
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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): May 1, 2020

GlycoMimetics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36177
(Commission File Number)

06-1686563
(IRS Employer
Identification No.)

9708 Medical Center Drive
Rockville, MD 20850
(Address of principal executive offices, including zip code)

(240) 243-1201
(Registrant's telephone number, including area code)

N/A
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value	GLYC	The Nasdaq Stock 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 May 1, 2020, GlycoMimetics, Inc. (the “**Registrant**” or the “**Company**”) issued a press release announcing its financial results for the first quarter ended March 31, 2020. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 hereto, 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 liability of that section, nor shall it be deemed incorporated by reference in any of the Registrant’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	<u>Press Release, dated May 1, 2020, “GlycoMimetics Reports Operational Highlights and Financial Results for First Quarter 2020”</u>

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.

GLYCOMIMETICS, INC.

Date: May 1, 2020

By: /s/ Brian M. Hahn
Brian M. Hahn
Chief Financial Officer and Senior Vice President



GLYCOMIMETICS REPORTS OPERATIONAL HIGHLIGHTS AND FINANCIAL RESULTS FOR FIRST QUARTER 2020

- *Entered into an exclusive collaboration and license agreement with Apollomics for development and commercialization of uproleselan and GMI-1687 in the Greater China region*
- *Announced first patient dosing in Phase 1b clinical trial of GMI-1359 in individuals with advanced breast cancer, led by co-principal investigators from the Duke Cancer Institute*
- *Reiterated a commitment to determine what, if any, next steps to take with respect to the rivipansel program following transfer from Pfizer of the IND and the full Phase 3 RESET dataset*
- *To host conference call and webcast today at 8:30 a.m. ET*

ROCKVILLE, MD, May 1, 2020 — GlycoMimetics, Inc. (Nasdaq: GLYC) today reported its financial results for the first quarter ended March 31, 2020 and highlighted recent company events. Cash and cash equivalents at March 31, 2020 were \$154.8 million.

“During the quarter, patient enrollment continued on track in GlycoMimetics’ Phase 3 registration program evaluating uproleselan in relapsed/refractory acute myeloid leukemia (AML) as well as in our collaboration with the National Cancer Institute (NCI) on a multi-center clinical trial evaluating the drug candidate in newly diagnosed patients fit for chemotherapy. Enrollment slowed in April as a result of the COVID-19 pandemic, and we continue to actively monitor the situation. At this time it is too early for us to comment on the potential impact of the pandemic on completion of enrollment in either trial, or the potential impact on cash burn. In addition, we are working closely with Apollomics in the Greater China region to initiate the Apollomics-funded third registration trial for uproleselan,” commented Rachel King, Chief Executive Officer.

“In early April, Pfizer transferred to us the rivipansel investigational new drug application (IND) as well as the study data set from its Phase 3 clinical trial evaluating the drug’s clinical effect in sickle cell vaso-occlusive crisis,” continued Ms. King. “We can now move forward to fully review the data to determine the next steps, if any, to take with respect to the rivipansel program now that we have worldwide development and commercialization rights.”

Operational Highlights

Uproleselan

- GlycoMimetics' pivotal Phase 3 trial in relapsed/refractory AML continued to activate clinical sites and enroll patients in the U.S., Australia and Europe through March 2020.
- The COVID-19 pandemic has resulted in slowed clinical site initiation, patient recruitment and enrollment rates beginning in April 2020, which we continue to closely monitor for any potential material impact on our expected completion of enrollment. Investigators continued to enroll patients in the NCI-sponsored Phase 3 clinical trial designed to evaluate uproleselan in newly diagnosed older adults with AML who are fit for chemotherapy, through March 2020.
- GlycoMimetics and Apollomics announced an exclusive collaboration and license agreement for the development and commercialization of uproleselan and GMI-1687 in Mainland China, Hong Kong, Macau and Taiwan (Greater China).

GMI-1359

- Duke University initiated a proof-of-concept Phase 1b study to evaluate GMI-1359 in patients with advanced breast cancer with bone metastases, and investigators dosed the first patient in January of this year. The trial is evaluating safety and pharmacodynamic biomarkers in individuals with hormone receptor positive metastatic breast cancer.
- A new composition of matter and formulation patent was issued in the United States for GMI-1359, and the U.S. Food and Drug Administration (FDA) granted orphan drug and rare pediatric disease designations for the drug candidate for the treatment of osteosarcoma that may provide future development support and marketing protections.

