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Achieve Life Sciences, Inc. (ACHV - NASDAQ)

Fourth Quarter and Full Year 2020 Results

Based on our DCF model and a 15% discount rate, ACHV is valued at approximately $50.00 per share. Our model applies a 30% probability of eventual cytisinicline sales based on historical Phase II trial success ratios and data generated to date. Our valuation includes geographic contributions from the United States only.

Current Price (3/12/2021)	$11.65
Valuation	**$50.00**

OUTLOOK

Achieve Life Sciences is developing cytisinicline for use as a smoking cessation treatment for approval and commercialization in the United States and RoW. The candidate recently completed a Ph2b optimization clinical trial which provided detailed data in September 2019.

Two Ph3 studies are planned with the first underway and the second based on availability of additional funding. The trials will compare cytisinicline with placebo combined with counseling. The primary endpoint is abstinence at 6 and 12 weeks.

Current products on the market have only limited effectiveness and come with unpleasant side effects including nausea, vivid dreams, insomnia and GI issues. Cytisinicline may fill a void in the prescription and NRT market by reducing nicotine cravings, the severity of withdrawal and the reward associated with smoking along with fewer side effects and shorter treatment duration. There are almost 40 million smokers in the US and over 1 billion globally, providing a substantial population demanding an improved smoking cessation product.

ACHV launched the first of its Ph3 trials in 3Q:20 and will begin enrolling in earnest by beginning of year 2021. We anticipate a 2024 commercialization of cytisinicline.

SUMMARY DATA

52-Week High	**18.26**
52-Week Low	**4.60**
One-Year Return (%)	**66.4**
Beta	**1.3**
Average Daily Volume (sh)	**309,334**
Shares Outstanding (mil)	**6.15**
Market Capitalization ($mil)	**71.6**
Short Interest Ratio (days)	**1.95**
Institutional Ownership (%)	**15.1**
Insider Ownership (%)	**0.48**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2021					$0.0 E
2022					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$17.57 A	-$10.08 A	-$9.07 A	-$5.91 A	-$39.76 A
2020	-$2.15 A	-$1.68 A	-$1.14 A	-$1.11 A	-$5.42 A
2021					-$4.33 E
2022					-$3.55 E

*2019 quarterly does not sum to full year due to distorting effects of share issuance

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WHAT'S NEW

Fourth Quarter and Fiscal Year 2020 Results

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported fourth quarter and fiscal year 2020 results in a press release and conference call held after market close on March 12, 2021. The company concurrently filed its 10-K with the SEC. Highlights from 2020 include the initiation of Phase III ORCA-2 trial, the closing of $17.3 million financing, and the hosting of a smoking cessation Key Opinion Leader (KOL) Virtual Roundtable. In February following the reporting period, Achieve also presented survey data on smoker and e-cigarette user attitudes and perceptions on quitting at the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting.

Achieve produced no revenues in FY:20 or in FY:19 and generated operating expense of $14.8 million and $16.5 million in each of the years, respectively.

For the fiscal year ending December 31, 2020 and versus the fiscal year ending December 31, 2019:

- Research & development expense was $6.88 million down 29% from $9.67 million driven primarily by the completion of ORCA-1 trial in June 2019, partially offset by costs related to the initiation of ORCA-2 trial in October 2020;
- General & administrative expense rose 15% to $7.87 million from $6.85 million due to higher employee costs, increased patent development activity, additional market research and public relations activity, as well as increased insurance premiums, partially offset by lower travel expenses;
- Interest income totaled $69,000, down 60% from $170,000;
- Other expenses of ($49,000) compare to prior period amount of ($37,000);
- Net loss was ($14.7) million vs. prior period loss of ($16.4) million;

