April 28, 2014

OUTPERFORM

Reason for report:

INITIATION

Jason M. Gerberry, JD
(617) 918-4549
Jason.Gerberry@Leerink.com

Christopher W. Kuehnle, JD
(617) 918-4851
Chris.Kuehnle@Leerink.com

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CORIUM INTERNATIONAL, INC.

Attractive Entry Point for High Barrier Transdermal Business; Initiate at OP

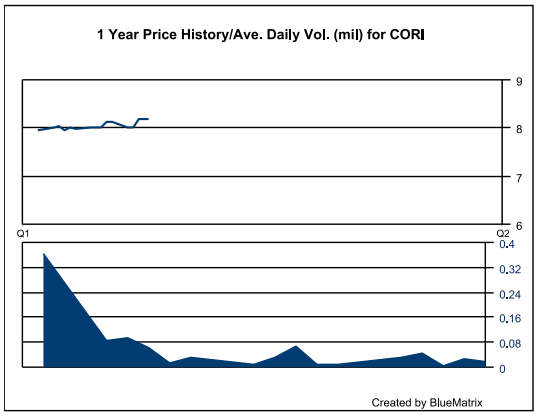
• **Bottom Line:** We are initiating coverage of CORI with an Outperform rating and a price target of ~$11.25/shr. CORI's current valuation largely reflects its base business – a stable, transdermal patch mfg business. While CORI's pipeline gets little credit in the current valuation, we view the risk/reward as favorable keyed by Phase 3 Twirla, a contraceptive patch partnered with Agile Therapeutics. We view Twirla as a low development risk (75% probability of success) product with potential to reach $400m in peak US sales. Beyond Twirla – CORI has several self-funded Phase 2 assets which have the potential to generate non-dilutive partnership dollars sometime in 2015. Also, we are confident in the ability of CORI mgmt to build a diversified transdermal product portfolio based on their experience at Alza, a pioneer in transdermal delivery systems.

• **Validated transdermal platform drives bulk of current valuation.** CORI's base business is keyed to three partnered, adhesive products, which account for most of the company's ~$45m/year in sales. Base biz sales are expected to decline Y/Y in F'14E, as CORI benefitted from 1x competitor supply issues in F'13. After re-basing this fiscal year, we view CORI's base biz as highly durable given: (1) mfg barriers to entry on relatively niche products; and (2) CORI has a solid mfg track record. Assuming a 2.5x EV/S valuation – consistent with durable generic pharma assets – CORI's base business represents ~$7.00/shr, or ~85% of the current price.

• **Favorable risk/reward heading into Ph. 3 data for Twirla in '15.** Two earlier Phase 3 studies for twirla (contraceptive patch partnered with Agile) resulted in a CRL due to "study conduct" issues which led the FDA to conclude study results were un-interpretable. Agile plans to address study protocol issues by limiting upcoming Ph. 3 enrollment to: (1) more experienced study sites; and (2) ensuring tighter enrollment of pts groups more likely to comply with therapy. MEDACorp physician specialists believe Agile's pending Ph. 3 protocols should significantly improve Twirla odds of study success. While the contraceptive market is large and competitive, we forecast a 3-5% peak share based on physician feedback & need for a low-dose hormone patch.

• **Pipeline full of potential call options.** CORI has 3 partnered pipeline products subject to pending marketing applications and 12 partnered or self-funded products in earlier stages. More notable are Ph. 2 assets – Corplex-tamsulosin for BPH and MicroCor-PTH for osteoporosis – which receive little or no credit and could drive 2015 partnership dollars. Also, several earlier stage programs have potential to become more visible in next 12-18 months. While CORI's MicroCor platform isn't factored into our valuation, its potential to transdermally transport larger molecules (biologics & peptides), a major limitation of current transdermal tech, has potential to create a multiplier effect on the stock price longer term.

Key Stats:	**(NASDAQ:CORI)**
S&P 600 Health Care Index:	**1,229.39**
Price:	**$8.19**
Price Target:	$11.25
Methodology:	Sum-of-Parts DCF Analysis
52 Week High:	$8.48
52 Week Low:	$7.67
Shares Outstanding (mil):	18.2
Market Capitalization (mil):	$149.1
Book Value/Share:	$0.00
Cash Per Share:	$3.30
Dividend (ann):	$0.00
Dividend Yield:	0.0%



Sep Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2013A	--	--	--	--	50.3	--	--	--	--	(2.40)	NM
2014E	10.5A	10.8	11.3	11.1	43.6	(0.21)A	(0.17)	(0.26)	(0.47)	(1.15)	NM
2015E	--	--	--	--	50.8	--	--	--	--	(0.95)	NM

Source: Company Information and Leerink Partners LLC Research
Revenues in millions.
GAAP EPS.

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CORI Initiation of Coverage Report

JASON GERBERRY, JD
DIRECTOR, SPECIALTY PHARMACEUTICALS ANALYST
JASON.GERBERRY@LEERINK.COM
617.918.4549

CHRIS KUEHNLE, JD
ASSOCIATE, SPECIALTY PHARMACEUTICALS
CHRIS.KUEHNLE@LEERINK.COM
617.918.4851

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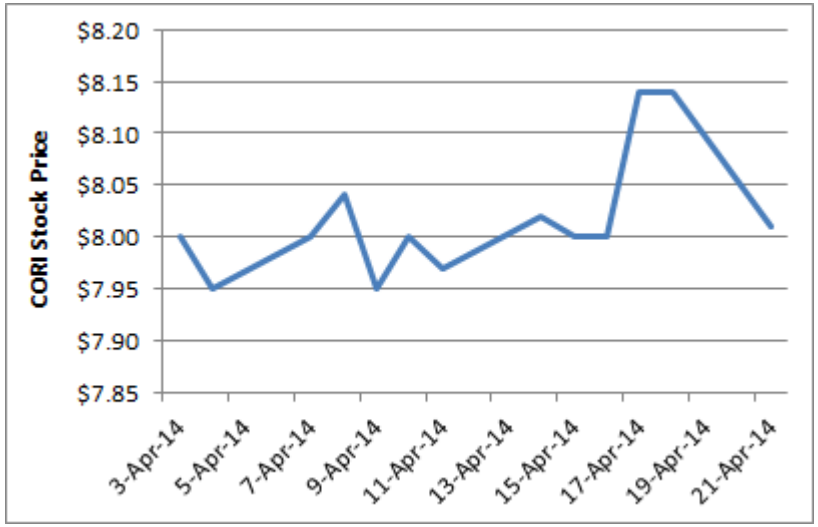
Corium International (CORI): Outperform

Rating: Outperform

Current Price: $8.19

Leerink Price Target: ~$11.25

Market Cap: $149M



Source: FactSet

Leerink Estimates (Revenues in $MM)

LP Ests	CORI Revenue	GAAP Diluted EPS
F'2014	43.6	(0.96)
F'2015	50.8	(0.95)
F'2016	67.1	(0.67)

- Investment thesis: We are initiating coverage of CORI with an Outperform rating and a price target of ~$11.25/shr. CORI's current valuation largely reflects its base business – a stable, transdermal patch mfg business. While CORI's pipeline gets little credit in the current valuation, we view the risk/reward as favorable keyed by Phase 3 Twirla, a contraceptive patch partnered with Agile Therapeutics. We view Twirla as a low development risk (75% probability of success [POS]) product with the potential to reach $400m in peak US sales. Beyond Twirla – CORI has several self-funded Phase 2 assets which have the potential to generate non-dilutive partnership dollars sometime in 2015. With its recent IPO proceeds, we believe CORI will be able to leverage its transdermal formulation expertise & secure better partnership terms which should dramatically alter the margin profile of the company. Lastly, we are confident in CORI mgmt's ability to build a diversified transdermal-delivery spec pharma company based on their experience at Alza, a pioneer in transdermal and modified delivery drugs.

