2022R00630/KMR

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Hon.
	:	
v.	:	Criminal No. 24-243 (KMW)
	:	
DALE CHAPPELL	:	Count 1
	:	18 U.S.C. § 1348;
	:	18 U.S.C. § 2
	:	(Securities Fraud)
	:	
	:	Counts 2-5
	:	15 U.S.C. §§ 78j(b) & 78ff; 17
	:	C.F.R. § 240.10b-5; 18 U.S.C. § 2
	:	(Securities Fraud)
	:	

INDICTMENT

The Grand Jury in and for the District of New Jersey, sitting at Newark, charges:

COUNT 1
(Securities Fraud)

Overview of the Securities Fraud Scheme

1. From in or around January 2021 to in or around August 2021, defendant DALE CHAPPELL ("CHAPPELL") used his position at a publicly traded company, Humanigen, Inc. ("Humanigen"), to engage in a securities fraud scheme that enabled him to sell Humanigen securities based on material non-public information.

Background

2. At all times relevant to this Indictment:

a. Humanigen was a publicly traded biopharmaceutical company with offices in New Jersey and California whose shares traded on the NASDAQ national securities exchange. Humanigen was an issuer with securities registered under Section 12 of the Securities Exchange Act of 1934 (the "Exchange Act") and was required to file reports under Section 13 of the Exchange Act.

b. CHAPPELL, a resident of Switzerland, was the Chief Scientific Officer of Humanigen and became a Director of Humanigen on or about February 8, 2021. CHAPPELL held Humanigen stock in three separate funds that he controlled, including: Black Horse Capital Master Fund Ltd., Cheval Holdings, Ltd., and Black Horse Capital LP (together, the "CHAPPELL FUNDS").

c. As an executive of Humanigen, CHAPPELL had access to material non-public information belonging to Humanigen, including information about the status of regulatory review and approval for Lenzilumab, a pharmaceutical product under development by Humanigen. As an officer and member of the Board of Directors, CHAPPELL was a corporate insider and owed a fiduciary duty and duty of trust and confidence to Humanigen and its shareholders. Among other things, these duties required that CHAPPELL abstain from trading his Humanigen stock while in possession of material non-public information.

d. A "Rule 10b5-1 plan" under the Exchange Act allowed a corporate insider of a publicly traded company to set up a trading plan for buying or selling

stock. If the corporate insider followed the requirements of Rule 10b5-1, the trades pursuant to the plan were insulated against charges of insider trading. Rule 10b5-1 required that the corporate insider establishing the plan could not possess material non-public information about the company at the time he or she entered into the plan; if the insider did have material non-public information at the time he or she entered into the plan, the plan provided no defense to insider trading charges. Additionally, trading pursuant to a Rule 10b5-1 plan provided no defense to insider trading charges if the plan was not entered in good faith or was entered into as part of an effort or scheme to evade the prohibitions of Rule 10b5-1 against insider trading.

e. Humanigen had an Insider Trading Policy, which prohibited insiders from trading in Humanigen securities, directly or indirectly, while aware of material non-public information relating to Humanigen. The Insider Trading Policy stated, "it does not matter that you may have decided to engage in a transaction before becoming aware of material non-public information or that the material non-public information did not affect your decision to engage in the transaction." The Insider Trading Policy also stated that "questions concerning the materiality of particular information should be resolved in favor of materiality."

f. Humanigen's Insider Trading Policy imposed restrictions on when Humanigen executives or employees were allowed to trade their own stock, called "blackout periods," which restrictions allowed trading only during dates falling outside those periods, referred to as "trading windows."

g. Humanigen's Insider Trading Policy provided that "a 10b5-1 plan must be entered into before [an executive is] aware of material nonpublic information." The Insider Trading Policy emphasized this rule by reiterating that Rule 10b5-1 plans "may only be adopted before the person adopting the plan is aware of material nonpublic information."

h. CHAPPELL agreed in writing to comply with Humanigen's Insider Trading Policy in his employment agreement with the Company that he signed on or about September 18, 2020.

i. The NASDAQ was a United States stock exchange with servers located in New Jersey and elsewhere.