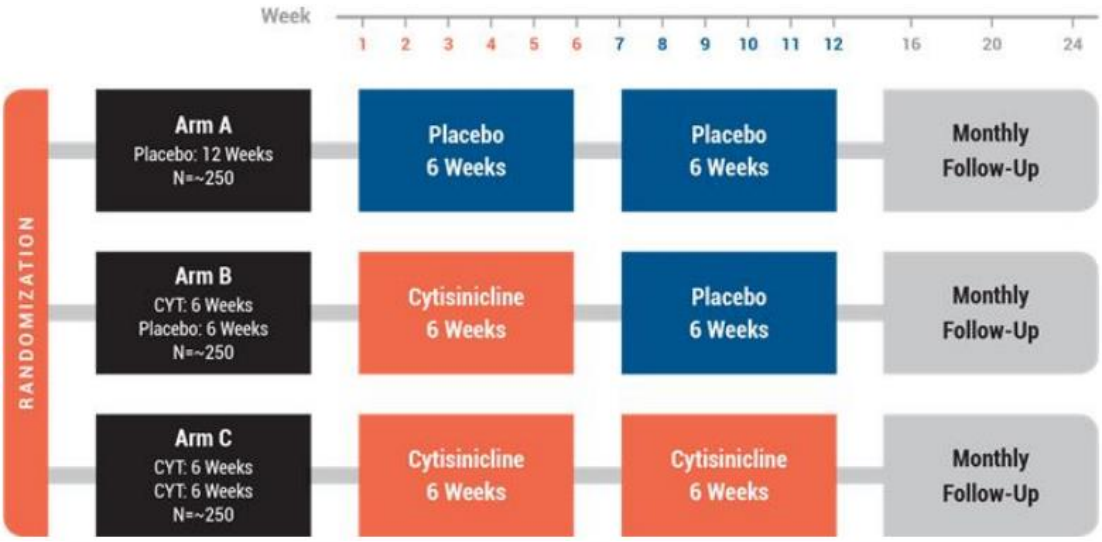
As of December 31, 2020, cash and equivalents stood at $35.9 million, which includes proceeds from the $17.3 million raise completed in December 2020. This amount compares to $16.7 million in cash and equivalents held at the end of 2019. Cash used in operations was $13.5 million, about $2 million better vs. the $15.3 million consumed in 2019. Cash contributed from financing in 2020 was $32.7 million, sourced from warrant exercise, private placements, registered direct offerings and public offerings throughout the year.

ORCA-2 Phase III Trial

Achieve announced the start of its Phase III ORCA-2 trial on October 7th 2020, targeting enrollment of 750 smokers at 15 clinical sites throughout the United States. The trial is a multi-center, double-blind, randomized, placebo-controlled Phase III study that will enroll adult cigarette smokers who intend to quit smoking. Subjects will be randomized into one of three arms which include 12 weeks of placebo, six weeks of cytisinicline then six weeks of placebo or 12 weeks of cytisinicline. Dosing will be 3.0 mg, three times daily in each of the treatment cohorts. This dosing regimen is expected to be effective against even high nicotine use prior to cessation as cytisinicline efficiently binds nicotinic acetylcholine receptors.

The trial began with metered enrollment to ensure it launched successfully. The ramp was expected to begin in earnest following the New Year to coincide with traditional resolutions to stop smoking. However, enrollment has been slower than anticipated and did not experience the assertive start that was observed in ORCA-1. The slow beginning was attributed to impacts from the pandemic and winter weather that made it difficult to reach clinical sites. In contrast to January and February, March 2021 has seen a jump in enrollment that matches initial expectations. Measures are now being taken to encourage further enrollment in ORCA-2, including radio interviews with local principal investigators to stimulate interest and web and social media advertising.

Exhibit I – ORCA-2 Phase III Trial Design[1]



The primary endpoints for the ORCA-2 study will be the rate of smoking abstinence at the end of 6- and 12-week treatment periods compared to placebo. Abstinence will be defined as no smoking during the last four weeks of treatment using weekly CO biochemical verification. Secondary endpoints will be based upon continued smoking abstinence until week 24 from the end of treatment and identify a reduction in the risk of relapse for subjects on the 6 week treatment regimen compared to the 12 week. Efforts have been made to prepare sites to comply with COVID-19 restrictions.

An important modification of the ORCA-2 study that is in contrast to the historical dosing conventions is the extension of treatment with cytisinicline from 25 days to 12 and 24 weeks. In the Phase III trial, smoking abstinence is measured as continuous abstinence during the last four weeks of treatment. Extending the dosing period will allow trial participants to be on therapy while they are being measured for abstinence. Quit rates are higher when subjects are on treatment and this change should align measurement of cytisinicline's effectiveness to be on par with other smoking cessation therapies that have been approved.

