
**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): March 3, 2021

MAGENTA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38541
(Commission
File Number)

81-0724163
(I.R.S. Employer
Identification Number)

100 Technology Square
Cambridge, Massachusetts
(Address of principal executive offices)

02139
(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 March 3, 2021, Magenta Therapeutics, Inc. announced its financial results for the quarter and full year ended December 31, 2020. 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 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 9.01 Financial Statements and Exhibits.

(d) Exhibits:

The following exhibit relating to Item 2.02 shall be deemed furnished, and not filed:

99.1 [Press Release dated March 3, 2021.](#)

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: March 3, 2021

By: /s/ Jason Gardner

Title: President and Chief Executive Officer



Magenta Therapeutics Reports Fourth Quarter and Full-Year 2020 Financial Results and Recent Program Highlights

— *Magenta’s stem cell mobilization and targeted antibody-drug conjugate conditioning programs continue to advance, with four clinical trials ongoing or planned in 2021 –*

— *Ended year with approximately \$148.8 million in cash, cash equivalents and marketable securities and maintains guidance that its cash reserves are expected to fund its operating plan into 2023 –*

Cambridge, MA – March 3, 2021 – Magenta Therapeutics (Nasdaq: MGTA), a clinical-stage biotechnology company developing novel medicines to bring the curative power of stem cell transplants to more patients, today reported financial results for the fourth quarter and full-year ended December 31, 2020 and recent program highlights.

“Building on our momentum from 2020, we continue to advance our portfolio with now two active Phase 2 clinical trials evaluating MGTA-145 plus plerixafor in patients with blood cancers undergoing autologous and allogeneic stem cell transplant and an additional planned Phase 2 clinical trial evaluating stem cell mobilization and collection in patients with sickle cell disease in partnership with bluebird bio. We have also made additional progress in our preparations for an IND filing for our MGTA-117 targeted conditioning program based on communications with the FDA and the advancement of our IND-enabling studies,” said Jason Gardner, D.Phil., President and Chief Executive Officer, Magenta Therapeutics. “We very much look forward to generating clinical data during the course of 2021 in these multiple disease settings.”

Program Highlights:

MGTA-145: Stem Cell Mobilization and Collection for Hematopoietic Stem Cell Transplantation and Gene Therapy –

Magenta is developing MGTA-145 plus plerixafor to harness these agents’ complementary mechanisms to mobilize hematopoietic stem cells (HSCs) for collection and transplantation, including for use with gene

therapies. The ability to provide rapid, reliable, predictable and safe mobilization and collection of HSCs in stem cell transplantation and gene therapy could position MGTA-145 plus plerixafor to be the preferred mobilization regimen across multiple diseases due to improved patient experience and collection outcomes.

MGTA-145 Current and Planned Activity:

- **Two active MGTA-145 Phase 2 clinical trials; One additional planned Phase 2 clinical trial:**
 - **Autologous stem cell transplant in patients with Multiple Myeloma.** Magenta announced in December 2020 that enrollment had commenced and is ongoing in an investigator-initiated Phase 2 clinical trial of Multiple Myeloma patients at Stanford University. The clinical trial is evaluating the ability of MGTA-145, in combination with plerixafor, to mobilize stem cells for collection prior to autologous stem cell transplant in Multiple Myeloma patients. Initial mobilization, collection and engraftment data from this trial are expected in mid-2021.
 - **Allogeneic donor stem cell mobilization and collection for stem cell transplant in patients with Acute Myeloid Leukemia (AML), Acute Lymphocytic Lymphoma (ALL) and Myelodysplastic Syndromes (MDS).** Through a collaboration with the National Marrow Donor Program®/Be The Match®, Magenta has initiated a Phase 2 clinical trial evaluating 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. Initial data from this trial are expected in the second half of 2021.
 - **Stem cell mobilization and collection in patients with Sickle Cell Disease.** As announced in December 2020, Magenta and bluebird bio, Inc. entered into a Phase 2 clinical trial collaboration 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. Under the agreement, the companies will co-fund the clinical trial, which is currently expected to initiate in the second half of 2021.

