(Unaudited)

	September 30, 2021	December 31, 2020
Cash, cash equivalents and investments	$ 102,839	$ 88,222
Working capital[(1)]	98,809	84,158
Total assets	107,027	90,842
Total liabilities	7,654	6,407
Accumulated deficit	(133,178)	(96,113)
Total stockholders' equity	99,373	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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 10,397	$ 9,533	$ 27,586	$ 23,195
General and administrative	3,262	2,961	9,522	6,953
Total operating expenses	13,659	12,494	37,108	30,148
Loss from operations	(13,659)	(12,494)	(37,108)	(30,148)
Total other income, (net):				
Interest income	30	126	161	368
Other expense	(18)	(55)	(118)	(62)
Total other income, (net)	12	71	43	306
Net loss	$ (13,647)	$ (12,423)	$ (37,065)	$ (29,842)
Accretion of Series B convertible preferred stock	—	—	—	(7,858)
Net loss attributable to common stockholders—basic and diluted	$ (13,647)	$ (12,423)	$ (37,065)	$ (37,700)
Weighted-average common shares outstanding—basic and diluted	24,898,346	17,349,813	20,099,976	12,696,368
Net loss per share attributable to common stockholders—basic and diluted	$ (0.55)	$ (0.72)	$ (1.84)	$ (2.97)
Comprehensive loss:				
Net loss	$ (13,647)	$ (12,423)	$ (37,065)	$ (29,842)
Other comprehensive income:				
Unrealized loss on investments	(2)	(24)	(6)	(8)
Comprehensive loss	$ (13,649)	$ (12,447)	$ (37,071)	$ (29,850)