Management provided an update on remaining NDA-enabling actions regarding ORCA-2. Achieve recently submitted 9-month chronic toxicity study required for the NDA. Over the next few months, management anticipates the completion of the carcinogenicity study and has already submitted the second carcinogenicity protocol for FDA review as Special Protocol Assessment (SPA), with an update anticipated in April 2021. Pending feedback from the FDA, the second carcinogenicity study would commence, the final nonclinical study required. Management also guided toward the initiation of required abuse liability studies in 2Q:21.

Capital Raises

Achieve completed a registered direct offering of 731,707 shares at $8.20 per share on July 1, 2020. This effort raised gross proceeds of $6.0 million and net funds of $5.5 million. On August 3rd, 2020, Achieve announced a public offering of 712,000 shares and pre-funded warrants for $10.50 per unit. The effort is expected to raise $7.5 million gross and $6.8 million in net proceeds. The underwriter has an option to purchase 93,000 additional shares.

On October 20, 2020 Achieve terminated its At-The-Market (ATM) Offering Agreement that it signed with H.C.Wainwright in June 2019. No sales were made under this facility.

In December 2020, Achieve successfully closed a public offering of 2,472,500 shares at a price of $7.00 per share for total gross proceeds of $17.3 million. Underwriter over-allotment was fully exercised for 322,500 additional shares.

Achieve successfully raised funds from warrant exercises during 2020 which generated $3.2 million in cash.

[1] Source: Achieve Life Sciences S-1 Filed November 6, 2019.

Virtual Smoking Cessation KOL Roundtable

Achieve hosted a web conference on November 17, 2020 featuring company management, equity analysts and key opinion leaders (KOLs) in the tobacco and nicotine addiction space. The group presented data from Achieve's ORCA-1 trial and from the New Zealand RAUORA study, highlighted features of cytisinicline that moderate the side effect profile, examined the relationship between COVID and smoking and reviewed the ORCA-2 trial.

Achieve Life Sciences Participants:

- John Bencich, Chief Executive Officer
- Cindy Jacobs, Ph.D., M.D., President and Chief Medical Officer
- Dr. Anthony Clarke, Chief Scientific Officer

Moderators:

- Michael Higgins – Ladenburg Thalmann
- Thomas Flaten – Lake Street Capital Markets

Panel Participants:

- Nancy Rigotti, M.D. – Professor of Medicine, Harvard Medical School, Director of Tobacco Research & Treatment, Massachusetts General Hospital, and ORCA-2 Principal Investigator
- Mitchell Nides, Ph.D. – President, LA Clinical Trials LLC, ORCA-1 Principal Investigator
- Neal Benowitz, M.D. – Professor of Medicine, Emeritus, University of California, San Francisco
- Judith Prochaska, Ph.D., MPH – Professor of Medicine, Stanford University
- Scott Leischow, Ph.D. – Professor and Director, Clinical and Translational Science, Arizona State University, Former Senior Advisor for Tobacco Policy at HHS

The event featured highly esteemed individuals with a stake in the success of new tobacco and nicotine addiction medicine, and Achieve's cytisinicline was at its centerpoint, a potential win in a battle with an addiction that has plagued human health for over a century. The drug's efficacy and improved side effect profile compared to alternatives is a material benefit that may be confirmed in the ongoing Phase III trial. Additional presentation details are discussed in our article.

Presentation of Data on Smoker and E-Cigarette User Attitudes and Perceptions Toward Quitting

Achieve presented three posters on February 25, 2021 at the Society for Research on Nicotine & Tobacco (SRNT) Annual Meeting, held virtually this year. The posters featured survey data on smoker and e-cigarette user behavior. A recap of the survey results are discussed in our recent article.

The posters were entitled:

- "A Survey in the United States of Attitudes to Nicotine Cessation in Smokers: Smokers' Satisfaction with Available Treatments" (PH-293)
- "A Survey in the United States of Attitudes to Nicotine Cessation in Vapers: Reasons for Choosing to Vape" (PH-294)
- "A Survey in the United States of Attitudes to Nicotine Cessation in Vapers: Their Plans to Quit Vaping" (PH-295)

Dr. Anthony Clarke, Chief Scientific Officer for Achieve, presented data from Achieve's 15-minute online survey in adults aged 19-64 who were current daily smokers or smokers who had quit in the past year. In total, 1,122 current and former smokers participated in the survey with 986 current smokers and 136 recent quitters. All participants had also used an FDA-approved prescription pill (varenicline or bupropion) and/or nicotine replacement therapy at least once in a prior quit attempt.

