
**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): March 2, 2021

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 March 2, 2021, GlycoMimetics, Inc. (the “*Registrant*”) issued a press release announcing its financial results for the fourth quarter and full year ended December 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 March 2, 2021, “GlycoMimetics Reports Highlights and Financial Results for Fourth Quarter and Full Year 2020”</u>
104	Cover Page Interactive Data File (the cover page XBRL tags are 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.

GLYCOMIMETICS, INC.

Date: March 2, 2021

By: /s/ Brian M. Hahn

Brian M. Hahn
Chief Financial Officer and Senior Vice President



**GLYCOMIMETICS REPORTS HIGHLIGHTS AND FINANCIAL RESULTS FOR
FOURTH QUARTER AND FULL YEAR 2020**

- *Second half of 2021 remains the target for completion of enrollment of the GlycoMimetics-sponsored pivotal Phase 3 trial evaluating uproleselan in patients with relapsed/refractory acute myeloid leukemia (AML)*
- *Enrollment in 2021 is expected to support a planned interim analysis based on event-free survival in the National Cancer Institute's (NCI) registration trial evaluating uproleselan in newly diagnosed AML patients over the age of 60 years and fit for chemotherapy*
- *The Company announces plans to take GMI-1687 forward toward an investigational new drug (IND) filing, with acute treatment of acute vaso-occlusive crisis (VOC) in outpatient settings as one possible use. The Company discontinues development of rivipansel*
- *Evidence of biologic activity in first patients treated in Phase 1b study of GMI-1359 in advanced breast cancer has been submitted to a scientific meeting for presentation*
- *Hosting a conference call and webcast today at 8:30 a.m. ET*

Rockville, MD — March 2, 2021 — GlycoMimetics, Inc. (Nasdaq: GLYC) today reported its financial results for the fourth quarter and year ended December 31, 2020, and highlighted recent Company events, including several accomplishments reported to date in 2021. Cash and cash equivalents at December 31, 2020 were \$137.0 million.

“During 2020, we remained on track to complete enrollment of our uproleselan pivotal trial in the second half of 2021. Uproleselan continues to have strong support from collaborators working with us in the clinical and preclinical arenas. We believe this broad-based support for uproleselan reflects confidence in our approach to establish this product candidate as a potential foundational therapy across the spectrum of AML. In addition, the Chinese regulatory authority granted Breakthrough Therapy designation for uproleselan for the treatment of relapsed/refractory AML, complementing a prior designation by the FDA. We will seek to demonstrate in both ongoing and new clinical trials that uproleselan in combination with standard treatments may both extend survival and ameliorate the severe side effects experienced by cancer patients,” commented Rachel King, Chief Executive Officer.

“December’s ASH meeting gave us an opportunity to share an in-depth understanding of the rivipansel Phase 3 and subsequent Open Label Extension (OLE) data demonstrating the key role of E-selectin and importance of early treatment in VOC. Nevertheless, based on input from the FDA with respect to rivipansel as well as input from key opinion leaders in sickle cell disease, we intend to focus development in this setting on our GMI-1687 product candidate,” she added. “We believe that development of GMI-1687 will be a better option than additional clinical work on rivipansel. This is particularly important since the care of

individuals with sickle cell disease has continued to shift to the outpatient setting, a trend which has accelerated during the pandemic. As a potentially subcutaneously available compound, GMI-1687 may be ideally suited to this changing landscape, and we have, therefore, initiated IND-enabling work with the compound. Our current cash position provides a runway into the fourth quarter of 2022 and through several key milestones in the uproleselan program, based on our current plan.”