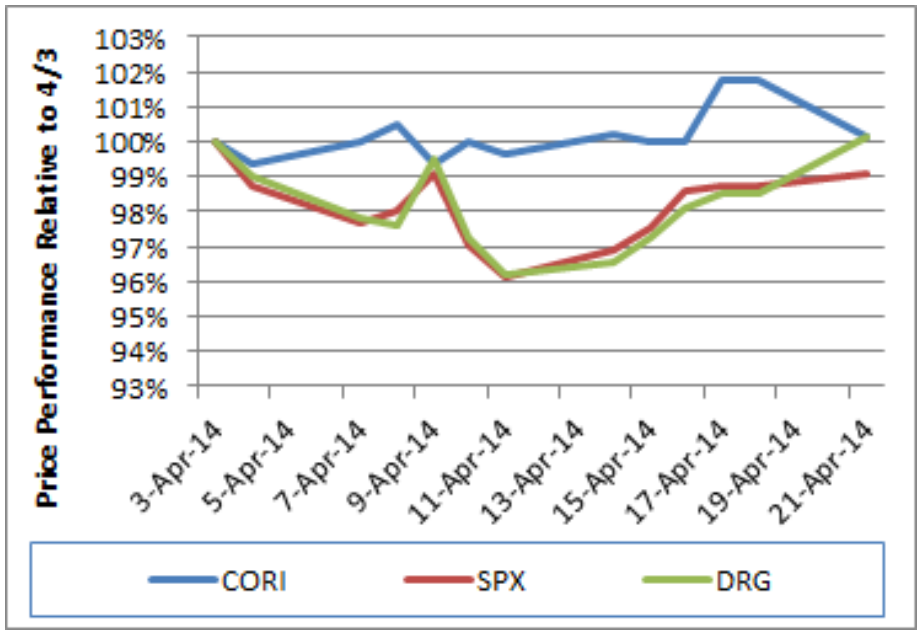
- Valuation: Our ~$11.25 PT is based on a sum-of-the-parts valuation analysis: (1) base business = ~$7.00, based on 2.5x multiple on ~$50m F'15E revenue from base business products, (2) Twirla = ~$1.75, (3) Ph. II products = ~$2.00, (4) Microcor = ~$0.75, (5) net debt of (35c).

- Risks to Valuation: Potential risks to CORI valuation include: (1) clinical failure of Twirla Ph. III; (2) incremental competitive headwinds in fentanyl and/or clonidine transdermal delivery system (TDS) markets; & (3) product recalls and/or current good manufacturing practice (cGMP) issues relating to existing commercial products could negatively impact valuation.

To Date, CORI Has Been a Relative Market Performer

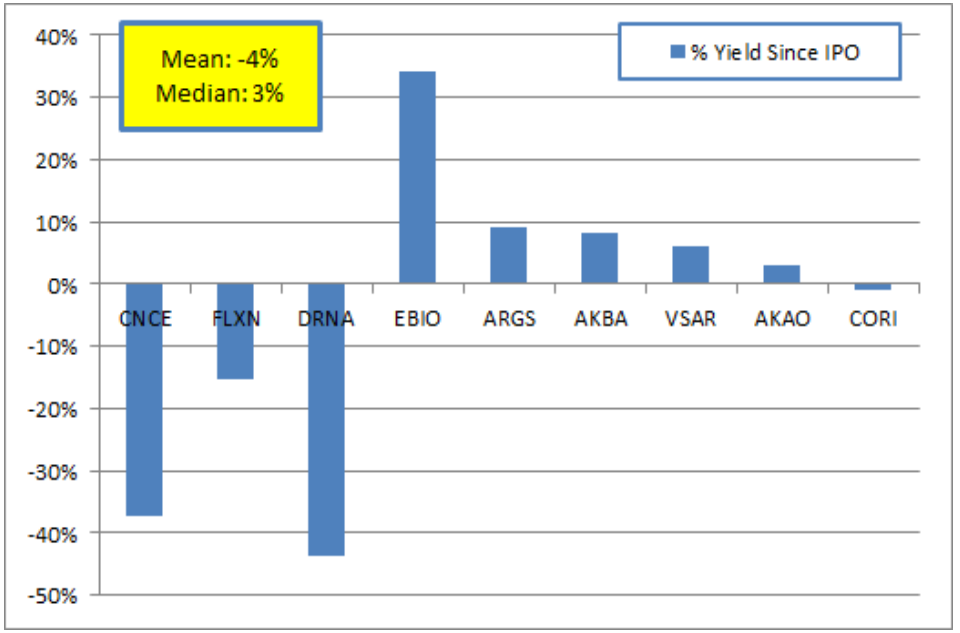
- On April 3, shares of CORI were listed on the NASDAQ. Pricing of common shares IPO (initial public offering) was set at $8/shr. Since the IPO, CORI shares have traded in line with the market and the DRG pharmaceutical index. Relative to other biopharma IPOs in 2014, CORI's to date performance has been relatively in line.

CORI stock performance post IPO



Source: FactSet

Performance Relative to Rest of 2014 IPO Class



Note: performance following IPO pricing
Source: FactSet

CORI Is Focused on Development of Transdermal Drug Delivery Systems

- **Company summary**: CORI is a biopharmaceutical company with a focus on developing specialty pharma products using transdermal and transmucosal delivery systems. CORI's current business model is predicated on partnerships with marketing partners, although the company may look to vertically integrate longer term depending on the success of its product development strategy. With its partners, CORI has successfully developed six marketed products in the prescription and consumer markets, including clonidine transdermal delivery system (TDS), fentanyl TDS & 4 Crest Whitestrip products. CORI's pipeline consists of three partnered products and 12 partner- or self-funded programs at earlier stages. Late stage pipeline consists of: (1) Twirla, a Ph. 3 contraceptive patch; and (2) two late stage generic ANDAs under TEVA (OP) partnership. CORI is one of only a few companies with the capability to develop and manufacture transdermal products. The company has two proprietary technology platforms: Corplex (small molecules) and MicroCor (for biologics & vaccines) which were designed for broad use in multiple drug categories.

- **History of CORI**: The company was founded in 1999. CORI has commercial manufacturing facilities in Grand Rapids, MI which range from complete process development and scale-up services to commercial manufacture. The company's R&D and office facilities are located in Menlo Park, CA. Peter Staple has served as CEO & Director of the Board since 2008. Key partnerships on marketed products include: (1) in 2002, CORI entered into deal to mfg and supply generic Duragesic, which Par Pharma currently markets; (2) in 2004, CORI entered into a deal with TEVA for four TDS products; & (3) in 2005, CORI entered into a deal with P&G that included four oral care whitestrip products. CORI plans to use IPO proceeds to fund: (1) Phase 2 development costs for MicroCor PTH and Corplex Tamsulosin (brand Flomax); (2) scale up of production capability for MicroCor products; & (3) formulation and development costs for proprietary Corplex products, including feasibility testing on several central nervous system (CNS) products.

Management Team Has Deep Experience in the Transdermal Delivery Business

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- Peter Staple (President & CEO since 2008)
  - Previously CEO at BioSeek, Inc., a drug discovery company that applied predictive human biology, from 2002-07. Prior to BioSeek, starting in 1994, Mr. Staple held various positions at Alza Corp., most recently as Executive VP, Chief Administrative Officer and General Counsel
- Robert Breuil (CFO since 2012)
  - Previously CFO of Codexis, Inc., a developer of biocatalysts for the pharmaceutical and fine chemical production industries, from 2006-09. Prior to Codexis, Mr. Breuil was CFO of Aerogen, Inc., from 2002 to Oct. 2005. Prior to Aerogen, Mr. Breuil held numerous positions at Alza, including Director of Corp Planning and Analysis and Controller.
- Parminder Singh, Ph.D. (Chief Technology Officer & VP of R&D since 2002)
  - Previously held R&D and senior management positions at Novartis International AG, Ciba-Geigy and Vyteris. Dr. Singh holds a Ph.D. in Pharmaceutics from the University of Queensland, Australia

Both the CEO and CFO trace their roots back to Alza, a pharma company that helped pioneer novel drug delivery systems including transdermal drug delivery and controlled-release oral delivery of tablets

Key Investment Issues

- **We expect CORI shares to outperform the market over the next 12-18 months due to:**
  - **Durability of base business**. Currently, investors expect significant competitive headwinds to CORI's base business products, namely clonidine and fentanyl TDS. While clonidine benefitted in F'13 from competitor supply disruptions, the product still competes in a generic duopoly, and we expect pricing to remain favorable in that market. In the larger fentanyl category, we forecast the TEVA/CORI product losing ~200 bps of market share as competitors using a different technology (matrix patches) appear to be growing in favor. Overall, we see the competitive pressures to clonidine/fentanyl as a 1x re-basing relative to historical sales levels, and we remind investors that the CORI products have been relatively stable in these markets for 4-7 years and there is little incentive for new entrants to pony up the capital investment to compete in these niche markets.
  - **Phase 3 data for Twirla in the 2H'15 likely to be positive and serve as a meaningful catalyst for CORI**. High Pearl Index scores confounded FDA analysis of two earlier Phase 3 trials, but (1) screening of new users and other non-compliant patient groups and (2) exclusion of poorly monitored study sites will likely address prior study protocol issues. We view Twirla as a $400m potential peak sales product – given large category size, high degree of product "churn" and unmet need for low hormone patch product.
  - **CORI has a deep early stage pipeline; partnerships and data flow over the next 12-18 months could surprise**. In our view, the most likely sequence of catalysts to come from CORI's pipeline include: (1) potential partnership dollars for Corplex-tamsulosin and/or MicroCor PTH sometime in 2015; (2) potential data flow for Corplex-CNS programs, which CORI is self-funding through feasibility stage; and (3) potential updates on CORI's 10-12 other less visible pipeline programs.