Of those that attempted to quit using a prescription pill, the full 12-week course was not completed in a majority of cases. 53% completed less than one month of therapy, with about half of those completing three weeks or less.

Side-effects were reported in 61% of respondents as a key reason for non-compliance. In those who had not used a prescription pill, fear of side effects was reported by 49% of responders. Lack of efficacy was reported by 27% of those using prescription medicine and by 42% of those using non-prescription medicine. The results indicated that the satisfaction and perceived efficacy of available cessation treatments was low.

Exhibit II - Perceived Effectiveness and Satisfaction with Cessation Available Treatments[2]

	Effectiveness	Satisfaction
Chantix (varenicline)	29%	30%
Zyban (bupropion)	22%	24%
e-cigarettes	30%	33%
Behavioral counselling	28%	30%
℞ NRT	22%	23%
OTC NRT	17%	18%

Less than a third of respondents who attempted to quit using prescription pills reported perceived efficacy and satisfaction. E-cigarettes were comparable in efficacy, trending superior, although as revealed by Achieve's other survey in vape users, e-cigarettes are not effective in addressing the underlying nicotine addiction.

In addition to the data from the aforementioned survey in smokers, Dr. Anthony Clarke also presented data from another survey regarding vape user behavior and quit intentions. 508 individuals completed the survey between February 29 and March 12, 2020. The population comprised 249 past smokers, 247 dual users, and 12 never smokers.

The most common reason cited to begin vaping was to quit smoking. A quarter of vapers planned to quit vaping in the next three months, a third in the next three to six months, and 43% in the next 12 months. Almost three quarters of dual users expressed interest in a new prescription treatment to help them quit. Finally, 84% of dual users and 50% of past smokers consulted their primary care physician for advice on cessation.

In the press release announcing the presentations and posters at SRNT, John Bencich, Achieve's CEO, commented that the combined evidence indicated the substantial need for a new therapeutic option for smokers who largely wish to quit but face the limitations of current standard of care. Bencich reminded investors that Achieve's lead candidate, cytisinicline, has demonstrated a favorable tolerability profile and a lack of common side effects that may help smokers adhere to treatment and overcome their addiction.

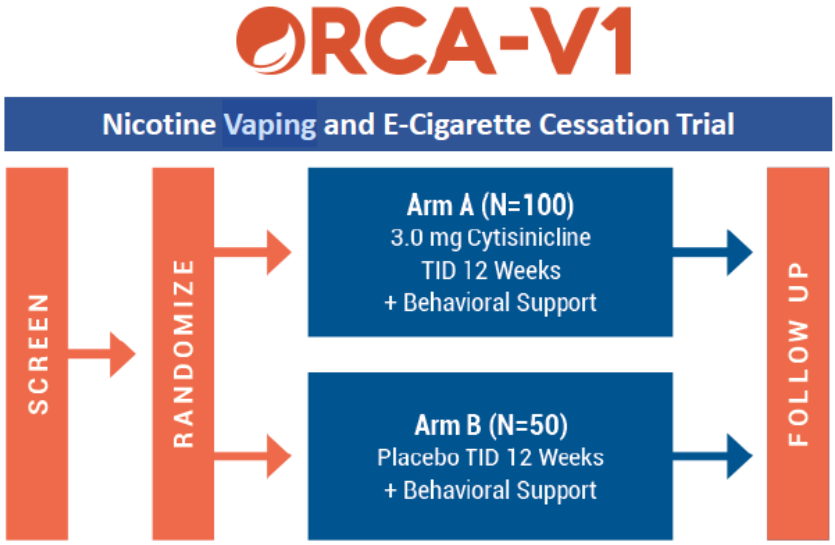
ORCA Vaping Trial

While smoking has shown declines in prevalence in the last decades, it has been replaced by another popular form of nicotine consumption: vaping. Last year, Achieve announced a collaboration with the FreeMind Group to identify non-dilutive funding to support the launch of a clinical trial that will evaluate the effectiveness of cytisinicline in subjects that are vaping and using e-cigarettes. The study will likely include 150 subjects that are vaping, but not smoking. Randomization will be divided into a 2:1 split with 100 receiving twelve weeks of cytisinicline and 50 on placebo. Dosing is expected to follow the regimen evaluated in ORCA-2: 3 mg three times daily. The Phase II study will examine vaping cessation as the endpoint at the six week and twelve week point by measuring cotinine levels.[3] If the trial is successful and generates statistically significant results, it could provide support, along with a successful ORCA-2, to require only one Phase III to obtain approval. Achieve continues to explore funding opportunities for Phase II ORCA-V1, and expects to share additional details on its application status in 2Q:21.