Clinical Trials and Regulatory Review of Drugs

j. The U.S. Food and Drug Administration ("FDA") was a federal regulatory agency responsible for, among other things, ensuring the safety, efficacy, and security of drugs and pharmaceutical products before they could be sold. The FDA did not conduct its own tests of a proposed drug. Instead, its physicians, statisticians, chemists, pharmacologists, and other scientists reviewed data received from pharmaceutical companies, like Humanigen, to determine whether the drug could be offered to the public.

k. The FDA required companies conducting studies of proposed drugs to the FDA to, among other things, obtain approval to begin a clinical trial and to provide the results of any clinical trial before approval could be obtained.

l. To help those conducting studies of proposed drugs, the FDA issued "Guidance for Industry" regarding "E9 Statistical Principles for Clinical Trials," which was publicly available online. Among other things, the guidance addressed "Subgroups, Interactions, and Covariates," and stated that "[a]ny conclusion of treatment efficacy (or lack thereof) or safety based solely on exploratory subgroup analyses is unlikely to be accepted."

m. Based on a shortage of adequate treatments for COVID-19, in the spring of 2020 the FDA began reviewing COVID-19 treatment applications for drugs from pharmaceutical companies under the Emergency Use Authorization ("EUA") process, which was an approval process the FDA used during public-health emergencies, including the COVID-19 pandemic.

n. Throughout 2020 and 2021, Humanigen did not have any pharmaceutical products on the market, any product sales, or any revenue. It was facing significant net financial losses and negative operating cash flow. As a result, the development of Lenzilumab was of paramount importance to Humanigen's financial stability.

o. In or around April 2020, Humanigen obtained FDA approval to begin a clinical trial for Lenzilumab to treat COVID-19, and, in or around August 2020, started a clinical trial for Lenzilumab for treatment of patients hospitalized with COVID-19 (the "Clinical Trial"). Humanigen developed the protocol for the Clinical Trial, which described how the Clinical Trial would be conducted and how its success would be measured.

The Scheme to Defraud

3. From in or around January 2021 to in or around August 2021, in the District of New Jersey and elsewhere, defendant

DALE CHAPPELL

did knowingly and intentionally execute and attempt to execute a scheme and artifice to defraud persons in connection with a security of Humanigen.

Goal of the Scheme to Defraud

4. The goal of the scheme was for CHAPPELL to enrich himself by selling Humanigen shares when he, but not the public, knew that the FDA had notified Humanigen that it was unlikely to meet the criteria for issuance of an EUA for Lenzilumab based on results from the Clinical Trial, and to conceal and cause to be concealed the scheme to defraud.

Manner and Means of the Scheme to Defraud

5. It was part of the scheme to defraud that:

a. In or around January 2021, Humanigen changed the primary endpoint of the Clinical Trial and notified the FDA of the change. On or about January 14, 2021, the FDA told Humanigen that it "do[es] not agree with changing the primary endpoint." The FDA's response to Humanigen was not public.

b. On or about March 19, 2021, Humanigen requested a meeting with the FDA to discuss the Clinical Trial. On or about April 2, 2021, Humanigen sent the FDA a briefing package detailing the "topline results" of the Clinical Trial.

c. On or about March 29, 2021, Humanigen issued a press release announcing that Lenzilumab had shown positive "topline results" from the Clinical Trial. In that same release, Humanigen announced its plan to submit an application to the FDA for EUA approval for Lenzilumab "as soon as possible." The press release did not mention the FDA's stated concerns about the change in the Clinical Trial's primary endpoint. Following the press release, Humanigen's stock price rose by approximately 50%.

