

Agile Therapeutics, Inc.

Third-Quarter Earnings Provide Update on Clinical and Business Developments, Outperform

- After the markets closed on Thursday, November 13, Agile Therapeutics announced its third-quarter earnings results and highlights from the quarter. The company's primary update was regarding their pivotal Phase III study (also known as SECURE) of lead product Twirla, a once-weekly transdermal contraceptive patch. The company and its partner, contract research organization Parexel (PRXL \$56.36; Outperform), have continued to select, activate, and train trial sites with roughly 50 of the 70 clinical sites activated. The company remains on track to complete patient enrollment by the end of the first quarter of 2015 with study completion by the first quarter of 2016. During the third quarter, the company also expanded its board of directors with the addition of Dr. James Tursi, chief medical officer of Auxilium Pharmaceuticals (AUXL \$32.35). We believe that Dr. Tursi will add regulatory expertise to the board as Auxilium's Testim product is regulated by the division of bone, reproductive, and urologic drugs, the same division that reviews the contraceptive products.
- In September, the company announced the dosing of the first patients in SECURE. The trial is a single-arm, open-label, multicenter trial that will assess the safety and efficacy of Twirla in roughly 2,100 female subjects in the United States for up to one year. The Phase III trial will assess the efficacy of Twirla in preventing pregnancy using the widely accepted Pearl Index as the primary endpoint. In the past decade, some oral contraceptive products have been approved with overall Pearl rates of about 2.0, while the highest approved upper bound of the 95% confidence interval was 5.03 for Seasonale in 2003. In addition, the most-recent approval of a contraceptive was Quartette, which had a Pearl rate of 3.19. We believe new management team members, including new Chief Medical Officer Elizabeth Garner, M.D., who came to Agile with an impressive women's health background, should be able to run a trial focused on achieving an approvable Pearl Index score of less than 3.19 (or lower) given the standard estrogen/progestin components and pharmacokinetics of the product.
- Agile had previously conducted a Phase III clinical program for Twirla and filed an NDA with the FDA in April 2012. The FDA issued a Complete Response Letter (CRL) in February 2013 and requested additional clinical data, quality control information, and manufacturing/control information. The company analyzed the data from the program and determined several flaws in trial design, execution, and conduct. The Pearl Index for Twirla was 5.76, pooling both Phase III trials; however, the combined oral contraceptive control in the Phase III studies yielded a Pearl Index score of 6.72. The flaws that resulted in high Pearl Index scores included poor subject compliance, a concentration of unplanned pregnancies at a few study sites (36% of on-drug pregnancies reported at 4 of 96 sites, representing 15% of the randomized subject population), and a disproportionately high number of subjects at higher risk of noncompliance and pregnancy. Agile will use the results from SECURE to address issues raised in the Agency's CRL, and we believe the FDA has given the company a relatively achievable path to approval and we believe the company is on track for a regulatory decision in late 2016 and launch in 2017.

Agile Therapeutics, based in Princeton, New Jersey, is a developer of therapeutics for the women's health setting.

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November 13, 2014

Stock Rating: **Outperform**
Company Profile: **Aggressive Growth**
Price Target: \$18.00

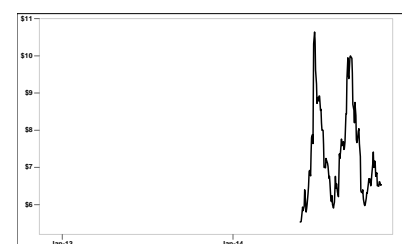
Symbol: AGRX (NASDAQ)
Price: \$6.45 (52-Wk.: \$5-\$13)
Market Value (mil.): \$121
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

	2013A	2014E	2015E
Estimates			
EPS FY		\$-1.46	\$-1.58
CY		\$-1.46	\$-1.58
Sales (mil.)	NA	0	0
Valuation			
FY P/E	NA	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	9
Float (mil.)	2
Average Daily Volume	39,271

