

UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES EXCHANGE ACT OF 1934
Release No. 86708 / August 20, 2019

ADMINISTRATIVE PROCEEDING
File No. 3-19362

<p>In the Matter of</p> <p>THERAPEUTICSM D, INC.</p> <p>Respondent.</p>
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ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING CIVIL PENALTIES AND A CEASE-AND-DESIST ORDER

I.

The Securities and Exchange Commission (“Commission”) deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 21C of the Securities Exchange Act of 1934 (“Exchange Act”) against TherapeuticsMD, Inc. (“TherapeuticsMD,” “Respondent,” or “the Company”).

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the “Offer”) that the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission’s jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing Civil Penalties and a Cease-and-Desist Order (“Order”), as set forth below.

III.

On the basis of this Order and Respondent’s Offer, the Commission finds¹ that:

¹ The findings herein are made pursuant to Respondent’s Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

A. SUMMARY

1. This matter concerns selective disclosures of material nonpublic information on two separate occasions in 2017 by TherapeuticsMD to sell-side research analysts who covered the Company. Both disclosures related to the Company's interactions with the Food and Drug Administration ("FDA") concerning potential approval of a TherapeuticsMD drug, TX-004HR. At the time, TX-004HR was one of only two drugs in the Company's development pipeline, and the only drug that was under FDA review.

2. The first selective disclosure followed a June 14, 2017 meeting with the FDA. Following the meeting, on June 15th and 16th, a TherapeuticsMD executive communicated with at least six sell-side analysts about the meeting. On June 16th, TherapeuticsMD's stock price increased significantly, closing up 19.4%, which prompted the New York Stock Exchange ("NYSE") to inquire whether a disclosure of material information might be affecting the stock. TherapeuticsMD did not publicly disclose information about the June 14th meeting that had been shared with the analysts.

3. The second selective disclosure occurred on July 17, 2017, following the Company's early-morning release of an SEC Form 8-K stating that it received the FDA meeting minutes and had submitted new information to the FDA in support of its application for approval. The 8-K contained little detail about the status of approval for TX-004HR, and the Company's stock declined 16% in early trading. Less than an hour later, TherapeuticsMD executives held a call with analysts, disclosing specific details about the discussions at the FDA meeting and the new information submitted in support of TX-004HR's approval. The analysts published notes that afternoon and evening containing details from the call. TherapeuticsMD's stock recovered to close down only 6.6% by market close. TherapeuticsMD did not publicly disclose the specific details about the FDA meeting that had been shared with analysts, or the new information relevant to TX-004HR's approval, until its earnings call held on August 3, 2017.

4. As a result of its conduct, TherapeuticsMD violated Section 13(a) of the Exchange Act and Regulation FD thereunder.

B. RESPONDENT

5. TherapeuticsMD is a public corporation domiciled in Nevada with its principal place of business in Boca Raton, Florida. The Company researches, develops, and commercializes pharmaceutical drugs for women's health issues. TherapeuticsMD's common stock is registered pursuant to Section 12(g) of the Exchange Act and currently trades on NASDAQ. From April 23, 2013 to October 6, 2017, TherapeuticsMD's stock was listed on the NYSE American exchange.

C. FACTS

Background

6. Since at least 2015, TherapeuticsMD has been developing TX-004HR, a hormone drug therapy. On July 7, 2016, TherapeuticsMD submitted an initial New Drug Application (“NDA”) to the Food and Drug Administration (“FDA”) for approval of TX-004HR. On September 19, 2016, the FDA officially accepted the NDA and notified TherapeuticsMD that a Prescription Drug User Fee Act (“PDUFA”) action date—the date by which the FDA was to complete its review of TX-004HR—was set for May 7, 2017. At the time, TX-004HR was one of two drugs TherapeuticsMD had in its development pipeline, and TX-004HR was the only drug yet to advance to the NDA stage.

7. Consistent with the timing specified under PDUFA after filing the NDA for TX-004HR, TherapeuticsMD expected to begin communicating with the FDA on proposed labeling and post-marketing requirements at the beginning of April 2017. However, TherapeuticsMD instead received a letter from the FDA noting that unspecified deficiencies precluded such discussions. TherapeuticsMD disclosed the receipt of the letter in an 8-K and press release on April 10, 2017, resulting in a 19% decline in the Company’s stock on heavy volume.

