

## COLLABORATIVE INSIGHTS

July 25, 2019

- Cannabis
- WRG Cannabis

### COWEN WASHINGTON RESEARCH GROUP MACRO POLICY

**Eric Assaraf**  
202 868 5304  
eric.assaraf@cowen.com

### COWEN RESEARCH

#### EQUITY RESEARCH

**Vivien Azer**  
646 562 1351  
vivien.azer@cowen.com

**Gerald Pascarelli, CFA**  
646 562 1362  
gerald.pascarelli@cowen.com

**Steven Schneiderman**  
646 562 1306  
steven.schneiderman@cowen.com

Any portion of this report prepared by a member of Cowen Washington Research Group is intended as commentary on political, economic or market conditions and is not intended as a research report as defined by applicable regulation.

## COLLABORATIVE INSIGHTS

# FDA UPDATE ON CBD COMING THIS FALL, BUT DON'T EXPECT SWIFT ACTION

### THE COWEN INSIGHT

FDA will issue an update this fall on the agency's plan for developing a regulatory pathway for cannabis-derived products including CBD. However, we doubt that it will provide any regulatory certainty for CBD and that congressional intervention will likely be needed.

#### What Happened (Eric Assaraf - Cowen Washington Research Group)

FDA will issue an update this fall on the agency's plan for developing a regulatory pathway for cannabis-derived products including cannabidiol (CBD), according to comments this week from FDA Principal Deputy Commissioner Amy Abernethy.

The statement from Abernethy, who also co-chairs the FDA's CBD working group, follows an active few weeks on cannabis for the agency. The FDA received a total of 4,492 comments at the close of its comment period last week on the regulation of cannabis products.

On Tuesday, Acting FDA Commissioner Ned Sharpless also outlined a [warning letter](#) the agency sent to CBD manufacturer Curaleaf for making unsubstantiated health claims for CBD, including treating cancer and Alzheimer's, among other conditions, while also selling unapproved CBD products online. Of note, CVS announced that they were pulling Curaleaf's products from its shelves today.

Several other companies were sent similar warning letters earlier this year, and in our view, the fact that FDA has taken the extra step of issuing an [announcement](#) shows that it wants to use the warning letter as a teaching moment -- how far a company has to go to incite a response and letting the litany of unsupported claims carry the message. At the same time, the situation allows the agency to restate its intention of advancing the development of lawful cannabis-derived products.

This morning, Abernethy also testified before the Senate Agriculture Committee on the topic of "Hemp Production and the 2018 Farm Bill." In her [opening statement](#), Abernethy repeated the FDA's message -- the 2018 Farm Bill did not change FDA's authority over CBD and since there is now an FDA-approved drug with CBD as an active ingredient (**GW Pharma's Epidiolex**), CBD cannot be added to food products sold across state lines or marketed as a dietary supplement.

Further, Abernethy states that although current law allows the FDA to make certain exceptions through notice and comment rulemaking on provisions that prohibit adding active drug ingredients to foods or marketing them as dietary supplements, "it is important to note that it can take three to five years to complete even an expedited notice and comment rulemaking process..." However, Abernethy asserts that the agency is "exploring options to reach a resolution more quickly and efficiently."

As we wrote in our [Feb. 28 Bulletin](#), we believe the FDA is sincere in wanting to explore new pathways for hemp-derived CBD to be sold legally in the food and supplement markets, while protecting research into future pharmaceutical applications. However, those actions will have to fit under the confines of current law and further legislation will likely be needed to speed up the process.

We also doubt that the FDA's update this fall will provide any regulatory certainty for CBD. In our view, the agency is more likely to issue a summary of the comments it received, outline the regulatory history of CBD, and provide an initial definition of key baseline terms differentiating between Hemp/CBD/ THC and what the Farm Bill said in layman terms. The agency may also make a determination on whether a new regulatory framework that addresses safety concerns is even possible. However, we believe that would likely be the start of the process and not the conclusion.



For a primer on the CBD industry see Cowen's Feb. 25 report, "[Cowen's Collective View of CBD - Ahead of the Curve Series](#)."

### **What It Means for Companies (Vivien Azer)**

We do not envision a near-term change to CBD form factor availability from cannabis-based companies. While we think that companies will continue to focus on CBD vapor, topicals, and tinctures, the product offerings are unlikely to make health-based claims in order to stay off the FDA's radar. Further, though companies are currently selling CBD food and beverage products for interstate commerce (most notably via e-commerce), that could face incremental regulatory headwinds. In aggregate, we note that food and beverages represent only \$3.5 bn of our \$16 bn CBD TAM.

