

**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 3, 2022

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 3, 2022, GlycoMimetics, Inc. (the “**Company**”) issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2021. 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 Company’s filings under the Securities Act of 1933, as amended (the “**Securities Act**”), 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**

Exhibit Number	Exhibit Description
99.1	<u>Press Release, dated March 3, 2022, “GlycoMimetics Reports Highlights and Financial Results for Fourth Quarter and Full Year 2021”</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 3, 2022

By: /s/ Brian M. Hahn

Brian M. Hahn

Senior Vice President and Chief Financial Officer



GlycoMimetics Reports Highlights and Financial Results for Fourth Quarter and Full Year 2021

- Post year-end 2022 remains target for top-line data release of GlycoMimetics-sponsored pivotal Phase 3 trial evaluating uproleselan in relapsed/refractory acute myeloid leukemia (AML)
- National Cancer Institute (NCI) to conduct post-Phase 2 interim analysis based on event-free survival for the NCI-sponsored Phase 2/3 registration trial evaluating uproleselan in older, newly diagnosed AML patients fit for chemotherapy
- Apollomics' Phase 3 uproleselan trial in Greater China initiated in November 2021
- Investigational New Drug (IND) activities continued for GMI-1687 for treatment of acute vaso-occlusive crisis (VOC) of sickle cell disease; IND submission targeted for first half 2022
- Conference call and webcast today at 8:30 a.m. ET

ROCKVILLE, MD -- March 3, 2022-- GlycoMimetics, Inc. (Nasdaq: GLYC) today reported its financial results and highlights for the fourth quarter and year ended December 31, 2021. Cash and cash equivalents at December 31, 2021 were \$90.3 million.

"During 2021, we focused on completing enrollment of our pivotal trial evaluating uproleselan in AML. Towards the end of the year, within two weeks of each other, GlycoMimetics completed enrollment of our Phase 3 trial and the NCI completed enrollment of the Phase 2 portion of its Phase 2/3 trial. This represents a significant achievement for our entire organization, particularly during a global pandemic that has negatively impacted enrollment rates for numerous clinical studies. The top-line data from these two trials of uproleselan in AML will undoubtedly be transformative for the organization. As the survival data matures, we are actively preparing for a potential regulatory submission and subsequent commercialization of uproleselan," commented Harout Semerjian, Chief Executive Officer.

Operational Highlights

Uroleselan

- GlycoMimetics' pivotal Phase 3 trial in relapsed/refractory AML completed enrollment of 388 patients across 70 sites in the U.S., Australia and Europe. The Company reiterates its projection of a topline data release after year-end 2022.
- In parallel, the NCI-sponsored Phase 2/3 clinical trial, which is evaluating uproleselan in newly diagnosed older adults with AML who are fit for chemotherapy, completed its Phase 2 enrollment of 267 patients. The Company intends to share topline results from the NCI's planned interim analysis of Phase 2 data based on event-free survival.
- Efficacy and safety data from a Phase 1/2 clinical study of uproleselan were published online September 16, 2021, in the journal *BLOOD*. An analysis of minimal residual disease (MRD) showed an MRD negative rate of 69 percent in patients with relapsed/refractory AML, indicating an enhanced depth of response following addition of uproleselan to salvage therapy.

- Investigator-sponsored clinical trials to evaluate expanded indications for uproleselan were initiated at the University of California-Davis, Washington University at St. Louis, MD Anderson Cancer Center and the University of Michigan.
- Apollomics, our exclusive collaborator for development and commercialization of uproleselan in Greater China, received Breakthrough Therapy designation from the China National Medical Products Administration and initiated a Phase 3 registrational study in November 2021.

GMI-1687

- In 2021, the Company advanced an IND-enabling program for GMI-1687, with sickle cell disease acute VOC as the lead indication. The Company reiterates its plan to submit an IND to the FDA in the first half of 2022.

GMI-1359

- At the 63rd Annual meeting of the American Society of Hematology in December, the Company's collaborators at MD Anderson highlighted the potential for GMI-1359 in breaking resistance in AML, particularly in patients with FLT-3 ITD mutations. Subject to available funding, the Company plans to evaluate potential indications for further clinical development.

GMI-2093

- At the 2021 American Association for Cancer Research annual meeting, preclinical data was provided for the first time, as a late-breaking abstract, on the impact of one of the Company's galectin-3 inhibitors on tumor fibrosis, mononuclear cell infiltration, and antitumor activity in a pancreatic adenocarcinoma model when given in combination with an anti-PD-L1 inhibitor.
- In late 2021, the Company nominated GMI-2093 as a development lead candidate after observing high affinity and selectivity for galectin-3 with oral bioavailability. The role of galectin-3 in cancer, fibrosis and other inflammatory disease is emerging as a therapeutic target, and the Company plans to advance this program through potential strategic partnerships.

