UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 5, 2022

Humanigen, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35798**	**77-0557236**
(State or other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

830 Morris Turnpike, 4th Floor
Short Hills, NJ 07078

(Address of principal executive offices, including zip code)

(973) 200-3100
(Registrant's telephone number, including area code)

533 Airport Boulevard, Suite 400
Burlingame, CA 94010

(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 (see General Instruction A.2):

☐ 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	HGEN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 5, 2022, Humanigen, Inc. (the "Company") issued a press release regarding the Company's financial results for its first fiscal quarter ended March 31, 2022 and providing a corporate update. A copy of the press release is attached to this report as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Press release, dated May 5, 2022
104	Cover Page Interactive Data File (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.

HUMANIGEN, INC.

By: /s/ Cameron Durrant
Name: Cameron Durrant
Title: Chairman of the Board and Chief Executive Officer

Dated: May 5, 2022

Exhibit 99.1

Humanigen Reports First Quarter 2022 Financial Results

SHORT HILLS, N.J. May 5, 2022--(Business Wire)--Humanigen, Inc. (Nasdaq: HGEN) ("Humanigen"), a clinical stage biopharmaceutical company focused on preventing and treating an immune hyper-response called "cytokine storm" with its lead drug candidate, lenzilumab (LENZ®), today provided a corporate update and reported financial results for the first quarter ended March 31, 2022.

"A key highlight of the first quarter was the completion of enrollment in the ACTIV-5/BET-B study. We also held a productive Type B pre-EUA meeting with FDA where we gained alignment on the data and statistical analysis plan to be included as part of the amendment to our EUA for LENZ in COVID-19 patients. In concert with the NIH, we anticipate top-line data in the primary analysis population to be reported in the second quarter, with an amendment to our EUA submission planned to follow," stated Cameron Durrant, Chairman and Chief Executive Officer, Humanigen. "We anticipate hospitalizations from COVID-19 will continue for years to come. Published data on LENZ, confirmed by key opinion leaders and national guideline committees, including NIH, supports treatment guidance based on CRP levels and first-line utilization in hypoxic patients."

"Hospitalizations from COVID-19 in the US continue to remain steady with a 7-day average of 2,072 new daily hospitalizations. While there have been more than 900,000 people already hospitalized in the US this year to date,[1] synergizing results from multiple forecasting models prepared by leading experts in epidemiology in four different scenarios forecast additional COVID-19 hospitalizations in the United States, to range from approximately 500,000 to 1,200,000 for the remainder of 2022.[2] Variant agnostic treatments for hospitalized patients are still desperately needed," commented Edward Jordan, Chief Commercial Officer, Humanigen.

"As well as its clinical benefit in reducing invasive mechanical ventilation and death, LENZ could deliver significant economic savings to health care systems. LENZ can be used in combination with remdesivir, which is currently used in 50% of hospitalized COVID-19 patients in the U.S.[3] Sales of the top two hospital treatments for COVID-19 exceeded $7 billion in global revenue in 2021.[4,5] We believe LENZ is well positioned to participate in this sizable and sustainable market," he added.

Lenzilumab is an investigational product and is not currently authorized or approved in any country.

First Quarter and Recent Highlights:

Lenzilumab in COVID-19 patients

- Completed enrollment of the Phase 2/3 ACTIV-5/BET-B study, sponsored by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, and enrolled over 400 patients in the primary analysis population (patients with a C-reactive protein level at baseline of less than 150mg/L).
- Gained alignment with the FDA during a Type B pre-EUA meeting on the data and statistical analysis plan to be included in the amendment to the EUA.
- Announced a peer-reviewed publication in ClinicoEconomics and Outcomes Research outlining the potential clinical and health economic benefits of lenzilumab, if authorized or approved for use in the United Kingdom.
- First subject dosed in the PK study in Korea.