While interstate commerce for food products would fall under the FDA's purview, we note that companies could still develop these products for intrastate commerce and operate within state borders that permit these products, albeit without scale benefits from interstate distribution which would likely prove expensive. As such, we think these products are more likely to originate from smaller, niche companies.

For companies under our coverage, we are not making changes to our financial estimates from today's commentary. While TLRY, WEED and TPB have already made initial forays into U.S. CBD, none of these companies have introduced food or beverage-based CBD products, nor do we reflect this possibility in our estimates. We note that WEED has discussed the possibility of a CBD "recovery drink" down the line, and may develop said product in Canada in the interim. While CRON and ACB have yet to formalize plans for U.S. entry, we would envision that given both of their positions on novel form factors in Canada that both would be most likely to pursue CBD vapor opportunities in the U.S, particularly CRON given their development of next generation vapor technology and relationship with MO. Earlier this week, ACB announced a joint research initiative on hemp-derived CBD with the UFC. In addition, we think today's hearing likely keeps PEP and KO on the sidelines for developing CBD and other cannabis-based products.

## VALUATION METHODOLOGY AND RISKS

---

### Valuation Methodology

---

**Cannabis:** Our valuation methodology is primarily based on Relative EV-to-Sales (EV-to-Sales divided by Sales-Growth), followed by EV-to-Sales.

### Investment Risks

---

**Cannabis:** Cannabis is an emerging industry and is subject to regulatory headwinds. While over 50% of the population is in favor of legalization, only a few states have thus far legalized cannabis for recreational use and the product remains illegal at the federal level. Looking forward, much work and change still needs to occur in order for this industry to realize its full potential.

**Risks Pertaining to U.S. Cannabis-Related Companies:** If you are considering investing in a U.S. company that is connected to the cannabis industry, be aware that cannabis-related companies may be at risk of federal and/or state criminal prosecution. The Department of Treasury has issued guidance that The Controlled Substances Act ("CSA") makes it illegal under U.S. federal law to manufacture, distribute, or dispense cannabis and cannabis-related products. Many states impose and enforce similar prohibitions. Notwithstanding the federal ban, however, many U.S. states and the District of Columbia have legalized certain cannabis-related activities.

**Risks Pertaining to Canadian Cannabis-Related Companies:** In Canada, cannabis is an emerging industry and is subject to regulatory headwinds. While both medical and adult-use cannabis is legal in Canada, the category will be subject a number of potential headwinds, including taxes and restrictions on form factors and packaging.

---

## ADDENDUM

### Important Disclosures and Information Relating to Cowen Washington Research Group

Cowen Washington Research Group produces commentaries on political, economic or market conditions. Commentaries produced by Cowen Washington Research Group are not intended as research reports as defined in FINRA Rule 2241 Research Analysts and Research Reports or FINRA Rule 2242 Debt Research Analysts and Debt Research Reports. Sections of this report noted as authored by Cowen Washington Research Group have not been prepared, are not intended, and should not be interpreted as a research report or investment recommendation regarding securities of any company. Investors should not consider purchasing or selling securities based upon any information contained in sections of the report denoted as authored by Cowen Washington Research Group.

### Cowen Research Analyst Certification

Each author of this research report hereby certifies that (i) the views expressed in the research report accurately reflect his or her personal views about any and all of the subject securities or issuers, and (ii) no part of his or her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed in this report.

### Important Disclosures Relating to Cowen Research

Cowen and Company, LLC compensates research analysts for activities and services intended to benefit the firm's investor clients. Individual compensation determinations for research analysts, including the author(s) of this report, are based on a variety of factors, including the overall profitability of the firm and the total revenue derived from all sources, including revenues from investment banking, sales and trading or principal trading revenues. Cowen and Company, LLC does not compensate research analysts based on specific investment banking transactions or specific sales and trading or principal trading revenues.

### Disclaimer

Our research reports and commentaries are simultaneously available to all clients on our client website. Research reports and commentaries are for our clients only. Not all research reports and commentaries are disseminated, e-mailed or made available to third-party aggregators. Cowen and Company, LLC is not responsible for the redistribution of research or commentaries by third party aggregators. Selected research reports and commentaries are available in printed form in addition to an electronic form. All published research reports and commentaries can be obtained on the firm's client website, <https://cowenlibrary.bluematrix.com/client/library.jsp>.