8. On May 5, 2017, TherapeuticsMD received a Complete Response Letter (“CRL”) from the FDA that cited a single deficiency in the NDA: the lack of long-term safety data for TX-004HR. TherapeuticsMD disclosed the receipt and contents of the CRL in a press release and 8-K before the market opened on May 8, 2017, the next trading day, and the Company’s stock price declined 10.5% that day on heavy volume. TherapeuticsMD requested a meeting with the FDA to discuss the CRL, and it received a meeting date of June 14, 2017. On May 31, 2017, TherapeuticsMD publicly announced the June 14th FDA meeting date in an 8-K that also described the contents of the CRL. The Company explained it had two likely paths forward depending on how the June 14th meeting went: either the FDA would allow them to resubmit a revised NDA (putting TX-004HR back on the path to approval), or the Company would pursue formal dispute resolution against the FDA.

FDA Meeting and Related Selective Disclosures

9. On June 14, 2017, TherapeuticsMD met with the FDA and discussed existing medical studies in support of the Company’s position that TX-004HR did not pose any concerns for endometrial safety. Additionally, TherapeuticsMD discussed preliminary data from a soon-to-be published, long-term NIH study with favorable indicators for TX-004HR. The meeting lasted an hour and ended without the FDA providing a clear path forward for approval of TX-004HR.

10. Certain sell-side research analysts covering TherapeuticsMD were favorable about TX-004HR’s prospects for approval going into the June 14th meeting, and TherapeuticsMD executives assumed analysts and investors would seek news about the status of the NDA following

the meeting. On June 15, 2017, TherapeuticsMD executives held an internal meeting to discuss next steps, including how the Company would respond to anticipated questions.

11. That afternoon, a TherapeuticsMD executive sent emails to each of the six sell-side research analysts covering TherapeuticsMD, writing that the June 14th meeting with the FDA was “very positive and productive,” and that they would be “waiting on meeting minutes to decide on the path forward.” The content of these messages was consistent with the plan that Company executives had developed that morning for responding to anticipated questions. Four of the emails concluded with an offer to discuss further, and at least three of the analysts arranged follow-up phone calls. In a follow-up email to one analyst (“Analyst A”), a TherapeuticsMD executive wrote that TherapeuticsMD was “pleasantly surprised at how accommodating they [FDA officials] were.”

12. On June 16, 2017, TherapeuticsMD’s stock price increased significantly, closing up 19.4% on heavy volume. In the past, stock price and trading volume changes of similar magnitude had coincided with disclosures relating to the progress of TX-004HR through the FDA approval process (see paragraphs 7 and 8 above). At 1:16 PM, a market watch official at NYSE contacted TherapeuticsMD executives, noting that the stock was trading up approximately 21% on heavy volume and asking whether the Company was aware of material information that could be affecting the stock. The Company executives who responded did not know of the emails sent to analysts the prior day and were anticipating market events that day that could cause possible volatility.² They replied that they were not aware of any material information. The executives did not conduct any inquiry to determine the cause of the significant stock price movement, or to assess whether the magnitude of the price movement could be explained by the anticipated volume or possible market volatility that day.

13. On June 19, 2017, Analyst A published a research note about the June 14th meeting calling it “positive,” “productive,” and “accommodating”—using the same language in the TherapeuticsMD executive’s June 15th emails. Analyst A’s report also noted that the fact that the meeting lasted most of the scheduled hour was a positive sign because in a “wors[t] case scenario,” the FDA simply reads the CRL and then the meeting adjourns.

14. TherapeuticsMD did not make any public disclosures about the June 14th FDA meeting until July 17, 2017.

² These executives received a general email notice from NYSE to listed companies on June 15, 2017, about a quarterly market event set to occur on June 16, 2017, when several options and futures contracts would expire on the same day. These NYSE notices were sent every quarter to remind companies that there may be high trading volume and the possibility of extra volatility. In prior quarters on days when these expirations occurred, TherapeuticsMD’s stock saw increased trading volume, but minimal impact on stock price, which traded up only 1% to 4.5%.