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	0.0
Return on Equity (TTM)	-340.3

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

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- In the third quarter, the company published safety and tolerability data from the previous two phase III trials with Twirla that has tested more than 2,000 healthy women from 17-40 years of age (N=1579 for Twirla and N=581 with combination oral contraceptives, N=375 with 20 µg of ethinyl estradiol and N=206 with 30 µg of ethinyl estradiol). The safety results of the study, as shown in exhibit 1, conclude that the proportion of women who experienced any treatment-emergent adverse event was not significantly different among the three groups (Twirla = 47.5%, 20 µg of ethinyl estradiol = 47.4%, 30 µg of ethinyl estradiol = 46.8%). In addition, the treatment-emergent adverse events were similar when the participants were stratified into obese versus non-obese.
- For third-quarter earnings, the company reported a net loss of \$6.4 million or \$0.34 per share, slightly lower than our estimate of a loss of \$6 million or \$0.32 per share, but higher than consensus of a loss of \$8.4 million or \$0.52 per share. The company's R&D expenses were \$4.6 million and SG&A expenses were \$1.4 million, as the company continues to enroll the SECURE study. For our model adjustments moving forward, we will continue to increase R&D costs as the company completes the Phase III pivotal trial, with a ramp up of SG&A expenses in the second half of 2016, when we expect Twirla to be launched. The company ended the quarter with \$45.7 million in cash and cash equivalents.
- We continue to believe that shares of Agile hold a strong risk/reward profile, given the well-defined efficacy of ethinyl estradiol/levonorgestrel products and the clear pathway for approval of contraception products. However, shareholders will likely have to be patient for several months when news flow regarding the company's main product may be scarce, and share prices of development-stage therapeutics companies tend to trade in line with the markets until a clear catalyst approaches. Ultimately, we believe in the strong management at Agile and view the current Phase III study for Twirla as achievable. The company believes that it is sufficiently funded through the first quarter of 2016 (with about \$31 million needed to conduct the Phase III trial). We therefore maintain our Outperform rating on Agile Therapeutics and our \$18 price target.

Exhibit 1

Agile Therapeutics, Inc.

Treatment-emergent adverse events reported in ≥2% of participants in any treatment group

Percentage of Participants	LNG/EE Patch n=1220	COC20 n=344	COC30 n=188
Any TEAE excluding patch site reactions	41.9	47.4	46.8
Any TEAE including patch reactions	47.5	47.4	46.8
Nasopharyngitis	5.2	3.5	4.3
Nausea	4.1	4.1	5.9
Upper respiratory infection	3.5	2.0	4.3
Headache	3.4	4.7	1.1
Sinusitis	2.9	2.6	2.7
Cervical dysplasia	2.3	4.9	5.9
Urinary tract infection	2.1	3.2	2.1
Breast tenderness	2.0	1.5	0.0
Weight increased	1.9	0.6	2.1
Dysmenorrhea	1.8	2.6	0.5
Vomiting	1.4	2.9	3.2
Acne	1.4	2.3	1.1
Asthma	1.2	2.0	1.1
Fungal infection	1.0	2.0	1.6
HPV positive	1.0	2.0	2.7
Application site irritation	2.0	0.0	0.0

COC: Combination oral contraceptive, COC20: COC with Levonorgestrel 100 µg/Ethinyl Estradiol 20 µg, COC30: Levonorgestrel 100 µg/Ethinyl Estradiol 30 µg

Source: Kaunitz. Safety and tolerability of a new low-dose contraceptive patch. Am J Obstet Gynecol 2014.

