Zacks Small-Cap Research

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Correvio Pharma Corp. (CORV - NASDAQ)

US Brinavess Launch Now Reflected

Based on our DCF model and a 15% discount rate, Correvio is valued at approximately $7.50 per share. Our model applies a 60% probability of China & US approval and commercialization of Brinavess and 70% probability of EMA approval and European commercialization for Trevyent.

Current Price (8/17/2018)	$5.13
Valuation	**$7.50**

OUTLOOK

Correvio has a portfolio of six hospital-based medicines in cardiology and infectious disease. In November 2013, former entity Cardiome acquired Aggrastat and Correvio in a transformation acquisition that provided the infrastructure for recent and future acquisition growth.

The company's strategy is to acquire drugs in existing and adjacent spaces of hospital care to leverage their commercialization platform. Currently, there are five revenue-generating products.

The groundwork undertaken for Xydalba in 2017 combined with new sales from Zevtera should accelerate growth for 2018. Sales from Esmocard Lyo and potentially other additions may also augment the growth trajectory. Regulatory clarity in the pathway for Brinavess in the US and China provides justification for valuation in these regions.

In 2015, the company signed a license agreement for commercialization of Trevyent in the EU, Canada and Middle East. An MAA and NDS are expected to be filed for approval in the EU and Canada respectively in 2018 and sales are expected in 2019. Additional upside exists as Trevyent is approved and commercialized.

SUMMARY DATA

52-Week High	**5.14**
52-Week Low	**1.31**
One-Year Return (%)	**31.9**
Beta	**-1.09**
Average Daily Volume (sh)	**225,079**
Shares Outstanding (mil)	**34.9**
Market Capitalization ($mil)	**179.0**
Short Interest Ratio (days)	**0.69**
Institutional Ownership (%)	**48.8**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**2,943**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	$5.2 A	$5.8 A	$6.0 A	$7.0 A	$24.0 A
2018	$6.5 A	$6.2 A	$6.9 E	$7.7 E	$27.3 E
2019					$36.4 E
2020					$68.7 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.20 A	-$0.26 A	-$0.20 A	-$0.25 A	-$0.90 A
2018	-$0.24 A	$0.16 A	-$0.18 E	-$0.16 E	-$0.44 E
2019					-$0.57 E
2020					-$0.26 E

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What's New

2Q:18 Operational and Financial Results

Since our last report, Brinavess has been on a roll. Enrollment was completed in the European Phase IV SPECTRUM study and data is expected by September in this 2,000 person post-approval trial. Movement forward occurred in China, with partner Eddingpharm enrolling in its Phase III and the CFDA identifying the drug as clinically urgently needed. There was also advancement in the US with the FDA allowing for a pre-NDA meeting and resubmission of the NDA, which is expected to occur early next year. Pharmacoeconomically supportive survey results in Belgium and recognition of Brinavess research by a Spanish medical journal also encourage deeper penetration. These positive factors will drive an increase in our target price. The favorable news for Brinavess does not detract from the trends for Zevtera/ Mabelio and Xydalba, which saw strong revenue increases and launches in new territories offset by weaker trends in Aggrastat.

Correvio Pharma Corp. (NASDAQ: CORV) issued a press release reporting second quarter 2018 results on August 12, 2018, and later filed its second quarter financial statements and management discussion & analysis. The company posted quarterly revenues of $6.2 million, and earnings of $0.16 per share. After adjusting for the gain from the Cipher transaction ($18.5 million) and associated costs (-$1.8 million), net loss was ($0.32) per share or ($14.8) million. During the second quarter and to date, Correvio advanced the Brinavess franchise globally, completed its transaction with Cipher (TSX: CPH) raised additional capital and launched in several new regions. The SteadyMed (NASDAQ: STDY) and United Therapeutics (NASDAQ: UTHR) proposed transaction was approved by shareholders and is on track for a 3Q:18 close after required waiting periods.

Second quarter revenues rose 7.4% on a year over year basis to $6.2 million below our estimate of $7.2 million due to weaker Aggrastat sales partially offset by strength in anti-infectives. Direct sales continued to comprise a larger share of revenues, making up 58% of 1H:18 totals compared to 41% in 2017 and 27% in 2016. Gross margins of 68.1% fell compared to the prior year due to product mix, but rose sequentially.

