Zacks Small-Cap Research

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Cipher Pharmaceuticals Inc. (DND-TSX)

DND: Absorica Powers Cipher To Another Earnings Beat…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	01/03/2012
Current Price (07/31/13)	$5.80
Target Price	**$9.25**

UPDATE

On July 31, 2013, Cipher reported financial results for the second quarter 2013. Revenues exceeded our expectations, as they have the previous few quarters. The solid results were driven by strong sales of Absorica at U.S. partner Ranbaxy, which doubled our sales expectations for the quarter. For the second quarter in a row, we have increased our forecasts for Absorica sales in 2013, and beyond.

We believe that Cipher remains highly attractive. We forecast EPS in 2013 at $0.60 per share, growing to $1.03 per share in 2014. The stock is trading at only 6X our projected 2014 EPS figure. We are reiterating our Buy rating and raising our target to $9.25 per share.

SUMMARY DATA

52-Week High	**6.80**
52-Week Low	**1.46**
One-Year Return (%)	**287**
Beta	**1.22**
Average Daily Volume (sh)	**94,889**
Shares Outstanding (mil)	**24.5**
Market Capitalization ($mil)	**142.1**
Short Interest Ratio (days)	**1.6**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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 2013 Estimate	**11.7**
P/E using 2014 Estimate	**6.9**

Risk Level	**Average,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(millions of CAD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	1.8 A	1.6 A	2.1 A	2.9 A	8.5 A
2013	3.3 A	5.5 A	6.2 E	7.6 E	22.7 E
2014					38.8 E
2015					52.8 E

Earnings per Share
(EPS is operating earnings)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	$0.01 A	$0.01 A	$0.03 A	$0.05 A	$0.10 A
2013	$0.06 A	$0.12 A	$0.16 E	$0.20 E	$0.55 E
2014					$0.86 E
2015					$1.02 E

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WHAT'S NEW

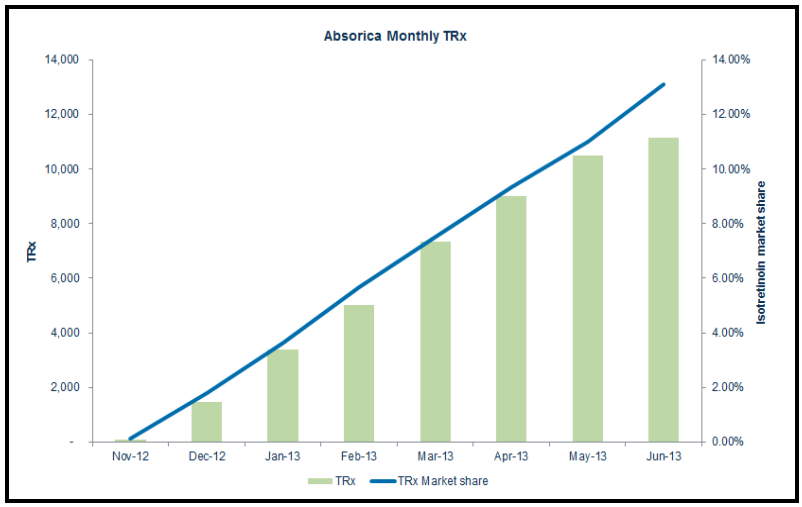
Strong Second Quarter Results

On July 31, 2013, Cipher Pharmaceuticals reported financial results for the second quarter 2013. Total revenues in the quarter were $5.4 million, up 241% over the second quarter 2012 and crushed our estimate for revenues of $3.4 million. The revenue up-tick was driven by the strong performance of the launch of Absorica (CIP-Isotretinoin) at Ranbaxy, and continued solid royalties from partners on Lipofen and ConZip / Durela. We note the company recorded its first product revenues of $0.088 million in the second quarter from the launch of Epuris in Canada in late June 2013.