- We forecast CORI's three base business products remaining relatively stable at ~$35m in our F'14-F'19 forecast period. In addition, we forecast CORI's pipeline reaching sales of ~$35-40m in F'19 led by Twirla revenue contribution. Currently, there is no sell-side consensus for CORI sales.

Sum-of-Parts Valuation Suggests a ~$11.25/shr Valuation for CORI

Base Business (EV/S)	2.5x F'15 sales of ~$50m = ~$125m, or ~$7.00/share
Twirla (risk adj NPV)	Peak sales of $400m at 75% POS translates to NPV of ~$1.75/share
Phase 2 Products	Using deal comps and assuming 30% probability of success – we est. ~$2.00/share
Net Debt	Post-IPO, CORI has pre-existing cash of $7.4m + net proceeds of $52m less outstanding debt of $65.9m, or net debt of $7m or -35c/share
Total Sum-of-Parts Valuation	**~$10.50/share** **+~$0.75 / share for Microcor technology** **= ~$11.25**

Source: Leerink Research ests

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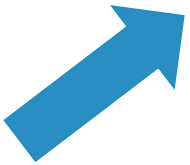
CORI Pipeline & Upcoming Events

Brand	Platform	Partner	Indication	Current status	Next milestone	Timing	p/s terms (actual or LP forecast)
Scopolamine	Patch	TEVA	Motion sickness	Registered	launch	1Q'15	~10% margin
Urologic product	Patch	TEVA	Overactive bladder	ANDA approved	Settlement to launch	2015	~10% margin
Twirla	Patch	Agile	Contraception	Ph. 3	Ph. 3 data	2H'15	~10% margin
Tamsulosin	Patch	none	BPH	Ph. 2 ready	Ph. 2 data	mid-2015	margin+ royalty or ~40% margin
Aricept/Namenda	Patch	none	Alzheimer's	feasibility stage	Ph. 1 human studies	1H'16	margin + royalty
Requip/Mirapex	Patch	none	Parkinson's	feasibility stage	Ph. 1 human studies	1H'16	margin + royalty
PTH	MicroCor	none	Hyperparathyroidism	Ph. 2 ready	Start Ph. 2a PK	2H'14	profit share or 50/50

BPH = benign prostatic hyperplasia
Source: CORI company presentations & Leerink Research estimates



These are Leerink Partners estimates of possible evolution of CORI deal terms

Key to the CORI development strategy is to self-fund products further into development and obtain more favorable economics on partnership terms

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Pivotal Data for Twirla the Biggest Catalyst in the 12-18 Month Time Horizon

CORI - Key Upcoming Events

Date	Event	Comments
Mid 2014	Partner Agile to initiate Ph. 3 for Twirla (OC patch)	
2H'14	Start of Ph. 2a PK trial for MicroCor hPTH product	
4Q'14/1Q'15	Possible ANDA approval - motion sickness drug	
2015	Settlement to launch oxybutynin (partner TEVA)	
2H'15	Est. Ph. 3 Twirla data	
Late 2016	Target Twirla US launch	

Source: Company information; Leerink ests

Phase 3 data for Twirla (contraceptive) is the biggest catalyst for CORI in the next 24 months, but Phase 2 assets (PTH & Corplex-tamsulosin) have the potential to yield partnerships with non-dilutive upfront dollars

Passive Transdermal Delivery (Small Molecules)

Passive Drug Delivery Portfolio: Cheat Sheet

Background

- **Portfolio description**: CORI develops and manufactures passively delivered small molecules, which fall into one of two categories: (1) patches designed by partners, such as Agile's Ph. 3 Twirla and TEVA's clonidine; or (2) patches using CORI's proprietary Corplex technology, a drug-in-adhesive patch. In general, passive delivered TDS drugs offer the benefit of avoiding liver metabolism (safety), and patch delivered drugs improve compliance vs. oral drugs.

- **Product history**: Commercial products w/ adhesive patches – (1) fentanyl TDS, (2) clonidine TDS, (3) Crest whitestrips. Development stage products include Corplex-tamsulosin and Agile-designed Twirla.

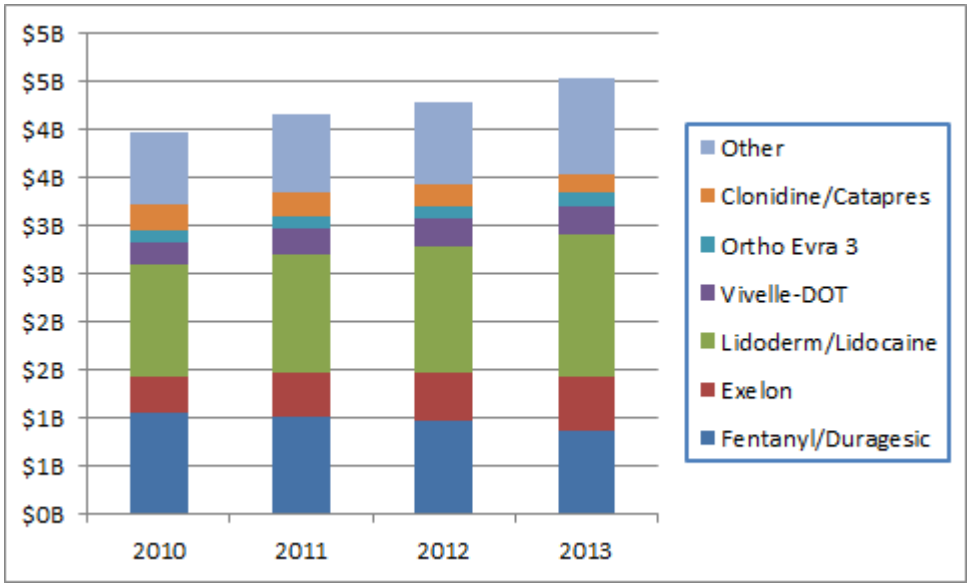
- **Patch markets**: The market for patch products is primarily dominated by small molecule, lower dose drugs in the hormone, pain, and smoking cessation spaces. CORI's two prescription patches are indicated for pain & hypertension. CORI's pipeline includes 4+ adhesive patch products targeting: (1) Twirla for contraception, (2) BPH – Corplex formulation, (3) motion sickness, (4) "urologic condition."

- **Intellectual property**: CORI currently has 28 patents covering Corplex. However, according to CORI, the IP covering passive delivery of small molecule drugs is largely in the public domain and generics could theoretically design around the technology. As such, trade secrets, cost barriers, and mfg know-how tend to be the primary barriers around passive delivered products.

Leerink Partners outlook for passive delivery market

- **Existing US market is largely generic**: Several of the largest TDS patch products currently have an interchangeable generic, such as ENDP's (OP) Lidoderm, and JNJ's (OP) Duragesic. In addition, some of the smaller patch products such as JNJ's Ortho Evra and NVS's Vivelle Dot are expected to see generic competition imminently. CORI's passive delivery product strategy is two-fold: (1) self-fund early development of off-patent drugs and improve the tolerability, convenience, and potential efficacy profile – e.g., brands such as Flomax and Aricept; & (2) pursue partnerships where CORI develops TDS for proprietary molecules.

TDS US annual revenue history



Source: IMS

Background on Transdermal Drug Delivery

- **How it works:** The primary challenge of TDS is circumventing the skin's outermost layer, the stratum corneum – typically the drug leaves the drug-containing adhesive and is transported across the stratum corneum via diffusion through intercellular lipids. Most FDA-approved patches consist of a backing, an adhesive (containing drug), and a liner protecting the adhesive layer. Variations of the 1st generation patches include multiple layers of drug in the adhesive, drug reservoirs attached to the adhesive, and "matrix" systems.

- **Types of molecules most applicable to TDS delivery:** Most transdermal products are best suited to low molecular weight compounds (few hundred Daltons) that are lipophilic and require low doses. Early patch technology is not well suited for large molecule and hydrophilic compositions.