Rivipansel

- GlycoMimetics and Pfizer worked closely to prepare for the transfer back to GlycoMimetics of the rivipansel program following Pfizer's April 2020 termination of the parties' 2011 license agreement for clinical development and commercialization of rivipansel in sickle cell disease (SCD). The transfer, now complete, includes the return of all rights and licenses previously granted, as well as the rivipansel IND and the Phase 3 RESET study data set.
- GlycoMimetics is committed to a detailed assessment of what, if any, next steps to take with respect to the rivipansel program after reviewing the Phase 3 clinical data.

First Quarter 2020 Financial Results

- Cash position: As of March 31, 2020, GlycoMimetics had cash and cash equivalents of \$154.8 million as compared to \$158.2 million as of December 31, 2019. In January 2020, GlycoMimetics received an upfront cash payment of \$9.0 million from Apollomics pursuant to the exclusive collaboration and license agreement for the development and commercialization of uproleselan and GMI-1687 in Greater China.
 - R&D Expenses: The Company's research and development expenses increased to \$12.7 million for the quarter ended March 31, 2020 as compared to \$ 11.8 million for the first quarter of 2019. Clinical development expenses increased by \$2.4 million based on the higher clinical costs related to the Company's ongoing Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML and the Phase 3 clinical trial being conducted by the NCI. In addition, personnel-related and stock-based
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compensation expenses increased by \$540,000 due to annual performance adjustments processed in the quarter ended March 31, 2020. These increases were offset in part by a \$2.1 million decrease in manufacturing and formulation due to lower raw material expenses in the first quarter ended March 31, 2020 as compared to the first quarter ended March 31, 2019.

- G&A Expenses: The Company's general and administrative expenses increased to \$4.4 million for the quarter ended March 31, 2020 as compared to \$3.4 million for the first quarter of 2019. Personnel-related expenses increased by \$684,000 due to additional general and administrative headcount and annual salary adjustments awarded in the first quarter of 2020. Patent, legal fees, consulting and other professional expenses, including director and officer's insurance premiums, increased by \$373,000 for the quarter ended March 31, 2020 as compared to March 31, 2019.
- Shares Outstanding: Shares of common stock outstanding as of March 31, 2020 were 43,582,979.

The Company will host a conference call and webcast today at 8:30 a.m. ET. The dial-in number for the conference call is (844) 413-7154 for domestic participants and (216) 562-0466 for international participants, with participant code 4567397. Participants are encouraged to connect 15 minutes in advance of the call to ensure that all callers are able to connect. A webcast replay will be available via the "Investors" tab on the GlycoMimetics website for 30 days following the call. A dial-in phone replay will be available for 24 hours after the close of the call by dialing (855) 859-2056 for domestic participants and (404) 537-3406 for international participants, participant code 4567397.

About Uproleselan and GMI-1687

Discovered and developed by GlycoMimetics, uproleselan and GMI-1687 are investigational, first-in-class, targeted inhibitors of E-selectin. Uproleselan (yoo' pro le' sel an), currently in a comprehensive Phase 3 development program in AML, has received Breakthrough Therapy Designation from the U.S. FDA for the treatment of adult AML patients with relapsed or refractory disease. Uproleselan is designed to block E-selectin (an adhesion molecule on cells in the bone marrow) from binding with blood cancer cells as a targeted approach to disrupting well-established mechanisms of leukemic cell resistance within the bone marrow microenvironment. In a Phase 1/2 clinical trial, uproleselan was evaluated in both newly diagnosed elderly and relapsed or refractory patients with AML. In both populations, patients treated with uproleselan together with standard chemotherapy achieved better-than-expected remission rates and overall survival compared to historical controls, which have been derived from results from third-party clinical trials evaluating standard chemotherapy, as well as lower-than-expected induction-related mortality rates. Treatment in these patient populations was generally well-tolerated, with fewer than expected adverse effects.

