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 Act of 1934

Date of Report (Date of earliest event reported): November 4, 2021

MAGENTA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38541**	**81-0724163**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**
100 Technology Square **Cambridge, Massachusetts**		**02139**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: (857) 242-0170

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 240.13d-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, $0.001 Par Value	**MGTA**	**The Nasdaq Global 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 November 4, 2021, Magenta Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Current Report on Form 8-K (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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On November 4, 2021, the Company announced upcoming data presentations at the 2021 American Society of Hematology ("ASH") Annual Meeting. The full text of the press release issued in connection with the announcement is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit 99.1 relating to Item 2.02 shall be deemed furnished, and not filed.

99.1	Press Release dated November 4, 2021 (earnings release).
99.2	Press Release dated November 4, 2021 (ASH Annual Meeting updates).
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

MAGENTA THERAPEUTICS, INC.

Date: November 4, 2021
By: /s/ Stephen Mahoney
Title: Chief Financial and Operating Officer

Magenta Therapeutics Reports Third Quarter Financial Results and Program Highlights

— Positive topline clinical data from all patients in an investigator-initiated Phase 2 clinical trial evaluating stem cell mobilization and transplant engraftment using MGTA-145 plus plerixafor in patients with multiple myeloma will be presented as a poster at the 2021 American Society of Hematology (ASH) Annual Meeting on December 13, 2021 —

— MGTA-117 targeted conditioning program clinical trial start-up activities are ongoing after clearance of Investigational New Drug (IND) Application; Phase 1/2 trial expected to open in December 2021 —

— Ended Q3 2021 with approximately $192.6 million in cash, cash equivalents and marketable securities, and the company maintains guidance that cash reserves are expected to fund the operating plan into Q3 2023 —

Cambridge, MA – November 4, 2021 – Magenta Therapeutics, Inc. (Nasdaq: MGTA), a clinical-stage biotechnology company developing novel medicines designed to bring the curative power of stem cell transplants to more patients, today reported financial results for the third quarter ended September 30, 2021, and recent program highlights.

“We are pleased with our recent execution across the portfolio as we look to continue to allocate our capital efficiently to our value-creating opportunities,” said Jason Gardner, D.Phil., President and Chief Executive Officer, Magenta Therapeutics. “In mid-September, we cleared the IND process for the MGTA-117 targeted conditioning program and are now conducting the clinical trial start-up activities with the continued expectation of opening the trial this year. The MGTA-145 stem cell mobilization program also continues to advance with a fully enrolled investigator-initiated trial in multiple myeloma patients, a Phase 2 clinical trial in allogeneic transplant and the expected start of a Phase 2 clinical trial evaluating mobilization and collection of stem cells from patients with sickle cell disease.”

Business Highlights:

In October 2021, Magenta welcomed Jeffrey Humphrey, M.D. to its Executive Team as Chief Medical Officer.

Program Highlights:

MGTA-145 Stem Cell Mobilization and Collection

Recent and Planned Activity:

Autologous Stem Cell Transplant: Multiple Myeloma

- **Investigator-Initiated Phase 2 Clinical Trial Design, Topline Data and Next Steps.**
  - Trial Design: Surbhi Sidana, M.D., Assistant Professor of Medicine in the Division of Blood and Marrow Transplantation and Cellular Therapy at Stanford University School of Medicine led this investigator-initiated, Phase 2 open-label clinical trial. The trial evaluated the ability of MGTA-145, in combination with plerixafor, to mobilize stem cells for autologous stem cell transplantation in patients with multiple myeloma.
  - Top-Line Clinical Data in Poster Presentation at 2021 ASH Annual Meeting: Top line clinical data from the fully enrolled investigator-initiated clinical trial will be included in a poster presentation at the ASH Annual Meeting, held December 11-14, 2021. As disclosed separately, the clinical data showed that eighty-eight percent (88%) of patients (22/25) treated with MGTA-145 plus plerixafor met the primary endpoint of sufficient stem cell mobilization and collection for transplant. Also, as of the time of the data submission for the ASH meeting, all patients (18/18) transplanted with stem cells mobilized by MGTA-145 plus plerixafor successfully engrafted. MGTA-145 plus plerixafor was well tolerated.
  - Next Steps in Multiple Myeloma: The results from this investigator-initiated trial represent a positive step forward in the development of MGTA-145, in combination with plerixafor, as a potential first line stem cell mobilization regimen. Based on the encouraging collection and engraftment data, the company intends to explore further development of MGTA-145 in a Phase 2b clinical setting. This approach would enable a comprehensive evaluation of the multiple myeloma patient population and allow for adjustments of dosing and administration which the company, in both cases, has identified as opportunities for optimization as a result of this investigator-initiated study and the company's other MGTA-145 development efforts.

