

# Biotechnology

Price:	\$6.05
Fair Value Estimate:	\$17.00
52-Week Range:	\$5.05 - \$12.55
Market Cap (MM):	\$112
Shr.O/S-Diluted (mm):	18.6
Average Daily Volume:	30,187
Yield:	0.0%
Cash/Share:	\$(1.03)
FCF Yield:	(23.6)%
Debt/Cap:	117%

2013E	2014E	2015E
(1.59)A	(1.25)E	(1.53)E
	(0.73)	(0.99)
NM	-1.24	-1.41
NA	NA	NA
	(1.59)A NM	(1.59)A (1.25)E (0.73) NM -1.24

### Quarterly EPS:

Q1	 0.09A	(0.42)E
Q2	 (0.46)A	(0.41)E
Q3	 (0.34)A	(0.38)E
Q4	 (0.41)E	(0.32)E

# Quarterly Revenue (M):

Q1		0E	0E
Q2		0E	0E
Q3 Q4 Year:		0E	0E
Q4		0E	0E
Year:	0E	0E	0E

December 17, 2014

# Agile Therapeutics, Inc.

(AGRX) - BUY

# Resuming Coverage: Buy Rating, \$17 FV

# PORTFOLIO MANAGER BRIEF

We are resuming coverage of Agile Therapeutics (AGRX) based on the potential of its lead product candidate, Twirla, a combined hormonal contraceptive patch. The company's Skinfusion technology allows for seven-day dosing, making for improved efficacy and increased patient compliance. With average branded pricing assumption, a 1% market share would equate to over \$100M in sales; thus, Twirla represents a blockbuster opportunity with just 10% of the market. Buy rating, \$17 FV.

# **ANALYST NOTES**

- Twirla The low-dose weekly contraceptive path: Currently in Phase 3, Twirla looks to deliver on safety and efficacy as a low-dose weekly transdermal contraceptive patch that is comparable to currently marketed low-dose orals. The once weekly dosing should offer easier compliance and convenience compared to a daily pill.
- Validated market through Ortho Evra: The patch market has already been validated by the successful launch of Ortho Evra and OB/GYNs already have experience with patch technology. Ortho Evra garnered 10% market share 1.5 years after launch and peaked at 11% share before it received a black box warning due to the high estrogen dose causing the potential for deep vein thromboses (DVT).
- De-risked clinical path to approval: Following the Complete Response Letter (CRL) from the initial Phase 3, AGRX received clear guidance from the FDA regarding a new Phase 3 study design that would be acceptable for approval. The design is a simple single-arm study with robust powering and fewer, hand-selected clinical research organizations and 21<sup>st</sup> century data collection. We believe that AGRX has taken the necessary steps in order to ensure a successful Phase 3. We firmly expect positive data in 1Q16.
- Blockbuster potential with small market share: In 2013, total sales in the combined hormone contraceptive market was \$4.2B, with slightly more than 50% of sales generated by branded products. With an average branded pricing assumption, a 1% market share would equate to over \$100M in sales, therefore Twirla represents a blockbuster opportunity with just 10% of market share. Our FV of \$17 is based on 2017 sales of \$152M at a 3x multiple discounted back 25% with \$1.50/share cash (end 15) and tech.



# **INVESTMENT THESIS**

Agile Therapeutics (AGRX) is a development stage specialty pharmaceutical company that is focused on developing and commercializing its proprietary transdermal patch technology into new prescription contraceptive products for women that offer greater convenience and higher compliance rates. AGRX's lead product candidate is Twirla, also known as AG200-15, a once weekly contraceptive patch currently in Phase 3 clinical trials. Other pipeline candidates include AG200-ER, an extended cycle regimen that allows women to extend the time between episodes of withdrawal bleeding, and AG200-SP, a 28-day regimen includes a shortened hormone-free interval resulting in shorter, lighter withdrawal bleeds and potentially improved contraceptive efficacy.