…Absorica…

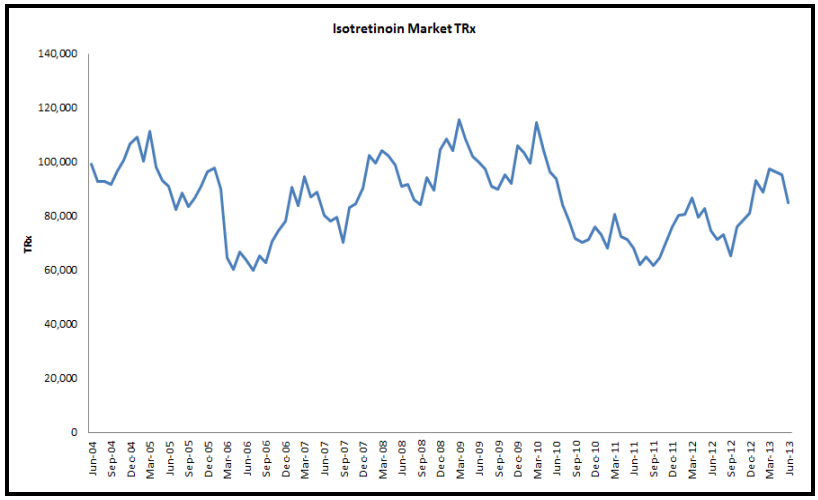
Total net Absorica revenues in the second quarter 2013 were $4.2 million, comprised of $0.5 million in amortization of upfront licensing fee and $3.7 million in royalties on U.S. sales at Ranbaxy. We note that Cipher receives a "mid-teens" royalty on U.S. sales of Absorica at Ranbaxy, meaning that sales in the second quarter equated to roughly $25 million. This doubled our expectations!

The launch to date has clearly been impressive. Ranbaxy has 50 sales representatives promoting Absorica to roughly 3,500 prescribing dermatologists. Cipher reported that Absorica held roughly 13.1% market share at the end of June 2013. The product has been gaining approximately 2% market share per month since the launch in December 2012. Market share since December 2012 to June 2013 has been 1.9%, 3.6%, 5.7%, 7.5%, 9.1%, 11.0%, and 13.1% (see graph below). This is one impressive ramp, and clearly driven by the improved formulation advantages of Absorica over generic isotretinoin.



The market share gains are clearly encouraging, but what's even more exciting is that the overall isotretinoin market seems to be bouncing as well (see graph below) – perhaps driven by Ranbaxy's active promotion of Absorica. Management noted that total U.S. isotretinoin prescriptions grew by 12% in 2012, with a surge at the end of the year. Total isotretinoin prescriptions in the first quarter 2013 grew by 13%. That number increased to 15% in the second quarter.

It will be interesting to see what the market does in the third quarter, which is usually hit by a summer slow-down. Continued growth will be a good sign for the overall isotretinoin market. Nevertheless, at this point it looks like Absorica is a differentiated product, promoted by a highly motivated and focused sales force, into a nicely growing market. The trend should continue.



Based on existing prescriptions, the total isotretinoin market, when equated into Absorica (branded) price, is around $800 million. Ranbaxy's 13.1% market share at the end of June 2013 equates to a $100 million annualized run rate. We previously believed that Ranbaxy could capture 25% market share at peak, putting sales in the $200 million range. We have now upped that target to 35% market share, putting peak sales for Absorica at around $300 million. If the overall isotretinoin market continues to bounce higher into 2014, Absorica could exceed this number easily. For 2013, we see Cipher collecting net Absorica revenues of $16.2 million. That's over three-times what we suspected when the product launched in December 2012.

…Lipofen…

Net Lipofen revenues in the second quarter 2013 were $0.8 million, slightly below our forecast for $0.9 million. Cipher noted lower-than-expected shipments in the quarter. Prescriptions shrank by 6% compared to the second quarter 2012. However, due to a 3% higher royalty rate, net Lipofen revenues were roughly flat. In the second quarter 2013 Impax Labs launched a generic version of AbbVie's TriLipix (fenofibric acid), making Lipofen the only remaining non-generic fenofibrate product on the market.

At this point we are unsure how this will affect future Lipofen prescriptions. While it is nice from Kowa's perspective to be the sole branded voice promoting to physicians, the pricing environment is getting increasing more difficult. That being said, Lipofen is becoming less and less important to Cipher. Revenue of $0.8 million were essentially in-line with our thinking. For all of 2013, we model revenues of $3.4 million. The goal at Kowa is to maintain the current run-rate up to the patent expiration in 2015. For 2014, we see revenues flat at $3.5 million for Lipofen.