Sales, general and administrative expenses were $12.6 million, increasing 32% due mostly to the additional $1.8 million in expenses related to the Cipher transaction. Interest expense increased in 2Q:18 to $1.7 million due to higher average debt levels. The net of these revenue and expense items and the contribution from the Canadian operations sale resulted in a quarterly net profit of $5.5 million or $0.16 per share which compares to 2Q:17 net loss of ($8.5) million or ($0.26) per share. On an adjusted basis, we estimate a net loss of ($0.32) per share in 2Q:18, excluding gains and costs related to the Cipher transaction. This compares to our estimate of ($0.20), with the difference attributable to lower than expected revenues and higher core SG&A and higher interest expense. June 30 cash stands at $23.9 million compared to $22.1 million at the end of 2017 including the $18.5 million from the Cipher deal. Cash burn in 2Q:18 was ($10.1) million and no cash was expended or received from financing.

Following the Cipher transaction, sufficient cash exists on the balance sheet to advance the company into 2019 without additional financing. Despite the favorable cash position, the company secured an at-the-money (ATM) facility with B. Riley FBR with $13 million in capacity. This relatively low cost access to capital can extend the runway further, but will be insufficient to support the company's desired new product transaction in the anti-infective space.

Cipher Pharmaceuticals

On March 20, 2018, Correvio (then known as Cardiome) and Cipher Pharmaceuticals announced an arrangement where Cipher will acquire Correvio's Canadian business portfolio. The portfolio includes Aggrastat, Brinavess, Esmocard, Xydalba and Trevyent. The transaction was consummated on May 15th, and Cipher acquired all of the shares of Cardiome, followed by a restructuring where Cardiome shareholders received shares of the new entity in a 1:1 ratio. The deal will provide cash of US$20 million to the company and will lighten the cost structure related to Canadian sales and regulatory efforts. It will also allow further focus on Cardiome/Correvio's primary market in Europe.

The transaction was executed on May 15, 2018, followed by an official name change to Correvio and new ticker symbol CORV. The transaction provides a substantial level of NOLs along with the Canadian rights to Cardiome's portfolio and the salespeople associated with it. The amount of the NOLs transferred was approximately CAD$200 million. There remains CAD$100 million in NOLs that Correvio will be able to use against eventual profits in Europe which will remain on the company's balance sheet. The transfer of the business entity is expected to reduce revenue forecasts by approximately $1 million in 2018.

Brinavess

The FDA notified Correvio on June 8th that it may schedule a pre-NDA meeting and resubmit an NDA for Brinavess. Based on the correspondence and interaction with the agency, the company believes that a pre-NDA meeting can take place in 4Q:18. Management is currently preparing for the meeting and could potentially use data from electronic health records obtained in ex-US use of the drug in support of approval. In a favorable scenario, Correvio could be in a position to resubmit the NDA in 2Q:19 and receive an FDA response by 4Q:19, following a six month review. A substantial amount of post-approval work that has been done worldwide including the recently completed SPECTRUM study, which may be used and is supportive of a favorable action by the FDA. An estimated 40 thousand patients in 42 countries have been administered Brinavess, which provides a substantial data set for the agency's consideration.

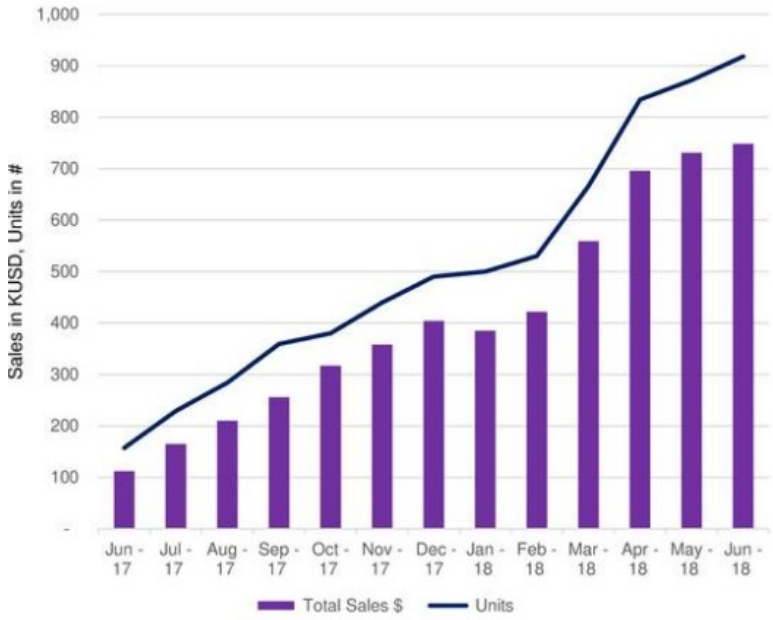
Brinavess saw several successes in Asia as well, with partner Eddingpharm enrolling its first patient in the Phase III trial in the country and the China Food and Drug Administration identifying Brinavess as a "clinically urgently needed new drug." The clinical trial will evaluate Brinavess compared to a placebo in patients with recent onset atrial fibrillation and will enroll ~240 patients in 30 sites. The CFDA classification will allow for a 60-day priority review in China of the drug if a new drug application is accepted. The data package must include data with proof that there are no differences in Brinavess' safety or efficacy across ethnicities. It is unclear if additional data will be needed as many global trials have already been conducted including a Merck Asia Pacific study.