d. On or about April 12, 2021, the FDA sent preliminary comments to Humanigen about the Clinical Trial. In its comments, the FDA stated, among other things, that "there are insufficient data to characterize the benefit-risk of your product," and identified four main concerns with the Clinical Trial, including (i) the change in primary endpoint, (ii) the modified intent-to-treat population, (iii) the lack of statistical significance in secondary endpoints, and (iv) an insufficiently large database to evaluate safety. Therefore, the FDA stated, "the criteria for issuance of an EUA are unlikely to be met based on results" from the Clinical Trial.

e. On or about April 14, 2021, CHAPPELL, and others, participated in a telephonic meeting with the FDA about Lenzilumab's progress towards an EUA. According to minutes of the meeting, the FDA repeated that "[w]hile available data for your product are promising, the criteria for issuance of an EUA are unlikely to be met based on results" from the Clinical Trial. Further, the FDA reported that the results from the Clinical Trial "are not sufficient to characterize the potential benefits and risks of your product." The FDA told Humanigen that it would need to conduct

"an additional confirmatory trial." Ultimately, the FDA "discouraged submission of an EUA at this time."

f. On or about April 20, 2021, the Humanigen Board of Directors, including CHAPPELL, met by video. During the meeting, CHAPPELL gave a presentation to the Board "derived from the topline data," which focused on a subset of patients who participated in the Clinical Trial. CHAPPELL also "outlined a potential" additional clinical trial focusing on this subset as a "potential course of action to be discussed with FDA." In doing so, CHAPPELL misrepresented the FDA's message by knowingly omitting that his proposed analysis conflicted with FDA public guidance on subset analysis.

g. Thereafter, CHAPPELL continued to exercise his influence within Humanigen to prevent the company from disclosing the FDA's negative message about the Clinical Trial to the public. For example, on or about May 4, 2021, Executive 1 at Humanigen sent an email to CHAPPELL and others in which Executive 1 suggested that the company's current disclosure about the EUA was not "sufficient" and suggested that the company should disclose their then-existing plan to initiate a second clinical trial. In response, CHAPPELL discouraged making that public disclosure because a second clinical trial was "not necessarily" needed because of data showing "which patients benefitted from" taking Lenzilumab. CHAPPELL responded that the "data have materially changed and continue to materially change for the better as we do more analysis." Again, CHAPPELL was aware based on FDA

public guidance that his post-hoc analysis was not likely to be adequate to obtain EUA approval.

h. On or about May 13, 2021, the FDA shared written minutes of its April 14, 2021 meeting with Humanigen, including with CHAPPELL. The minutes repeated what was discussed during the meeting and added "post meeting comments." The post-meeting comments "reiterate[d the FDA's] concerns conveyed during the meeting on April 14, 2021, as well as FDA's feedback that the totality of scientific evidence currently available for [Lenzilumab] is unlikely to satisfy the criteria for issuance of an EUA," and suggested "in lieu of an EUA request, we strongly recommend that you submit a meeting request to further discuss your continued development program."

i. On or about May 13, 2021, after market close, Humanigen announced its first quarter 2021 results in a Form 10-Q filed with the Securities and Exchange Commission ("SEC"). In the filing, Humanigen reiterated its intention to seek an EUA for Lenzilumab "at the end of May 2021." The filing did not disclose: that the FDA had expressed doubt about the submission; that the FDA recommended that Humanigen not submit the EUA application; or that the FDA had stated that it would not be able to assess Lenzilumab's safety and efficacy without an additional clinical trial.

j. On or about May 13, 2021, a press release announcing the 10-Q stated that Humanigen had "recently held a meeting with FDA to discuss the filing of an EUA for [Lenzilumab]," but again omitted: that the FDA had expressed doubt

about the submission; that the FDA recommended that Humanigen not submit the EUA application; and that the FDA had stated it would not be able to assess Lenzilumab's safety and efficacy without an additional clinical trial.

k. On or about May 28, 2021, Humanigen publicly announced that it had applied to the FDA for an EUA for Lenzilumab. Again, this announcement did not disclose any of the FDA's concerns about the Clinical Trial or the negative assessment the FDA had provided to Humanigen.