Exhibit 2
Agile Therapeutics, Inc.
Third Quarter Results and Estimates

	AGRX Q3 14A	WB Q3 14E	Consensus Q3 14E	Y/Y Growth
(\$ in thousands except EPS)				
Total Revenue	\$ -	\$ -	\$ -	NA
R&D	\$ 4,602.5	\$ 5,000.0	\$ 7,000.0	92%
G&A	\$ 1,446.4	\$ 1,470.0	\$ 1,400.0	57%
Operating Income (loss)	\$ (6,048.9)	\$ (6,470.0)	\$ (8,400.0)	-82%
Net Income	\$ (6,353.4)	\$ (6,000.0)	\$ (8,400.0)	-72%
EPS	\$ (0.34)	\$ (0.32)	\$ (0.52)	NM

Source: Company reports, William Blair & Company L.L.C. estimates
Consensus estimates reported by FactSet

Valuation

We rate Agile Therapeutics as Outperform with a price target of \$18, based on an NPV of the company's lead development program, Twirla. In this calculation, we assume a launch of Twirla in mid-2016, after Agile responds to the agency's CRL with data provided from the SECURE Phase III trial. We assume Twirla peak sales will approach \$400 million, which we project as only 5.0% penetration into the total prescription contraception market.

Risks

An investment in shares of Agile Therapeutics involves clinical, regulatory, and financial risks that are typical of development-stage biopharmaceutical companies. In addition, Agile may face manufacturing, intellectual property, and competitive risks. We estimate that Agile will incur losses through 2017, given the commencement of Twirla's Phase III trial and expenses needed to bring the product to market.

Our model is included on the following page.

William Blair

Agile Therapeutics
Earnings Model

11/13/14
(\$ in millions except EPS data)

Company Rating: Outperform
Company Profile: Aggressive Growth

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	2012(A)	2013(A)	Q1(A)	Q2(A)	Q3(A)	Q4(E)	2014(E)	2015(E)	2016(E)	2017(E)	2018(E)	2019(E)
Product Revenue	-	-	-	-	-	-	-	-	-	-	-	-
Twirla	-	-	-	-	-	-	-	-	9,812	117,740	228,121	343,408
Royalty/Milestone Revenue	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	-	-	-	-	-	-	-	-	9,812	117,739.8	228,120.8	343,407.7
yr/yr growth	NA	NA	NA	NA	NA	NA	NA	NA	NA	1100.0%	93.8%	50.5%
q/q growth	NA	NA	NA	NA	NA	NA	NA	NA	NA			
incremental rev q/q												
Cost of Goods Sold	-	-	-	-	-	-	-	-	981	11,774	22,812	34,341
Gross Profit	-	-	-	-	-	-	-	-	8,830	105,966	205,309	309,067
SG&A	17,387	9,154	1,053	1,104	1,446	1,470	4,900	6,500	18,250	48,500	50,300	52,000
Growth							-46%	33%	181%	166%	315%	329%
R&D	5,930	3,574	1,394	2,391	4,603	5,600	13,988	24,200	23,300	15,000	17,000	21,000
Growth		-40%	-	-	-	-	291%	73%	-4%	-36%	13%	24%
Total Operating Expenses	23,317	12,728	2,448	3,495	6,049	7,070	19,061	30,700	41,550	63,500	67,300	73,000
growth			NA	NA	NA	NA	50%	61%	35%	53%	6%	8%
Operating Income	(23,317)	(12,728)	(2,448)	(3,495)	(6,049)	(7,070)	(19,061)	(30,700)	(32,720)	42,466	138,009	236,067
EBIT Margin							NM	NM	NM	NM	60%	69%
growth y/y (%)			NA	NA	NA	NA	NM	NM	NM	NM	NM	NM
Depreciation and Amortization	-	-	250	5	250	250	1,000	1,000	1,000	1,000	1,000	1,000
EBITDA	(23,317)	(12,728)	(2,198)	(3,490)	(5,799)	(6,820)	(18,306.2)	(29,700.0)	(31,719.5)	43,466	139,009	237,067
Interest expense	(140)	(1,592)	(378)	(403.5)	(392)	(300)	(1,474)	2,000	1,500	1,500	8,000	8,000
Interest income	26	-	0	0.1	1.3	1.0						
Change in fair value of warrants	171.0	-	13	179.7	86.2	70.0						
Other	-	-	-	-	-	-	-	-	-	-	-	-
Income Before Taxes	(23,260)	(14,320)	(2,813)	(3,718)	(6,353)	(7,370)	(20,255)	(28,700)	(31,220)	43,966	146,009	244,067
Income Tax Provision	-	-	(3,652)	-	-	-	(3,652)	1,000	1,000	15,828	52,563	87,864
Effective Tax Rate	0.0%	0.0%	NA	NA	NA	NA	NM	NA	NA	36%	36%	36%
Beneficial conversino charge	(600)	-	-	-	-	-	-	-	-	-	-	-
Net Income (loss) Attributable to Common	(23,860)	(14,320)	839	(3,718)	(6,353)	(7,370)	(16,602)	(29,700)	(32,219)	28,138	93,446	156,203
Net loss per share	(845)	(405)	839	(3,718)	(6,353)	(7,370)	(16,602)	(29,700)	(32,219)	28,138	93,446	156,203
Net income to common per share (diluted)			5.62	(0.46)	(0.34)	(0.40)	(1.46)	(1.58)	(1.52)	1.31	3.60	5.87
Basic avg. number of shares	28	35	149	8,000	18,592	18,600	11,335	18,850	19,250	19,650	25,658	25,758
Key Ratios (GAAP unless noted)												
Gross Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	90.0%	90.0%	90.0%
R&D (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	NM	12.7%	7.5%	6.1%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	NM	41.2%	22.0%	15.1%
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	36.1%	60.5%	68.7%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	23.9%	41.0%	45.5%
Revenue Growth												
Growth Yr/Yr	NM	#DIV/0!	NM	NM	NM	NM	NM	NM	NM	1100%	94%	51%
Growth Q/Q	NM		NM	NM	NM	NM						
SG&A Growth												
Growth Yr/Yr	NM	-47%	NM	NM	NM	NM	-46%	33%	181%	166%	4%	3%
Growth Q/Q	NM		NM	NM	NM	NM						
R&D Growth												
Growth Yr/Yr	NM	-40%	NM	NM	NM	NM	291%	73%	-4%	-36%	13%	24%
Growth Q/Q	NM		NM	NM	NM	NM						