- **Benefits of TDS:** (1) less painful, less infection risk, and can be self-administered versus hypodermic needles; (2) more bioavailability than many oral drugs – which can be prematurely metabolized – meaning TDS delivered drugs may have a smoother release profile and may be more tolerable.

- **Mfg TDS systems:** Manufacture of 1st generation transdermal products is more complicated than typical oral/tablet drugs – requiring an additional heat seal laminate packaging step – but is generally viewed as easier than other complex products (respiratory, large molecule injectables, etc.). Manufacture of interchangeable generics can be complicated where variations in delivery technology (e.g., reservoir vs. matrix design, degree of adhesion) can draw concern from the FDA.

Base Biz: Topical Patch Tech Is Validated Through Partnerships & Commercial Track Record

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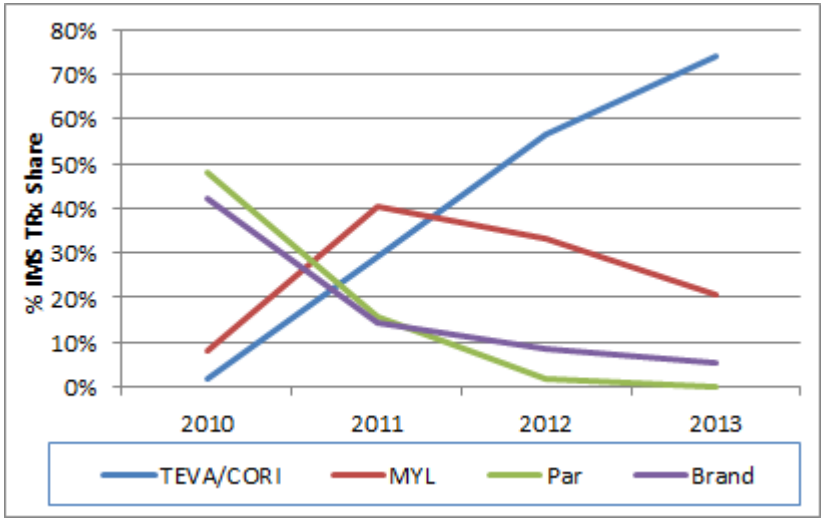
- **Generic clonidine has been a near-term revenue driver & durable contributor.**
  - The market for generic clonidine TDS came into formation in 2010 and has seen no more than three generic players to date. As shown on the right, TEVA/CORI have benefitted from competitor supply disruptions, notably MYL & Par's supply disruptions in 2012 and 2011, respectively.

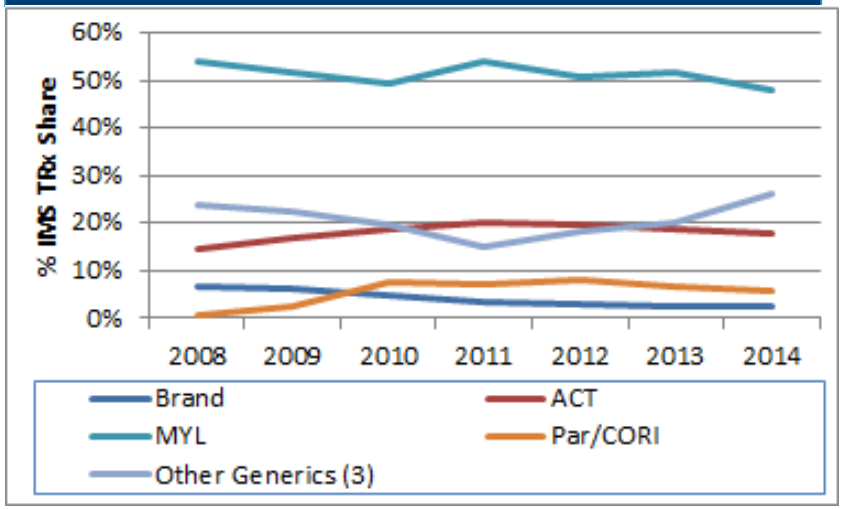
Generic clonidine market



Source: IMS

- **Generic fentanyl has been a strong contributor historically; some headwinds going forward however**:
  - Par sells generic fentanyl TDS that is mfg by CORI; the drug was approved in 2007. The Par product was subject to recalls in '08 & '10. The market has seen increased competition from MNK (MP) & Apotex. Partner Par has informed CORI that forecasted F'14 demand suggests sales down significantly vs. F'13.

Generic fentanyl TDS market



Source: IMS

Clonidine Has Been a Durable Contributor; Competitor MYL Has Fully Recovered From Supply Disruption

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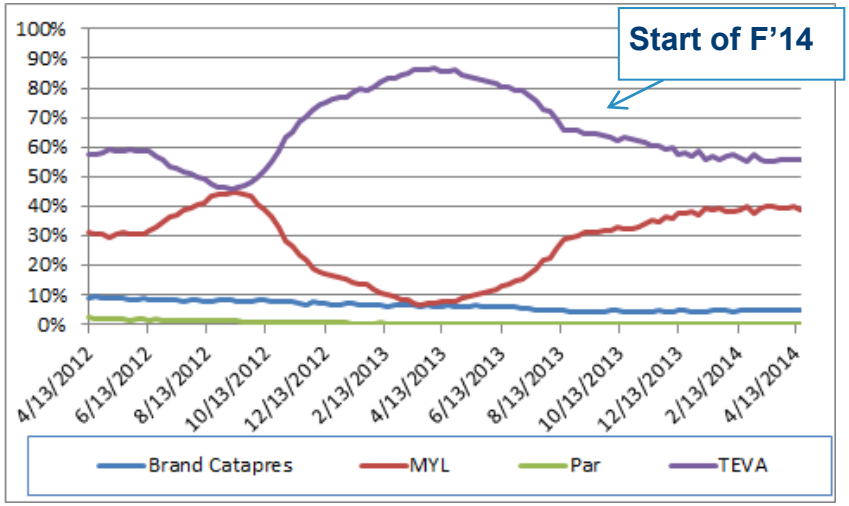
- **Background**: Clonidine TDS is the generic equivalent of Catapres TTS, a hypertension brand drug sold by Boehringer Ingelheim. TEVA markets generic clonidine TDS, which is manufactured by CORI. The TEVA product has historically served as a market leader in the category. In F'13, TEVA/CORI benefitted from a competitor (MYL) supply disruption. However, as of late 2013, MYL has returned to full supply and regained its lost market share. Competitor Par sells g-clonidine manufactured by partner Aveva, but the Par/Aveva product has been absent from the market as Aveva works to implement mfg process improvements.

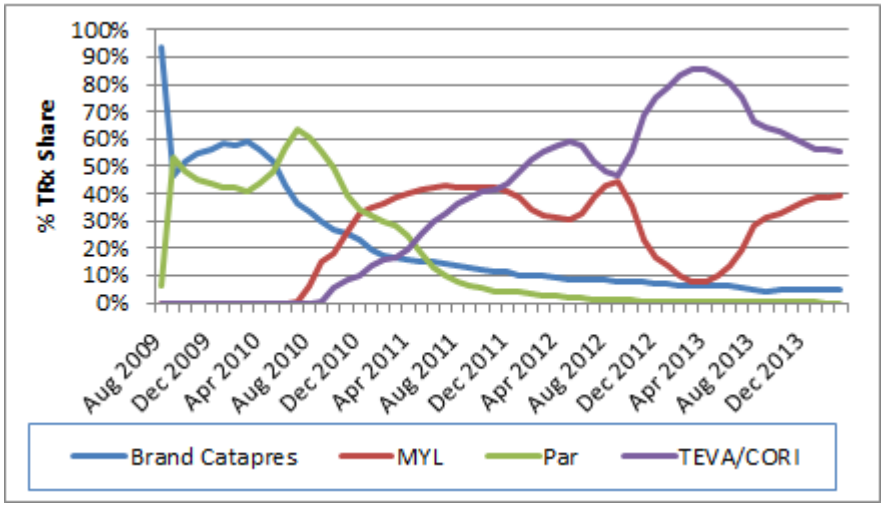
- **Leerink Partners outlook for clonidine in F'14 product**. Based on IMS script data, we est the TEVA/CORI product should capture ~55% share of the clonidine market vs. 75% in the prior year. Assuming pricing remains relatively stable (we est. 30% WAC price discount), we forecast $10.0m in F'14 sales. CORI books transfer pricing and a share of profits on clonidine, which we est. is ~10% of total TEVA sales sales.