# ISSUES TO CONSIDER

Key Issue	Our Position	Timing	Impact
Will the balance sheet hold up?	This is a question that comes up when talking with investors. We feel that although AGRX may be cutting it close in terms of running out of cash before data in 1Q16, the potential for renegotiation of its bond could allow for some breathing room, though returning to the capital markets is not out of the question.	6-12 Months	+ 0
Outcome of the Phase 3 trial?	We are positive on the outcome of the Phase 3 trial, as we feel AGRX has hired a rockstar CMO in Elizabeth Garner to run the trial. With her on board, site selection has been focused and 21st century technology has been brought to bear on a 21st century patient population. With the ability to follow patients in real time, we expect positive data in 1Q16.	6-12 Months	+ 0 -
Commercial strategy	One of the more compelling reasons to own AGRX is that the company does not need to have over 10% of the market to generate very significant revenues. At current branded pricing (~\$95), a 1% market share equals over \$100M in revenue. With the ease of Twirla's 7 day dosing and potential for alternative cycles, we feel that blockbuster status for Twirla is probable.	12-24 Months	+ 0 -

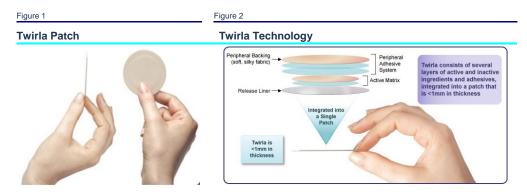
# **Company Description:**

Agile Therapeutics (AGRX) is a development stage specialty pharmaceutical company that is focused on developing and commercializing its proprietary transdermal patch technology into new prescription contraceptive products for women that offer greater convenience and higher compliance rates. The company's lead product candidate is Twirla, also known as AG200-15, a once weekly contraceptive patch currently in Phase 3 clinical trials. Other pipeline candidates include AG200-ER, an extended cycle regimen that allows women to extend the time between episodes of withdrawal bleeding, and AG200-SP, a 28-day regimen includes a shortened hormone-free interval resulting in shorter, lighter withdrawal bleeds and potentially improved contraceptive efficacy.

AGRX's lead product candidate is the Twirla patch, a low-dose combined hormone contraceptive patch that offers once weekly dosing

# The Twirla Patch:

AGRX's lead product candidate is the Twirla patch. Twirla is a combined hormone contraceptive patch that contains both EE and LND delivered via the unique and proprietary Skinfusion technology. The Skinfusion technology utilizes both an inner and outer adhesive system; the inner active matrix delivers both EE and LND at specific levels through the skin, while the peripheral system provides adherence, stability, and prevents ingredients from migrating to the outer edges. The Twirla patch delivers active ingredients over a seven-day dosing interval and uses a traditional 28-day contraceptive regimen where one patch is applied weekly for three straight weeks followed by a fourth patch-free week. Twirla can be worn on the buttock, abdomen, or upper torso.

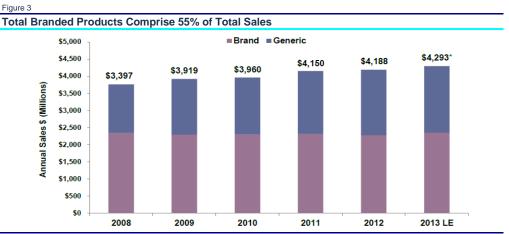


# Crowded Product Marketplace, But Branded Products Still Rule:

There are over 180 generic and brand CHC products on the market today which generates approximately \$4.2B in sales every year. Currently, the market is evenly split between brand and generic products with brand products taking the slight lead with ~55% of total sales.

Commercially significant, however is that only eight products hold  $\sim 50\%$  of the total market. The top selling product, Nuvaring brought in \$569M in 2013 annual sales and the Loestrin24/LoLoestrin brands turned in a combined \$685M in 2013. Rounding out the top 5 were Tri-Cyclen-Lo with \$469M as third and lastly, Evra with \$152M.

The CHC market generates over \$4.2B annually with branded products making up ~55% of the market.



Source: Company presentation \*2103 estimates based on MAT Oct 2012 - Sept 2013

Branded products can generate significant revenues. If these products are promoted successfully, many physicians will honor the requests of incoming patients who ask to try the promoted product, assuming no contraindications are present in the patient history. These products can achieve sales of over \$500M and command double-digit market share.

The majority of prescriptions are for oral formulations; however, with the popularity of the Nuvaring as well as the initial sales growth of Ortho Evra and increased use of IUDs, there appears to be a general preference towards an easier compliance regimen.

Figure 4

# Significant Revenue and Market Share in Branded Products

Brand	Peak TRx	Sales at Peak Share	Revenue at Current
Branu	Share	(year)	Average WAC*
Yaz	13%	\$771M (2009)	\$1.4B
Yasmin	13%	\$550M (2006)	\$1.4B
Ortho Evra	11%	\$414M (2005)	\$1.2B
Loestrin 24	10%	\$534M (2010)	\$1.1B
TriCyclen Lo	9%	\$396M (2006)	\$986M

<sup>\*</sup> Avg WAC price/TRx of \$88/cycle for branded products in 2013 1% of TRx = \$110M

Source: Company presentation \*2103 estimates based on MAT Oct 2012 - Sept 2013

Ortho Evra was the first approved clinical patch and experienced early and unparalleled clinical success, grabbing ~10% market share within the first 1.5 years of launch.

