

**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): November 7, 2019

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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 November 7, 2019, GlycoMimetics, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter ended September 30, 2019. 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 November 7, 2019, “GlycoMimetics Reports Third Quarter 2019 Financial Results and Recent Operational Developments”</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: November 7, 2019

By: /s/ Brian M. Hahn

Brian M. Hahn

Chief Financial Officer and Senior Vice President



GLYCOMIMETICS REPORTS THIRD QUARTER 2019 FINANCIAL RESULTS AND RECENT OPERATIONAL DEVELOPMENTS

- *Advanced its Phase 3 program for uproleselan in acute myeloid leukemia (AML) through both Company-sponsored and NCI-sponsored clinical trials*
- *Announced abstracts accepted for presentation in December at the Annual Meeting of the American Society of Hematology (ASH) in Orlando, which continue to demonstrate key role of E-selectin ligand and potential value of uproleselan in AML*
- *Announced that Pfizer's Phase 3 clinical trial evaluating rivipansel in sickle cell disease (SCD) failed to meet the primary endpoint and key secondary endpoints*
- *Eliminated certain non-core research and development spending commitments*

ROCKVILLE, MD, November 7, 2019 — GlycoMimetics, Inc. (Nasdaq: GLYC) today reported its financial results for the quarter ended September 30, 2019 and highlighted recent business developments. Quarter-end cash and cash equivalents were \$170.9 million.

“In the third quarter of 2019, we continued to progress the late-stage clinical development of our wholly-owned product candidate, uproleselan. Our Company-sponsored Phase 3 trial in relapsed or refractory AML patients and the NCI-sponsored Phase 3 trial for newly diagnosed patients with AML both advanced during the quarter. We are also working with the Duke Cancer Institute towards initiating a single center, proof-of-mechanism Phase 1b trial for GMI-1359, our dual antagonist of E-selectin and CXCR-4, in breast cancer patients with bone metastases,” said Rachel King, GlycoMimetics’ Chief Executive Officer.

Ms. King continued, “We are also very much looking forward to the ASH meeting in December, which has always been an important conference for us, and this year is no different. The key takeaway for us at this year’s ASH meeting is that data from multiple preclinical and clinical settings show that E-selectin ligand expression on leukemic cells is correlated with poor survival in AML. The data indicate that E-selectin ligand expression is a key driver of environmental-mediated chemoresistance in AML and suggest that uproleselan has the potential to break this chemoresistance, and thereby improve clinical outcomes. Based on this expanding dataset, we are exploring how use of biomarkers may help us in advancing our clinical program.”

“Finally, as previously announced, Pfizer reported that its Phase 3 clinical trial evaluating rivipansel in SCD failed to meet its primary endpoint and key secondary endpoints. Of course, this is disappointing, but for some time our operational focus has been on our uproleselan program in AML, and we continue to focus our efforts on diligently and efficiently progressing that exciting clinical program,” Ms. King added.

Key Third-Quarter 2019 and Recent Operational Developments:

- GlycoMimetics’ pivotal Phase 3 trial of uproleselan in relapsed/refractory AML continued to initiate and activate clinical sites and to enroll patients in the U.S., Australia and now in Europe.
- 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.
- Pfizer announced that the Phase 3 clinical trial evaluating rivipansel in SCD failed to meet the primary endpoint and key secondary endpoints.
- As part of a commitment to eliminate certain non-core research and development spending, GlycoMimetics discontinued plans to collaborate with the Haemato Oncology Foundation for Adults in the Netherlands on a Phase 2 trial of uproleselan in newly-diagnosed patients unfit for chemotherapy.

The Company continued to work closely with the Duke Cancer Institute to initiate a Phase 1b proof-of-mechanism clinical trial of GMI-1359 in individuals with breast cancer whose tumors have spread to bone. The trial will evaluate safety and biomarkers of cancer cell mobilization in individuals with hormone receptor positive metastatic breast cancer. The trial will be conducted at Duke University and is expected to initiate during the fourth quarter.

Third Quarter 2019 Financial Results:

- Cash position: As of September 30, 2019, GlycoMimetics had cash and cash equivalents of \$170.9 million as compared to \$209.9 million as of December 31, 2018.
 - R&D Expenses: The Company’s research and development expenses increased to \$10.7 million for the quarter ended September 30, 2019 as compared to \$9.7 million for the third quarter of 2018. This increase was primarily the result of expenses relating to the Company’s Phase 3 clinical trial of uproleselan in relapsed or refractory AML patients and supporting the clinical trials of uproleselan conducted by or in collaboration with third parties.
 - G&A Expenses: The Company’s general and administrative expenses increased to \$3.4 million for the quarter ended September 30, 2019 as compared to \$2.8 million for the third quarter of 2018. The increase was due to higher patent, legal and non-cash stock-based compensation expenses.
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Shares Outstanding: Shares outstanding as of September 30, 2019 were 43,359,949.

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 (U.S. and Canada) or (216) 562-0466 (international) with passcode 9845948. To access the live audio webcast, or the subsequent archived recording, visit the “Investors –Events & Presentations” section of the GlycoMimetics website at www.glycomimetics.com. The webcast will be recorded and available for replay on the GlycoMimetics website for 30 days following the call.

About Uproleselan (GMI-1271)

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. Food and Drug Administration (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.

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. GMI-1359 has completed a Phase 1

clinical trial in healthy volunteers. In the fourth quarter of 2019, the Company plans to initiate an exploratory clinical trial in individuals with breast cancer whose tumors have spread to bone.

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' wholly-owned 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 clinical development and potential benefits and impact of the Company's drug candidates. These forward-looking statements include those relating to the planned clinical development of the Company's wholly-owned product candidates and the expected timing for receiving additional data from Pfizer's Phase 3 clinical trial of rivipansel. 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 March 6, 2019, 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		Nine months ended	
	September 30,		September 30,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Revenue	\$ —	\$ —	\$ —	\$ —
Costs and expenses:				
Research and development expense	10,724	9,729	35,562	28,053
General and administrative expense	3,381	2,790	10,492	8,492
Total costs and expenses	<u>14,105</u>	<u>12,519</u>	<u>46,054</u>	<u>36,545</u>
Loss from operations	(14,105)	(12,519)	(46,054)	(36,545)
Other income	<u>853</u>	<u>944</u>	<u>2,888</u>	<u>2,178</u>
Net loss and comprehensive loss	<u>\$ (13,252)</u>	<u>\$ (11,575)</u>	<u>\$ (43,166)</u>	<u>\$ (34,367)</u>
Net loss per common share – basic and diluted	\$ (0.31)	\$ (0.27)	\$ (1.00)	\$ (0.85)
Weighted-average common shares – basic and diluted	43,295,397	43,069,282	43,215,125	40,345,071

GlycoMimetics, Inc.
Balance Sheet Data
(In thousands)

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
	(unaudited)	
Cash and cash equivalents	\$ 170,887	\$ 209,918
Working capital	164,360	203,506
Total assets	180,455	214,839
Total liabilities	13,374	9,375
Total stockholders' equity	167,081	205,464