l. On or about May 31, 2021, CHAPPELL emailed Broker-Dealer A to notify Broker-Dealer A of a Humanigen trading window he expected to open on June 2, 2021. CHAPPELL wrote that "I would like to sell 475,000 shares of [Humanigen] next week during this window." Thereafter, at CHAPPELL's direction, Broker-Dealer A sold 475,000 shares of Humanigen owned by CHAPPELL.

m. On or about June 12, 2021, CHAPPELL obtained approval from the Humanigen Board of Directors to execute a trading strategy called a no-cost collar, a trading strategy called a "hedge" that was typically used to prevent excessive losses. Board approval was required because Humanigen policy barred hedging strategies like no-cost collars.

n. On or about June 14, 2021, Broker-Dealer A notified CHAPPELL that Broker-Dealer A could not find buyers for the no-cost collar, so CHAPPELL told Broker-Dealer A to proceed with alternative "vanilla" 10b5-1 plans that CHAPPELL had prepared.

o. On or about June 15, 2021, CHAPPELL sent final executed copies of 10b5-1 plans for each of the CHAPPELL FUNDS to Broker-Dealer A. The plans proposed to sell approximately 3,360,000 Humanigen shares with a triggering price of $17 and to begin selling one day later, on or about June 16, 2021. The CHAPPELL FUNDS then sold those shares, pursuant to the 10b5-1 plans, between in or around June 2021 and in or around August 2021.

p. The Rule 10b5-1 plans that CHAPPELL executed required that CHAPPELL represent and warrant that he was "entering into this plan in good faith and [was] neither in possession of nor [was] aware of any material non-public information concerning [Humanigen] or any of its securities" and that CHAPPELL was "entering into this Trading Plan in good faith and not as part of a plan or scheme to evade the federal securities laws or any law governing insider trading."

q. In furtherance of the scheme and to conceal its true nature, CHAPPELL submitted false and misleading Rule 10b5-1 plans to his broker, filed misleading Form 4s for review by the investing public, and signed a false Form 144 that was sent to the SEC. This included:

i. On or about June 1, 2021, CHAPPELL signed a Rule 10b5-1 plan for each of the CHAPPELL FUNDS, each falsely representing and certifying that he was not in possession of material non-public information about Humanigen.

ii. On or about June 2, 2021, CHAPPELL submitted and caused to be submitted SEC Form 144 describing his sale of Humanigen

securities. CHAPPELL signed the Form 144, which was submitted to the SEC, and falsely certified he did "not know any material adverse information in regard to the current and prospective operations of the Issuer of the securities to be sold which ha[d] not been publicly disclosed."

iii. On or about June 15, 2021, CHAPPELL signed a Rule 10b5-1 plan for each of the CHAPPELL FUNDS, each falsely representing and certifying that he was not in possession of material non-public information about Humanigen.

iv. On or about June 15, 2021, CHAPPELL submitted and caused to be submitted SEC Form 144 describing his sale of Humanigen securities. CHAPPELL signed the Form 144, which was submitted to the SEC, and falsely certified that he did "not know any material adverse information in regard to the current and prospective operations of the Issuer of the securities to be sold which ha[d] not been publicly disclosed."

v. On or about June 7, 2021, and between on or about June 21, 2021, and continuing through on or about August 13, 2021, CHAPPELL submitted and caused to be submitted at least eight SEC Form 4s on behalf of the CHAPPELL FUNDS describing his sale of Humanigen securities to the investing public and omitting that he was in possession of material non-public information in

connection with each sale. CHAPPELL signed each Form 4 on behalf of his funds.

s. CHAPPELL misrepresented, concealed, and hid, and caused to be misrepresented, concealed, and hid, the existence, purpose, and acts done in furtherance of the scheme.

t. On or about September 9, 2021, after the FDA notified Humanigen that it had declined to approve the EUA for Lenzilumab, Humanigen publicly announced that the FDA had declined its EUA application for Lenzilumab. Following this announcement, the price of Humanigen's stock dropped approximately 50%, from approximately $15.11 at close on or about September 8, 2021 to approximately $7.97 at close on or about September 9, 2021.

u. During the scheme, by selling Humanigen shares on the basis of material non-public information, CHAPPELL avoided losses of approximately $38 million.