Weekly clonidine TDS Trends



Source: IMS

Monthly clonidine TDS Trends



Source: IMS

Fentanyl TDS Expected to Be Down Y/Y in More Competitive & Fragmented Market

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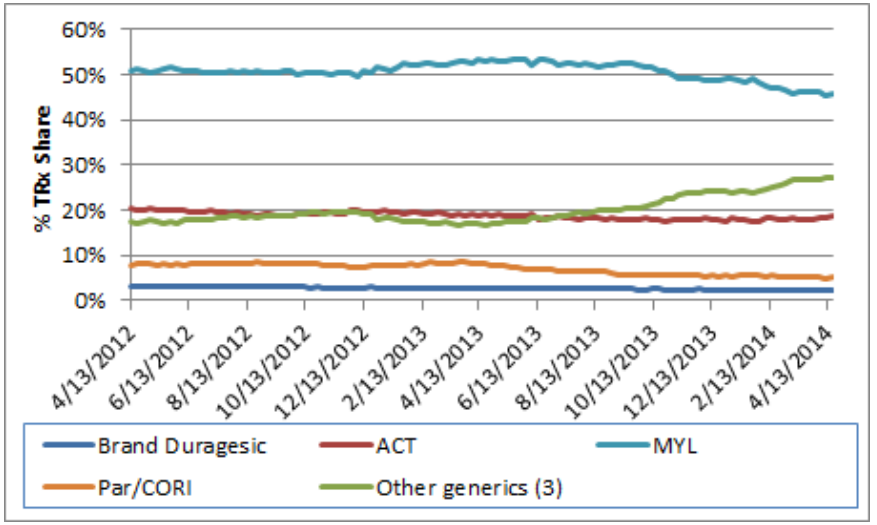
- **Background**: Fentanyl TDS is the generic equivalent of Duragesic, an opioid pain brand sold by JNJ's Janssen. Par Pharma markets generic fentanyl TDS, which is manufactured by CORI. The Par product has historically captured less than 10% market share. According to CORI, its fentanyl TDS uses a reservoir design whereas most of its competitors use a matrix, which may put the Par product at a competitive disadvantage vs. other competitors given abuse concerns associated with a reservoir product.

- **F'14 sales expected to be down due to competition**. The fentanyl TDS market is fragmented, as illustrated by script data on the right. CORI notes in its S-1, "forecasted demand that indicates we should expect revenues from Fentanyl TDS to decline significantly in fiscal 2014." Fiscal YTD, the IMS script trends suggest F'14 market share for the Par/CORI product will be down ~200 bps relative to F'13. We note that MNK is an active pharmaceutical ingredient (API) supplier of fentanyl and has a slight cost advantage in this market. CORI/Par are working on next-gen product and believe they may have an advantage if they can develop a matrix to go along with their reservoir product.

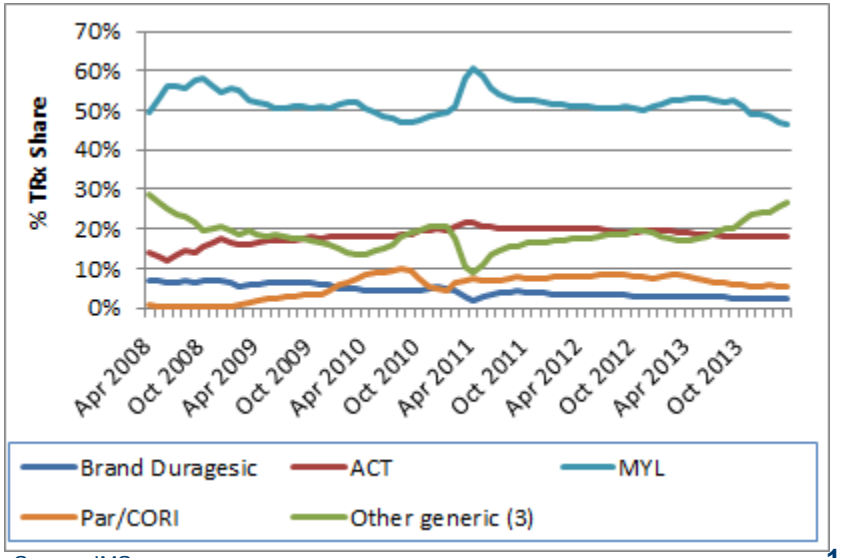
- **Fentanyl margins in line with other commercial products**. The economic terms on fentanyl include a transfer price, a profit share, and a cost true-up with partner Par. While CORI doesn't disclose the terms of its partnership, the company characterizes all of its products as equally important and we est. the company nets a 10% margin on its reported sales of fentanyl.

Weekly fentanyl TDS Trends



Source: IMS

Monthly fentanyl TDS Trends



Source: IMS

Passive Delivery Pipeline Provides Potential Optionality in 2015

- **Competition in patch delivery is limited**. Companies with capabilities to deliver small molecules transdermally include 3M, Johnson & Johnson, Lohmann Therapies Systems or LTS, MYL, Hisamitsu or Noven, and ACT
  - **Comps are either private (Noven & LTS) or too large/diversified to be considered CORI comps (JNJ, MYL, ACT)**

- **Late stage pipeline provides a few products that we expect to facilitate modest top-line growth offsetting declining base product sales**
  - **Next-gen whitestrips** should cannibalize existing strip products and perhaps drive modest growth
  - **Urology ANDA** (likely Oxybutynin) is a relatively small brand and TEVA settlement may not envision an OTC product (nat'l brand has 3-yr exclusivity)
  - **Scopolamine** is a $70-80m brand, which in a two-player market (brand & generic) could translate to $2-4m in CORI booked sales (assumes 10% of TEVA revenues)

- **Other pipeline agents are expected to provide a steady flow of catalysts in 2015…**
  - **Ph. 3 Twirla data in 2H'15** will serve as an important de-risking event
  - **Ph. 2 Tamsulosin TDS data** (mid-2015) potentially will establish non-inferiority and provide pot'l signals around differentiation

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Intellectual Property

- **Robust patent portfolio around platform technology**. At present, CORI holds 38 US issued patents and 147 foreign issued patents and 28 US pending patents and 60 foreign pending patents relating to Corplex and MicroCor technologies.
  - Of the issued US patents, 21 relate to composition of matter and 17 relate to use or process. The US issued patents will expire between 2019 and 2034.
- **Passive delivery covered by shorter-lived patents and generally rely on non-patent barriers to entry.** Most of the passive delivery patents expire in 2019. According to CORI, the more likely barriers to entry around the passive delivered drugs are trade secrets, mfg know-how, and financial barriers to entry. As a category – generic development of passive delivered drugs may be susceptible to design-around approaches, although with products such as clonidine we've seen very limited competition since TEVA launched in 2007 given the niche size of the brand and the cost of mfg the products.
- **MicroCor technology has larger IP barriers to entry.** CORI has patents covering MicroCor arrays (expire 2034) and the proprietary features associated with the micro needles. In addition, CORI will be able to file new patents for each drug/formulation that it develops.

Agile Appears to Have Taken Proper Steps to Ensure Twirla's Next Ph. 3 Will Succeed

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Background

- Twirla is a Phase 3 contraceptive patch containing the active ingredients levonorgestrel (progestin) and ethinyl estradiol (EE or estrogen), both of which are commonly used in marketed oral contraceptives. Based on Agile's pharmacokinetic study, Twirla was found to deliver 30mg/day of EE, which is generally considered a low dose. Twirla was designed using Agile's proprietary skinfusion technology. To date, Twirla has completed two Phase 3 studies, but the FDA ultimately raised concerns about study conduct and issued a July 2013 complete response letter (CRL) stating Agile would need to conduct a new Phase 3 before being considered for approval. Twirla has five issued patents that will expire in 2028.

Steps Taken by Agile to Address Study Conduct Issue

- **Recent complete response letter includes:** (1) upper bound 95% confidence interval around the Pearl Index exceeded 5, making study results insufficient to interpret; (2) low completion rate and missing data; (3) FDA does not believe an active comparator trial is necessary in third Phase 3 study.
- **Agile/Cori view**: (1) Pearl Index was similarly high with approved oral contraceptive, suggesting the problem with the study population; (2) high number of new users and minorities, both of which historically have lower compliance rates; (3) Agile will seek to address shortcomings through better investigator selection (have database of experienced users), trial will monitor diaries to disqualify non-compliant pts early, and will screen for women with prior pregnancy.