The information, opinions, estimates and forecasts are as of the date of this report and subject to change without prior notification. We seek to update our research and commentaries as appropriate, but various regulations may prevent us from doing so. Research reports and commentaries are published at irregular intervals as appropriate in the analyst's judgement.

Further information on subject securities may be obtained from our offices. This research report is published solely for information purposes, and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state where such an offer or solicitation would be illegal. Other than disclosures relating to Cowen and Company, LLC, the information herein is based on sources we believe to be reliable but is not guaranteed by us and does not purport to be a complete statement or summary of the available data. Any opinions expressed herein are statements of our judgment on this date and are subject to change without notice. The opinions and recommendations herein do not take into account individual client circumstances, objectives or needs and are not intended as recommendations of investment strategy. The recipients of this report must make their own independent decisions regarding any securities subject to this research report. In some cases, securities and other financial instruments may be difficult to value or sell and reliable information about the value or risks related to the security or financial instrument may be difficult to obtain. To the extent that this report discusses any legal proceedings or issues, it has not been prepared to express or intended to express any legal conclusion, opinion or advice. Our salespeople, traders and other professionals may provide oral or written market commentary or trading strategies to our clients that reflect opinions that are contrary to the opinions expressed in our research. Our principal trading area and investing businesses may make investment decisions that are inconsistent with recommendations or views expressed in our research. Cowen and Company, LLC maintains physical, electronic and procedural information barriers to address the flow of information between and among departments within Cowen and Company, LLC in order to prevent and avoid conflicts of interest with respect to analyst recommendations.

For important disclosures regarding the companies that are the subject of this research report, please contact Compliance Department, Cowen and Company, LLC, 599 Lexington Avenue, 20th Floor, New York, NY 10022. In addition, the same important disclosures, with the exception of the valuation methods and risks, are available on the Firm's disclosure website at <https://cowen.bluematrix.com/sellside/Disclosures.action>.

**Equity Research Price Targets:** Cowen and Company, LLC assigns price targets on all companies covered in equity research unless noted otherwise. The equity research price target for an issuer's stock represents the value that the analyst reasonably expects the stock to reach over a performance period of twelve months. Any price targets in equity securities in this report should be considered in the context of all prior published Cowen and Company, LLC equity research reports (including the disclosures in any such equity report or on the Firm's disclosure website), which may or may not include equity research price targets, as well as developments relating to the issuer, its industry and the financial markets. For equity research price target valuation methodology and risks associated with the achievement of any given equity research price target, please see the analyst's equity research report publishing such targets.

**Cowen Cross-Asset Research:** Due to the nature of the fixed income market, the issuers or debt securities of the issuers discussed in "Cowen Cross-Asset Research" reports do not assign ratings and price targets and may not be continuously followed. Accordingly, investors must regard such branded reports as providing stand-alone analysis and reflecting the analyst's opinion as of the date of the report and should not expect continuing analysis or additional reports relating to such issuers or debt securities of the issuers.

From time to time "Cowen Cross-Asset Research" analysts provide investment recommendations on securities that are the subject of this report. These recommendations are intended only as of the time and date of publication and only within the parameters specified in each individual report. "Cowen Cross-Asset Research" investment recommendations are made strictly on a case-by-case basis, and no recommendation is provided as part of an overarching rating system or other set of consistently applied benchmarks. The views expressed in "Cross-Asset Research" report may differ from the views offered in the firm's equity research reports prepared for our clients.

**Notice to UK Investors:** This publication is produced by Cowen and Company, LLC which is regulated in the United States by FINRA. It is to be communicated only to persons of a kind described in Articles 19 and 49 of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. It must not be further transmitted to any other person without our consent.

**Notice to European Union Investors:** Individuals producing recommendations are required to obtain certain licenses by the Financial Regulatory Authority (FINRA). You can review the author's current licensing status and history, employment history and, if any, reported regulatory, customer dispute, criminal and other matters via "Brokercheck by FINRA" at <http://brokercheck.finra.org/>. An individual's licensing status with FINRA should not be construed as an endorsement by FINRA. General biographical information is also available for each Research Analyst at [www.cowen.com](http://www.cowen.com).