Lenzilumab in Development in Other Therapeutic Areas

- Gained alignment with the FDA on the protocol for the planned registrational Phase 3 SHIELD study of lenzilumab for the prevention of CAR-T therapy related toxicities including Immune Effector Cell-Associated Neurotoxicity ("ICANS"), in which Humanigen intends to enroll the first patient in the second quarter.
- Announced a peer-reviewed publication in *Leukemia*, a leading oncology and hematology journal, entitled "GM-CSF disruption in CART cells modulates T cell activation and enhances CART cell anti-tumor activity."
- Notified by the University of Birmingham, UK, that the amended Investigational Medicinal Product Dossier has been accepted by Medicines & Healthcare products Regulatory Agency for the "RATinG" study. Humanigen believes the first patient will be enrolled in this Phase 2/3 potentially registrational trial for lenzilumab to treat patients who have undergone allogeneic hematopoietic stem cell therapy, who are at high and intermediate risk for acute Graft versus Host Disease ("aGvHD") in the second quarter.
- Continued enrollment in the PREACH-M study of lenzilumab in chronic myelomonocytic leukemia. Study sponsor planning for expansion of clinical sites.

First Quarter Ended March 31, 2022 Financial Results

Net loss for the quarter ended March 31, 2022 was $21.3 million, or $0.32 per share, as compared to $65.6 million, or $1.25 per share, for the quarter ended March 31, 2021. The decrease in net loss was due to a decrease in total expenses, mainly Research and Development ("R&D") expense. R&D expense decreased $42.7 million from $59.9 million for the three months ended March 31, 2021, to $17.2 million for the three months ended March 31, 2022. The decrease is primarily due to a decrease of $35.7 million in lenzilumab manufacturing costs.

Cash and Cash Equivalents

Net cash used in operating activities, net of balance sheet changes, was $19.4 million for the quarter ended March 31, 2022. During the first quarter of 2022, the company sold shares of its common stock under its At-the-Market or "ATM" facility, raising net proceeds of approximately $18 million. As of March 31, 2022, the company had cash and cash equivalents of approximately $69 million.

A summary of key financial highlights as of and for the three months ended March 31, 2022 and 2021 is as follows ($ in thousands):

	Three Months Ended March 31,	
	2022	2021
License revenue	$ 1,036	$ 486
Research and development	17,220	59,934
General and administrative	4,345	4,948
Loss from operations	(20,529)	(64,396)
Net loss	$ (21,278)	$ (65,567)
Net loss per common share	$ (0.32)	$ (1.25)
Weighted average common shares	65,590,724	52,655,756

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 68,948	$ 70,016
Current assets	$ 71,235	$ 70,971
Current liabilities	71,181	68,725
Working capital	$ 54	$ 2,246

About Lenzilumab

Lenzilumab is a proprietary Humaneered® first-in-class monoclonal antibody that has been proven to neutralize GM-CSF, a cytokine of critical importance in the hyperinflammatory cascade, sometimes referred to as cytokine release syndrome, or cytokine storm, associated with COVID-19 and other indications. Lenzilumab binds to and neutralizes GM-CSF, potentially improving outcomes for patients hospitalized with COVID-19. Humanigen believes that GM-CSF neutralization with lenzilumab also has the potential to reduce the hyper-inflammatory cascade known as cytokine release syndrome common to chimeric antigen receptor T-cell (CAR-T) therapy and acute Graft versus Host Disease (aGvHD).

In CAR-T, lenzilumab successfully achieved the pre-specified primary endpoint at the recommended dose in a Phase 1b study with Yescarta® in which the overall response rate was 100% and no patient experienced severe cytokine release syndrome or severe neurotoxicity. Based on these results, Humanigen plans to test lenzilumab in a randomized, multicenter, potentially registrational, Phase 3 SHIELD study to evaluate its efficacy and safety when combined with Yescarta and Tecartus® CAR-T therapies in non-Hodgkin lymphoma. Lenzilumab will also be tested to assess its ability to prevent and/or treat aGvHD in patients undergoing allogeneic hematopoietic stem cell transplantation.

A study of lenzilumab is also underway for patients with chronic myelomonocytic leukemia exhibiting RAS pathway mutations. This study builds on evidence from a Phase 1 study, conducted by Humanigen, that showed RAS mutations are associated with hyper-proliferative features, which may be sensitive to GM-CSF neutralization.

