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Achieve Life Sciences, Inc. (ACHV: NASDAQ)

ACHV: 2Q:23 Results

We employ a DCF model and a 15% discount rate to generate our valuation. Our model applies a 70% probability of eventual cytisinicline sales based on historical Phase III trial success ratios, trial progress and data generated to date. Our valuation includes geographic contributions only from the United States.

Current Price (8/15/2023)	$5.19
Valuation	**$56.00**

OUTLOOK

Achieve Life Sciences is developing cytisinicline for use as a smoking cessation treatment in the United States and rest of world. Topline results from ORCA-2 were reported in April 2022 and for ORCA-3 in May 2023. Results exceeded expectations on safety & efficacy parameters.

Both Phase III trials compare cytisinicline with placebo combined with counseling. The primary endpoint is abstinence at 6 & 12 weeks for the last 4 weeks of treatment. A Phase II trial in vaping cessation (ORCA-V1) reported topline in April 2023.

Existing cessation products provide limited effectiveness and produce unpleasant side effects including nausea, vivid dreams, insomnia & GI issues. Cytisinicline may fill a void in the prescription & NRT market by reducing nicotine cravings, severity of withdrawal & reward associated with smoking along with fewer side effects & 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. We anticipate a 2025 commercialization of cytisinicline.

SUMMARY DATA

52-Week High	**10.30**
52-Week Low	**2.00**
One-Year Return (%)	**-8.0**
Beta	**1.5**
Average Daily Volume (sh)	**129,474**
Shares Outstanding (mil)	**21.1**
Market Capitalization ($mil)	**109.5**
Short Interest Ratio (days)	**12.4**
Institutional Ownership (%)	**30.7**
Insider Ownership (%)	**7.8**
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 2023 Estimate	**N/A**
P/E using 2024 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)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2024					$0.0 E
2025					$97.1 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.80 A	-$1.09 A	-$1.35 A	-$0.83 A	-$4.00 A
2023	-$0.50 A	-$0.43 A	-$0.32 E	-$0.28 E	-$1.51 E
2024					-$1.55 E
2025					$2.24 E

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WHAT'S NEW

Second Quarter 2023 Results

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported second quarter 2023 results in a press release on August 14th and held a conference call the following morning. The company concurrently filed its Form 10-Q with the SEC. 2023 highlights to date include impressive topline results from the ORCA-V1 and ORCA-3 trials, participation in various investor and scientific conferences, publication of ORCA-2 results in the Journal of the American Medical Association (JAMA) and a capital raise that should provide sufficient funding to support operations for more than a year.

2023 achievements:

- Presentation at SRNT Annual Meeting – March
- Board of Director additions – March
- ORCA-V1 clinical trial results – April
- Refinancing of SVB Loan – May
- ORCA-3 topline results – May
- $16.5 million registered direct offering – May
- ORCA-2 smoking cessation trial published in JAMA – July
- Presentation at the American Society of Pharmacognosy 2023 Annual Meeting - July

No revenues were reported for 2Q:23. Operating expense was $7.7 million yielding a net loss of ($8.2) million or ($0.43) per share. For the quarter ending June 30, 2023 and versus the same ending June 30, 2021:

- Research & development expense totaled $4.6 million, down 36% from $7.2 million, as the ORCA-3 and ORCA-V1 trials wound down;
- General & administrative expense was $3.1 million, up 9% from $2.9 million on higher stock-based compensation and legal expenses resulting from corporate activities. Lower clinical trial awareness expenses partially offset this amount;
- Net interest expense was ($519,000) vs. ($404,000) due to a slightly higher debt balance and higher floating interest rates;
- Net loss was ($8.2) million vs. ($10.5) million or ($0.43) and ($1.09) per share, respectively.