GMI-1687 is a rationally designed, innovative antagonist of E-selectin that is potentially suitable for subcutaneous (SC) administration. When given by SC injection in preclinical models, GMI-1687 has been observed to have equivalent activity to uproleselan, but at an approximately 1,000-fold lower dose. GlycoMimetics believes that GMI-1687 could be developed as a potential life-cycle expansion to broaden the clinical usefulness of an E-selectin antagonist to conditions where outpatient treatment is preferred or required. GMI-1687 is currently undergoing IND-enabling studies.

About GMI-1359

GMI-1359 is designed to simultaneously inhibit both E-selectin and CXCR4. E-selectin and CXCR4 are both adhesion molecules involved in tumor trafficking and metastatic spread. Preclinical studies indicate that targeting both E-selectin and CXCR4 with a single compound could improve efficacy in the treatment of cancers that involve the bone marrow such as AML and multiple myeloma or in solid tumors that metastasize to the bone, such as prostate cancer and breast cancer, as well as in osteosarcoma, a rare pediatric tumor. GMI-1359 has completed a Phase 1 clinical trial in healthy volunteers. The Duke University Phase 1b clinical study in breast cancer patients is designed to enable investigators to identify an effective dose of the drug candidate and to generate initial biomarker data around the drug's activity. GMI-1359 has received Orphan Drug Designation and Rare Pediatric Disease Designation from the FDA for the treatment of osteosarcoma, a rare cancer affecting about 900 adolescents a year in the United States.

About GlycoMimetics, Inc.

GlycoMimetics is a clinical-stage biotechnology company focused on the discovery and development of novel glycomimetic drugs to address unmet medical needs resulting from diseases in which carbohydrate biology plays a key role. GlycoMimetics' drug candidate, uproleselan, an E-selectin antagonist, was evaluated in a Phase 1/2 clinical trial as a potential treatment for AML and is being evaluated across a range of patient populations including a Company-sponsored Phase 3 trial in relapsed/refractory AML. GlycoMimetics has also completed a Phase 1 clinical trial with another wholly-owned drug candidate, GMI-1359, a combined CXCR4 and E-selectin antagonist. GlycoMimetics is located in Rockville, MD in the BioHealth Capital Region. Learn more at www.glycomimetics.com.

Forward-Looking Statements

This press release contains forward-looking statements regarding the Company's strategy and the clinical development and potential benefits and impact of its drug candidates. These forward-looking statements include those relating to the planned clinical development of the Company's product candidates, including expectations with regard to the enrollment of patients in its ongoing Phase 3 clinical trial and the potential impact of the ongoing global COVID-19 pandemic on the Company's clinical programs, operations and cash burn, the expected timing for reviewing data from Pfizer's Phase 3 clinical trial of rivipansel, and its other plans for its current cash resources. Actual results may differ materially from those in these forward-looking statements. For a further description of the risks associated with these statements, as well as other risks facing GlycoMimetics, please see the risk factors described in the Company's annual report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on February 28, 2020, the updated risk factors described in the Company's quarterly report on Form 10-Q filed with the SEC on May 1, 2020, and other filings GlycoMimetics makes with the SEC from time to time. Forward-looking statements speak only as of the date of this release, and GlycoMimetics undertakes no obligation to update or revise these statements, except as may be required by law.

Source: GlycoMimetics, Inc.

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GlycoMimetics, Inc.
Condensed Statements of Operations
(In thousands, except share and per share data)

	Three months ended March 31,	
	2020	2019
	(Unaudited)	
Revenue	\$ 9,000	\$ —
Costs and expenses:		
Research and development expense	12,668	11,773
General and administrative expense	4,440	3,360
Total costs and expenses	<u>17,108</u>	<u>15,133</u>
Loss from operations	(8,108)	(15,133)
Interest income	445	1,049
Net loss and comprehensive loss	<u>\$ (7,663)</u>	<u>\$ (14,084)</u>
Net loss per common share – basic and diluted	\$ (0.18)	\$ (0.33)
Weighted-average common shares – basic and diluted	43,575,590	43,166,967

GlycoMimetics, Inc.
Balance Sheet Data
(In thousands)

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
	(unaudited)	
Cash and cash equivalents	\$ 154,823	\$ 158,201
Working capital	146,269	151,577
Total assets	162,099	167,970
Total liabilities	13,609	13,769
Total stockholders' equity	148,490	154,201
