Siena Market Line
2nd week of February 2015

ANI Pharmaceuticals, Inc.

NASDSAQ:ANIP

Analyst: Pamela Juergens
Sector: Healthcare

BUY

Price Target: $82.09

Key Statistics as of 2/12/2014

Market Price:	$61.94
Industry:	Biotechnology
Market Cap:	$705.37 M
52-Week Range:	$19.90-71.78
Beta:	3.6

Thesis Points:

- Diversified revenue and earnings base
- Focus on revenue growth, active with product acquisitions
- Deep pipeline, addressing large, diversified markets
- Relatively low risk compared to name brand biotechs

Company Description:

ANI Pharmaceuticals, Inc. is an integrated specialty pharmaceutical company that develops, manufactures and markets branded and generic prescription pharmaceuticals. They manufacture a wide range of drugs including solid dose products, as well as liquids, topicals, narcotics and potent products. Their targeted areas of development include pain management (narcotics), anti-cancer (oncolytics), and women's health (hormones and steroids). Their products include Esterified Estrogen with Methyltestosterone (EEMT) tablets for use in treating vasomotor symptoms of menopause, Fluvocamine Maleate to treat obsessions and compulsions in patients with obsessive-compulsive disorder, Hydrocortisone Enema and Cortenema for the treatment of ulcerative colitis, and Metoclopramide and Reglan for treating gastroesophageal reflux. ANI Pharmanceuticals markets and sells their products through wholesalers, retail market chains, distributors, mail order pharmacies, and hospitals.

Thesis

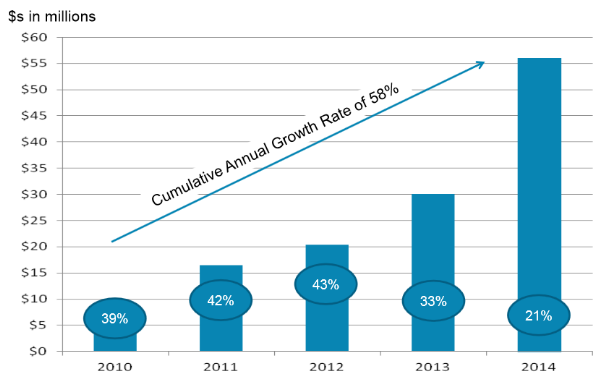
ANI Pharmaceuticals has a largely diversified portfolio with a total combine current market, as well as a pipeline of 48 products that they manufacture and products they acquire, with an addressable market of approximately $2.8 billion. The company is very active with product acquisitions, and it is likely to continue in the future, further diversifying their pipeline. Their revenue has been growing rapidly, and it is expected to continue to grow as they launch, as well as acquire more products. They expect to launch between five and six products in FY 2015, driving their topline growth. Since they develop generic drugs, they are relatively low risk compared to name brand drug makers.

Current Product Portfolio

ANI currently maintains a diversified product portfolio, where they have a leading market share for all of the different drugs that they offer. In ANI's current product portfolio their most important product is generic Esterified Estrogen with Methyltestosterone (EEMT). EEMT is indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause in patients not improved by estrogen alone. For the year ended December 31, 2014, EEMT comprised of 44% of ANI's sales , an increase from the 33% in FY 2013. This is partially because a large competitor stopped producing EEMT, which led to a large increase in market share and allowed them to significantly increase the price that they charge. They have a 44% market share with EEMT. Company management believes that ANI is on track to become the only supplier of EEMT, once the competition exhausts the supply of material, sometime during Q3 2014. If they were to become the sole supplier, this could translate to an increase in annual revenue of approximately $43 million, based on their current 44% market share. Another generic product is Fluvoxamine, which is indicated for the treatment of obsessions and compulsions in patients with obsessive compulsive disorder. It is generally used when the obsessions and compulsions interfere with the patient's ability to function socially and occupationally. It currently has a leading position in the market and a 55% market share. Another generic product they offer is hydrocortisone enema. HC Enema is used to treat mild or moderate ulcerative colitis. ANI also has a leading position in the market with HC Enema, and enjoys a 90% market share. Their next generic drug is Metoclopramide Solution, used as a short term (4 to 12 weeks) therapy for adults with symptomatic, documented gastroesophogeal reflux who fail to respond to conventional therapy. They have a number 2 position in the market and have a 29% market share. Another generic in their product portfolio is Opium tincture. It is an opiate used for treating diarrhea, which works by decreasing intestinal muscle contractions. ANI made two product acquisitions in July and August 2014 to add to their product portfolio. ANI acquired Lithobid in July 2014. It is used to treat the manic episodes of manic depression. Lithobid generated $3.3 million of sales in six months. They acquired Vanocin in August and it is used to treat several skin problems such as acne, acne rosacea, and seborrheic dermatitis. Vanocin generated $4.4 million of sales in 2014, representing five months of sales.

