September 4, 2024

Zacks Small-Cap Research (NOTE)

Sponsored – Impartial - Comprehensive

John D. Vandermosten, CFA
312-265-9588
jvandermosten@zacks.com

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Achieve Life Sciences, Inc. (ACHV: NASDAQ)

ACHV: New Skipper at the Helm

Research Note

Achieve Life Sciences, Inc. (NASDAQ: ACHV) announced a shift in its most senior ranks with Richard Stewart re-assuming his role as CEO and Thomas King, taking over as Executive Chairman. Richard Stewart had previously held the CEO role at Achieve changing the mantle of command to John Bencich in Fall of 2020. Mr. Stewart has now returned as negotiations with potential acquirors accelerate at flank speed. Now is the time for the co-founder and executive chairman to draw on their skills and experience in transactions and commercialization to illuminate the opportunities that lay ahead for cytisinicline. The senior team plans to demonstrate the potential of the drug by identifying and characterizing the broad markets that it can serve in smoking cessation, vaping cessation and in patients with comorbidities such as Chronic Obstructive Pulmonary Disease (COPD).

Achieve has completed two pivotal Phase III studies for smoking cessation and one Phase II study in vaping cessation. An open label (OL) safety trial is now underway designated the ORCA-OL study which is expected to support a new drug application (NDA) filing in 1H:25. As these final pieces are put into place, management has been interacting with potential acquirors. The goal is to demonstrate that the nicotine addiction market of almost 20 years ago when Chantix was approved has evolved and there are many new opportunities. In the mid-2000s, vaping was rare and those with nicotine addiction were influenced through different media and methods.

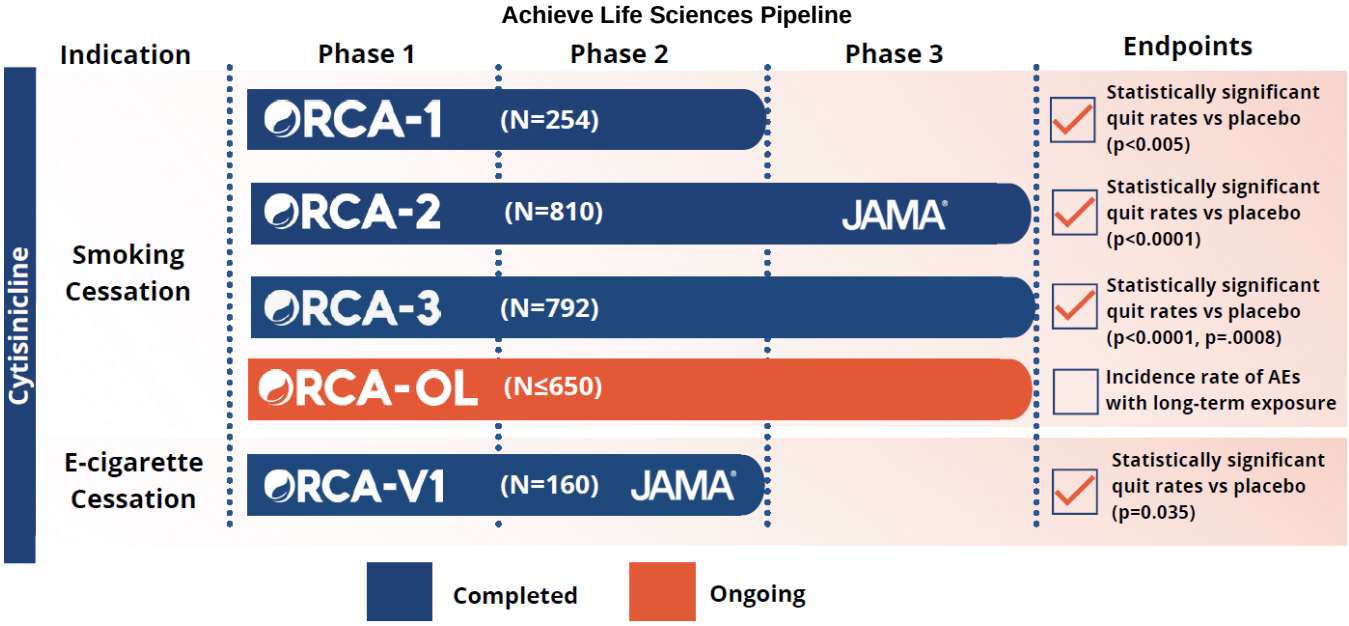
With the advent of vaping, which had been seen as a method of smoking cessation, the nicotine addiction environment has changed. There are an estimated 11 million adult e-cigarette users in the United States and over two million students using the devices. Vapers are markedly younger than smokers and are more likely to respond to different awareness strategies due to changes in the way these individuals respond to marketing, their health profile and the way medical products and services are commercialized compared to 20 years ago. Management identified a few broad categories, each of which requires a different approach. These include three approximately evenly distributed groups: dual users, vapers who are former smokers and vapers who have never smoked.