# Ortho Evra – The First Patch and a Brief History

Ortho-Evra was approved in 2002 as the first contraceptive patch available in the US. The initial approved label for Evra indicated that it delivered a daily EE dose of 20 micrograms. The early success was unparalleled and Evra achieved a 10% share of the CHC market by September 2003. Soon afterwards reports began coming into the FDA that indicated that Evra users were experiencing thrombotic and thromboembolic events. This culminated in April of 2004 when a 19 year old fashion student collapsed while waiting for the subway in New York City and later died. In November 2005, Johnson & Johnson revised the Evra label to contraceptive containing 35 micrograms of EE. Johnson & Johnson was later sued and settled for \$68.7M in 2008. Ultimately Evra received a black box warning and bolded warnings unique to Evra's profile. The fallout was swift. The Evra market share declined rapidly from peak share of 11% in 2005 to 4% and the end of 2006 to 1.4% by the end of 2013.

# Twirla is Not Ortho Evra... It's better:

Twirla and Ortho Evra differ from each other in several key characteristics. The first and most important is that Twirla uses a safer, 2<sup>nd</sup> generation progestin where Evra uses a 3<sup>rd</sup> generation progestin. Second is that the EE concentrations from Twirla over a 3 week cycle are substantially less than Evra. Lastly, the Skinfusion technology allows for each of application and removal without the darkened ring of residue, which is common cosmetic complaint.

The Twirla patch uses a safer 2<sup>nd</sup> generation progestin where there may be an increased risk of DVT in newer 3<sup>rd</sup> and 4<sup>th</sup> generation progestins. <u>Progestins:</u> The overall safety profile associated with the different generations of progestins used on CHC is a hotly debated subject. The majority of these studies are observational and retrospective in nature, which are not ideal for generating solid evidence.

Though some experts believe that these studies do not show any significant difference in VTE risks among the current marketed COCs, there are others who claim that CHCs with 3<sup>rd</sup> and 4<sup>th</sup> generation progestins can significantly increase the risk of developing a DVT. Twirla uses Levonorgestrel (LND), a 2<sup>nd</sup> generation progestin while Ortho Evra uses Norelgestromine, a 3<sup>rd</sup> generation progestin.

igure 5

## Generations of Progestins

Generation	Progestins
First	Norethindrone
Testosterone derived estranes	Norethynodrel
	Norethindrone acetate
	Ethynodiol diacetate
Second	Levonorgestrel
Testosterone derived gonanes	Norestrel
Third	Desogestrel
Levonorgestrel derivatives	Gestodene
	Norgestimate/Norelgestromine
	Etonorgestrel
Fourth	Dienogest
Non-ethylated estranes	Dropirenone
Pregnanes	Nestrone
	Nomegestrol acetate
	Trimegestone

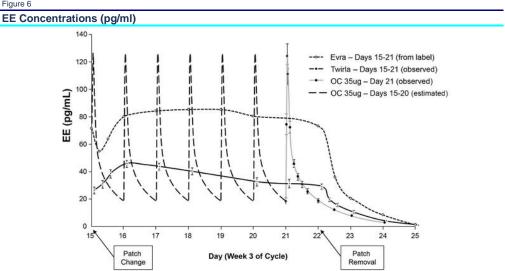
Source: Janney research

To keep things in perspective, *any* woman on a CHC has increased risk of a VTE; that risk rising from 4-5/10,000 to 8-9/10,000, about twice as likely. To add to this perspective, the risk of developing a VTE during pregnancy can be as high as 29/10,000 or post-partum at 300/10,000. In looking at these

numbers, overall the likelihood of developing a VTE on any CHC is less than .5%, several fold less than normal pregnancy or postpartum.

EE Concentrations: Within the CHC product market, there are low dose options (20mcg) and higher dose options (~50 mcg), with the average dose of 30-35 mcg. As EE is rapidly metabolized, it is important to understand that a low dose EE CHC must be taken daily or else there is an increased risk of pregnancy. The higher dose EE CHCs have enough EE to allow the patient to miss a day (or two) and still have protection against pregnancy. Another effect of the low dose is spotting and breakthrough bleeding which usually does not occur with higher doses. Though no direct head-tohead comparisons have been done between Twirla and Ortho Evra, a PK study has been conducted with Twirla that was of similar design to the PK study conducted with Evra that ultimately provided the EE concentration information for the Evra package insert. The chart below combines the results. Twirla clearly shows a decreased and lower dose of EE at ~30 mcg as compared to Evra at ~56mcg.