Executive Management Team

- The Company expanded its executive management in late 2021 and early 2022:
 - Lisa DeLuca, Ph.D., was hired in November as Vice President, Regulatory Affairs
 - Bruce Johnson was hired in February 2022 as Senior Vice President and Chief Commercial Officer
 - Deepak Tiwari was hired in March 2022 as Vice President, Technical Operations

Fourth Quarter and Year-end 2021 Financial Results:

- Cash position: As of December 31, 2021, GlycoMimetics had cash and cash equivalents of \$90.3 million as compared to \$137.0 million as of December 31, 2020.
 - Revenue: During the years ended December 31, 2021 and 2020, the Company recognized revenue of \$1.2 million and \$10.2 million, respectively, all of which was the result of payments received under our license and collaboration agreement with Apollomics for the development and commercialization of uproleselan and GMI-1687 in Greater China.
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- R&D Expenses: The Company's research and development expenses increased to \$12.9 million for the quarter ended December 31, 2021, as compared to \$11.7 million for the fourth quarter of 2020 due to higher development expenses related to manufacturing costs for the uproleselan validation batches and increased costs for IND enabling activities of GMI-1687.

Research and development expenses for the year ended December 31, 2021 increased to \$47.5 million as compared to \$44.9 million in the prior year. The increase in expenses was due to higher clinical development expenses related to our ongoing global Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML, increased manufacturing costs and increased IND enabling activities related to GMI-1687.

- G&A Expenses: The Company's general and administrative expenses increased to \$4.5 million for the quarter ended December 31, 2021, as compared to \$4.0 million for the fourth quarter of 2020. General and administrative expenses for the year ended December 31, 2021, increased to \$17.1 million as compared to \$16.7 million in the prior year. These increases were due to higher recruiting, consulting and legal expenses incurred in 2021 offset by lower personnel-related expenses due to the CEO transition.
- Shares Outstanding: Shares of common stock outstanding as of December 31, 2021 were 52,313,894.

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 4048456. Participants are encouraged to connect 15 minutes in advance of the call to ensure they 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, with participant code 4048456.

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 National Medical Products Administration 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.

About GMI-1687

Discovered and developed by GlycoMimetics, GMI-1687 is a highly potent E-selectin antagonist that represents a potential life-cycle extension to uproleselan. GMI-1687 has been shown in animal models to be fully bioavailable following subcutaneous administration. As such, GMI-1687 is being positioned as a potentially self-administered drug to be used in the outpatient setting for the treatment of hematologic malignancies, such as AML and MDS, as well as inflammatory diseases such as acute vaso-occlusive crisis of sickle cell disease.

About GMI-1359

GMI-1359 is designed to simultaneously inhibit both E-selectin and CXCR4 — 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 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 GMI-2093

GMI-2093 is a galectin-3 inhibitor discovered and being developed by GlycoMimetics. Available evidence indicates that the galectin-3 class may activate a variety of profibrotic factors, promote fibroblast proliferation and transformation, and mediate collagen production. Recent studies have defined key roles for galectin-3 in fibrogenesis in diverse organ systems, including liver, kidney, lung, and heart. Additionally, galectin-3 has been shown in preclinical models to be closely involved in tumor cell transformation, migration, invasion, and metastasis. GMI-2093 is being developed as a therapeutic strategy against tissue fibrosis and the treatment of certain cancers.

About GlycoMimetics, Inc.

GlycoMimetics is a clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers, including acute myeloid leukemia (AML), and for inflammatory diseases with high unmet need. The Company's science is based on an understanding of the role that carbohydrates play on the surface of every living cell and applying its specialized chemistry platform to discover small molecule drugs, known as glycomimetics, which alter these carbohydrate-mediated pathways in a variety of disease states, including signaling in cancer and inflammation. As a leader in this space, GlycoMimetics is leveraging this unique targeted approach to advance its pipeline of wholly owned drug candidates, with the goal of developing transformative therapies for serious diseases. 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, regulatory interactions and submissions, and commercialization of the Company's product candidates, as well as the conduct of, and data from, preclinical studies and clinical trials, and the potential benefits and impact of the Company's drug candidates. 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 3, 2022, 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,	
	2021	2020	2021	2020
	(Unaudited)			
Revenue from collaboration and license agreements	\$ 18	\$ 163	\$ 1,160	\$ 10,163
Costs and expenses:				
Research and development expense	12,896	11,720	47,492	44,929
General and administrative expense	4,548	4,011	17,115	16,743
Total costs and expenses	<u>17,444</u>	<u>15,731</u>	<u>64,607</u>	<u>61,672</u>
Loss from operations	(17,426)	(15,568)	(63,447)	(51,509)
Interest income	4	5	20	482
Net loss and comprehensive loss	<u>\$ (17,422)</u>	<u>\$ (15,563)</u>	<u>\$ (63,427)</u>	<u>\$ (51,027)</u>
Net loss per common share – basic and diluted	\$ (0.33)	\$ (0.32)	\$ (1.23)	\$ (1.12)
Weighted-average common shares outstanding – basic and diluted	52,011,950	47,995,898	51,453,294	45,721,139

GlycoMimetics, Inc.
Balance Sheet Data
(In thousands)

	December 31, 2021	December 31, 2020
Cash and cash equivalents	\$ 90,255	\$ 137,035
Working capital	78,964	125,845
Total assets	94,347	142,832
Total liabilities	12,743	14,613
Total stockholders' equity	81,604	128,219