As of June 30, 2023, cash and equivalents totaled $25.1 million. This amount compares to a $24.8 million balance in cash and equivalents held at the end of 2022. Achieve has assumed $15 million of convertible debt related to its loan facility originally with SVB and now with First Citizens Bank & Trust Company. It is carried at $15.7 million on the balance sheet and includes accrued interest. The term loan was modified in May and now matures in December 2024. 2Q:23 cash used in operations was ($6.7) million versus ($8.3) million in the prior year period. Cash flows from financing of $15.3 million reflected the May 2023 private placement.

May Direct Offering

Achieve sold 3.0 million shares of common stock at $5.50 per share and raised gross proceeds of $16.5 million and net proceeds of $15.3 million in a May 2023 transaction. No warrants were issued in conjunction with the transaction. Proceeds will be used to fund product development and regulatory activities, and for working capital and general corporate purposes.

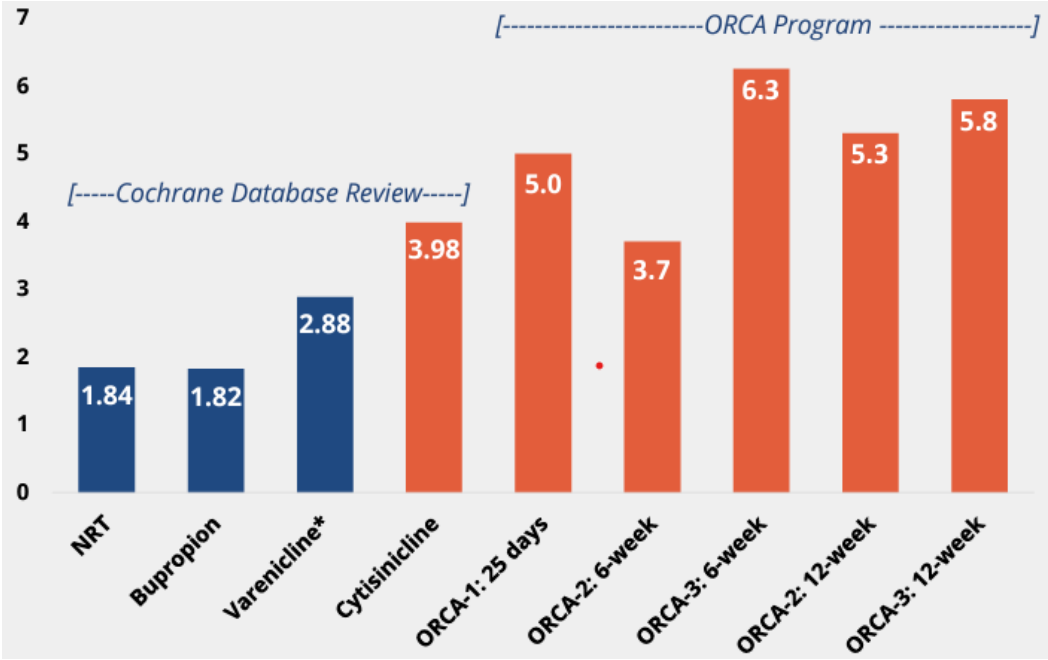
Publications

Achieve's ORCA-2 results were published in the July issue of the Journal of the American Medical Association (JAMA). Cytisinicline for Smoking Cessation highlighted the results of the 810 subject trial concluding that Both 6- and 12-week cytisinicline schedules, with behavioral support, demonstrated smoking cessation efficacy and excellent tolerability, offering new nicotine dependence treatment options.

ORCA-3 Topline Results

Achieve reported topline results from the second Phase III pivotal trial of cytisinicline on May 23, 2023. Results were discussed with analysts and investors in a conference call held that morning. On average, odds ratios were lower than that achieved in ORCA-2, but still well ahead of other alternatives and previous regimens of cytisinicline. The data provided from the ORCA-3 trial are strongly supportive of safety, efficacy and FDA approval. Based on the favorable results, we increased our target price.

