AEGIS CAPITAL CORP

Biopharmaceuticals
Difei Yang, Ph.D.
646-502-2436
dyang@aegiscap.com

Initiating Coverage

November 22, 2016

Key Metrics

MNTA - NASDAQ	$14.53
Pricing Date	Nov 21 2016
Price Target	$15.00
52-Week Range	$18.26 - $7.86
Shares Outstanding (mm)	71.0
Market Capitalization (mm)	$1,031.6
3-Mo Average Daily Volume	628,885
Book Value/Share	$4.72
Price/Book	3.1x

EPS FY: December

	2015A	Prior 2016E	Curr. 2016E	Prior 2017E	Curr. 2017E
1Q-Mar	(0.40)	--	(0.35)A	--	(0.21)E
2Q-Jun	(0.04)	--	(0.31)A	--	(0.19)E
3Q-Sep	(0.44)	--	(0.26)A	--	(0.16)E
4Q-Dec	(0.43)	--	(0.32)E	--	(0.15)E
FY	(1.32)	--	(1.23)E	--	(0.71)E
P/E	NM		NM		NM

REVENUE

	2015A	Prior 2016E	Curr. 2016E	Prior 2017E	Curr. 2017E
1Q-Mar	8.6	--	19.9A	--	25.7E
2Q-Jun	44.9	--	26.4A	--	27.1E
3Q-Sep	13.8	--	29.1A	--	30.1E
4Q-Dec	22.4	--	24.7E	--	31.6E
FY	89.7	--	100.1E	--	114.5E

Company Description:
Momenta is a biotechnology company focused on developing generic versions of complex drugs, biosimilars and novel therapeutics for oncology and autoimmune disease.

Momenta Pharmaceuticals Inc.

Rating: Hold

40mg Glatopa Commercial Launch Not Expected in 2017, Initiate with a HOLD and PT $15

Investment Highlights:

- **Biosimilars and Complex Generics.** In the business of bringing complex generics and biosimilar products to market, Momenta has developed an integrated platform of chemical/structural/biological analytics, process development, and regulatory/legal expertise. Enoxaparin served the purpose of validating the Momenta platform; further validated by Glatopa's (Generic 20 mg/ml COPAXONE) ANDA approval. In addition to honing in on Glotapa 40 mg approval, the company is also developing biosimilar products and novel therapeutics, each targeting a multi-billion dollar market. In our valuation we have given little consideration to the company's biosimilar and novel drug development programs due to uncertain market opportunities and/or being early in development cycle.
- **ANDA approval of Glatopa 40 mg is key, but at-risk launch not likely in our view.** The ANDA for 3-times-a-week generic Copaxone 40 mg submitted by Sandoz is currently under FDA review for which Momenta expects to secure approval 1Q2017. However, we believe that the litigation process is more complex than noted and Teva will likely exhaust all legal avenues before giving up. Until the patent situation is resolved, we expect the Copaxone 40 mg market to remain free of generics.
- **Return of Humira commercialization rights sours outlook.** In September 2016, stemming from the Shire-Baxalta merger, worldwide commercialization and development rights for Humira (M923) were returned to Momenta. Pursuant to the original agreement, the collaboration will terminate twelve months after notice, of which Shire will continue to cover program costs. We look to phase III trial results, expected before year end 2016. If positive the M923 timeline has the potential to include a submission for marketing approval around mid-2017. In terms of commercialization, we view Momenta's new search for a partner as another hurdle on the path towards the previously expected potential 2018 launch.
- **Valuation.** For valuation considerations, we assumed 40% market share capture by the generics to 20mg Copaxone at the end of 2016. We believe Glatopa may be the only generic to 20mg Copaxone for an extended period of time and our valuation for the generic We further assumed 40mg Glatopa will launch 2019. As a result, Copaxone franchise (20mg & 40mg) is $11/share. The cash position at the end of September 2016 is estimated to be $4/share. Therefore we reach a final target price of $15/share.
- **Risks.** Other than typical risks associated with investing in companies in the healthcare industries, such as R&D, regulatory, manufacturing, and commercialization risks, investing in Momenta Pharmaceuticals, Inc. carries several firm-specific risks: 1) ANDA approval in 1Q2017 may not materialize; 2) unpredictable outcomes and timelines surrounding litigation surrounding IP and patents.

The Disclosure section may be found on pages 5 - 6 of this report.