- **Allogeneic Stem Cell Transplant: Acute Myeloid Leukemia (AML), Acute Lymphocytic Leukemia (ALL) and Myelodysplastic Syndromes (MDS**)

- **Phase 2 Clinical Trial and Next Steps.**
    - Trial Design. This Phase 2 clinical trial is designed to evaluate MGTA-145 in combination with plerixafor, in the mobilization and collection of stem cells from allogeneic donors for transplant in patients with AML, ALL and MDS.
    - Next Steps. Based on what Magenta has learned to date from the totality of the MGTA-145 program-related clinical trial data and other relevant information, Magenta believes it has identified an opportunity to optimize certain elements of the dosing and administration of the MGTA-145 mobilization regimen. Accordingly, Magenta intends to amend the Phase 2 allogeneic clinical trial to include a higher dose of MGTA-145 that matches the dose level used in the Phase 2 multiple myeloma clinical trial.
- **Stem Cell Mobilization of Patients with Sickle Cell Disease in Collaboration with bluebird bio.**

  Magenta expects to open the Phase 2 clinical trial in December 2021. The trial is designed to evaluate the utility of MGTA-145 in combination with plerixafor, for the mobilization and collection of stem cells in patients with sickle cell disease where mobilization and collection is difficult and there is a clear unmet medical need.

MGTA-117 Targeted Conditioning

Recent and Planned Activity:

- **Phase 1/2 Clinical Trial Start-Up Activities Ongoing.** The IND for the company's MGTA-117 antibody-drug conjugate (ADC) targeted conditioning program is active with the U.S. Food and Drug Administration (FDA). The company expects to open the multi-center Phase 1/2 clinical trial in December 2021. The Phase 1/2 trial is designed to utilize dose escalating cohorts to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of MGTA-117 as a single dose with possible anti-tumor therapeutic benefit in patients with relapsed/refractory AML and MDS. As previously disclosed, Magenta expects to work with the FDA on an ongoing basis to transition the clinical trial to the primary target population of hematopoietic stem cell (HSC) transplant-eligible patients with AML and MDS after adequate data related to the safety, pharmacokinetics and pharmacodynamics of MGTA-117 have been collected in this initial patient population. As the program progresses, Magenta also plans to explore MGTA-117 as a targeted conditioning agent prior to the delivery of gene-corrected cells associated with stem cell gene therapy.

- **Oral Presentation at the 2021 American Society of Hematology (ASH) Annual Meeting.** As disclosed by Magenta in a separate press release, preclinical data showing that a single dose of a tool CD117 antibody drug conjugate (CD117-ADC) supports efficient engraftment of gene-modified CD34+ stem cells in a rhesus gene therapy model. The CD117-ADC utilized in this study had minimal toxicities unlike busulfan conditioning. The data will be the subject of an oral presentation at the ASH Annual Meeting on December 13, 2021.

Financial Results:

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2021, were $192.6 million, compared to $148.8 million as of December 31, 2020. Magenta anticipates that its cash, cash equivalents and marketable securities will be sufficient to fund operations and capital expenditures into the third quarter of 2023.

Research and Development Expenses: Research and development expenses were $10.8 million in the third quarter of 2021, compared to $11.8 million in the third quarter of 2020. The decrease was driven primarily by the completion of the GMP manufacturing activities to support the IND application for MGTA-117 and future clinical trials offset by an increase in personnel related costs.

General and Administrative Expenses: General and administrative expenses were $7.5 million for the third quarter of 2021, compared to $6.6 million for the third quarter of 2020. The increase was primarily due to an increase in personnel related costs.