In violation of Title 18, United States Code, Section 1348 and Section 2.

Counts 2-5
(Securities Fraud)

6. The allegations in paragraphs 1-2 and 4-5 of Count 1 are realleged here.

7. On or about the dates specified as to each count below, in the District of New Jersey, and elsewhere, defendant

DALE CHAPPELL

did knowingly and willfully, directly and indirectly, by use of the means and instrumentalities of interstate commerce, and of the mails and facilities of national securities exchanges, in connection with the purchase and sale of securities, use and employ, and cause others to use and employ, manipulative and deceptive devices and contrivances, in violation of Title 17, Code of Federal Regulations, Section 240.10b-5 by: (a) employing, and causing others to employ, devices, schemes, and artifices to defraud; (b) making, and causing others to make, untrue statements of material fact and omitting to state, and causing others to omit to state, material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; and (c) engaging, and causing others to engage, in acts, practices, and courses of business which operated and would operate as a fraud and deceit upon persons, to wit: defendant executed and willfully caused to be executed the securities transactions listed below on the basis of material nonpublic information used in breach of a duty of trust and confidence owed directly and indirectly to Humanigen and its shareholders.

Specific Transactions

Count	Approx. Date	Approx. Number of Humanigen Shares Sold	Approx. Price per Share
2	June 2, 2021	475,000	$18.61
3	June 16, 2021	158,486	$19.41
4	June 25, 2021	1,000,000	$17.80
5	July 23, 2021	5,584	$17.04

In violation of Title 15, United States Code, Sections 78j(b) and 78ff; Title 17, Code of Federal Regulations, Section 240.10b-5; and Title 18, United States Code, Section 2.

FORFEITURE ALLEGATION

1. Upon conviction of one or more of the offenses constituting specified unlawful activity, as defined in 18 U.S.C. § 1956(c)(7), charged in Counts 1 through 5 of this Indictment, defendant DALE CHAPPELL shall forfeit to the United States, pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), all property, real and personal, defendant DALE CHAPPELL obtained that constitutes or is derived from proceeds traceable to the commission of such offenses, and all property traceable to such property.

2. The property subject to forfeiture includes, but is not limited to, the following:

a. Approximately $1,610,582.98 formerly on deposit in Cowen/Pershing account no. PHW-0035XX in the name of Black Horse Capital Master Fund Ltd.;

b. Approximately $4,616,476.16 formerly on deposit in Cowen/Pershing account no. PHW-00097XX in the name of Cheval Holdings Ltd.;

c. Approximately $526,476.97 formerly on deposit in Cowen/Pershing account no. PHW-0031XX in the name of Black Horse Capital LP;

and all property traceable to such property.

Substitute Assets Provision

3. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third person;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be subdivided without difficulty,

it is the intent of the United States, pursuant to 21 U.S.C. § 853(p), as incorporated by 28 U.S.C. § 2461(c), to seek forfeiture of any other property of the defendant up to the value of the forfeitable property described above.

A TRUE BILL

[redacted]

FOREPERSON

Philip R. Sellinger

PHILIP R. SELLINGER
United States Attorney

Glenn A Leon/LSO

GLENN S. LEON
Chief, Fraud Section
United States Department of Justice

CASE NUMBER: _____

United States District Court
District of New Jersey

UNITED STATES OF AMERICA

v.

DALE CHAPPELL

INDICTMENT FOR

18 U.S.C. § 1348
15 U.S.C. §§ 78j(b) & 78ff
17 C.F.R. § 240.10b-5
18 U.S.C. § 2

A True Bill,

[redacted]

Foreperson

PHILIP R. SELLINGER
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FOR THE DISTRICT OF NEW JERSEY

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