Summary of Twirla Phase 3 data

Ph. 3 Study	Number of subjects	Design	Pearl Index		Range for FDA approved drugs
			Drug	comparator	
Pooled data	1900	Open label, randomized, active comparator (oral contraceptive)	5.76	6.72	1.34-3.19

Source: clinicaltrials.gov

Study sites	% distribution of study pregnancies
60 sites	0%
1 site	19%
4 sites	36%
31 sites	45%

Source: Agile Therapeutics S-1

A large percentage of on-treatment pregnancies occurred at 5 treatment centers

Leerink Partners Outlook for Twirla and MEDACorp OB/GYN Specialists' Feedback

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Planned Ph. 3	Design
Treatment arms	Single-arm study
# of subjects/tx duration	2,000 female patients treated for up to 1 year
# of study sites	50-70 US sites with experience conducting contraceptive studies
Other protocols	Subjects will use an electronic diary to record data key to calculation of Pearl Index (PI); pts conducting themselves in non-compliant manner will be pulled from study

- **In general, specialists believe highly diverse study population led to study conduct issues.** Physician specialists indicated to us that they believe earlier Twirla studies likely failed because the highly diverse study population included so many patient groups with a track record of poor compliance. The specialists generally believe Twirla is efficacious and should generate an interpretable result if a more conservative study population is evaluated in the next Phase 3; this was born out in subset data.

- **Twirla would provide a differentiated product**: (1) lower dose than brand/generic Ortho Evra, which has higher dose of EE; & (2) there are no other contraceptive patches on the market besides Ortho Evra. Physician specialists we've spoken with say that patches provide a convenience benefit, which was the main benefit with Ortho Evra vs orally dosed products.

- **Contraceptive market is large & consumers like product variety**: According to physician specialists, female patients tend to trial a number of different contraceptive products in their lifetime, meaning contraception is a high churn market and a safe, low dose alternative has a good chance of being trialed by pts.

- **Ortho Evra launch provides some evidence of market demand for a patch**. Ortho Evra launched in early 2002 and achieved 10% market share by Sept. 2003. However, subsequently, Ortho Evra required label changes indicating its EE dosage levels were 60% higher than an 35mg OC (vs. initial labeling of 20mg). Ortho Evra's share has rapidly declined from peak share of 11% (2005) to 1.4% in 2013.

- **However, we don't see Twirla as a $1B product given competitive landscape**. While Ortho Evra experienced a stellar launch in early 2002, we'd caution investors from using the same launch trajectory for Twirla, given the fact that since the Ortho Evra launch there are: (1) more low dose hormone alternatives; (2) including ring and IUD contraceptive products. Specialists envision Twirla being a niche product that could capture 5-10% share of the contraception market.

Source: MEDACorp formulation specialist calls

MicroCor Active Delivery (Large Molecules)

MicroCorTechnology: Cheat Sheet

- **Portfolio description**: CORI currently has one product in human clinical development with the MicroCor system (hPTH for osteoporosis) but intends to pursue numerous additional opportunities. The key technical hurdles to developing micro needle delivery of drugs is making the formulation tolerable and ensuring room temperature stability.

- **Product history**: To date, the market for biodegradable microneedles has yet to be validated – in addition to CORI's osteoporosis product which is the most advanced microneedle, there are two firms (Theraject & Fujifilm) which have developed biodegradable microneedle tech but remain unpartnered.

- **How it works:** Microneedles represent the 3rd generation of transdermal technology in which drug is delivered to the system via very small needles that painlessly pierce the stratum corneum. There are four broad categories of microneedle development: (1) solid microneedles for skin pre-treatment before application of drug, (2) microneedles coated with drug, (3) hollow microneedles for infusion of liquid formulations, (4) biodegradable microneedles which dissolve in the skin.

- **Pipeline for passive delivery drugs**: Aside from biodegradable microneedle patches, there are two other microneedle formulations in development: (1) hollow microneedle patch by 3M/Radius for osteoporosis, with a New Drug Application (NDA) expected in '19; and (2) drug coated microneedle by Zosano for severe osteoporosis, Ph. III-ready, which remains un-partnered.

- **Intellectual property**: MicroCor IP is comprised of 22 patents covering array composition and method of manufacturing, with expirations extending to 2034.

- **Product classes being targeted with MicroCor technology**: MicroCor holds the potential to provide an alternative route of delivery for vaccines, peptides, and certain biologic drugs. The theoretical benefit of MicroCor delivery is to: (1) eliminate the need for cold storage; and (2) avoid needles.

Source: Company filings, USPTO

Comparison of Active Delivery Approaches

Development-stage Passive Delivery Systems

Technology	Company	Description of technology	Most advanced drug	Leerink Comments
MicroCor	Corium	Biodegradable polymer based microstructure	hPTH(1-34) for Osteoporosis	Potential to deliver greater drug than competitor hollow microneedles
Microneedle patch system	Zosano	Patch is size of a quarter, contains up to 1,500 titanium microneedles 0.22mm; needles are coated w/drug	ZP-PTH for severe osteoporosis; also partnered with Novo Nordisk on GLP-1 analogue for type 2 diabetes	Ph. III ready; 2-year shelf life
Hollow microneedle	3M	Contains 18 needles arranged across an array that is about the size of a U.S. dime. Designed to provide high-volume (0.5-2 mL) delivery of liquid formulations.	BA058-TD for osteoporosis; partnership with Radius	Ph. II complete; data "support the continued development of an injection-free delivery system." Expect to file NDA in 2019.
Dissolvable microneedles	Theraject	1 cm disc with 29 micro-needles made of sugar which dissolve when inserted into the skin	Seeking partnership	
Dissolvable microneedle	Fujifilm	Micro-needle array with projections of 100-2000 micrometers; polysaccharide micro-needles are dissolvable	Seeking partnership	

Source: Company filings

PTH Represents Potential Validation of MicroCor Platform, Which Remains a "Show Me" Story

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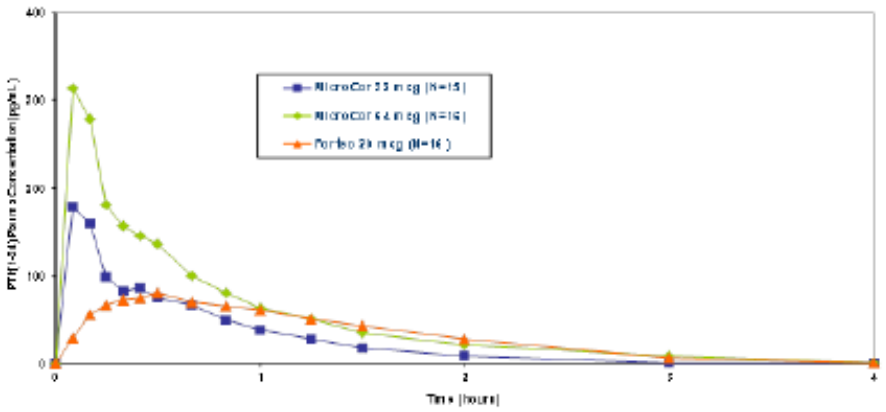
- **Background**: LLY (OP) markets Forteo (PTH) for treatment of osteoporosis. US and international sales of Forteo were ~$510M and ~$730M in 2013, respectively. Forteo is once-daily subcutaneously delivered and has US patents protecting the franchise until Aug. '19. CORI is developing a transdermally delivered version of PTH with a similar dosing profile (once-daily) but with improved PK characteristics (faster onset and shorter half-life). In addition, CORI believes patch delivery will be preferred and could offer LLY a potential life cycle extension product. CORI's plan is to fund development of its PTH product through Phase 2, after which the company will pursue partnership opportunities.

- **MicroCor development pathway/milestones**
  - **Ph. 2a –** ongoing; running a PK study in the target population of osteoporosis pts
  - **Ph. 2b –** a 6-month safety/efficacy trial
  - **Ph. 3 –** a 12-month non-inferiority study under the 505(b)(2) pathway and a dermal toxicity study as a toxicology bridge
  - **Mfg** – currently, CORI can mfg at Phase 2 scale and plans to scale up to Phase 3 scale with IPO proceeds

Phase 1 PK Profile of MicroCor PTH



Source: CORI investor presentation

Pipeline of PTH follow-on Products

Company	Route of delivery	Status
CORI	Transdermal patch	Ph. II ready
Zosano	Transdermal patch	Ph. II complete
Radius/3M	Subcutaneous	Ph. II complete
Bone Medical	Oral	Evaluating dosing for Ph. IIb as of 5/15/13
Critical Pharmaceuticals	Intranasal	Ph. I initiated 4/15/14

Source: Company filings

Use of Proceeds from Recent IPO Offering

- $15 million to $18 million for Phase II clinical trials for MicroCor hPTH(1-34) and Corplex Tamsulosin
- $15 million to $18 million for scale-up of production capability for its MicroCor products;
- $5 million to $7 million for formulation and development of its proprietary Corplex products;
- $2 million to $4 million for advancement of its MicroCor technology;
- $5.2 million for the repurchase of shares of common stock;
- Any remaining balance for working capital and other general corporate purposes.