Exhibit I – Odds Ratios for Smoking Cessation Alternatives[1]



Achieve reported statistically significant results from the ORCA-3 trial, with a marked improvement in cessation from the six- and twelve-week dosing regimens both in terms of odds ratio and quit rate. Adverse events were only slightly more elevated for the cytisinicline arms compared with the placebo arms. See below for a summary of topline performance for the ORCA-3 trial:

Exhibit II – ORCA-3 Primary Endpoints[2]

ORCA-3 (n=792)	Abstinence Rate - Last Four Weeks	
Treatment	Six Weeks	Twelve Weeks
Cytisinicline	14.8%	30.3%
Placebo	6.0%	9.4%
Odds Ratio	2.85	4.4
p-value	0.0008	<0.0001

Exhibit III – ORCA-3 Secondary Endpoints[3]

ORCA-3 (n=792)	Abstinence Rate Following Treatment	
Treatment	Six Weeks	Twelve Weeks
Cytisinicline	6.8%	20.5%
Placebo	1.1%	4.2%
Odds Ratio	6.25	5.79
p-value	0.0006	<0.0001

About two-thirds of cytisinicline subjects experienced mild to moderate adverse events, which was only slightly ahead of the placebo arm rate. Primary adverse events recorded were insomnia, abnormal dreams, headaches and

[1] Source: Achieve Life Sciences ORCA-3 Phase III Topline Data accompanying presentation, May 23, 2023
[2] Source: Analyst compilation of data from Achieve Life Sciences ORCA-3 Phase III Topline Data, May 23, 2023
[3] Source: Analyst compilation of data from Achieve Life Sciences ORCA-3 Phase III Topline Data, May 23, 2023

nausea. Notably, nausea was generally lower in the cytisinicline arms vs. placebo, which supports patients' use of therapy to conclusion as opposed to stopping early due to discomfort. Achieve's Chief Medical Officer, Dr. Jacobs, provided context regarding the discontinuation rates noting that historical data for varenicline ranged from 35% to 45% with about 12% - 13% due to adverse events. This compares to cytisinicline that has a ~21% discontinuation rate with about 2% - 3% due to adverse events.

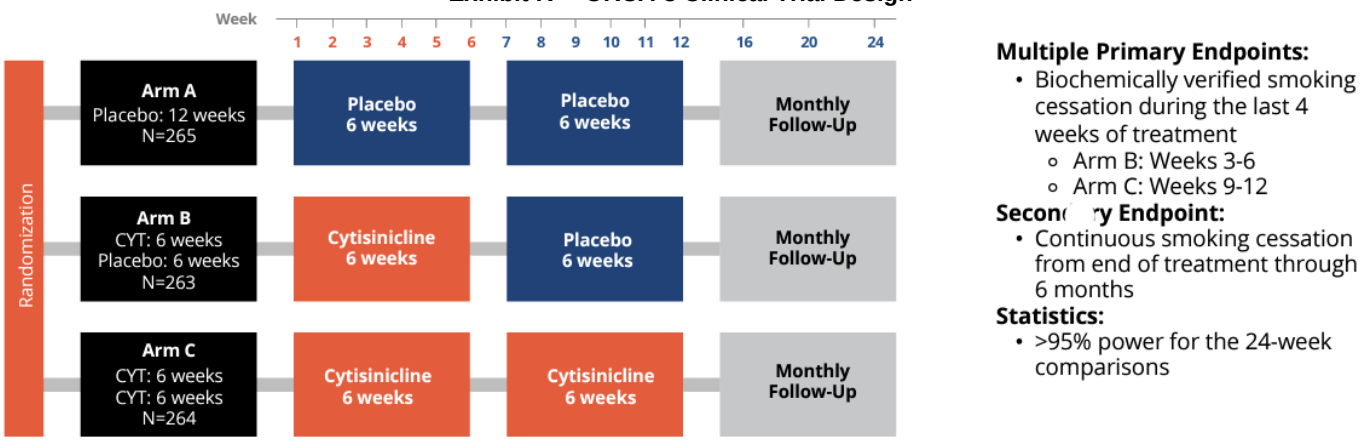
Exhibit III – ORCA-2 & 3 Most Commonly Reported Adverse Events (>5% Overall)[4]