Focus on Immediate Revenue Growth

In June 2013 ANI and BioSante Pharmaceuticals merged, and the combined company became known as ANI Pharmaceuticals. Prior to the merger ANI had 11 products in development, which addressed markets with total sales of approximately $775 million. Since the merger ANI's pipeline has expanded to 49 products in development, addressing markets with total sales of $2.7 billion. Additionally, in 2014 ANI acquire Lithobid and Vanocin. ANI actively looks to acquire products to expand their portfolio. In December 2014, ANI closed an offering of 3% Convertible Senior Notes due 2019. Prior to this they were completely debt free. After the offering, they are sitting on approximately $165.5 million in cash. ANI's CEO has stated that they have the capacity to accommodate their existing pipeline and more for the next ten years and their facilities are fully owned, therefore the bulk of their funds will be used for accretive product acquisition. Their future acquisitions will target immediate revenue growth for the company. They have a CAGR for the last 5 years of 58%, with the trend likely to continue in the future.



Pipeline

After their merger ANI is sitting on an impressive pipeline of 49 products, 5 of which they plan to release in FY 2015. Two of the products that they plan to launch this year that are already approved, are Teva Pharmaceuticals testosterones (Bio-t-gel). ANI will receive a 5% royalty from all TEVA testosterone sales in the US, and they still retain global rights outside of the US to Bio-t-gel. Another promising pipeline asset is the GVAX portfolio. In 2013, BioSante sold their GVAX Cancer Immunotherapy portfolio to Audro Biotech for $1 million and future royalty, milestone and sub-license payments. The GVAX portfolio contains immunotherapy vaccines for pancreatic cancer, Melanoma, Leukemia, Prostate, Breast, Multiple Myeloma and colon cancer, three of which have orphan drug designation. Since Audro bought the GVAX portfolio they have signed several deals with Johnson and Johnson worth up to $1.182 billion in up-front and milestone payments, as well as future royalties. This portfolio has large potential for approvals because of the orphan drug designations, as well as future sales. The merger with BioSante gave ANI a stake in a number of products in development, and since development costs are solely the responsibility of other companies ANI will incur no expenses related to the development and only stands to generate revenues in the future.

Products	ANI	Partnered	Total
At FDA	6	3	9
Development	5	3	8
Acquired Products	29	-	29
Totals	40	6	46

Relatively Low Risk

Since their merger with BioSante, ANI has created a company in which some of the typical risks of a biotech stock are minimized. Since they create generic drugs, they submit ANDAs for approval instead of NDAs. An ANDA (Abbreviated New Drug Application) is submitted to the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, and provides for the review and ultimate approval of a generic drug product. Generic drug approvals are abbreviated because they are generally not required to include preclinical and clinical data to establish safety and effectiveness. Instead, generic drug applicants must scientifically demonstrate that their product is bioequivalent. There is a greater level of certainty in obtaining an ANDA approval, both in the cost, because there are no surprise requirements imposed by the FDA, and in receiving approval then there is with an NDA. ANI's focus on generics and mature branded products is a conservative approach to using their cash. However, they target the higher margin products in those two groups, which has allowed them to continue to grow, and provide a good return on investment.

Conclusion

ANI is positioned to continue to grow as they have up to this point, both organically and inorganically. They are actively acquiring products where they will incur no more costs, and only stand to benefit when the drugs go to market. They also have a diversified portfolio of generic and non-generic drugs on the market where they have significant market share.

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ANI Pharmaceuticals, Inc. ANIP	Analyst	Current Price	Intrinsic Value	Target Value	Divident Yield	Target Return	BULLISH
	Pamela Juergens	$61.94	$73.71	$82.09	0%	32.54%	

General Info

Sector	Healthcare
Industry	Pharmaceuticals
Last Guidance	Feb-19-2015
Next earnings date	NM

Market Data

Enterprise value	$647.03
Market Capitalization	$705.37
Daily volume	0.31
Shares outstanding	11.39
Diluted shares outstanding	11.05
% shares held by institutions	47.86%
% shares held by insiders	3.12%
Short interest	13.93%
Days to cover short interest	4.68
52 week high	$71.78
52-week low	$19.90
5y Beta	0.00
6-month volatility	59.80%

Peers	Market Cap.

Current Capital Structure

Total debt/market cap	17.11%
Cost of Borrowing	0.00%
Interest Coverage	2542.06%
Altman Z	3.00
Debt Rating	AAA
Levered Beta	1.54
WACC (based on market value weights)	10.03%

Management

Professional	Title	Comp. FY2012	Comp. FY2013	Comp. FY2014
Przybyl, Arthur	Chief Executive Officer, Presiden	$ -	$ 4,992,811.00	$ -
Arnold, Charlotte	Chief Financial Officer, Vice Presi	$ -	$ 2,037,441.00	$ -
Marken, James	Vice President of Operations	$ -	$ 1,454,632.00	$ -
Schrepfer, Robert	Vice President of New Business	$ -	$ 1,309,377.00	$ -
Sullivan, David	Vice President of Quality Operati	$ -	$ -	$ -