Receipt of FDA Minutes and Related Selective Disclosures

15. On July 5, 2017, TherapeuticsMD received the meeting minutes for the June 14th meeting from the FDA.

16. In the early hours of July 17, 2017, TherapeuticsMD released an 8-K and press release updating the investing public on TX-004HR's regulatory approval status following receipt of the formal minutes regarding the June 14th FDA meeting. The press release stated that the meeting had "enabled the Company to present new information" to the FDA that could "address concerns raised by the FDA in the C[omplete] R[esponse] L[etter] and positively affect the status of the NDA for TX-004HR." The release also said that the meeting minutes did not put TX-004HR on a formal timeline for approval, and that TherapeuticsMD continued to reserve its options for moving forward. The press release did not identify or discuss details about the new information provided to the FDA.

17. After TherapeuticsMD published the press release at 6:56 AM on July 17th, its stock price began to decline sharply, falling approximately 16% in pre-market and early trading. Analysts immediately responded in emails to the Company with questions about what the press release meant.

18. At 7:30 AM, TherapeuticsMD executives held a pre-scheduled conference call with the sell-side analysts. During the call TherapeuticsMD executives discussed the meeting with the FDA, identified the new information submitted—which consisted of three previously published medical studies, as well as introducing the FDA to the authors of an ongoing long-term NIH study whose results had not yet been published (the "Newly Submitted Data")—and discussed the significance and relevance of that data to TX-004HR's safety. During the call, at 8:10 AM, a TherapeuticsMD employee sent an email to the analysts attaching the three medical studies that TherapeuticsMD had submitted to the FDA. The email also included a summary from TherapeuticsMD's Chief Medical Officer describing why the Company believed the studies supported their position regarding TX-004HR's safety, and concluding that based upon the findings in these studies, TX-004HR did not have a negative impact on the endometrium and therefore posed no safety risk.

19. Thereafter, in the following hours, each analyst published a research note that included specific information about the FDA meeting and the Newly Submitted Data.

- One analyst's ("Analyst B") report, published at 12:05 PM, stated that the "FDA confirmed there were NO safety signals or hyperplasia in the TX-004HR program" (emphasis in original). Analyst B's report also noted that TherapeuticsMD had submitted safety data to the FDA that the agency had requested, including "details of an NIH-sponsored, long term study."

- Similarly, Analyst A’s report, published at approximately 12:45 PM, noted that the FDA “confirmed no ‘004 safety signal,” and that the FDA and TherapeuticsMD had “discussed NIH data in 93K+ women dose with vaginal E suggesting no LT safety risks,” of which the analyst noted the FDA was reportedly unaware. Analyst A’s report was bullish on TherapeuticsMD’s chances for approval, citing by name one of the studies included in the Newly Submitted Data that the TherapeuticsMD employee had forwarded to the analysts by email that morning, and echoing that email’s explanation for why the study proved TX-004 had no safety issues. The report concluded that the Newly Submitted Data was a positive sign that TX-004HR would be approved.
- Four other analyst reports published on July 17th contained similar information.

20. By the end of the day on July 17th, the stock had rebounded from its 16% downward movement in the early hours of trading to finish down only 6.6% by market close.

21. TherapeuticsMD did not publicly disclose what Newly Submitted Data it had provided to the FDA, or the Newly Submitted Data’s application to TX-004HR in terms of safety, until its earnings call held on August 3, 2017.

22. In June and July 2017, the time of the conduct described above, TherapeuticsMD did not have policies or procedures relating to compliance with Regulation FD. TherapeuticsMD subsequently implemented policies and procedures which, among other things, (a) require public disclosure of material, nonpublic information in connection with Regulation FD, (b) provide examples of types of material, nonpublic information that may arise in light of TherapeuticsMD’s business model, and (c) establish specific review protocols for all external communications, including earnings calls, analyst meetings, and press releases. TherapeuticsMD also now requires Regulation FD Training for employees.