Net Loss: Net loss was $17.4 million for the third quarter of 2021, compared to net loss of $17.7 million for the third quarter of 2020.

About Magenta Therapeutics

Magenta Therapeutics is a clinical-stage biotechnology company developing medicines designed to bring the curative power of stem cell transplants to more patients with blood cancers, genetic diseases and autoimmune diseases. Magenta is combining leadership in stem cell biology and biotherapeutics development with clinical and regulatory expertise and broad networks in the stem cell transplant community to revolutionize immune reset for more patients.

Magenta is based in Cambridge, Massachusetts. For more information, please visit www.magentatx.com.

Follow Magenta on Twitter: @magentatx.

Forward-Looking Statement

This press release may contain forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 and other federal securities laws, including express or implied statements regarding Magenta's future expectations, plans and prospects, including, without limitation, statements regarding expectations and plans for presenting pre-clinical and clinical data, the initiation of clinical trials or the results of ongoing and planned clinical trials, the development of product candidates and advancement of preclinical programs, projections regarding future revenues and financing performance, long-term growth, cash, cash equivalents and marketable securities, the anticipated timing of clinical trials and regulatory filings, the potential benefits of product candidates, the timing, progress and success of collaborations, as well as other statements containing the words "anticipate," "believe," "continue," "could," "endeavor," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "target," "will" or "would" and similar expressions that constitute forward-looking statements under the Private Securities Litigation Reform Act of 1995. The express or implied forward-looking statements included in this press release are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation: uncertainties inherent in clinical studies and in the availability and timing of data from ongoing clinical studies; whether interim results from a clinical trial will be predictive of the final results of the trial; whether results from preclinical studies or earlier clinical studies will be predictive of the results of future trials; the expected timing of submissions for regulatory approval or review by governmental authorities; discussions with governmental agencies such as the FDA; regulatory approvals to conduct trials or to market products; whether Magenta's cash resources will be sufficient to fund Magenta's foreseeable and unforeseeable operating expenses and capital expenditure requirements; risks, uncertainties and assumptions regarding the impact of the continuing COVID-19 pandemic on Magenta's business, operations, strategy, goals and anticipated timelines, Magenta's ongoing and planned preclinical activities, Magenta's ability to initiate, enroll, conduct or complete ongoing and planned clinical trials, Magenta's timelines for regulatory submissions and Magenta's financial position; and other risks concerning Magenta's programs and operations are described in additional detail in its Annual Report on Form 10-K filed on March 3, 2021, as updated by Magenta's most recent Quarterly Report on Form 10-Q, and its other filings made with the Securities and Exchange Commission from time to time. Although Magenta's forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Magenta. As a result, you are cautioned not to rely on these forward-looking statements. Any forward-looking statement made in this press release speaks only as of the date on which it is made. Magenta undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

Contacts
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Magenta Therapeutics, Inc.

STATEMENTS OF OPERATIONS
(unaudited)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 10,795	$ 11,786	$ 33,652	$ 38,359
General and administrative	7,450	6,595	20,900	21,278
Total operating expenses	18,245	18,381	54,552	59,637
Loss from operations	(18,245)	(18,381)	(54,552)	(59,637)
Interest and other income, net	818	703	2,708	2,869
Net loss	$ (17,427)	$ (17,678)	$ (51,844)	$ (56,768)
Net loss per share, basic and diluted	$ (0.30)	$ (0.37)	$ (0.97)	$ (1.34)
Weighted average common shares outstanding, basic and diluted	58,583,476	48,255,353	53,655,314	42,431,874

BALANCE SHEET DATA
(unaudited)
(In thousands)

	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 192,616	$ 148,835
Working capital	186,328	140,097
Total assets	206,236	161,619
Stockholders’ equity	189,688	143,906

Exhibit 99.2

Magenta Therapeutics Announces Data Presentations Related to its Mobilization and Conditioning Programs at the 2021 American Society of Hematology (ASH) Annual Meeting

— Positive topline clinical data from MGTA-145 investigator-initiated Phase 2 clinical trial in multiple myeloma —

— Successful conditioning with monotherapy CD117 antibody drug conjugate in a primate model of transplant for gene therapy of sickle cell disease —