Source: Company filing

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CORI Revenue Forecasts

CORI Annual Product Summary

(Fiscal Year End Last Friday of September)	2012	2013	1Q 12/13	2Q 3/14E	3Q 6/14E	4Q 9/14E	2014E	2015E	2016E	2017E	2018E	2019E	CAGR 14-16E	CAGR 14-19E
clonidinne TDS, partner TEVA (brand: Catapres TTS)	10.7	12.5	2.6	2.5	2.5	2.4	10.0	8.8	8.8	7.9	7.9	7.9	-6%	-5%
fentanyl TDS, partner Par (brand: Duragesic)	15.0	16.4	3.1	3.0	3.0	2.9	12.0	11.6	10.5	10.5	10.5	10.5	-6%	-3%
Crest White Strips, partner P&G	10.0	9.8	2.4	2.8	2.9	3.0	11.0	12.0	13.2	14.5	16.0	17.6	10%	10%
Total in-line patch sales	**35.7**	**38.7**	**8.1**	**8.3**	**8.4**	**8.3**	**33.0**	**32.3**	**32.5**	**32.9**	**34.3**	**35.9**	**-1%**	**2%**
scopolamine TDS, partner TEVA (brand: Transderm Scop)	-	-	-	-	-	-	-	3.5	3.0	3.0	3.0	3.0	na	na
oxybutynin TDS, partner TEVA (brand: Oxytrol)	-	-	-	-	-	-	-	-	-	-	-	-	na	na
AG200-15 contraceptive patch, partner Agile	-	-	-	-	-	-	-	-	4.0	10.0	16.0	20.0	na	na
P&G OTC cosmetic product	-	-	-	-	-	-	-	-	4.0	6.0	9.0	14.0	na	na
Corplex Tamsulosin	-	-	-	-	-	-	-	-	-	-	-	-	na	na
Alzheimer's TDS (505b2 path)	-	-	-	-	-	-	-	-	-	-	-	-	na	na
Parkinson't TDS (505b2 path)	-	-	-	-	-	-	-	-	-	-	-	-	na	na
Total pipeline patch product sales	-	-	-	-	-	-	-	**3.5**	**11.0**	**19.0**	**28.0**	**37.0**	**na**	**na**
hPTH (1-34) TDS	-	-	-	-	-	-	-	-	-	-	-	-	na	na
Product royalties	-	-	-	-	-	-	-	-	-	-	-	-	na	na
Contract Research & Development	6.8	10.8	2.1	2.3	2.6	2.5	9.5	13.0	16.0	20.0	24.0	26.0	30%	22%
License & Collaboration Revenue	0.3	0.8	0.3	0.2	0.3	0.3	1.1	2.0	7.7	14.3	21.7	23.0	164%	84%
Total Revenues	**42.9**	**50.27**	**10.5**	**10.8**	**11.3**	**11.1**	**43.6**	**50.8**	**67.1**	**86.2**	**108.0**	**121.9**	**24%**	**23%**
% Y/Y growth	na	17.3%					-13.3%	16.6%	32.0%	28.5%	25.3%	12.9%		

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Source: Company reports and Leerink Research estimates

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CORI P&L Forecasts

CORI P&L Summary (Adj. Basis)

(Fiscal Year End Last Friday of September)	2012	2013	1Q 12/13	2Q 3/14E	3Q 6/14E	4Q 9/14E	2014E	2015E	2016E	2017E	2018E	2019E	CAGR 14-16E	CAGR 14-19E
Total Revenues	**42.9**	**50.27**	**10.5**	**10.8**	**11.3**	**11.1**	**43.6**	**50.8**	**67.1**	**86.2**	**108.0**	**121.9**	**24%**	**23%**
% Y/Y growth	na	17.3%					-13.3%	16.6%	32.0%	28.5%	25.3%	12.9%		
COGS	34.6	36.7	8.8	9.3	9.6	10.6	38.2	41.9	53.8	65.9	80.0	90.0	19%	19%
% of net sales	80.7%	73.0%	83.7%	86.5%	85.0%	95.3%	87.7%	82.5%	80.2%	76.4%	74.0%	73.8%		
Gross Income	**8.3**	**13.6**	**1.7**	**1.5**	**1.7**	**0.5**	**5.4**	**8.9**	**13.3**	**20.4**	**28.1**	**31.9**	**57%**	**43%**
% of product sales	19.3%	27.0%	16.3%	13.5%	15.0%	4.7%	12.3%	17.5%	19.8%	23.6%	26.0%	26.2%		
G&A	4.6	6.5	1.8	2.0	3.0	3.2	10.0	10.2	10.4	10.5	10.6	10.6	2%	1%
% of net sales	11%	13%	17.3%	18.6%	26.5%	28.8%	22.9%	20.1%	15.5%	12.2%	9.8%	8.7%		
R&D	4.0	5.5	0.9	2.0	3.0	4.1	10.0	12.0	11.0	10.0	10.0	10.0	5%	0%
% of net sales	9.3%	10.9%	8.2%	18.6%	26.5%	37.3%	22.9%	23.6%	16.4%	11.6%	9.3%	8.2%		
Amortization	0.5	1	0.1	-	-	(0.1)	-	-	-	-	-	-	na	na
% of net sales	1.2%	1.1%	1.2%	0.0%	0.0%	-1.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		
Gain on equipment sale	-0.1	-0.2	(0)	-	-	0	-	-	-	-	-	-	na	na
% of net sales	-0.1%	-0.4%	-0.4%	0	0.0%	0.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		
Operating Income	**(0.8)**	**1.2**	**(1)**	**(3)**	**(4)**	**(7)**	**(15)**	**(13)**	**(8)**	**(0)**	**7**	**11**	**-26%**	NA
% of net sales	-1.9%	2.4%					-33.6%	-26.2%	-12.1%	-0.2%	6.9%	9.3%		
Net financial expense	(4.6)	(15.1)	(1.0)	(0.5)	(0.5)	(1.9)	(3.9)	(4.0)	(4.0)	(4.0)	(4.0)	(4.0)	1%	0%
Pretax Income	**(5.5)**	**(13.9)**	**(2)**	**(3)**	**(5)**	**(9)**	**(18.6)**	**(17.3)**	**(12.1)**	**(4.1)**	**3.5**	**7.3**	**-19%**	**na**
% Pre-tax margin	-12.7%	-27.6%	-20.0%	-28.4%	-42.5%	-77.8%	-42.6%	-34.0%	-18.0%	-4.8%	3.2%	6.0%		
Income Taxes (benefit)	(0)	0	-	-	-	-	-	-	-	-	-	-	na	na
% Tax rate	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		
GAAP Net Income	**(5.4)**	**(13.9)**	**-2**	**-3**	**-5**	**-9**	**(18.6)**	**(17.3)**	**(12.1)**	**(4.1)**	**3.5**	**7.3**	**NA**	**na**
% of net sales			-20.0%	-28.4%	-42.5%	-77.8%								
Diluted GAAP EPS	**(2.47)**	**(2.40)**	**(0.21)**	**(0.17)**	**(0.26)**	**(0.47)**	**(1.15)**	**(0.95)**	**(0.67)**	**(0.23)**	**0.19**	**0.40**	**NA**	**NA**
% growth	nm	nm					nm	nm	nm	nm	nm	111%		
Weighted Average Diluted Shares	2.2	5.8	10.1	18.2	18.2	18.2	16.2	18.2	18.2	18.2	18.2	18.2	6%	2%
% growth		163%	238%	333%	213%	79%	179%	12%	0%	0%	0%	0%		

Source: Company information, Leerink Research estimates.