Operational Highlights

Uproleselan

- GlycoMimetics’ pivotal Phase 3 trial in relapsed/refractory AML continued to enroll patients in the U.S., Australia and in Europe at a steady pace in the fourth quarter of 2020. With momentum carrying into 2021 and building further with newly added sites, the Company reiterates its projection that enrollment will be completed in the second half of 2021.
- In parallel, the NCI-sponsored Phase 3 clinical trial, which is designed to evaluate uproleselan in newly diagnosed older adults with AML who are fit for chemotherapy, has continued to enroll patients. Based on the NCI’s public disclosures, the Company anticipates the trial will achieve enrollment of the initial 262 patients necessary for the interim event-free survival assessment before the 2021 year-end.
- Apollomics, our exclusive collaborator for development and commercialization of uproleselan in Greater China, received Breakthrough Therapy designation from the China National Medical Products Administration (NMPA) in early 2021.
- Uproleselan was featured in December 2020 at the Annual Meeting of the American Society of Hematology (ASH), in a presentation by the MD Anderson Cancer Center Department of Leukemia. Specifically, new preclinical data were presented elucidating how inhibiting E-selectin with uproleselan overcomes microenvironment-mediated resistance to venetoclax/HMA therapy, resulting in prolonged survival. We are now working actively toward exploring this combination through an investigator-sponsored clinical trial.

GMI-1687

- At the Annual Scientific Conference on Sickle Cell and Thalassemia (ASCAT) meeting in October and at the ASH meeting in December, GlycoMimetics gave oral presentations on the effects of GMI-1687 in two separate preclinical models of VOC. These presentations highlighted the drug candidate’s ability to prevent sickle red blood cell adherence to inflamed vasculature, inhibit vessel occlusion and restore normal blood flow within 90 minutes of administration. Suitable for subcutaneous dosing, the data support the development of GMI-1687 as a fast-acting, E-selectin inhibitor that could potentially be self-administered at the time of VOC onset to obviate the need for opioids, acute care visits and inpatient hospitalization.
- In 2020, the Company initiated an IND-enabling program with sickle cell disease VOC as a potential lead indication.

Rivipansel

- GlycoMimetics completed and presented at the December ASH meeting a comprehensive review of the Phase 3 RESET data and for the first time, results of the OLE study. The analyses demonstrated that administration of rivipansel early during the cascade of VOC (within approximately 26-30 hours of the onset of VOC) resulted in statistically significant improvement on key clinical outcomes, particularly in the pediatric subgroup.
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- Today, GlycoMimetics announced that rather than continuing to focus on rivipansel, it plans to take GMI-1687 forward toward an IND, with treatment of acute VOC as one possible use.

GMI-1359

- The Company has observed evidence of biologic activity in the initial patients treated in a Phase 1b proof-of-concept trial. The analyses are based on pharmacodynamic biomarkers, and have been submitted for presentation at a major medical meeting.

Executive Management Team

- The Company announced the promotion of Eric Feldman, M.D., to Senior Vice President and Chief Medical Officer in February 2021.

Fourth Quarter and Year-end 2020 Financial Results:

- Cash position: As of December 31, 2020, GlycoMimetics had cash and cash equivalents of \$137.0 million as compared to \$158.2 million as of December 31, 2019.
- Revenue: During the year ended December 31, 2020, the Company recognized revenue of \$10.2 million, all of which was the result of payments received under our agreements with Apollomics for the development and commercialization of uproleselan and GMI-1687 in Greater China. There was no revenue recognized during the year ended December 31, 2019.
- R&D Expenses: The Company's research and development expenses increased to \$11.7 million for the quarter ended December 31, 2020 as compared to \$11.5 million for the fourth quarter of 2019 due to higher clinical development expenses. Clinical expenses were higher as a result of increased number of sites and enrollment in the Company's ongoing global Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML.

Research and development expenses for the year ended December 31, 2020 decreased to \$44.9 million as compared to \$47.0 million in the prior year. The decrease in expenses was due to lower raw material purchases in the year ended December 31, 2020 offset by the higher clinical development expenses resulting from the increased number of sites and enrollment in the Company's ongoing global Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML.

