

**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 13, 2019

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 November 13, 2019, Magenta Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2019. 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 November 13, 2019.](#)

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 13, 2019

By: /s/ Jason Gardner

Title: President and Chief Executive Officer



Magenta Therapeutics Reports Third Quarter 2019 Financial Results and Recent Business Highlights

–Early clinical data from Phase 1 study of MGTA-145 show successful mobilization of target number of cells in 11 of 12 healthy volunteers; updated data to be presented at ASH–

–Reported first-ever successful gene therapy transplant of non-human primates with targeted single-agent CD117-ADC with no chemotherapy; updated data to be presented at ASH –

–Presented successful immune reset results with CD45-ADC in models of multiple autoimmune diseases at ACR–

–Exercised option with Heidelberg Pharma for antibody-drug conjugates using an amanitin payload and targeting CD45 –

–Received U.S. Food and Drug Administration Regenerative Medicine Advanced Therapies designation for MGTA-456 cell therapy –

–Ended quarter with \$160.6 million in cash, cash equivalents and marketable securities –

Cambridge, MA – November 13, 2019 – Magenta Therapeutics (NASDAQ: MGTA), a clinical-stage biotechnology company developing novel medicines to bring the curative power of stem cell transplant to more patients, today reported financial results for the third quarter ended September 30, 2019 and recent business highlights.

“Magenta has a big vision: to bring the curative power of immune reset through stem cell transplant to patients with autoimmune diseases, genetic diseases and blood cancers. At ASH next month, we are looking forward to sharing important new data from across our portfolio. These will include clinical data from our MGTA-145 program, which we are developing as a new first-line standard of care for stem cell mobilization. We will also present the first gene therapy data on our CD117-ADC, which we are developing as a non-genotoxic preparation regimen for gene therapy and transplant,” said Jason Gardner, D.Phil., Chief Executive Officer and President, Magenta Therapeutics. “In addition, earlier this week we presented our first data in autoimmune disease, showing that a single dose of our CD45-ADC led to successful immune reset in disease models of multiple sclerosis, systemic sclerosis and inflammatory arthritis. Immune reset through stem cell transplant has previously demonstrated durable remissions in thousands of patients with autoimmune diseases such as multiple sclerosis and systemic sclerosis, and it is recommended in multiple guidelines in US and Europe.”

Recent Business Highlights:

First clinical data for MGTA-145 stem cell mobilization program and groundbreaking CD117-ADC gene therapy data to be presented at the American Society of Hematology (ASH) annual meeting: On November 6th, 2019, Magenta announced that the Company will share results from six abstracts at ASH in December 2019, covering Magenta's patient preparation, mobilization and cell therapy programs. The Company will present clinical data for the MGTA-145 stem cell mobilization program, building on the positive early data in the ASH abstract. Magenta is developing MGTA-145 to be the new standard of care for first-line stem cell mobilization, with mobilization and collection taking place in a single day without the use of G-CSF, the current standard of care. The Company will also highlight important proof-of-concept data from the CD117-ADC patient preparation program. In a rhesus model of gene therapy, a single dose of CD117-ADC enabled engraftment of stem cells modified with the β -globin gene, the gene that causes sickle cell disease and β -thalassemia when mutated. These results showed for the first time that a single dose of CD117-ADC can enable successful gene therapy transplant in non-human primates without the need for chemotherapy or radiation.

First Magenta preclinical immune reset data presented at the American College of Rheumatology (ACR) annual meeting: On November 10th, 2019, Magenta presented the first data on the use of targeted antibody-drug conjugates (ADCs) to reset the immune system and halt progression of autoimmune disease. Results showed that a single dose of C45-ADC removed disease-causing cells, enabled successful reset and rebuild of the immune system and was well tolerated in models of multiple sclerosis, systemic sclerosis and inflammatory arthritis. Further, a single dose of CD45-ADC significantly delayed disease onset in a model of multiple sclerosis that has successfully provided preclinical proof of concept for many clinically validated standard of care therapies.

Exercised option with Heidelberg Pharma for ADCs using an amanitin payload and targeting CD45: On November 11th, 2019, Magenta announced that it had exercised its option with Heidelberg Pharma for exclusive worldwide development and marketing rights for ADCs using an amanitin payload and targeting CD45.