…ConZip / Durela…

Net revenues from ConZip / Durela in the second quarter 2013 totaled $0.5 million, mostly driven by sales of ConZip by Vertical Pharmaceuticals Inc. in the U.S. We note that Vertical expanded its sales force on ConZip in the fourth quarter 2012 from 60 to 75 representatives. We are expecting to see this increase promotion out of Vertical Health reflexed in the ConZip royalty payments coming in the next few quarters. We note that total ConZip prescriptions grew by a solid 15% in the first quarter and 5% in the second quarter year-over-year.

Sales of extended release tramadol products totaled roughly $100 million in the U.S. in 2012. Tramadol-ER controls only 2.2% of the total tramadol market. We think that Cipher will benefit not only from Vertical gaining market share from Ultram-ER and Ryzolt in 2013, but all three products picking up market share on generic immediate-release tramadol products.

We note that Cipher has the potential to earn an additional $3.8 million in future milestones from Vertical Pharmaceuticals, contingent upon the achievement of certain future net sales targets. We do not include any additional sales milestones for ConZip in our model given the slow ramp to date. However, should Vertical gain traction and pick up meaningful market share, this additional $3.8 million represents upside to our model.

Sales of Durela by Medical Futures in Canada remain underwhelming to date, although management did note on the second quarter earnings call that there has been signs of steady improvement by Medical Futures in the second quarter 2013. Medical continue to promote the product with 22 sales representatives in Canada. The issue is that

the Canadian tramadol-ER market is only around $20-25 million and Durela has struggled to gain market share against cheaper immediate-release tramadol products. Ultimately, Durela looks like a $1-2 million product, at best.

One area we may see some new growth from the CIP-tramadol-ER franchise is in Latin America. In late April 2013, Cipher entered into an exclusive distribution and supply agreement with Tecnofarma International Ltd. for the right to market and distribute CIP-tramadol-ER in 18 Latin American countries, including Brazil and Mexico. Under the terms of the agreement, Cipher received an upfront payment and is eligible for additional milestones based upon regulatory approval in Brazil and Mexico. Cipher will supply product to Tecnofarma at a fixed-transfer price.

Cipher and Tecnofarma are working towards regulatory filings in these 18 countries. Management tells us that some of the small countries, ones that work of the U.S. FDA or Canadian regulatory authority, may see some approvals in 2014. Larger countries, like Brazil for instance, may see filings in 2014 and regulatory approvals in 2015. We do not model meaningful revenues from CIP-tramadol-ER outside the U.S. or Canada, so if Tecnofarma can being to generate revenues and start paying royalties to Cipher in 2014 and 2015 it would represent upside to our model.

…Tight Cost Control…

One of the things that has impressed us at Cipher over the past year has been management's ability to control costs despite a surging top-line. Operating expenses for the second quarter 2013 totaled approximately $2.5 million, of which $0.5 million was associated with preparing for the launch of Epuris which took place in late June 2013. Back out that one-time $0.5 million expense and expense were generally flat with the first quarter 2013.

We are impressed that the company can grow its top-line by 241% while seeing its expenses only go up by $1 million (~67%) year-over-year. Cipher now has 3 products on the market with Lipofen, ConZip/Durela, and the recently launched Absorica for which it has virtually no ongoing expenses. That said, with Epuris now on the market in Canada, we do see operating expenses increasing in the second half of the year, by roughly $1.0 to $1.5 million over the comparable period in 2012, but this should be off-set by a growing top-line.

Targeting Canada

Cipher has done an outstanding job over the past few years out-licensing its products to U.S. partners. This has allowed the company to sit back and collect license fees and royalties, growing the top-line nicely while keeping operating overhead low – as noted above. However, in late June 2013, Cipher launched Epuris (the same product Ranbaxy launched in November 2012 as Absorica), on its own. This is a big shift in strategy for the company.