$MM, except per share data

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CORI Balance Sheet

Balance Sheet	2012	2013	2014E	2015E	2016E	2017E	2018E	2019E
Cash and cash equivalents	12.2	13.6	44.7	25.2	11.8	10.4	13.6	20.6
Accounts receivable, net	2.8	3.1	2.9	3.4	4.5	5.7	7.2	8.1
Unbilled accounts receivable	2.2	1.5	1.0	1.0	1.0	1.0	1.0	1.0
Inventories	4.4	4.5	4.8	5.2	6.7	8.2	10.0	11.2
Prepaid expenses & other current assets	0.9	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Total Current Assets	**22.5**	**23.8**	**54.4**	**35.8**	**25.0**	**26.3**	**32.8**	**42.0**
PPE, net	7.0	12.6	10.9	12.7	16.8	21.6	27.0	30.5
Debt financing costs	1.1	0.9	1.0	1.0	-	-	-	-
Intangible assets	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6
Notes receivable	-	0.1	-	-	-	-	-	-
Total Long-term assets	14.7	20.3	18.5	20.4	23.4	28.2	33.7	37.1
Total Assets	**37.2**	**44.0**	**73.0**	**56.2**	**48.4**	**54.5**	**66.4**	**79.2**
Liabilities & Shareholder's Equity								
Accounts Payable	3.3	2.7	3.5	3.8	4.9	6.0	7.3	8.2
Accrued expenses & other current	3.4	3.4	3.4	3.4	3.4	3.4	3.4	3.4
Bank lines of credit	1.6	3.9	1.0	1.0	1.0	1.0	1.0	1.0
Long-term debt, current portion	0.6	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Capital lease	0.6	1.0	0.5	0.5	0.5	0.5	0.5	0.5
Preferred stock warrant liability	0.5	0.6	0.5	0.5	0.5	0.5	0.5	0.5
Recall liability, current portion	0.5	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Deferred contract revenue	0.9	2.1	1.0	1.0	1.0	1.0	1.0	1.0
Total Current Liabilities	**11.4**	**15.2**	**11.3**	**11.6**	**12.7**	**13.8**	**15.1**	**16.0**
Long-term interest payable	9.9	11.6	11.6	11.6	11.6	11.6	11.6	11.6
Long-term debt	29.2	37.0	37.0	37.0	37.0	(0.0)	(0.0)	(0.0)
Convertible notes	10.0	9.4	9.4	9.4	9.4	9.4	9.4	9.4
Subordinated note	13.0	13.0	13.0	13.0	13.0	13.0	13.0	13.0
Subordinated note, derivative liability	-	7.4	7.4	7.4	7.4	7.4	7.4	7.4
Capital lease oblig, net of current	0.4	1.7	1.7	1.7	1.7	1.7	1.7	1.7
Recall liability, net of current	4.5	3.8	3.8	3.8	3.8	3.8	3.8	3.8
Deferred contract revenue, net of current	4.6	3.7	3.7	3.7	3.7	3.7	3.7	3.7
Long-term liabilities	71.7	87.5	87.5	87.5	87.5	50.5	50.5	50.5
Total Liabilities	**83.1**	**102.6**	**98.8**	**99.1**	**100.2**	**64.3**	**65.6**	**66.5**
Total Shareholders' Equity	(45.9)	(58.6)	(25.8)	(43.0)	(51.8)	(9.8)	0.8	12.7
Total Liabilities & Shareholders' Equity	37.2	44.0	73.0	56.2	48.4	54.5	66.4	79.2

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Source: Company reports and Leerink Research estimates

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CORI Statement of Cash Flows

Reported Cash Flow	2012	2013	2014E	2015E	2016E	2017E	2018E	2019E
Operating Activities								
GAAP Net Income	(5.4)	(13.9)	(18.6)	(17.3)	(12.1)	(4.1)	3.5	7.3
Depreciation & amortization	2.0	1.9	1.9	1.9	1.9	1.9	1.9	1.9
Share-based comp	0.1	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Other operating activities	(2.1)	8.4	-	-	-	-	-	-
Changes in Working Capital	5.6	2.3	2.0	2.0	2.0	2.0	2.0	2.0
Net Operating Cash Flow	0.0	(1.0)	(14.4)	(13.1)	(7.9)	0.1	7.7	11.6
Investing Activities								
Capex	(1.9)	(7.2)	(6.0)	(6.0)	(5.0)	(4.0)	(4.0)	(4.0)
Proceeds from sale of equipment	0.0	0.0	-	-	-	-	-	-
Increase in notes receivable	(0.0)	(0.1)	-	-	-	-	-	-
Payments for patents & licensing rights	(0.5)	(0.7)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)
Net Financing Cash Flow	(2.4)	(7.9)	(6.5)	(6.5)	(5.5)	(4.5)	(4.5)	(4.5)
Financing Activities								
Proceeds from issuance long-term debt	36.5	7.2	-	-	-	-	-	-
Proceeds from issuance capital leases	0.1	2.3	-	-	-	-	-	-
Payments convertible notes	(10.0)	-	-	-	-	-	-	-
Payment of transaction costs, l-temr debt	(1.7)	(0.1)	-	-	-	-	-	-
Principle payments l-term debt	(8.8)	(0.8)	-	-	-	(37.0)	-	-
Principle payments capital lease oblig	(0.5)	(0.6)	-	-	-	-	-	-
Borrowing on bank line of credit	24.7	5.8	-	-	-	-	-	-
Proceeds from exercise of stock options	(26.3)	(3.5)	-	-	-	-	-	-
Other financing items, net	0.0	0.0	52.0	-	-	40.0	-	-
Net Financing Cash Flow	**14.0**	**10.3**	**52.0**	-	-	**3.0**	-	-
Net Change in Cash	**11.7**	**1.3**	**31.1**	**(19.6)**	**(13.4)**	**(1.4)**	**3.2**	**7.1**
Cash - Beginning Balance (Oct. 1)	0.6	12.2	13.6	44.7	25.2	11.8	10.4	13.6
Cash - Ending Balance (Last Friday of Sep	**12.2**	**13.6**	**44.7**	**25.2**	**11.8**	**10.4**	**13.6**	**20.6**

$MM
Source: Company reports and Leerink Research estimates

Disclosures Appendix

Analyst Certification

I, Jason M. Gerberry, JD, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Distribution of Ratings/Investment Banking Services (IB) as of 03/31/14				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	131	68.23	46	35.11
HOLD [MP]	61	31.77	3	4.92
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

Important Disclosures

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While IMS Health has been used as a source, the analysis contained herein has been arrived at independently by the firm and IMS is not responsible for the analysis or use of the data.

Leerink Partners LLC Equity Research

Director of Equity Research	**John L. Sullivan, CFA**	(617) 918-4875	john.sullivan@leerink.com
Associate Director of Research	**Alice C. Avanian, CFA**	(617) 918-4544	alice.avanian@leerink.com
Healthcare Strategy	**John L. Sullivan, CFA**	(617) 918-4875	john.sullivan@leerink.com
	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Biotechnology	**Howard Liang, Ph.D.**	(617) 918-4857	howard.liang@leerink.com
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com
	Marko Kozul, M.D.	(415) 905-7221	marko.kozul@leerink.com
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com
	Irene Lau	(415) 905-7256	irene.lau@leerink.com
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com
	Gena Wang, Ph.D., CFA	(212) 277-6073	gena.wang@leerink.com
	Richard Goss	(617) 918-4059	richard.goss@leerink.com
Life Science Tools and Diagnostics	**Dan Leonard**	(212) 277-6116	dan.leonard@leerink.com
	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com
Pharmaceuticals/Major	**Seamus Fernandez**	(617) 918-4011	seamus.fernandez@leerink.com
	Ario Arabi	(617) 918-4568	ario.arabi@leerink.com
Specialty Pharmaceuticals, Generics	**Jason M. Gerberry, JD**	(617) 918-4549	jason.gerberry@leerink.com
	Christopher W. Kuehnle, JD	(617) 918-4851	chris.kuehnle@leerink.com
Medical Devices, Cardiology & Orthopedics	**Danielle Antalffy**	(212) 277-6044	danielle.antalffy@leerink.com
	Richard Newitter	(212) 277-6088	richard.newitter@leerink.com
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com
Healthcare Services	**Ana Gupte, Ph.D.**	(212) 277-6040	ana.gupte@leerink.com
Healthcare Technology & Distribution	**David Larsen, CFA**	(617) 918-4502	david.larsen@leerink.com
	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com
Sr. Editor/Supervisory Analyst	**Mary Ellen Eagan, CFA**	(617) 918-4837	maryellen.eagan@leerink.com
Supervisory Analysts	Robert Egan		bob.egan@leerink.com
	Amy N. Sonne		amy.sonne@leerink.com

New York
299 Park Avenue, 21st floor
New York, NY 10171
(888) 778-1653

Boston
One Federal Street, 37th Floor
Boston, MA 02110
(800) 808-7525

San Francisco
201 Spear Street, 16th Floor
San Francisco, CA 94105
(800) 778-1164