- **Biosimilars and Complex Generics.** In the business of bringing complex generics and biosimilar products to market, Momenta has developed an integrated platform of chemical/structural/biological analytics, process development, and regulatory/legal expertise. Enoxaparin served the purpose of validating the Momenta platform; further validated by Glatopa's (Generic 20 mg/ml COPAXONE) ANDA approval, which recently posted higher-than-expected revenue. In addition to honing in on Glotapa 40 mg approval, the company is also developing biosimilar products and novel therapeutics, each targeting a multiple billion dollar market. In our valuation we have given little consideration to the company's biosimilar and novel drug development programs as multiple developmental milestones need to be hit before we can have reasonable confidence of future revenue generation .
- **ANDA approval of Glatopa 40 mg is key.** The ANDA for 3-times-a-week generic Copaxone 40 mg submitted by Sandoz is currently under FDA review. Given that the approval only requires a review of a reformulation, as opposed to the comprehensive review of generic Copaxone 20 mg where the active pharmaceutical ingredient was investigated, Momenta expects to secure tentative FDA approval by early 2017. Management recently stated that they are confident in the ANDA approval and patent litigation against Teva, which is unlike previous litigations (e.g. Enoxaparin). However, we believe that the process is more complex than noted. The district court trial of Sandoz vs. Teva concluded on October 6, 2016 and we now look to 1Q17 (late January / early February) for a decision to be issued. If the outcome is favorable for Momenta, it is a positive step in the right direction, but Teva will likely appeal the decision. Until the patent situation is resolved, we expect the Copaxone 40 mg market to remain free of generics.
- **Grounded assumption of 2019 launch of generic 40mg Copaxone.** While the patent trial and appeal board's (PTAB's) invalidation of two of TEVA's patents are certainly a positive for Momenta, we see more hurdles as needing to be crossed before commercialization of 40mg Copaxone becomes a reality. There are currently five orange book listed patents for 40mg Copaxone that include '250, '413, '302, '776 and '874. The decision takes out '250 and '413, even if '302 patent is found invalid, there are still two patents, '776 and '874 to be litigated between Teva and generic challengers that include Momenta. Given the importance of 40mg Copaxone to Teva, we expect Teva to exhaust all legal avenues, e.g., it has already announced that it will challenge the decision on '250 and '413. Hence, it is difficult for us to believe an early 2017 commercial launch is feasible.
- **Return of Humira commercialization rights sours outlook.** In September 2016, stemming from the Shire-Baxalta merger, worldwide commercialization and development rights for Humira (M923) were returned to Momenta. Pursuant to the original agreement, the collaboration will terminate twelve months after notice, of which Shire will continue to cover program costs. We look to phase III trial results, expected before year end 2016. If positive the M923 timeline has the potential to include a submission for marketing approval around mid-2017. In terms of commercialization, we view Momenta's new search for a partner as another hurdle on the path towards the previously expected potential 2018 launch. At this stage in the game, we ultimately view the return of Humira commercialization rights as a damper on the company's outlook.
- **Crowded market space for Humira Biosimilars.** Given the high level of competition and crowded space surrounding Humira biosimilars, our views differ from Momenta's in terms of finding a suitable partner for M923. Amgen's Amjevita, the Humira Biosimilar closest to market, is currently slated to take the lion share of biosimilar market share. Other names with Humira biolsimilars in late stage development, chasing the same revenue, include Pfizer, Oncobiologics, Mylan, as well as a slew of Asian based competitors. We believe it may be difficult to find a sizable partner with favorable economics terms on M923 simultaneously.
- **Discontinue Necuparanib Phase II trial.** Late on August 3rd, 2016, the DSMB (Data Safety Management Board) issued a recommendation that Momenta discontinue the Phase II trial of its Necuparanib drug, which was designed to treat pancreatic cancer. The recommendation comes after the results from a planned interim futility analysis.

- **Slight beat in Third Quarter 2016.** Momenta reported 3Q16 numbers, slightly beating street's estimates. Revenue came in at $29.1 mil vs. consensus estimates of $26.1 mil and earnings loss per share came in at $(0.26) vs. consensus estimates of $(0.29). The bulk of revenue for the quarter came from Sandoz's Glatopa 20 mg sales ($23.3 mil). Going forward the next potential catalyst is surrounding Glatopa 40 mg tentative ANDA approval 1Q2017. However, we believe the market has priced in 40mg Glatopa not launching in 2017. Hence, it is possible that share price would not move upon the approval.