D. LEGAL ANALYSIS

23. Regulation FD prohibits public companies, or persons acting on their behalf, from selectively disclosing material, nonpublic information to certain persons outside the company, including institutional investors, securities analysts, and other securities professionals. *See generally* Final Rule: Selective Disclosure and Insider Trading, Exchange Act Rel. No. 43154, 65 Fed. Reg. 51,716 (Aug. 15, 2000) (hereinafter the “Adopting Release”). Whenever a public company discloses material, nonpublic information to any such person, Regulation FD requires that the company also disclose the information to the public. 17 C.F.R. § 243.100(a). Information is material if there is a substantial likelihood that a reasonable investor would consider the information important in making an investment decision or if the information would significantly alter the total mix of available information.³ *Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988).

³ Regulation FD applies the definition of “materiality” established by existing case law. *See* Adopting Release at 51721.

Information is nonpublic if it has not been disseminated in a manner making it available to investors generally. Adopting Release, 65 Fed. Reg. at 51721.

24. Where a selective disclosure is “intentional,” the company must simultaneously make public disclosure with the selective disclosure. 17 C.F.R. § 243.100(a)(1). Under Regulation FD, intentional is defined as “when the person making the disclosure either knows, or is reckless in not knowing, that the information he or she is communicating is both material and nonpublic.” 17 C.F.R. § 243.101(a). When the disclosure is “non-intentional,” the public disclosure must be made “promptly,” which Regulation FD defines to mean “as soon as reasonably practicable (but in no event after the later of 24 hours or the commencement of the next day’s trading on the New York Stock Exchange).” 17 C.F.R. §§ 243.100(a)(2) and 243.101(d). A public company’s failure to make a required public disclosure pursuant to Regulation FD constitutes violations of both Regulation FD and Section 13(a) of the Exchange Act. *See* Adopting Release, 65 Fed. Reg. at 51726.

25. As Regulation FD created reporting duties for issuers under Section 13(a) of the Exchange Act, by violating Regulation FD an issuer also violates Section 13(a). *See* “Final Rule: Selective Disclosure and Insider Trading,” Exchange Act Rel. 34-43154 (August 15, 2000) (noting that an issuer that fails to comply with Regulation FD is subject to an enforcement action under Section 13(a)).

26. As a result of the conduct described above, TherapeuticsMD violated Regulation FD and Exchange Act Section 13(a) in June and July 2017 by providing material, nonpublic information bearing on TX-004HR’s approval prospects to its sell-side analysts, and by failing to simultaneously or promptly publicly disclose that information as required by Regulation FD. Because TherapeuticsMD failed to simultaneously publicly disseminate the material information in accordance with Regulation FD, the investing public was placed at a disadvantage relative to the analysts and their subscribers who were privy to the selective disclosures.

27. In determining to accept the Offer, the Commission considered cooperation afforded the Commission staff and remedial acts undertaken by Respondent.

IV.

Based on the forgoing, the Commission finds that TherapeuticsMD violated Section 13(a) of the Exchange Act, 15 U.S.C. § 78m(a), and Regulation FD, 17 C.F.R. § 243.100, et seq.

V.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Respondent’s Offer.

Accordingly, it is hereby ORDERED that:

A. Pursuant to Section 21C of the Exchange Act, Respondent cease and desist from committing or causing any violations and any future violations of Section 13(a) of the Exchange Act and Regulation FD.

B. Respondent shall, within 14 days of the entry of this Order, pay a civil money penalty in the amount of \$200,000.00 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. §3717.

Payment must be made in one of the following ways:

- (1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;
- (2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at <http://www.sec.gov/about/offices/ofm.htm>; or
- (3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center
Accounts Receivable Branch
HQ Bldg., Room 181, AMZ-341
6500 South MacArthur Boulevard
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying TherapeuticsMD as the Respondent in this proceeding, and the file number of this proceeding; a copy of the cover letter and check or money order must be sent to Carolyn Welshhans, Associate Director, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Washington, DC 20549.

C. Amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed

an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a “Related Investor Action” means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

By the Commission.

Vanessa A. Countryman
Secretary