During the first quarter 2013, the company hired Joan Chypyha as Vice President of Marketing and Sales. Ms. Chypyha will head up the company's commercial operations in Canada, and manage the recently created 6-person sales force contracted for the Epuris launch. We note that Ms. Chypyha seems uniquely qualified for this role, having spent more than 25 years in the pharmaceutical industry with an emphasis on marketing, sales and business development in the dermatology area. We note her previous role as for 16 years with Hoffman-La Roche, escalating to Business Unit Director for the Dermatology franchise where she was responsible for the management of a specialty sales force that promoted Accutane, among other brands.

On the first quarter conference call, Cipher management noted that this specialty sales force that promoted Accutane was 6 to 8 representatives and achieved peak sales between $25 and $30 million. The current Canadian isotretinoin market is only around $15 million in size, but it has been fully genericized and there is no active promotion of any branded products. We believe that Epuris can be a $10 to $15 million product for Cipher in Canada based on the early success of Absorica in the U.S. Cipher noted that half of the sales reps the company hired to promote Epuris have prior experience promoting Accutane at Roche in Canada. Some private insurers have already picked up coverage of Epuris and Cipher has submitted dossiers to each Providence in Canada for public reimbursement. We suspect this process will take six to eight months, so by the end of the first quarter 2014 we should see broad coverage reimbursement for Epuris throughout the country.

We remind investors that Cipher plans to file the new drug submission (NDS) for the Betesil Patch in Canada by the end of the year. If approved, we think the Betesil Patch is an excellent complement dermatology product for Cipher's contract sales force to co-promote along with Epuris. We would also not be surprised to see the company look to in-license or acquire another specialty dermatology product in Canada. We think Cipher can achieve breakeven Canadian operations based on the launch of Epuris alone by the end of 2014. This would be sales in the area of $3 million.

…Solid Cash Position…

Cipher exited the second quarter 2013 approximately $17.8 million in cash and investments. The company generated $1.3 million in cash during the second quarter. We find the current balance sufficient to fund operations for the foreseeable future, as we believe that Cipher will continue to report positive cash flow throughout 2013 even in the face of launching its own specialty dermatology sales force to promote Epuris and Betesil Patch in Canada.

Stock Still Attractive

Based on our financial projections, Cipher should report total revenues in 2013 of around $22.7 million, with net income of $13.4 million, or $0.55 per share. This equates to a P/E ratio of only 11.8x our 2013 figure. In 2014, we model growth in revenues to $38.8 million, net income of $25.2 million and EPS of $1.01. A P/E ratio of 12.5X our 2014 estimate for $0.86 in EPS yields a price target of $10.75 per share. A P/S ratio of 5.0x our 2014 projected revenue forecast of $38.8 million yields a price target of $7.80 per share. We note our EPS forecast of $0. 86 includes only a 15% tax rate given the company held $22.4 million in deferred income tax credits as of the end of the second quarter 2013. Our price target, based on averaging our P/E and P/S calculations is $9.25 per share.

We expect the company to continue to receive growth from existing products, led by Absorica, while they focus more and more on building a commercial sales and marketing presence in Canada. The company began marketing Epuris in Canada in late June 2013. This will be complemented by the Betesil Patch, should it receive Health Canada approval, in 2014. In addition, we fully expect the company to license in and/or acquire other products, with an emphasis on late-stage to commercial-stage product candidates in specialty dermatology market in Canada. Finally, we expect the company to leverage its regulatory approvals in U.S. and Canada to pursue licensing agreements in other markets for our once-daily CIP-tramadol and CIP-isotretinoin products.