In the European sphere, Correvio has completed enrollment in the Phase IV SPECTRUM study, which should yield top line data in September. Publication of the data is expected in late 2018 or early 2019. SPECTRUM evaluated Brinavess in the EU, post-authorization, and enrolled 2,000 patients to evaluate normal conditions of use dosing and safety. Brinavess also appeared in a Spanish medical journal in a study entitled "Vernakalant in hospital emergency practice: safety and effectiveness" and was awarded a prize for best work. The publisher of the study, Dr. Carbajosa Dalmau, received the award in Toledo, Spain. The drug was also part of a successful survey in Belgium that generated data showing Brinavess avoided hospitalization for 85% of treated patients and reduced the need for electric cardioversion in 84% of patients. The study showed that 85% of atrial fibrillation patients had normal heart rhythm restored, allowing for earlier discharge. The survey makes an economic, efficacy and safety case for the drug

Xydalba

Xydalba continues to show sales increases, reaching ~$750,000 in the second quarter. An MAA was recently submitted for Switzerland, a launch took place in Spain and further product launches are expected in the fourth quarter for Belgium and the Netherlands.

Exhibit I – Xydalba Three Month Rolling Sales & Units



Trevyent

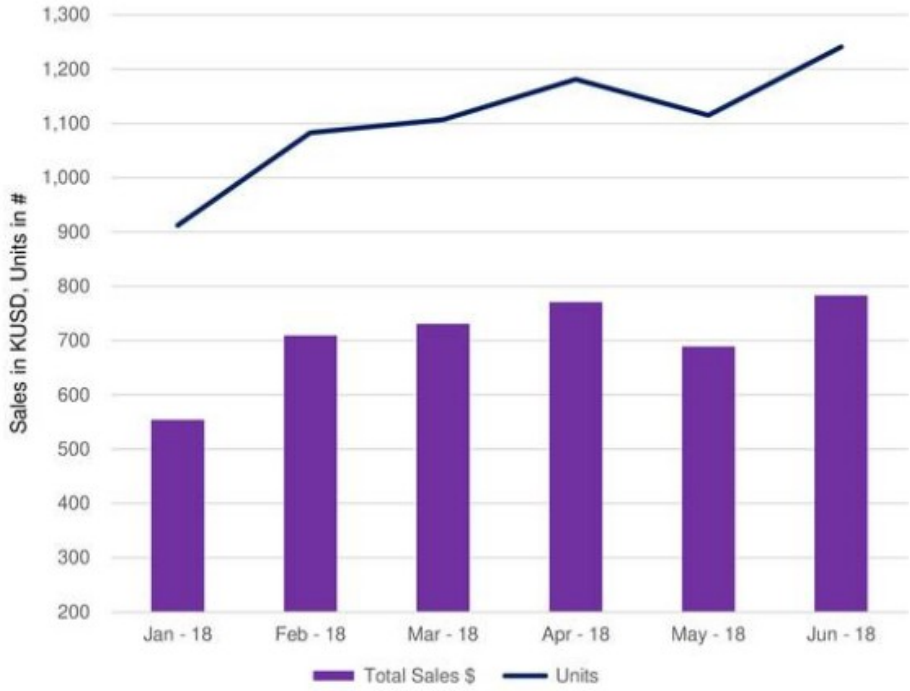
On April 30, United Therapeutics and SteadyMed announced a merger agreement where shareholders of SteadyMed will receive $216 million in a deal that is expected to be complete in 3Q:18. SteadyMed will maintain its current supply chain partners and the arrangement between SteadyMed and Correvio regarding Trevyent will remain the same. The combination with a stronger partner that has development, regulatory and commercialization experience could improve the position of Trevyent in the US as well as provide a more secure supply chain for Correvio. We believe that the acquisition is a strategy by United Therapeutics to extend the life cycle of its current product, Remodulin, which is expected to lose patent protection in 2018.