MOMENTA PHARMACEUTICALS, INC: CONSOLIDATED INCOME STATEMENT
(All figures in thousands of US Dollar, except per share items)

Period Ending	2012A	2013A	2014A	Q115A	Q215A	Q315A	Q415A	2015A	Q116A	Q216E	Q316A	Q416E	2016E	Q117E	Q217E	Q317E	Q417E	2017E
Enoxaparin Royalty Income	$54,772	$16,701	$19,963	$2,722	$100	$0	$2,200	$5,022					$0					$0
Generic Copaxone Income			$0		$19,205	$8,666	$15,610	$43,481	$14,800	$20,692	$23,339	$19,691	$78,522	$20,672	$22,148	$25,102	$26,578	$94,500
Research and Development	$9,149	$18,764	$32,287	$5,840	$25,595	$5,129	$4,583	$41,147	$5,050	$5,738	$5,805	$5,000	$21,593	$5,000	$5,000	$5,000	$5,000	$20,000
Total revenues	**$63,921**	**$35,465**	**$52,250**	**$8,562**	**$44,900**	**$13,795**	**$22,393**	**$89,650**	**$19,850**	**$26,430**	**$29,144**	**$24,691**	**$100,115**	**$25,672**	**$27,148**	**$30,102**	**$31,578**	**$114,500**
Research and development	$80,345	$103,999	$106,482	$22,749	$33,983	$31,733	$37,568	$126,033	$28,757	$33,173	$31,568	$31,252	$124,750	$24,443	$24,199	$24,441	$24,685	$97,769
General and administrative	$43,682	$41,057	$45,164	$7,890	$13,329	$12,459	$14,373	$48,051	$15,647	$14,896	$15,758	$16,073	$62,374	$15,912	$16,390	$16,881	$17,388	$66,572
Total costs and expenses	**$124,027**	**$145,056**	**$151,646**	**$30,639**	**$47,312**	**$44,192**	**$51,941**	**$174,084**	**$44,404**	**$48,069**	**$47,326**	**$47,325**	**$187,124**	**$40,356**	**$40,589**	**$41,323**	**$42,073**	**$164,341**
Operating (loss) income	**($60,106)**	**($109,591)**	**($99,396)**	**($22,077)**	**($2,412)**	**($30,397)**	**($29,548)**	**($84,434)**	**($24,554)**	**($21,639)**	**($18,182)**	**($22,634)**	**($87,009)**	**($14,684)**	**($13,440)**	**($11,221)**	**($10,495)**	**($49,841)**
Interest and other income (expense), net	$1,458	$1,183	$796	$200	$190	$347	$384	$1,121	$542	$653	$638	$638	$2,471	$200	$200	$200	$200	$800
Foreign currency transaction gain	$0	$0	$0					$0					$0					$0
	$0	$0	$0					$0					$0					$0
Income (loss) before income tax benefit (expense)	($58,648)	($108,408)	($98,600)	($21,877)	($2,222)	($30,050)	($29,164)	($83,313)	($24,012)	($20,986)	($17,544)	($21,996)	($84,538)	($14,484)	($13,240)	($11,021)	($10,295)	($49,041)
Income tax benefit (expense)	$0	$0	$0					$0					$0					$0
		$0	$0					$0					$0					$0
Consolidated net income (loss)	($58,648)	($108,408)	($98,600)	($21,877)	($2,222)	($30,050)	($29,164)	($83,313)	($24,012)	($20,986)	($17,544)	($21,996)	($84,538)	($14,484)	($13,240)	($11,021)	($10,295)	($49,041)
Net loss attributable to noncontrolling interest	$0	$0	$0					$0					$0					$0
Net income (loss) attributable to Momenta Pharmaceuticals, Inc.	**($58,648)**	**($108,408)**	**($98,600)**	**($21,877)**	**($2,222)**	**($30,050)**	**($29,164)**	**($83,313)**	**($24,012)**	**($20,986)**	**($17,544)**	**($21,996)**	**($84,538)**	**($14,484)**	**($13,240)**	**($11,021)**	**($10,295)**	**($49,041)**
Diluted EPS	**($1.16)**	**($2.13)**	**($1.91)**	**($0.40)**	**($0.04)**	**($0.44)**	**($0.43)**	**($1.32)**	**($0.35)**	**($0.31)**	**($0.26)**	**($0.32)**	**($1.23)**	**($0.21)**	**($0.19)**	**($0.16)**	**($0.15)**	**($0.71)**
Weighted average shares used to calculate income (loss) per common Diluted	50,411	50,907	51,664	54,492	61,680	68,004	68,138	63,130	68,285	68,532	68,799	69,005	68,655	69,212	69,420	69,628	69,837	69,524

Source: Aegis Capital Analysis

Required Disclosures

Price Target

$15

Valuation Methodology

For valuation considerations, we assumed 40% market share capture by the generics to 20mg Copaxone at the end of 2016. We believe Glatopa may be the only generic to 20mg Copaxone for an extended period of time and our valuation for the generic Copaxone franchise (20mg & 40mg) is $11/share. The cash position at the end of September 2016 is estimated to be $4/share. Therefore we reach a final target price of $15/share.