- G&A Expenses: The Company's general and administrative expenses increased to \$4.0 million for the quarter ended December 31, 2020 as compared to \$3.9 million for the fourth quarter of 2019. General and administrative expenses for the year ended December 31, 2020 increased to \$16.7 million as compared to \$14.4 million in the prior year. These increases were due to a significant increase in the cost of directors and officers liability insurance in 2020 as compared to 2019. In addition, personnel-related and stock-based compensation expenses increased due to additional headcount, annual salary adjustments and retention bonuses. Other expenses decreased as compared to the prior year due to lower travel, meals and conference registration expenses as a result of travel restrictions due to the COVID-19 pandemic.
 - Shares Outstanding: Shares of common stock outstanding as of December 31, 2020 were 49,017,622.
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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 or (216) 562-0466 for international participants, with participant code 1034166. 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 1034166.

About Uproleselan

Discovered and developed by GlycoMimetics, uproleselan is an investigational, first-in-class, targeted inhibitor 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 and from the Chinese NMPA 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-1687

Discovered and developed by GlycoMimetics, GMI-1687 is a highly-targeted, highly-potent E-selectin antagonist. It has been shown in preclinical studies to be bioavailable via subcutaneous administration. During 2020, data from oral presentations at major scientific conferences pointed to the potential for a self-administered drug to treat VOC of sickle cell disease. Previously, GlycoMimetics has also demonstrated in preclinical models that GMI-1687 could be a potentially self-administered drug to be used in treatment of AML. The investigational drug also represents a potential life cycle extension opportunity for uproleselan.

About Rivipansel

Rivipansel, the Company's wholly-owned glycomimetic drug candidate that binds to all three members of the selectin family (E-, P- and L-selectin), was GlycoMimetics' first drug candidate to enter clinical development. Rivipansel has been granted a Rare Pediatric Disease designation for treatment of sickle cell disease in patients 18 years old and younger, and has also received Orphan Drug and Fast Track designations from the FDA. GlycoMimetics is discontinuing development of rivipansel as a treatment for VOC of sickle cell disease.

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 affecting about 900 adolescents a year in the United States. GMI-1359 has completed a

Phase 1 clinical trial in healthy volunteers. A Phase 1b clinical study is underway in breast cancer patients and 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.

About GlycoMimetics, Inc.

GlycoMimetics is a biotechnology company with a focus in hematology-oncology and a pipeline of novel glycomimetic drugs, all designed 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 in a Company-sponsored Phase 3 trial in relapsed/refractory AML. GlycoMimetics has an ongoing Phase 1b clinical trial evaluating GMI-1359, a combined CXCR4 and E-selectin antagonist, also a wholly-owned drug candidate,. 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. These forward-looking statements include those relating to the planned or potential clinical development of the Company's product candidates, as well as the presentation of data from preclinical studies and clinical trials, the potential benefits and impact of the Company's drug candidates and the Company's expectations regarding its cash runway. Actual results may differ materially from those described 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 2, 2021, 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.

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

	Three months ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
	(Unaudited)			
Revenue	\$ 163	\$ —	\$ 10,163	\$ —
Costs and expenses:				
Research and development expense	11,720	11,467	44,929	47,029
General and administrative expense	4,011	3,868	16,743	14,360
Total costs and expenses	<u>15,731</u>	<u>15,335</u>	<u>61,672</u>	<u>61,389</u>
Loss from operations	(15,568)	(15,335)	(51,509)	(61,389)
Interest income	<u>5</u>	<u>609</u>	<u>482</u>	<u>3,497</u>
Net loss and comprehensive loss	<u>\$ (15,563)</u>	<u>\$ (14,726)</u>	<u>\$ (51,027)</u>	<u>\$ (57,892)</u>
Net loss per common share – basic and diluted				
	\$ (0.32)	\$ (0.34)	\$ (1.12)	\$ (1.34)
Weighted-average common shares – basic and diluted	47,995,898	43,373,753	45,721,139	43,254,782

GlycoMimetics, Inc.
Balance Sheet Data
(In thousands)

	<u>December 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Cash and cash equivalents	\$ 137,035	\$ 158,201
Working capital	125,845	151,577
Total assets	142,832	167,970
Total liabilities	14,613	13,769
Total stockholders' equity	128,219	154,201