Historical Performance

	ANIP	Peers	Industry	All U.S. firms
Growth	77.2%		15.2%	6.0%
Retention Ratio	0.0%		103.4%	61.6%
ROIC			15.0%	11.8%
EBITA Margin	0.0%		19.0%	13.7%
Revenues/Invested capital	76.8%		91.9%	202.3%
Excess Cash/Revenue			44.9%	18.5%
Unlevered Beta			0.92	0.95
TEV/REV	8.4x		4.0x	2.4x
TEV/EBITDA	24.6x		12.4x	11.3x
TEV/EBITA	25.8x		15.3x	15.4x
TEV/UFCF			29.6x	26.8x

Past Earning Surprises

	Revenue	EBITDA	Norm. EPS
Last Quarter	17.0%	29.5%	19.6%
Last Quarter-1	19.2%	34.4%	43.5%
Last Quarter -2	-16.4%	-87.2%	
Last Quarter -3	-4.6%	18.1%	-2.9%
Last Quarter -4	14.7%	22.8%	40.0%

Non GAAP Adjustments

Operating Leases Capitalization	100%	Straightline	10 years
R&D Exp. Capitalization	100%	Straightline	10 years
Expl./Drilling Exp. Capitalization	0%	N/A	N/A
SG&A Capitalization	0%	N/A	N/A

Proforma Assumptions

Operating. Cash/Cash	0.0%
Unlevered Beta	1.40
Rev/Invested Capital	100.0%
Continuing Period Revenue Growth	3.0%
Long Term ROIC	11.1%
Invested Capital Growth	Equals to Maintenance
Justified TEV/REV	2.0x
Justified TEV/EBITDA	20.0x
Justified TEV/EBITA	15.0x
Justified TEV/UFCF	29.0x

Forecasted Profitability

Period	Rev. Growth	Adj. Op. Cost/Rev	Revenue	NOPLAT	Invested capital	UFCF
LTM	86%	47%	$55.97	$24.30	$87.70	$24.30
LTM+1Y	65%	49%	$92.35	$33.53	$105.90	$15.33
LTM+2Y	50%	51%	$138.53	$45.06	$126.23	$24.73
LTM+3Y	45%	51%	$200.86	$62.22	$152.52	$35.93
LTM+4Y	19%	52%	$239.03	$72.18	$169.49	$55.21
LTM+5Y	13%	52%	$270.53	$80.60	$183.74	$66.35
LTM+6Y	11%	52%	$301.52	$89.17	$198.06	$74.84
LTM+7Y	10%	52%	$332.27	$97.88	$211.51	$84.44
LTM+8Y	4%	52%	$345.81	$101.63	$218.16	$94.98
LTM+9Y	4%	53%	$358.34	$103.18	$224.19	$97.15

Valuation

	ROIC	WACC	EVA	Enterprise Value	Total Debt	Other claims	Equity	Adjusted Price
LTM	27.7%	10.0%	$15.51	$827.68	$110.69	-$111.53	$828.52	$74.67
LTM+1Y	38.2%	10.2%	$29.68	$904.38	$110.69	-$126.30	$919.99	$82.84
LTM+2Y	42.6%	10.3%	$40.68	$973.76	$110.69	-$144.60	$1,007.67	$90.50
LTM+3Y	49.3%	10.4%	$59.24	$1,042.53	$110.69	-$173.10	$1,104.94	$98.90
LTM+4Y	47.3%	10.6%	$62.32	$1,085.19	$110.69	-$221.04	$1,195.53	$107.03
LTM+5Y	47.6%	10.7%	$67.77	$1,124.96	$110.69	-$280.29	$1,294.56	$116.16
LTM+6Y	48.5%	10.8%	$74.77	$1,162.02	$110.69	-$348.15	$1,399.48	$125.12
LTM+7Y	49.4%	10.9%	$81.49	$1,193.29	$110.69	-$425.71	$1,508.32	$134.66
LTM+8Y	48.1%	11.0%	$80.83	$1,212.32	$110.69	-$514.92	$1,616.55	$144.27
LTM+9Y	47.3%	11.1%	$81.14	$1,233.08	$110.69	-$607.31	$1,729.70	$151.89

Monte Carlo Simulation Assumptions

	Base	Stdev	Min	Max	Distribution
Revenue Variation	0	10%	N/A	N/A	Normal
Op. Costs Variation	0	10%	N/A	N/A	Normal
Market Risk Premium	6%	N/A	5%	7%	Triangular
Long term Growth	3%	N/A	3%	77%	Triangular
Terminal Value	0	0.1	N/A	N/A	Normal

Monte Carlo Simulation Results

	Intrinsic Value	1y-Target
Mean est.	$74.67	$82.84
σ(ε)	$0.32	$0.25
3 σ(ε) adjusted price	$73.71	$82.09
Current Price	$61.94	
Analysts' median est.		$75.33