Management will approach the nicotine addiction market in a new way that may be able to dramatically expand penetration into categories that were previously ignored. One example is Chronic Obstructive Pulmonary Disease (COPD). COPD patients have acquired their disease most often from irritating gasses or particulate matter, most often from cigarette smoke. Smoking cessation for these individuals slows disease progression, reduces symptoms, decreases inflammation and improves overall health, which can extend life and reduce care costs. About 15% of smokers have COPD (about 4.2 million), and if they lack the will to quit, they will need the encouragement and support of their pulmonologist to identify a safe and effective treatment. To access the COPD market in the US, a sales team can pursue critical care physicians and pulmonologists identifying cytisinicline as an alternative way to treat the condition through smoking cessation. Other diseases that are exacerbated by smoking are also potential candidates for cytisinicline. Success in these indications could be effectively evaluated through the use of biomarkers such as lung function for COPD.

© Copyright 2024, Zacks Investment Research. All Rights Reserved.

Achieve management's strategy will expand advocacy from participation in Society for Research on Nicotine and Tobacco (SRNT) events and conferences to other groups including the American Heart Association and the American Cancer Society. Marketing will be another focal point that may be better served through a digital strategy in contrast to hiring large salesforces to support physician awareness. The digital strategy may also be more effective in raising awareness in young vapers who may not understand the risks they are taking with the product.

Running several cytisinicline trials has provided insight into the market helping Achieve understand which physicians are writing the scripts and how patients respond. To further expand this knowledge, the company has been working with a medical affairs expert that has deep connections in the community. This individual will help build a network that can identify patient groups that can best benefit from cytisinicline. The preparation will demonstrate the value of cytisinicline and its broad opportunities to potential suitors and maximize the drug's value in the market. Achieve management expects to look deep into its own data augmented by a commissioned study to identify the best approach for pursuing these opportunities.



Source: Achieve Life Sciences July 2024 Corporate Presentation

Summary

Achieve has shown impressive safety and efficacy in its Phase III trials and is in the last stages of preparing for submission of an NDA. The FDA's request for a long-term safety study has materialized into ORCA-OL which has successfully launched and enrolled at a better-than-expected pace. Now that the company has everything in place to generate and prepare the necessary data for a successful NDA submission, we will watch closely to see if some of the timelines can be narrowed from the announced 1H:25 submission target. The management change shifting Richard Stewart to the CEO role and Thomas King to Executive Chairman was effected to put two experts with a wealth of experience in transactions and commercialization in positions of leadership. This new senior team plans to show that cytisinicline's applicability is much broader than what it was for Chantix almost 20 years ago. Vapers have different characteristics than smokers, particularly their age and how they respond to marketing. Sales methods have also changed, with large primary care sales teams less effective and more expensive than they used to be. Furthermore, the market can be increasingly segmented with better data and complementary analysis. There are diseases related to smoking that have not previously been pursued using a nicotine addiction product and where cytisinicline could serve as indirect therapy. We expect to hear additional updates on Achieve's message in coming months as management refines its strategy while maintaining their course preparing and submitting an NDA to the FDA next year.

DISCLOSURE

SUBSCRIBE TO ZACKS SMALL CAP RESEARCH to receive our articles and reports emailed directly to you each morning. Please visit our website for additional information on Zacks SCR.

DISCLOSURE: Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm, engaged by the issuer, for providing research coverage for a period of no less than one year. Research articles, as seen here, are part of the service Zacks provides and Zacks receives payments for these services. Full Disclaimer HERE.