In August 2017, the FDA issued a refuse-to-file notice to SteadyMed regarding its NDA for Trevyent. The agency determined that the submission did not have sufficient information to conduct a review. Following a Type A meeting and the submission of the necessary information, the FDA accepted the response from SteadyMed and concluded that no additional work was required to resubmit the drug application. With this hurdle surpassed, a resubmission and response are expected in the latter half of 2018. Correvio anticipates submitting its own package to the EMA following these efforts in 1H:19.

Zevtera/Mabelio

Zevtera sales have continued to exceed management's internal expectations over the last two quarters. June revenues were the highest in the drug's history, which is supportive of continued growth in coming quarters. In May, Correvio launched the drug in Spain and is expecting first sales in 3Q:18.

Exhibit II – Zevtera/Mabelio Three Month Rolling Sales & Units



Commercialization

There are a several external products that are working their way through the regulatory process in the anti-infective space that would complement the current portfolio and that should be approvable in 2019. Correvio is evaluating these candidates and is likely to add one to its portfolio in the next year. Management is confident they will be able to obtain funding from financial partners to pursue such a deal. This approach is attractive as there are few incremental costs to the sales and marketing effort with a salesforce already in place and contacts already developed in the key hospitals the candidates would target. High incremental margins would be rapidly accretive and could help Correvio achieve profitability more quickly than from organic growth alone.

Correvio made additional progress in the first months of the year, advancing its drug products into new markets and forging additional and stronger relationships with partners. The leading product, Aggrastat, saw an expansion of its

indication in China to include patients with STEMI, and the approval of a high dose bolus regimen in Canada. The company also entered into a distribution agreement with ZAO Firma Euroservice, who is expected to submit an MMA to Russian regulatory authorities in 4Q:18. Partner Aspen launched Brinavess in South Africa, partner ATCO Lab submitted an MAA in Pakistan and partner Tzamal is expect to file an MAA in Israel in 4Q:18. Brinavess launched in the UAE and partner Algorithm expects to commence commercialization activities for the drug in 2Q:18. Partner Eddingpharm has enrolled its first patients in a Phase III trial for atrial fibrillation in China with an expected 240 person cohort. Xydalba began its launch in Sweden, Finland, Luxembourg and the Republic of Ireland. Esmocard saw first sales in Italy and France in the fourth quarter, and wins so far total $3.4 million over the next four years.

Significant Event Timeline

Correvio has a number of recent and upcoming milestones related to new geographic launches, interacting with regulatory authorities regarding the approval process and completing the transaction with Cipher. Below we include these significant events.

- April 30, 2018 – United Therapeutics Announcement to acquire SteadyMed
- May 2018 – Complete transaction with Cipher and Ticker Change
- May 2018 – First Patient Enrolled in Phase 3 Brinavess Trial in China
- 2Q:18 – Launch of Zevtera/Mabelio in Spain & Ireland
- 2Q:18 – Launch of Xydalba in Wales & Luxembourg
- 2Q:18 – FDA Provides Regulatory Pathway for Brinavess Approval
- 3Q:18 – Close of United Therapeutics and SteadyMed Acquisition
- 3Q:18 – MAA submission in Switzerland
- 3Q:18 – Brinavess launch in UAE
- 3Q:18 – CFDA Identifies Brinavess as Urgently Needed
- 4Q:18 – ZAO Firma Euroservice to Submit MAA for Aggrastat in Russia
- 4Q:18 – Trevyent NDA Submission
- 4Q:18 – Launch Xydalba in Belgium & Netherlands
- 4Q:18 – Partner Tzamal MAA filing for Xydalba in Israel
- 1H:19 – Filing for approval of Trevyent in EU
- FY:20 – Launch of Brinavess in United States
- FY:20 – Launch of Brinavess in China
- FY:20 – Launch of Trevyent in EU and other regions

Valuation

Correvio has experienced several positive catalysts since our last report. The most important factor increasing our valuation is the improved pathway for Brinavess, which is in a more favorable regulatory position after the FDA's acceptance of moving forward with an NDA in the United States and several advances in China both with the regulatory authorities and with partner Eddingpharm. We believe the catalyst for the favorable action is the completion of the SPECTRUM Phase IV study in Europe, which has disclosed no safety issues and should provide additional evidence of efficacy for the drug. Based on the improved profile, we have added a valuation component for Brinavess sales in the US and China. We anticipate a 2020 launch of the drug in both regions and a 60% probability of approval and ultimate commercialization. For US markets we anticipate an addressible market of 4.4 million, half of which are appropriate for Brinavess therapy and mid-single digit penetration over the forecast period. Pricing will be strong, at about a 70% premium to European pricing at ~$450 per 10 mg dose. Although we do not know if Correvio will develop Brinavess in the US itself or seek a partner to commercialize, our estimates anticpate Correvio will develop a 40 person sales force and commercialize internally. In China, we see the economically feasible population being approximately 260 million, pricing at a discount to the US and Europe at about $200 for a 10 mg dose and also mid-single digit penetration. Partner Eddingpharm will be commercializing the drug and we anticipate a 25% share of economic value[1] (represented as the royalty) to accrue to Correvio.