Adverse Event (AE)	Placebo		6-week CYT		12-week CYT	
	ORCA-2	ORCA-3	ORCA-2	ORCA-3	ORCA-2	ORCA-3
At least 1 TEAE	166 (61.5%)	164 (62.6%)	172 (63.9%)	170 (64.6%)	184 (68.1%)	168 (64.5%)
Insomnia	13 (4.8%)	20 (7.6%)	23 (8.6%)	29 (11.0%)	26 (9.6%)	31 (11.9%)
Abnormal Dreams	8 (3.0%)	15 (5.7%)	22 (8.2%)	24 (9.1%)	21 (7.8%)	20 (7.7%)
Nausea	20 (7.4%)	19 (7.3%)	16 (5.9%)	25 (9.5%)	15 (5.6%)	18 (6.9%)
Headache	22 (8.1%)	16 (6.1%)	18 (6.7%)	20 (7.6%)	21 (7.8%)	22 (8.5%)

ORCA-3 Trial Design

The ORCA-3 trial targeted enrollment of 750 subjects across 15 clinical trial sites, randomized into three arms and ultimately enrolled 792 subjects with 265 in the placebo group, 263 in the six-week arm and 264 in the twelve-week arm. Subjects were administered 3 mg three times per day (TID). As with the first Phase III trial, the primary outcome measure for ORCA-3 is biochemically verified continuous abstinence during the last 4 weeks of treatment in the 6 and 12-week cytisinicline treatment arms compared to placebo. Each treatment arm was compared independently to the placebo arm. Secondary outcome measures will be conducted to assess continued abstinence rates through six months from the start of study treatment.

Exhibit IV – ORCA-3 Clinical Trial Design[5]

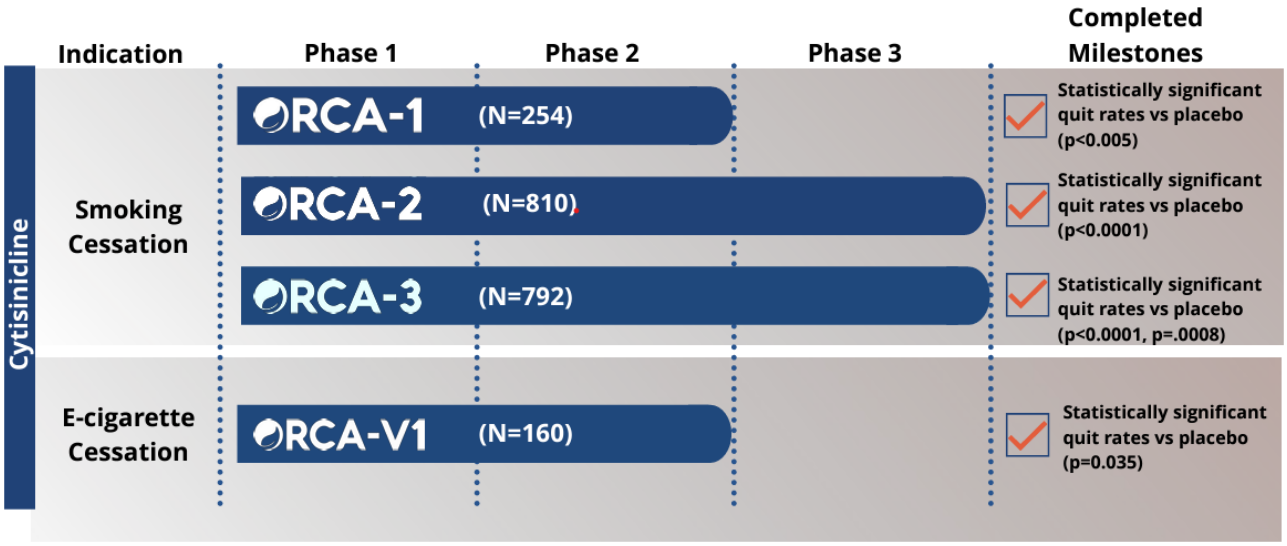


A clinical study report (CSR) and several supporting efforts including pharmacokinetic (PK), renal impairment and QT-QTc interval prolongation studies are expected to be complete by year-end. Related materials will be submitted along with the ORCA data to the FDA. Following the scheduling of and participation in the pre-NDA meeting, we expect to see refined estimates for timing of the NDA submission. In the second quarter earnings update, management targeted a 1H:24 NDA submission. When the submission is made, Achieve will seek a label for both the six week and twelve week treatment regimens.