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William Blair intends to seek investment banking compensation in the next three months from Agile Therapeutics, Inc.

Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with Agile Therapeutics, Inc.

Additional information is available upon request.

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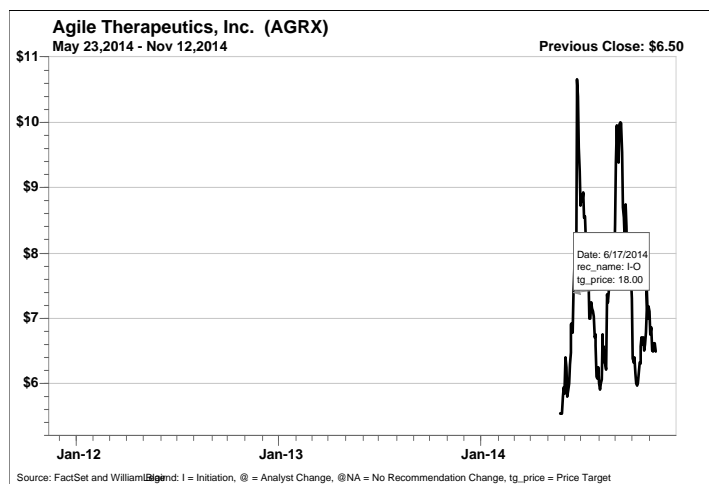
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DOW JONES: 17,612.20

S&P 500: 2,038.25

NASDAQ: 4,675.14



Current Rating Distribution (as of 10/31/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	65	Outperform (Buy)	16
Market Perform (Hold)	31	Market Perform (Hold)	3
Underperform (Sell)	1	Underperform (Sell)	0

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