— Successful conditioning with CD117 antibody drug conjugate in combination with lymphodepleting antibodies leading to effective allogeneic hematopoietic stem cell transplant in a murine model of acute myeloid leukemia —

Cambridge, MA – November 4, 2021 - **Magenta Therapeutics** (Nasdaq: MGTA), a clinical-stage biotechnology company developing novel medicines designed to bring the curative power of stem cell transplants to more patients, today announced positive top-line results from an investigator-initiated Phase 2 clinical trial of MGTA-145 stem cell mobilization in multiple myeloma. The data were accepted for a poster presentation at the 2021 American Society of Hematology (ASH) Annual Meeting, to be held in Atlanta and virtually from December 11-14, 2021. Oral and poster presentations of preclinical data related to the company's CD117 targeted conditioning program will also be made at the ASH Annual Meeting.

"We have made significant progress with our mobilization and targeted conditioning programs and we look forward to the presentation of the data that have been generated to support both programs," said Jason Gardner, D.Phil., President and Chief Executive Officer, Magenta Therapeutics.

Stem Cell Mobilization and Collection Program (MGTA-145)

Poster Presentation Highlighting Investigator-Initiated Phase 2 Clinical Data of MGTA-145 Stem Cell Mobilization in Multiple Myeloma:

Title: MGTA-145 + Plerixafor Provides G-CSF-Free Rapid and Reliable Hematopoietic Stem Cell Mobilization for Autologous Stem Cell Transplant in Patients with Multiple Myeloma: A Phase 2 Study (Poster #3888)

Date and Time to View Poster Presentation: Monday, December 13, 2021, 6:00pm – 8:00pm ET

Trial Design

Surbhi Sidana, M.D., Assistant Professor of Medicine in the Division of Blood and Marrow Transplantation and Cellular Therapy at Stanford University School of Medicine led this investigator-initiated, Phase 2 open-label clinical trial. The trial evaluated the ability of MGTA-145, in combination with plerixafor, to mobilize stem cells for autologous stem cell transplantation in patients with multiple myeloma. This trial had broad inclusion criteria and included the transplant-eligible population of patients with multiple myeloma who may have a variety of risk factors for mobilization.

Topline Clinical Data

- *Primary and Secondary Endpoints.* The trial has fully enrolled 25 patients with multiple myeloma. 88% of patients (22/25) treated with MGTA-145 plus plerixafor met the primary endpoint of mobilization and collection of 2 million CD34+ stem cells per kg in up to two days of same-day mobilization and apheresis. 68% of patients (17/25) achieved the primary endpoint in a single day of dosing and collection. Three patients who did not meet the primary endpoint successfully collected hematopoietic stem cells (HSCs) with subsequent G-CSF plus plerixafor dosing and 2-3 apheresis sessions. Secondary endpoints of 4 million and 6 million CD34+ stem cells per kg in up to two days were met in 68% (17/25) and 40% (10/25) patients, respectively.
- *Days of Stem Cell Collection.* The median number of 5.0 million CD34+ stem cells per kg were collected cumulatively over one or two days of dosing and stem cell collection. In contrast, current standard of care with G-CSF-based regimens require a minimum of five days of dosing prior to initiating stem cell collection over one to four days.

- *Safety Profile.* The regimen of MGTA-145 and plerixafor was well tolerated. Treatment emergent pain was seen in 44% of patients (11/25). Acute, transient, MGTA-145-related grade 1 bone or musculoskeletal pain was observed in 38% of patients (9/25) shortly after MGTA-145 infusion, resolving within seven minutes for all patients.
- *Engraftment.* All transplanted patients (18/18), evaluable as of the cutoff date, successfully engrafted. Neutrophils recovered after a median of 12 days and platelets after a median of 17.5 days, which are comparable to historical data. Red blood cell transfusion was needed in 17% of patients (3/25).
- *100 Day Follow-Up.* All 14 transplanted patients as of the cut-off date had completed day-100 follow up with durable engraftment.
- *CD34+CD90+ Cells.* The collected CD34+ stem cells contain a high percentage of CD34+CD90+ cells, a stem cell population associated with multi-lineage, long-term engraftment. 74% of grafts (17/23) were negative for minimal residual disease using next generation flow cytometry.