[2] A Survey in the United States of Attitudes to Nicotine Cessation in Smokers: Smokers; Satisfaction with Available Treatments. Clarke, Xinos, Stewart. Achieve Life Sciences - SRNT 2021

[3] Cotinine is a metabolite of nicotine, and cotinine urine or blood testing is considered highly accurate for assessing nicotine use, including vaping.

Exhibit III – Anticipated Vaping Trial Structure[4]



Key Events

- Presentation of ORCA-1 data at SRNT New Orleans – March 2020
- Complete animal toxicity study – 2Q:20
- RAUORA Data Presentation at SRNT Virtual – September 2020
- Second chronic toxicology study submission to FDA – 4Q:20
- Launch Phase III ORCA-2 trial – October 2020
- KOL Roundtable - November 2020
- $17.3 million raise - December 2020
- SRNT poster presentations - February 2021
- Completion of enrollment in ORCA-2 – 1H:21
- Additional detail on funding application status for vaping trial – 2Q:21
- Topline readout of ORCA-2 – 2021
- Possible vaping trial ORCA-VI – 2021/2022
- Initiation of ORCA-3 - 2022

Summary

Highlights from Achieve's fiscal year 2020 included the initiation of Phase III ORCA-2 trial, the closing of $17.3 million financing, and the hosting of a smoking cessation KOL Virtual Roundtable. Following the reporting period, Achieve also presented data on smoker and e-cigarette user attitudes and perceptions on quitting at the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting.

Enrollment for ORCA-2 began at a slower pace than anticipated due to the pandemic and winter weather. Management has taken steps to drive enrollment to the study via advertisements and anticipates full enrollment by mid-2021. Following completion of ORCA-2, Management expects ORCA-3 to initiate sometime in 2022. Vaping presents yet another opportunity for cytisinicline, and non-dilutive funding opportunities are currently being explored, with an update expected in 2Q:21.

Cytisinicline, with its established use in Central and Eastern Europe and potentially superior data in pivotal trials has a material opportunity to provide for an unmet need for smokers who wish to quit, but are wary of side effects and lack of efficacy in existing alternatives. US patents for Pfizer's Chantix, which represents standard of care in smoking cessation, expired in November 2020,[5] and generic competition is expected to mount within a year or two. This gives an opportunity to cytisinicline to come to market, offering both a low-side effect alternative to Chantix and several years of intellectual property protection. We maintain our price target of $50.00.

[4] Source: Achieve Life Sciences October 2020 Corporate Presentation
[5] Pfizer FY:20 10-K

PROJECTED FINANCIALS

Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2019 A	Q1 A	Q2 A	Q3 A	Q4 A	2020 A	2021 E	2022 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
R&D	$9.7	$1.5	$1.1	$1.9	$2.3	$6.9	$19.0	$21.5
G&A	$6.9	$1.8	$1.8	$1.9	$2.4	$7.9	$8.0	$8.3
Operating Income	($16.5)	($3.4)	($2.9)	($3.8)	($4.7)	($14.8)	($27.0)	($29.8)
Operating Margin	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	
Interest Income	$0.0					$0.0	$0.0	$0.0
Total Other Income	$0.1	$0.0	($0.0)	($0.0)	($0.0)	$0.0	$0.0	$0.0
Pre-Tax Income	($16.4)	($3.3)	($2.9)	($3.8)	($4.7)	($14.7)	($27.0)	($29.8)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*$0.0*	*0%*
Net Income	($16.4)	($3.3)	($2.9)	($3.8)	($4.7)	($14.7)	($27.0)	($29.8)
Reported EPS	**($39.76)**	**($2.15)**	**($1.68)**	**($1.14)**	**($1.11)**	**($5.42)**	**($4.33)**	**($3.55)**
YOY Growth								
Shares Outstanding	0.412	1.547	1.744	3.289	4.266	2.719	6.230	8.400

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Achieve Life Sciences, Inc. – Stock Price Chart[6]



[6] Source: Zacks Research System

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