Humanigen

NEWS RELEASE

Humanigen Reports Second Quarter 2021 Financial Results

8/12/2021

BURLINGAME, Calif.--(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, today provided a corporate and regulatory update and reported financial results for the second quarter and six months ended June 30, 2021.

Update on Status of Emergency Use Authorization (“EUA”) Application

On May 28, 2021, Humanigen submitted an EUA application for lenzilumab in patients hospitalized with COVID-19. Since that time, the company has responded to several requests from the U.S. Food and Drug Administration (“FDA”) regarding the application. No formal timelines exist for the FDA to complete their review of our EUA application and as a result the company is unable to give guidance on the timing of a decision by the FDA.

“We remain firm in our belief the results of our LIVE-AIR Phase 3 study warrant lenzilumab being granted emergency use authorization. The achievement of the primary endpoint for the overall patient population, and the recent supplemental subset analysis which showed significant response to treatment by Black and African-American patients in the study, support our view of the potential benefit lenzilumab could bring to patient care if authorization were to be granted,” said Cameron Durrant, MD, Chief Executive Officer, Humanigen.

Timothy Morris, CFO and COO, Humanigen, noted, “While the review of the EUA application continues, we are preparing for potential launch in the U.S., and simultaneously working to complete, before the end of the third quarter 2021, the submission of the Marketing Authorization Application (“MAA”) to the Medicines Healthcare products Regulatory Agency (“MHRA”) in the U.K. We have initiated the MAA process to the European Medicines Agency (“EMA”) and anticipate the appointment of rapporteurs in the near term.”

Second Quarter and Recent Highlights:

Lenzilumab in hospitalized COVID-19

- Submitted an application to the FDA for an EUA for lenzilumab for the treatment of patients hospitalized with COVID-19.
- Initiated filing and received acknowledgement the UK submission for Marketing Authorization for lenzilumab in COVID-19 has been accepted for expedited COVID-related rolling review by the MHRA. The submission is expected to be completed by September 30, 2021.
- Initiated the process to make a submission to the European Medicines Agency for Marketing Authorization of lenzilumab in COVID-19.
- The company's commercial partners in South Korea and the Philippines, KPM Tech and Telcon RF Pharmaceutical, received approval from South Korea's Ministry of Food and Drug Safety, the South Korean equivalent of FDA, to conduct a Phase 1 clinical study of lenzilumab, to enable submission and potential approval in South Korea.
- Announced analysis of results from our Phase 3 LIVE-AIR study of lenzilumab in hospitalized patients with COVID-19 suggesting Black and African-American patients having a CRP<150 mg/L may be the highest responders to treatment, with a nearly 9-fold increase in likelihood of survival without ventilation ("SWOV") [n=51, p-value=0.0418]. In the overall population with CRP<150 mg/L, LIVE-AIR Phase 3 results show patients treated with lenzilumab demonstrated a 2.5-fold increased likelihood of SWOV [mITT, n=351, p-value=0.0009].
- Entered into manufacturing agreement with Chime Biologics to produce lenzilumab bulk drug substance and drug product to be sold, with requisite regulatory authorization, in regions outside the United States.

Corporate

- Completed underwritten public offering of common stock, raising net proceeds of $94.2 million.
- The company was added to the Russell 3000® Index in June 2021.
- Ken Trbovich was appointed to the newly-created role of SVP Investor Relations.

ACTIV-5 Update

In August 2021, the National Institutes of Health ("NIH") announced the expansion of the Accelerating COVID-19 Therapeutic Interventions and Vaccines ("ACTIV-5") and Big Effect Trial, in the "B" arm of the trial ("BET-B"), referred to as ACTIV-5/BET-B. Following feedback from and consultation with the company, the NIH advanced the study to a Phase 2/3 study with target enrollment of at least 400 patients and amended the protocol for ACTIV-5/BET-B in a manner that aligns with the design of the company's LIVE-AIR trial. As a result of the advancement to a Phase 2/3 and amended protocol, the company anticipates that ACTIV-5/BET-B may serve as a second confirmatory study required for submission to FDA as part of a Biologics License Application ("BLA") that the company would submit if the ACTIV-5/BET-B data further validate the benefits of lenzilumab in COVID-19 patients.