About Humanigen, Inc.

Humanigen, Inc. (Nasdaq: HGEN) (Humanigen), is a clinical-stage biopharmaceutical company focused on preventing and treating an immune hyper-response called ‘cytokine storm’. Lenzilumab is a first-in class antibody that binds to and neutralizes granulocyte-macrophage colony-stimulating factor (GM-CSF). Results from preclinical models indicate GM-CSF is an upstream regulator of many inflammatory cytokines and chemokines involved in the cytokine storm. Humanigen is developing lenzilumab as a treatment for cytokine storm associated with COVID-19 and CD19-targeted CAR-T cell therapies and is also exploring the effectiveness of lenzilumab in other inflammatory conditions such as acute Graft versus Host Disease in patients undergoing allogeneic hematopoietic stem cell transplantation and in eosinophilic asthma, and rheumatoid arthritis. For more information, visit www.humanigen.com and follow Humanigen on LinkedIn, Twitter, and Facebook.

Forward-Looking Statements

All statements other than statements of historical facts contained in this press release are forward-looking statements. Forward-looking statements reflect management's current knowledge, assumptions, judgment, and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct, and you should be aware that actual events or results may differ materially from those contained in the forward-looking statements. Words such as "will," "expect," "intend," "plan," "potential," "possible," "goals," "accelerate," "continue," and similar expressions identify forward-looking statements, including, without limitation, statements regarding: Humanigen’s beliefs as to the potential benefits of lenzilumab as a treatment for hospitalized COVID-19 patients; the timeline for announcement of release of topline results from the ACTIV-5/BET-B study being conducted by NIH; its efforts and potential timeline to make future regulatory submissions in respect of potential emergency use authorization from FDA for commercial use of lenzilumab in COVID-19 patients; statements regarding Humanigen’s beliefs as to the evolving nature of COVID-19 and the likelihood of continued hospitalizations and the size of the future market for leading COVID-19 therapeutics; and its other plans to initiate, continue or participate in planned or ongoing clinical trials and otherwise explore the effectiveness of lenzilumab and other candidates in its development portfolio as therapies for other inflammation and immune-oncology indications.

Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the risks inherent in the company's lack of profitability and need for additional capital to conduct its business as a going concern; its dependence on partners to further the development of its product candidates; the uncertainties inherent in the development, attainment of the requisite regulatory authorizations and approvals (including EUA in the United States and CMA in the United Kingdom and European Union) and launch of any new pharmaceutical product; challenges associated with manufacturing and commercializing a biologic such as lenzilumab; the outcome of pending or future litigation or arbitration; and the various risks and uncertainties described in the "Risk Factors" sections and elsewhere in Humanigen's periodic and other filings with the Securities and Exchange Commission.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You should not rely upon any forward-looking statements as predictions of future events. The Company undertakes no obligation to revise or update any forward-looking statements made in this press release to reflect events or circumstances after the date hereof or to reflect new information or the occurrence of unanticipated events, except as required by law.

References

1. Centers for Disease Control and Prevention. (2022, May 4). *CDC Covid Data tracker*. Retrieved May 4, 2022, from https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions

2. COVID-19 Scenario Modeling Hub. (2022, April 30). *Round 13 Model Projection*. Retrieved May 1, 2022, from https://covid19scenariomodelinghub.org/viz.html

3. Gilead Sciences, Inc. (2022, April 28). *Q122 Financial Results Presentation*. Retrieved May 3, 2022, from https://investors.gilead.com/static-files/857208c8-3ef2-4d47-a7a5-433e001ed581

4. Gilead Sciences, Inc. (2022, February 1). *Q4 & FY21 Financial Results.* Retrieved May 3, 2022, from https://investors.gilead.com/static-files/857208c8-3ef2-4d47-a7a5-433e001ed581

5. Roche (2022, February 3). *2021 Results Presentation and Investor Update*. Retrieved May 4, 2022, from https://www.roche.com/investors/events/annual-results-2021

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