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 9, 2022

GlycoMimetics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36177**	**06-1686563**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 9, 2022, GlycoMimetics, Inc. (the "***Company***") issued a press release announcing its financial results for the third quarter ended September 30, 2022. 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	Press Release, dated November 9, 2022, "GlycoMimetics Reports Highlights and Financial Results for Third Quarter 2022"
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.

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

Date: November 9, 2022

GlycoMimetics Reports Highlights and Financial Results for Third Quarter 2022

- U.S. Food and Drug Administration (FDA) clears protocol amendment to conduct an interim utility analysis of pivotal Phase 3 study of uproleselan in relapsed/refractory acute myeloid leukemia (AML)
- Blinded pooled survival data show patients in the Phase 3 study continue to live longer than historically expected; final survival events trigger now projected around year-end 2023
- Independent Data Monitoring Committee (DMC) to determine by end Q1 2023 if the study should continue as planned or be immediately unblinded for full analysis if efficacy data is compelling
- Cash runway extended to the end of 2023
- Conference call and webcast today at 8:30 a.m. ET

ROCKVILLE, Md.--(BUSINESS WIRE) – November 9, 2022-- GlycoMimetics, Inc. (Nasdaq: GLYC), a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers and inflammatory diseases, today reported its financial results and highlights for the third quarter ended September 30, 2022. Cash and cash equivalents as of September 30, 2022, were $51.6 million.

“Blinded pooled survival data in our pivotal Phase 3 study show patients living longer than what would be expected based on publicly available historical data. We approached the FDA as we felt an ethical obligation to conduct an interim analysis and have the independent DMC assess whether the prolonged survival observed is linked to treatment with uproleselan,” said Harout Semerjian, Chief Executive Officer. “We are pleased the FDA is aligned with our position. Whether the DMC recommends that we continue the study as originally planned or immediately unblind for full analysis, we remain confident and excited in the potential of uproleselan to improve outcomes in relapsed/refractory AML.”

The statistical plan cleared with FDA is for the independent DMC to review efficacy and safety data at around 80% of planned survival events. The company has initiated the required regulatory and Institutional Review Board (IRB) approvals to amend the protocol to conduct the interim utility analysis and share the data with the DMC by end of Q1 2023. The DMC is then expected to meet to review the data and recommend whether the study should continue as planned or should be immediately unblinded for full analysis, which could occur if the efficacy data from treatment with uproleselan in combination with standard chemotherapy is observed to be compelling.

As part of its ongoing monitoring of blinded pooled survival data within the Phase 3 pivotal study, the company is now projecting the final survival events trigger to occur around year-end 2023. This change in timeline is the result of patients continuing to live longer than observed in historical benchmarks used to design the study and was the primary rationale for the company to approach the FDA regarding conduct of an interim utility analysis.

The company's cash runway now extends to year-end 2023 as a result of the decrease in expenses from the transition of the Phase 3 relapsed/refractory AML clinical trial to follow-up, the completion of key uproleselan commercial manufacturing activities, and the realization of savings from a headcount reduction earlier this year. The company's allocation of its capital resources will continue to prioritize the advancement of the uproleselan development program, including key regulatory and pre-commercial activities.

The pivotal Phase 3 trial evaluating uproleselan in addition to a standard chemotherapy regimen in patients with relapsed/refractory AML completed enrollment in November of 2021. A total of 388 patients across 70 sites in nine countries were randomized in the clinical trial, which has a primary endpoint of overall survival.

Operational Highlights

- Following alignment with the FDA on conducting an interim analysis, GlycoMimetics initiated the required regulatory and IRB approvals to update the protocol of the company's pivotal Phase 3 study of uproleselan in relapsed/refractory AML. These efforts are ongoing and are expected to be completed in Q1 2023.
- Initial clinical data from two investigator-sponsored trials studying the use of uproleselan in combination with other treatments in patients with different forms of AML have been accepted for poster presentation at the 64th American Society of Hematology (ASH) Annual Meeting (ASH Press Release). These studies examine the safety and potential efficacy of uproleselan to benefit patients across the AML spectrum, including older, unfit treatment naïve patients and those with treated secondary AML.
- The National Cancer Institute (NCI) continues to prepare for its planned interim analysis of event-free survival of the 267 patients in its Phase 2/3 clinical trial evaluating uproleselan in newly diagnosed older adults with AML who are fit for chemotherapy. When available, the company intends to share the outcome of the NCI's interim analysis of the Phase 2 data and whether the trial will reopen for Phase 3 recruitment. The NCI will determine the timing and medical meeting to present the full results of the Phase 2 study.