[1] This includes milestones, royalties and other payments.

Given the favorable safety, efficacy and pharmacoeconomic study in Belgium, launch of the product in the UAE and an award in a Spanish journal, we see a supportive environment for increased sales in currently approved regions. Therefore, we increase our Brinavess estimates in Europe and partner regions.

Beyond Brinavess the other moving parts for the company, including the strength in the anti-infectives business offset by weakness in Aggrastat will reduce our 2018 revenue and earnings estimates. Estimates will increase for 2019 due to faster growth of Brinavess and continued strength in the other portfolio members. The launch of Brinavess in the US and China are felt in 2020, where we see an increase in revenues, partially offset by new costs to support a sales force.

The net impact of these adjustments increase our target price from $4.00 to $7.50 with the vast majority of the increase attributable to success of Brinavess in the United States.

Summary

Correvio continues to execute on its efforts to obtain regulatory approval for its portfolio of products, create new relationships with partners for distribution outside its core areas and penetrate individual countries with price negotiation efforts and product inclusion on hospital formularies. We adjust our 2018 forecasts to reflect individual product trends and reflect 2Q:18 actuals.

We expect accelerating 2018 revenue growth as last year's groundwork produces increased penetration with a larger salesforce and additional products to sell. The transaction with Cipher will produce a more focused and streamlined company with additional capital that should help support operation costs until 2019. Due to multiple positive catalysts for Brinavess and increased likelihood of commercialization in the US and China, we increase our target price to $7.50 per share.

PROJECTED FINANCIALS

Correvio Pharma Corp. - Income Statement

Correvio Pharma Corp (USD)	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 E
Product & royalty revenues	$23.8	$6.5	$6.2	$6.9	$7.7	$27.2	$36.2	$68.5
Licensing & other fees	$0.2	$0.0	$0.0	$0.1	$0.1	$0.2	$0.2	$0.2
Total Revenues	**$24.0**	**$6.5**	**$6.2**	**$6.9**	**$7.7**	**$27.3**	**$36.4**	**$68.7**
	-4.9%	25.9%	7.4%	14.6%	10.0%	13.8%	33.2%	88.7%
Cost of Product Sales	$6.8	$2.3	$2.0	$1.9	$2.1	$8.3	$10.9	$20.5
Gross Margin	71.5%	64.7%	68.1%	72.0%	72.0%	69.4%	70.0%	70.0%
SG&A	$36.7	$10.9	$12.6	$9.2	$9.3	$42.0	$39.0	$49.0
Amortization	$3.5	$1.0	$1.2	$1.0	$1.0	$4.1	$3.6	$3.6
Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($23.0)	($7.6)	($9.6)	($5.2)	($4.6)	($27.1)	($17.1)	($4.5)
Operating Margin	*-95.7%*	*-116.4%*	*-155.9%*	*-75.3%*	*-60.3%*	*-99.1%*	*-46.9%*	*-6.5%*
Interest Expense	$5.7	$1.1	$1.7	$1.7	$1.7	$6.1	$6.8	$6.8
Total Other Income	$0.8	($0.3)	($16.8)	$0.0	$0.0	($17.0)	$0.0	$0.0
Pre-Tax Income	($29.4)	($8.4)	$5.5	($6.9)	($6.3)	($16.2)	($23.9)	($11.3)
Taxes & Other	$0.4	$0.1	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0
Tax Rate	*-1.2%*	*-0.7%*	*0.0%*	*0.0%*	*0.0%*	*-0.3%*	*0.0%*	*0.0%*
Net Income	($29.8)	($8.5)	$5.5	($6.9)	($6.3)	($16.2)	($23.9)	($11.3)
Reported EPS	**($0.90)**	**($0.24)**	**$0.16**	**($0.18)**	**($0.16)**	**($0.44)**	**($0.57)**	**($0.26)**
YOY Growth	*15.8%*	*22.9%*	*-159.6%*	*-9.5%*	*-35.0%*	*-51.2%*	*29.7%*	*-54.9%*
Shares Outstanding	33.2	34.7	35.0	39.0	39.5	37.0	42.0	44.0

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

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HISTORICAL STOCK PRICE

Correvio Pharma Corp. – Five Year Price Chart[2]



[2] Chart provided courtesy of barchart.com

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