Discussions with partners are expected to expand now that the data from ORCA-3 are available. Based on management's comments, we feel as if there are already multiple contenders for the asset, and that more will enter the fray now that the critical pivotal data is available.

[4] Source: Achieve Life Sciences ORCA-3 Phase III Topline Data accompanying presentation, May 23, 2023
[5] Source: Achieve Life Sciences ORCA-3 Phase III Topline Data accompanying presentation, May 23, 2023

Exhibit V – Cytisinicline Development Program[6]



Milestones

- Mock FDA inspections with Sopharma – 2022/2023
- Completion of cytisinicline supportive studies - 2023
  - PK study, renal impairment
  - PK study, steady state concentration of 3mg, 3x per day
  - QT interval prolongation
- Cytisinicline NDA filing – 1H:24
- FDA target action date – 1H:25

Summary

Achieve Life Sciences has completed both of the required pivotal studies for cytisinicline in combustible cigarettes in its ORCA-2 and ORCA-3 trials. Results have exceeded other smoking cessation therapy success rates and provide a less difficult adverse event profile. There are a few odds and ends that need to be wrapped up including completion of ancillary trials for its cytisinicline product prior to an anticipated new drug application (NDA) next year. However, all of the major efforts to obtain FDA approval for cytisinicline have been completed. As Achieve now has pivotal data in hand, it can offer potential partners a compelling product with strongly supportive data and we anticipate negotiations with them will crescendo as the year progresses.

Following the ORCA-3 results, we increased our valuation to $56 per share. Achieve represents an outstanding value with numerous comparative clinical trials run on the cytisinicline, a deep understanding of the safety profile of the drug compared to other products, favorable efficacy results from trials already run and clear boundaries for the commercialization opportunity given the performance of varenicline. The latest data even further support the safety profile of cytisinicline which in some cases is better in the active arm than in the placebo arm. We see even greater opportunity for cytisinicline compared with varenicline given the likelihood of gaining approval to treat nicotine addiction in vaping and higher penetration in markets outside of the United States, especially Asia.

[6] Source: Achieve Life Sciences ORCA-3 Phase III Topline Data accompanying presentation, May 23, 2023

PROJECTED FINANCIALS

Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$97.1**
R&D	$30.1	$5.5	$4.6	$3.8	$3.0	$16.9	$8.0	$6.0
G&A	$10.7	$3.0	$3.1	$3.0	$3.0	$12.2	$22.0	$28.0
Operating Income	($40.8)	($8.6)	($7.7)	($6.8)	($6.0)	($29.1)	($36.0)	$54.9
Operating Margin								*56.6%*
Interest Income	$0.2	($0.4)	($0.5)	$0.0	$0.0	($0.9)	$0.0	$0.0
Total Other Income	($1.7)	($0.0)	($0.0)	$0.0	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($42.4)	($9.0)	($8.2)	($6.8)	($6.0)	($30.0)	($36.0)	$54.9
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%*
Net Income	($42.4)	($9.0)	($8.2)	($6.8)	($6.0)	($30.0)	($36.0)	$54.9
Reported EPS	**($4.00)**	**($0.50)**	**($0.43)**	**($0.32)**	**($0.28)**	**($1.51)**	**($1.55)**	**$2.24**
Shares Outstanding	10.593	17.9	19.0	21.2	21.4	19.9	23.2	24.5