Third Quarter 2022 Financial Results:

Cash position: As of September 30, 2022, GlycoMimetics had cash and cash equivalents of $51.6 million as compared to $90.3 million as of December 31, 2021.

Revenue: There was no revenue recognized during the three months ended September 30, 2022, compared to $87,000 of revenue recognized during the three months ended September 30, 2021.

R&D Expenses: Research and development expenses decreased to $4.9 million for the quarter ended September 30, 2022, as compared to $13.3 million for the same period in 2021. The significant decrease in expenses was primarily due to lower clinical trial and development costs related to the pivotal Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML as patient enrollment ended in November 2021.

G&A Expenses: General and administrative expenses decreased to $3.8 million for the quarter ended September 30, 2022, as compared to $4.1 million for the third quarter of 2021 primarily due to lower professional fees.

Shares Outstanding: Shares of common stock outstanding as of September 30, 2022, were 52,423,944.

The company will host a conference call and webcast today at 8:30 a.m. ET. To access the call by phone, please go to this registration link and you will be provided with dial in details. Participants are encouraged to connect 15 minutes in advance of the scheduled start time.

A live webcast of the call will be available on the "Investors" tab on the GlycoMimetics website. A webcast replay will be available for 30 days following the call.

About Uproleselan

Discovered and developed by GlycoMimetics, uproleselan is an investigational first-in-class, E-selectin antagonist. Uproleselan (yoo' pro le'se lan), currently in a comprehensive Phase 3 development program in acute myeloid leukemia (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 binding and stimulation of myeloid cells. E-selectin is expressed on the surface of blood vessels, and its binding to myeloid cells confers a pro-survival effect via NF-kB signaling. Uproleselan is designed to provide a novel approach to disrupting established mechanisms of leukemic cell resistance.

About GlycoMimetics, Inc.

GlycoMimetics is a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers, including AML, and for inflammatory diseases with high unmet needs. The company's science is based on an understanding of the role that carbohydrates play in cell recognition and its specialized chemistry platform to discover small molecule drugs, known as glycomimetics, which alter carbohydrate-mediated recognition in diverse disease states, including cancer and inflammation. As a leader in this science, GlycoMimetics leverages this unique approach to advance its pipeline of wholly-owned drug candidates, with the goal of developing transformative therapies for diseases with high unmet need. GlycoMimetics is headquartered 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 may include, but are not limited to, statements regarding the conduct of, and data from, clinical trials, planned or potential clinical development, regulatory interactions and submissions, the commercialization and potential benefits and impact of the company's drug candidates, and the company's expected 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 3, 2022, its Quarterly Report on Form 10-Q filed with the SEC on November 9, 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 September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Revenue from collaboration and license agreements	$ —	$ 87	$ 75	$ 1,142
Costs and expenses:				
Research and development expense	4,923	13,282	22,500	34,596
General and administrative expense	3,845	4,142	14,356	12,567
Total costs and expenses	8,768	17,424	36,856	47,163
Loss from operations	(8,768)	(17,337)	(36,781)	(46,021)
Interest income	244	5	336	15
Net loss and comprehensive loss	$ (8,524)	$ (17,332)	$ (36,445)	$ (46,006)
Net loss per common share – basic and diluted	$ (0.16)	$ (0.34)	$ (0.70)	$ (0.90)
Weighted-average common shares outstanding – basic and diluted	52,423,944	51,564,674	52,387,561	51,266,955

GlycoMimetics, Inc.
Balance Sheet Data
(In thousands)

	September 30, 2022 (unaudited)	December 31, 2021
Cash and cash equivalents	$ 51,625	$ 90,255
Working capital	46,100	78,964
Total assets	55,961	94,347
Total liabilities	7,844	12,743
Total stockholders' equity	48,118	81,604