MGTA-145 Recent and Upcoming Scientific Conference Presentations:

- **Magenta presented clinical data from its Phase 1 trial of MGTA-145 at the American Society of Hematology (ASH) Annual Meeting and Exposition, held December 5-8, 2020.**
 - The results provided proof-of-concept, demonstrating that all safety and efficacy endpoints were met and that mobilized stem cells showed functional superiority over stem cells collected from other mobilization approaches in preclinical studies. A single dose of MGTA-145, in combination with plerixafor, rapidly and reliably mobilized high numbers of stem cells in a single day without the need for G-CSF, demonstrating potential use in diseases that can benefit from autologous and/or allogeneic stem cell transplantation.

- **Magenta presented two oral presentations on MGTA-145 at the Transplantation and Cellular Therapy (TCT) Annual Meeting, held February 8-12, 2021.**
 - Data from the Phase 1 clinical trial with healthy volunteers underscored the potential utility of MGTA-145 plus plerixafor as an effective, single-day mobilization and collection regimen for autologous and allogeneic HSC transplant. The data show mobilization of high numbers of HSCs, durable engraftment, efficient gene modification and potent immunosuppressive properties by reducing Graft-versus-Host disease (GvHD) in preclinical models.
 - Data from a separate preclinical study demonstrated the potential of MGTA-145 plus plerixafor to serve as an efficient, single-dose mobilization regimen for *in vivo* HSC gene therapy where stem cells could be gene corrected or edited without having to remove them from the body.
- **Magenta will present data from the MGTA-145 program** at the upcoming European Society for Blood and Marrow Transplantation (EBMT) annual meeting, to be held March 14-17, 2021.

MGTA-117: Targeted Conditioning –

Magenta is developing a platform of novel antibody-drug conjugates (ADCs) for conditioning, a step in the transplant process that currently relies on the use of systemic chemotherapy agents and radiation. Magenta's targeted conditioning programs are designed to selectively eliminate stem cells and/or immune cells from a patient prior to transplant or gene therapy, and to reduce or potentially eliminate the need for high dose or high intensity chemotherapy-based regimens.

MGTA-117, Magenta's most advanced conditioning program, is a CD117-targeted antibody conjugated to amanitin and intended for use in patients undergoing transplant. MGTA-117 is designed to deplete hematopoietic stem and progenitor cells to clear space in the bone marrow prior to transplant in support of long-term engraftment and improved disease outcomes in patients. MGTA-117 has shown high selectivity, potent efficacy and tolerability in multiple preclinical studies.

Current and Planned Activity:

- **MGTA-117 IND Filing Anticipated Mid-2021.** Magenta recently completed its GLP toxicology studies, its GMP manufacturing process and has finished its pre-Investigational New Drug (IND) communications with the FDA and expects to file an IND application in mid-2021. Upon acceptance of the IND by the FDA, Magenta plans to initiate a Phase 1/2 clinical trial evaluating MGTA-117 in patients with AML and MDS to generate initial safety and pharmacokinetic data in the fourth quarter of 2021. These initial data are expected to be directional for the Company's dose escalation plans.

- **Magenta continues to evaluate CD45-ADC** preclinically in various transplant and autoimmune disease models.

Recent and Upcoming Scientific Conference Presentations:

- **Magenta provided updates on its MGTA-117 and CD45-ADC conditioning programs at the ASH Annual Meeting:**
 - In preclinical animal models of human AML, MGTA-117 decreased tumor burden leading to increased median survival rates versus a multi-day standard-of-care regimen.
 - Preclinical data from a study of Magenta's CD45-ADC conditioning program demonstrated the potential to achieve successful disease outcomes as a single agent in a fully mismatched allogeneic HSC transplant preclinical disease model.
- **Magenta gave an oral presentation of MGTA-117 and presented a poster of CD45-ADC at the TCT Annual Meeting:**
 - MGTA-117 was studied in multiple human leukemic xenograft preclinical models to mimic untreated and refractory AML. In preclinical models, MGTA-117 increased median survival versus a multi-day standard-of-care regimen using cytarabine.
 - Preclinical data demonstrated that conditioning with single agent CD45-ADC enabled complete chimerism in a full mismatch allogeneic HSC transplant model. Developing a broad targeting approach for safer patient conditioning prior to HSC transplant could bring the curative potential of allogeneic HSC transplant to more patients with both malignant and non-malignant disorders. Current conditioning regimens limit accessibility of this procedure due to toxicity.
- **Magenta will also present data on its MGTA-117 conditioning program** at the upcoming European Society for Blood and Marrow Transplantation (EBMT) annual meeting, to be held March 14-17, 2021.

Financial Results:

Cash Position: Cash, cash equivalents and marketable securities as of December 31, 2020, were \$148.8 million, compared to \$145.7 million as of December 31, 2019. Magenta anticipates that its cash, cash equivalents and marketable securities will be sufficient to fund operations and capital expenditures into 2023.

Research and Development Expenses: Research and development expenses were \$12.3 million in the fourth quarter of 2020, compared to \$18.7 million in the fourth quarter of 2019. The decrease was driven primarily by decreased preclinical costs for manufacturing related to the conditioning programs, lower manufacturing and clinical trial costs due to the discontinuance of enrollment in the Phase 2 clinical trial of MGTA-456 in inherited metabolic diseases in June 2020 and by lower clinical trial costs for the MGTA-145 Phase 1 clinical trial which was completed in the first quarter of 2020.

General and Administrative Expenses: General and administrative expenses were \$6.8 million for the fourth quarter of 2020, compared to \$5.9 million for the fourth quarter of 2019. The increase was primarily due to an increase in personnel costs, professional services and insurance costs associated with Magenta's expanded clinical trial preparations.

Net Loss: Net loss was \$18.2 million for the fourth quarter of 2020, compared to net loss of \$23.2 million for the fourth quarter of 2019.

About Magenta Therapeutics

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

Magenta is based in Cambridge, Mass. 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, projections regarding future revenues and financing performance, our long-term growth, cash, cash equivalents and marketable securities,

the anticipated timing of our clinical trials and regulatory filings, the development of our product candidates and advancement of our preclinical programs, the timing, progress and success of our collaborations, as well as other statements containing the words “anticipate,” “believe,” “continue,” “could,” “endeavor,” “estimate,” “expect,” “anticipate,” “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; 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 expected to be filed on or about March 3, 2021, its Quarterly Reports 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.

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Magenta Therapeutics, Inc.

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

	Three Months Ended		Year Ended December 31,	
	December 31,		2020	2019
	2020	2019	2020	2019
Operating expenses:				
Research and development	12,256	18,714	50,615	59,208
General and administrative	6,809	5,923	28,087	23,761
Total operating expenses	19,065	24,637	78,702	82,969
Loss from operations	(19,065)	(24,637)	(78,702)	(82,969)
Interest and other income, net	897	1,400	3,766	6,200
Net loss	<u>\$ (18,168)</u>	<u>\$ (23,237)</u>	<u>\$ (74,936)</u>	<u>\$ (76,769)</u>
Net loss per share, basic and diluted	<u>\$ (0.38)</u>	<u>\$ (0.59)</u>	<u>\$ (1.71)</u>	<u>\$ (2.07)</u>
Weighted average common shares outstanding, basic and diluted	<u>48,352,508</u>	<u>39,068,523</u>	<u>43,920,121</u>	<u>37,014,875</u>

BALANCE SHEET DATA
(unaudited)
(In thousands)

	December 31,	
	2020	2019
Cash, cash equivalents and marketable securities	\$ 148,835	\$ 145,729
Working capital	140,097	135,728
Total assets	161,619	161,514
Stockholders' equity	143,906	141,193