Received Regenerative Medicine Advanced Therapies (RMAT) Designation for MGTA-456 in inherited metabolic disorders: In September 2019, Magenta announced that the FDA granted RMAT designation for MGTA-456, a one-time cell therapy for the treatment of multiple inherited metabolic disorders, based on encouraging clinical data generated to date in the Company's ongoing Phase II trial. RMAT designation is a dedicated program designed to expedite the development and approval processes for promising pipeline products, including cell therapies. Potential advantages of the RMAT designation include all of the benefits of the fast track and breakthrough therapy designation programs, including early interactions with the FDA that may be used to discuss potential surrogate or intermediate endpoints to support accelerated approval.

Appointed Senior Vice President, Head of Translational Sciences; Chief Scientific Officer to transition out of Company: In October 2019, Magenta announced that it had hired Jan Pinkas, Ph.D., as Senior Vice President, Head of Translational Sciences. Dr. Pinkas is a seasoned scientist with deep expertise in leading drug development programs, including ADCs. Prior to joining Magenta, he was Head of Translational Research & Development at ImmunoGen, Inc., where he led nonclinical and translational research and development-related activities for all programs in discovery through late-stage clinical development. The Company also announced that Mike Cooke, Ph.D., Chief Scientific Officer, will leave Magenta to pursue other opportunities.

Financial Results:

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2019, were \$160.6 million compared to \$142.6 million on December 31, 2018. Magenta anticipates that its cash, cash equivalents and marketable securities will be sufficient to fund operations and capital expenditures into the second half of 2021.

Research and Development Expenses: Research and development expenses were \$16.5 million in the third quarter of 2019, compared to \$11.4 million in the third quarter of 2018. The increase was driven primarily by investments in clinical activities for MGTA-145, as well as manufacturing related to our patient preparation programs.

General and Administrative Expenses: General and administrative expenses were \$6.1 million for the third quarter of 2019, compared to \$5.3 million for the third quarter of 2018. The increase was primarily due to an increase in professional fees and facility costs associated with the growth of the Company.

Net Loss: Net loss was \$ 21.0 million for the third quarter of 2019, compared to net loss of \$16.0 million for the third quarter of 2018.

About Magenta Therapeutics

Headquartered in Cambridge, Mass., Magenta Therapeutics is a clinical-stage biotechnology company developing novel medicines for patients with autoimmune diseases, blood cancers and genetic diseases. By creating a platform focused on critical areas of unmet need, Magenta Therapeutics is pioneering an integrated approach to allow more patients to receive one-time, curative therapies by making the process more effective, safer and easier.

Forward-Looking Statement

This press release may contain forward-looking statements, 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, as well as other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "project," "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, including review under accelerated approval processes; orphan drug designation eligibility; 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; and other risks concerning Magenta's programs and operations are described in additional detail in its registration statement on Form S-1, its Annual Report on Form 10-K filed on March 19, 2019, 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.

Contact

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Magenta Therapeutics, Inc.
STATEMENTS OF OPERATIONS
(unaudited)
(In thousands, except share and per share data)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2019	2018	2019	2018
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	16,524	11,418	40,494	28,950
General and administrative	6,120	5,284	17,838	13,083
Total operating expenses	<u>22,644</u>	<u>16,702</u>	<u>58,332</u>	<u>42,033</u>
Loss from operations	(22,644)	(16,702)	(58,332)	(42,033)
Interest and other income, net	1,654	687	4,800	1,197
Net loss	(20,990)	(16,015)	(53,532)	(40,836)
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(88)
Net loss attributable to common stockholders	<u>\$ (20,990)</u>	<u>\$ (16,015)</u>	<u>\$ (53,532)</u>	<u>\$ (40,924)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.54)</u>	<u>\$ (0.49)</u>	<u>\$ (1.47)</u>	<u>\$ (3.05)</u>
Weighted average common shares outstanding, basic and diluted	<u>38,824,209</u>	<u>32,997,346</u>	<u>36,322,804</u>	<u>13,396,856</u>

BALANCE SHEET DATA
(unaudited)
(In thousands)

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
Cash, cash equivalents and marketable securities	\$ 160,570	\$ 142,570
Working capital	155,601	134,902
Total assets	177,233	157,313
Stockholders' equity	161,529	145,648