Risk Factors

Other than typical risks associated with investing in companies in the healthcare industries, such as R&D, regulatory, manufacturing, and commercialization risks, investing in Momenta Pharmaceuticals, Inc. carries several firm-specific risks: 1) potential multiple binary events; 2) competition; 3) pricing and reimbursement pressures; 4) The company has not shown a history of profitability; and 5) unpredictable litigation surrounding IP and patents.

For important disclosures go to www.aegiscap.com.

I, Difei Yang, Ph.D., hereby certify that the views expressed in this research report accurately reflect my personal views about the subject companies and their securities. I also certify that I have not been, do not, and will not be receiving direct or indirect compensation in exchange for expressing the specific recommendations in this report.

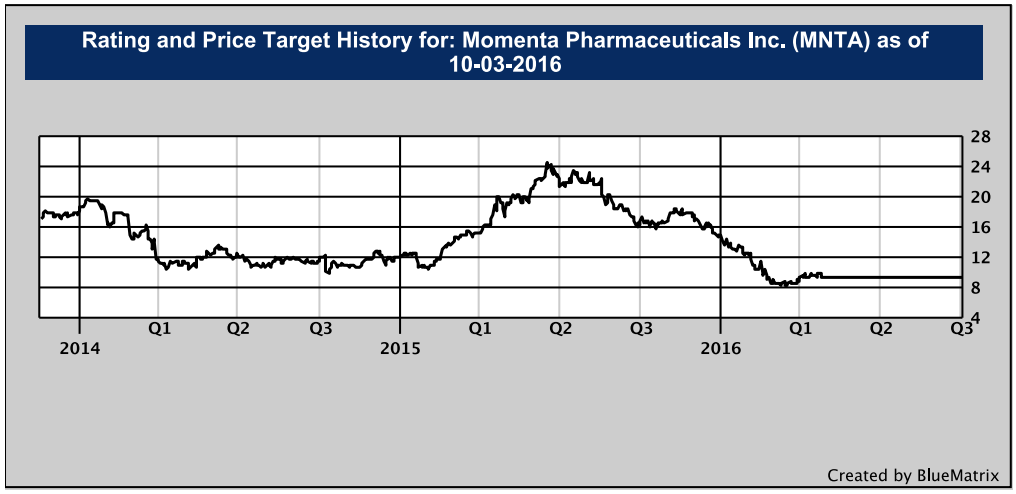
Research analyst compensation is not dependent upon investment banking revenues received by Aegis Capital Corp.

Aegis Capital Corp. intends to seek or expects to receive compensation for investment banking services from the subject company within the next three months.

The firm nor the Research Analyst have any material conflict of interest in which the Research Analyst has a reason to know or knows at the time of publication of this research report.

As of the report date neither Aegis Capital Corp. or its affiliates beneficially own 1% or more of any class of common equity securities of the subject company of this report.

Neither the research analyst who prepared this report or a member of the research analyst’s household has a financial position in the debt or equity securities of the subject company.



Rating	Percent	Investment Banking Services/Past 12 Mos. Percent
BUY [BUY]	87.63	40.00
HOLD [HOLD]	12.37	25.00
SELL [SELL]	0.00	0.00

Meaning of Ratings

A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.

B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.

C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

Other Disclosures

Other Disclosures The information contained herein is based upon sources believed to be reliable but is not guaranteed by us and is not considered to be all inclusive. It is not to be construed as an offer or the solicitation of an offer to sell or buy the securities mentioned herein. Aegis Capital Corp., its affiliates, shareholders, officers, staff, and/or members of their families, may have a position in the securities mentioned herein, and, before or after your receipt of this report, may make or recommend purchases and/or sales for their own accounts or for the accounts of other customers of the Firm from time to time in the open market or otherwise. Opinions expressed are our present opinions only and are subject to change without notice. Aegis Capital Corp. is under no obligation to provide updates to the opinions or information provided herein. Additional information is available upon request.

The common stock of the subject company in this report may not be suitable for certain investors based on their investment objectives, degree of risk, as well as their financial status.

Aegis Capital Corp.
(212) 813-1010
810 Seventh Avenue, 18th Floor
New York, New York 10019