Additionally, the complete preceding 12-month recommendations history related to recommendation in this research report is available at <https://cowen.bluematrix.com/sellside/Disclosures.action>

The recommendation contained in this report was produced at July 25, 2019, 16:40 ET. and disseminated at July 25, 2019, 16:40 ET.

**Copyright, User Agreement and other general information related to this report**

© 2019 Cowen and Company, LLC. All rights reserved. Member NYSE, FINRA and SIPC. This research report is prepared for the exclusive use of Cowen clients and may not be reproduced, displayed, modified, distributed, transmitted or disclosed, in whole or in part, or in any form or manner, to others outside your organization without the express prior written consent of Cowen. Cowen research reports are distributed simultaneously to all clients eligible to receive such research reports. Any unauthorized use or disclosure is prohibited. Receipt and/or review of this research constitutes your agreement not to reproduce, display, modify, distribute, transmit, or disclose to others outside your organization. All Cowen trademarks displayed in this report are owned by Cowen and may not be used without its prior written consent.

**Cowen and Company, LLC.** New York 646 562 1010 **Boston** 617 946 3700 **San Francisco** 415 646 7200 **Chicago** 312 577 2240 **Cleveland** 440 331 3531 **Atlanta** 866 544 7009 **Stamford** 646 616 3000 **Washington, D.C.** 202 868 5300 **London** (affiliate) 44 207 071 7500

**COWEN AND COMPANY EQUITY RESEARCH RATING DEFINITIONS**

**Outperform (1):** The stock is expected to achieve a total positive return of at least 15% over the next 12 months

**Market Perform (2):** The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

**Underperform (3):** Stock is expected to achieve a total negative return of at least 10% over the next 12 months

**Assumption:** The expected total return calculation includes anticipated dividend yield

**Cowen and Company Equity Research Rating Distribution**

**Distribution of Ratings/Investment Banking Services (IB) as of 06/30/19**

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	495	63.38%	114	23.03%
Hold (b)	279	35.72%	14	5.02%
Sell (c)	7	0.90%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's equity research rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's equity research ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's equity research ratings definitions. Cowen and Company Equity Research Rating Distribution Table does not include any company for which the equity research rating is currently suspended or any debt security followed by Cowen Credit Research and Trading.

Note: "Buy", "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with FINRA regulation.

This report is intended for jhallam@mmjgh.com.au. Unauthorized redistribution of this report is prohibited.

## POINTS OF CONTACT

### Author Profiles



**Eric Assaraf**  
Washington, DC  
202 868 5304  
eric.assaraf@cowen.com

Eric Assaraf is with Cowen Washington Research Group covering health care. He received degrees from the University of Maryland.



**Vivien Azer**  
New York  
646 562 1351  
vivien.azer@cowen.com

Vivien Azer is a senior analyst covering beverages, tobacco and cannabis. She joined Cowen in 2014.



**Gerald Pascarelli, CFA**  
New York  
646 562 1362  
gerald.pascarelli@cowen.com

Gerald Pascarelli is an associate covering beverages. He joined Cowen in 2014.



**Steven Schneiderman**  
New York  
646 562 1306  
steven.schneiderman@cowen.com

Steven Schneiderman is an associate covering tobacco and cannabis. He joined Cowen in 2018.

### Reaching Cowen

#### Main U.S. Locations

##### New York

599 Lexington Avenue  
New York, NY 10022  
646 562 1010  
800 221 5616

##### Atlanta

3399 Peachtree Road NE  
Suite 417  
Atlanta, GA 30326  
866 544 7009

##### Boston

Two International Place  
Boston, MA 02110  
617 946 3700  
800 343 7068

##### Chicago

181 West Madison Street  
Suite 3135  
Chicago, IL 60602  
312 577 2240

##### Cleveland

20006 Detroit Road  
Suite 100  
Rocky River, OH 44116  
440 331 3531

##### Stamford

262 Harbor Drive  
Stamford, CT 06902  
646 616 3000

##### San Francisco

One Maritime Plaza, 9th Floor  
San Francisco, CA 94111  
415 646 7200  
800 858 9316

##### Washington, D.C.

2900 K Street, NW  
Suite 520  
Washington, DC 20007  
202 868 5300

#### International Location

##### Cowen International Limited

##### London

1 Snowden Street - 11th Floor  
London EC2A 2DQ  
United Kingdom  
44 20 7071 7500