Second Quarter and Six Months Ended June 30, 2021 Financial Results

Net loss for the three months ended June 30, 2021 was $70.8 million or $1.20 per share as compared to $24.0 million or $0.79 per share for the three months ended June 30, 2020. The net loss for the six months ended June 30, 2021 was $136.4 million or $2.45 per share as compared to $26.5 million or $1.00 per share for the six months ended June 30, 2020. The increase in net loss for both periods was largely due to an increase in total expenses, mainly Research and Development ("R&D") expense which rose significantly as the company accelerated its efforts to manufacture lenzilumab for potential commercialization upon a regulatory authorization. R&D expense increased $41.9 million from $21.1 million for the three months ended June 30, 2020, to $63.0 million for the three months ended June 30, 2021, and increased $101.1 million from $21.8 million for the six months ended June 30, 2020, to $122.9 million for the six months ended June 30, 2021. The manufacturing expense included in R&D was $57.1 million for the second quarter of 2021 as compared to $17.1 million for the prior year quarter, and $107.1 million for the six months ended June 30, 2021, as compared to $17.4 million for the prior year period. The costs incurred to produce lenzilumab will continue to be included in R&D expense until lenzilumab is authorized or approved for commercial use, at which point the amounts expended for production would be reclassified as inventory. A meaningful portion of these expenses are associated with initiation of manufacturing processes on a site-by-site basis.

Cash and Cash Equivalents

Net cash used in operating activities, net of balance sheet changes, was $103.8 million for the six months ended June 30, 2021. During the same period, the company raised net proceeds of $36.1 million from the sale of shares of common stock under its At-the-Market offering program, drew the first tranche of $25.0 million under its credit facility with Hercules Capital, providing net proceeds of $24.4 million, and completed a public offering of common stock with net proceeds of $94.2 million. As of June 30, 2021, the company had cash and cash equivalents of $120.5 million. The company expects to continue to use its funds on the manufacturing of lenzilumab in anticipation of its potential commercialization under EUA in the US or conditional marketing authorization in the UK. For the third quarter of 2021 the company anticipates the R&D expense related to lenzilumab production will be same level as the second quarter of 2021. If an EUA or CMA for lenzilumab is not received in the third quarter of 2021, the company would seek to decrease its spending on lenzilumab production.

A summary of key financial highlights as of and for the three and six months ended June 30, 2021 and 2020 is as follows ($ in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
License revenue	$ 1,036	$ -	$ 1,522	$ -
Research and development	63,012	21,143	122,946	21,802
General and administrative	8,076	1,956	13,024	3,354
Loss from operations	(70,052)	(23,099)	(134,448)	(25,156)

Net loss	$ (70,803)	$ (24,022)	$ (136,370)	$ (26,489)
Net loss per common share	$ (1.20)	$ (0.79)	$ (2.45)	$ (1.00)
Weighted average common shares	58,843,567	30,222,568	55,735,008	26,538,337

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 120,536	$ 67,737
Current assets	$ 121,640	$ 68,212
Current liabilities	50,314	20,415
Working Capital	$ 71,326	$ 47,797

About Humanigen, Inc.

Humanigen, Inc. (Nasdaq: HGEN) ("Humanigen"), 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 of preclinical models indicate GM-CSF is an upstream regulator of many inflammatory cytokines and chemokines involved in the cytokine storm. Early in the COVID-19 pandemic, investigation showed high levels of GM-CSF secreting T cells were associated with disease severity and intensive care unit admission. Humanigen's Phase 3 LIVE-AIR study suggests early intervention with lenzilumab may prevent consequences of a full-blown cytokine storm in hospitalized patients with COVID-19. Humanigen is developing lenzilumab as a treatment for cytokine storm associated with CD19-targeted CAR-T cell therapies and exploring the effectiveness of lenzilumab in other inflammatory conditions such as acute Graft versus Host Disease (aGvHD) in patients undergoing allogeneic hematopoietic stem cell transplantation (HSCT), eosinophilic asthma, and rheumatoid arthritis. Humanigen is also developing a portfolio of clinical and pre-clinical therapies for the treatment of inflammation and immuno-oncology. 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 in COVID-19 patients; the timing for submission of applications for MAA in the U.K. and EU; the potential that the company will receive EUA or other marketing approval outside the United States for lenzilumab, which is not assured; the potential that ACTIV-5/BET-B

may serve as a confirmatory study to support a future BLA in the US or augment other regulatory applications; our anticipated spending to prepare to commercialize lenzilumab in the U.S. and other markets, if EUA or other marketing approval were granted; and statements regarding Humanigen's beliefs relating to the technologies in Humanigen's current pipeline.

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 potential need for additional capital to grow its business; its ability to successfully commercialize lenzilumab under an EUA or other conditional marketing authorizations, if granted; 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 and launch of any new pharmaceutical product; the outcome of pending or future litigation; 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.

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