PROJECTED FINANCIALS

Cipher Pharmaceuticals Inc.
Income Statement

Model in Canadian Dollars (IFRS)	2011 A	2012 A	Q1 A	Q2 A	Q3 E	Q4 E	2013 E	2014 E	2015 E	2016 E
Lipofen Net Revenues	**$2.2**	**$4.6**	**$0.8**	**$0.8**	**$0.9**	**$0.9**	**$3.4**	**$3.5**	**$2.0**	**$1.0**
CIP-Fenofibrate YOY Growth	*-56.0%*	*109.1%*	-	-	-	-	*-26.1%*	*2.9%*	*-42.9%*	*-50.0%*
ConZip / Durela Net Revenues	**$0.8**	**$1.4**	**$0.5**	**$0.5**	**$0.6**	**$0.7**	**$2.3**	**$5.0**	**$6.0**	**$8.5**
CIP Tramadol-ER YOY Growth	-	*75.0%*	-	-	-	-	*64.3%*	*117.4%*	*20.0%*	*41.7%*
Absorica Net Revenues	**$0.6**	**$2.6**	**$2.0**	**$4.2**	**$4.5**	**$5.5**	**$16.2**	**$28.3**	**$40.8**	**$46.0**
CIP-Isotretinoin YOY Growth	*50.0%*	*333.3%*	-	-	-	-	*523.1%*	*74.4%*	*44.4%*	*12.7%*
Product Sales (Canadian)	**$0**	**$0**	**$0**	**$0.1**	**$0.2**	**$0.5**	**$0.8**	**$2.0**	**$4.0**	**$6.0**
CIP-Isotretinoin YOY Growth	-	-	-	-	-	-	-	-	*100.0%*	*50.0%*
Total Revenues	**$3.569**	**$8.458**	**$3.293**	**$5.547**	**$6.2**	**$7.6**	**$22.7**	**$38.8**	**$52.8**	**$61.5**
YOY Growth	*-33.7%*	*137.0%*	*81.8%*	*240.5%*	*192.7%*	*162.1%*	*168.2%*	*70.8%*	*36.3%*	*16.5%*
Cost of Goods Sold	$0	$0	$0	$0.027	$0.1	$0.3	$0.4	$0.9	$1.6	$2.1
Product Gross Margin	-	-	-	-	*50.0%*	*50.0%*	*50.0%*	*55.0%*	*60.0%*	*65.0%*
Operating, General & Admin	$3.186	$3.527	$1.262	$1.901	$1.6	$1.9	$6.7	$10.0	$12.5	$15.0
% SG&A	*89.3%*	*41.7%*	*38.3%*	*34.3%*	*25.8%*	*25.0%*	*29.4%*	*25.8%*	*23.7%*	*24.4%*
Research & Development	$2.205	$1.517	$0.308	$0.341	$0.3	$0.3	$1.3	$2.0	$2.0	$2.0
% R&D	*61.8%*	*17.9%*	*9.4%*	*6.1%*	*5.2%*	*4.5%*	*5.8%*	*5.2%*	*3.8%*	*3.3%*
Amortization & Depreciation	$0.578	$1.025	$0.277	$0.277	$0.3	$0.3	$1.1	$0.8	$0.7	$0.6
Operating Income	($2.400)	$2.389	$1.446	$3.001	$3.9	$4.8	$13.2	$25.1	$36.0	$41.8
Operating Margin	*-67.2%*	*28.2%*	-	-	-	-	*58.2%*	*64.6%*	*68.2%*	*68.0%*
Interest & Other Net	$0.089	$0.155	$0.055	$0.060	$0.0	$0.1	$0.2	$0.1	$1.1	$2.1
Pre-Tax Income	($2.311)	$2.544	$1.501	$3.061	$3.9	$4.9	$13.4	$25.2	$37.1	$43.9
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$3.8	$11.1	$13.2
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*15%*	*30%*	*30%*
Net Income	($2.311)	$2.544	$1.501	$3.061	$3.9	$4.9	$13.4	$21.4	$26.0	$30.7
YOY Growth	-	*-210.1%*	-	-	-	-	*-680.2%*	*888.6%*	*93.7%*	*22.2%*
Reported EPS	**($0.10)**	**$0.10**	**$0.06**	**$0.13**	**$0.16**	**$0.20**	**$0.55**	**$0.86**	**$1.02**	**$1.18**
YOY Growth	-	*-209.3%*	-	-	-	-	*-672.3%*	*864.5%*	*86.5%*	*17.5%*
Shares Outstanding	24.2	24.4	24.4	24.5	24.6	24.7	24.6	25.0	25.5	26.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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HISTORICAL ZACKS RECOMMENDATIONS

Chart Generated by Yahoo! Inc.

Initiation of Coverage = 1/03/2012 @ $0.64 / share

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