Next Steps in Multiple Myeloma

As described in the company's third quarter earnings release, the results from this investigator-initiated trial represent a positive step forward in the development of MGTA-145, in combination with plerixafor, as a potential first line stem cell mobilization regimen. Based on the encouraging collection and engraftment data, the company intends to explore further development of MGTA-145 in a Phase 2b clinical setting. This approach would enable a comprehensive evaluation of the multiple myeloma patient population and allow for adjustments of dosing and administration which the company, in both cases, has identified as opportunities for optimization as a result of this investigator-initiated study and the company's other MGTA-145 development efforts.

“While Dr. Sidana and her team are collecting and analyzing additional patient-level data, these topline results are encouraging and support further development of MGTA-145.” commented Dr. Jeffrey Humphrey, M.D., the company’s Chief Medical Officer. “We believe this novel mobilization regimen has the potential to replace G-CSF regimens and to enable reliable, predictable, rapid and well-tolerated mobilization of stem cells for both transplant and gene therapies.”

MGTA-145 is also being evaluated for its ability to mobilize stem cells for collection from donors for allogenic transplantation in patients with acute lymphoblastic leukemia (ALL), acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) in a Phase 2 clinical trial. The company is planning to open an additional Phase 2 clinical trial for mobilization and collection of stem cells for patients with sickle cell disease in December 2021.

Antibody-Drug Conjugate (ADC) Targeted Conditioning Program

Oral Presentation Showcasing Non-human Primate Data of Targeted ADC Conditioning for Gene Therapy

Title: CD117 Antibody Drug Conjugate-Based Conditioning Allows for Efficient Engraftment of Gene-Modified CD34+ Cells in a Rhesus Gene Therapy Model (Oral Abstract #560)

Presenting Author: Naoya Uchida, M.D., National Institutes of Health

Date: Sunday, December 12, 2021, 4:45 PM

This preclinical study evaluated escalating doses of a tool CD117-ADC. As monotherapy conditioning, a single dose of the CD117-ADC allowed for efficient engraftment of gene-modified autologous stem cells in a rhesus model of gene therapy, without chemotherapy or radiation conditioning. Engraftment of gene-modified stem cells achieved with monotherapy CD117-ADC was robust and durable, equivalent to that achieved with four doses of myeloablative busulfan conditioning. Sustained gene expression of hemoglobin F was confirmed at the protein level in this CD117-ADC-conditioned rhesus transplant model of gene therapy for sickle cell disease. Compared to chemotherapy or radiation-based conditioning regimens, conditioning with monotherapy CD117-ADC could be both sufficiently potent and well tolerated to improve the safety and risk benefit profile for gene therapies that require stem cell transplantation.

Poster Presentation Highlighting Preclinical Data of Targeted ADC Conditioning Program:

Title: CD117-Targeted ADC, in Combination with Lymphodepleting Antibodies, Enables Allogeneic Hematopoietic Stem Cell Transplantation in Mice without Chemotherapy or Radiation (Poster #1682)

Presenting Author: Leanne Lanieri, M.S., Magenta Therapeutics, Inc.

Date to View Poster Presentation: Saturday, December 11, 2021, 5:30pm – 7:30pm ET

This study evaluated the combination of a tool CD117-ADC with lymphodepleting antibodies as the conditioning regimen in a murine model of allogeneic HSC transplantation. The targeted conditioning regimen enabled complete donor chimerism in a fully mismatched allogeneic HSC transplant murine model, without use of chemotherapy or radiation. Antibody-based targeted conditioning regimens could offer a more favorable risk-benefit profile over chemotherapy and radiation-based conditioning regimens. An improved risk benefit profile, in turn, could extend the curative potential of allogeneic HSC transplantation to more patients with malignant and non-malignant diseases who otherwise would not be eligible for HSC transplantation.

About Magenta Therapeutics

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Forward-Looking Statements

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and its other filings made with the Securities and Exchange Commission from time to time. Although Magenta's forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Magenta. As a result, you are cautioned not to rely on these forward-looking statements. Any forward-looking statement made in this press release speaks only as of the date on which it is made. Magenta undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

Contacts

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