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

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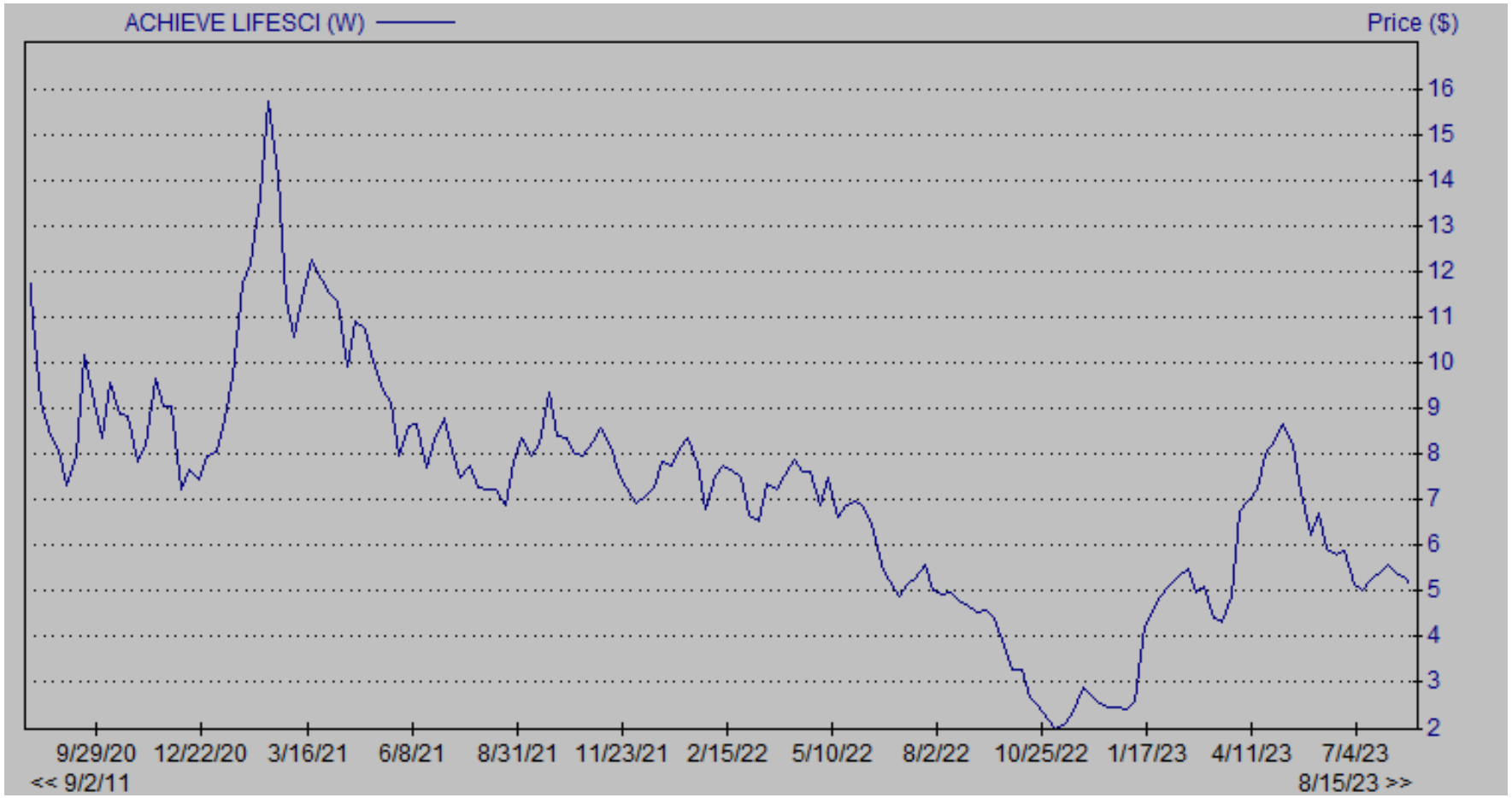
HISTORICAL STOCK PRICE

Achieve Life Sciences, Inc. – Stock Price Chart[7]



[7] Source: Zacks Research System

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