The unique Skinfusion technology allows for a steadier and lower release of EE when compared to Ortho Fyra.



Source: Company presentation

The Skinfusion technology also allows for a better patient experience with a soft, silky and stretchy top fabric and no debris ring upon removal.

Cosmetic Improvements: The Twirla patch itself is designed around a six layer system, with the top layers consisting of the peripheral adhesive system and the bottom layers consisting of the active matrix. The top, outer most layer is made of a soft, silky stretchy fabric, compared to Evra which is more of a smooth plastic film. Twirla is also specially designed to adhere to the skin for a full sevenday period through conditions of heat, humidity, water exposure, and vigorous exercise and to prevent seepage of the adhesive from around the edge of the patch. This seepage could collect dirt and leave a sticky black ring, which is a common cosmetic complaint of Evra users.

# The Failed Phase 3:

First and foremost, efficacy in a Phase III contraceptive trial is measured by the Pearl Index (PI). The PI is the rate of unintended pregnancies experienced by women over the course of the study. PI is expressed as the number of pregnancies per 100 woman-years of use (e.g. 100 women over one year of use). A lower PI index represents a lower chance of getting unintentionally pregnant.

AGRX has completed two Phase III trials, one enrolling 407 women for 6-months and the other enrolling 1504 for 12-months for an aggregate of over 1,900 participants. The trials were both openlabel, and consisted of one arm receiving Twirla patches and the other arm receiving an approved lowdose oral contraceptive.

The pooled PI value in the completed Phase III trials for the Twirla patch was 5.76 compared to the combined oral contraceptive control arms was 6.72. Historically, the PI range of pivotal studies conducted on products approved by the FDA in the previous 10 years has been 1.34-3.19. Twirla's PI was outside of this range.

In February 2013, AGRX received a complete response letter (CRL) from the FDA that indicated that the completed Phase III trials would not be sufficient for approval. An additional Phase III trial was proposed.

What happened?

Twirla failed a Phase 3 trial as the Pearl Index was 5.76 where historically approved products have ranged between 1.34 and 3.19. So why was the PI value so high in the Twirla and oral contraceptive arms? AGRX believes several issues in the study conduct contributed to the clinical results.

The high rate of enrollment lead to an overwhelming of current resources and an inability to manage the study population correctly.

Rapid Enrollment: Though most companies would like to see their trials experience a steady enrollment rate, with the Twirla study, there was a high rate of enrollment which led to an overwhelming of current resources and an inability to manage the study population, poor subject compliance and a high rate of loss to follow-up. For example, 19% of on-treatment pregnancies reported during the trial came from one site, which represented ~8% of the randomized subject population and 36% of on-treatment pregnancies were reported from four sites, representing ~15% of the randomized subject population.

There were a high number of new users which historically are more inconsistent with the use of a new contraceptive method.

• <u>Disproportionally high number of new users:</u> Experts agree and it makes logical sense that experienced hormonal contraceptive users would be less likely to have inconsistent and incorrect use of a new method. These experienced subjects are often selected for trial participation because their inclusion will lower failure rates. In the larger of the Phase III trials, AGRX had a lower proportion of subjects randomized to receive Twirla that were current users, only 17.8%. Another metric that can be quantified is the subject's use of hormonal contraceptives within the 6 months prior to trial enrollment. In the Phase III, there was a lower level of those experienced subjects at 44%. In both the oral contraceptive and the Twirla groups, new users had more than twice the rate of noncompliance compared to experienced users, as verified by blood tests.

There were a high number of minorities that as a patient group historically have higher noncompliance and failure rates.

• <u>Disproportionally high number of minorities:</u> Another factor that contributed to the outcome of the trial was the higher proportion of black and Hispanic subjects than most recent hormonal contraceptive trials. Within these patient groups, contraceptive failure rates are high, which has been well documented. In the larger Twirla Phase III trial, rates of labverified noncompliance were substantially higher in blacks and Hispanics compared to non-Hispanic white subjects. With a high level of new and inexperienced users coupled with a disproportionally high level of minority subjects, the PI values for that subgroup were dramatically higher.

# The New Phase 3:

In October 2013, the FDA met with AGRX and provided further guidance on the requirements for the Phase III trial. Additional follow-up meetings were held in February of 2014. The additional study design is a single-arm study with approximately  $\sim$ 2,000 female subjects on the Twirla patch for up to one year. AGRX will use between 50 and 70 US sites to conduct the studies.

What will be different? Going into the additional Phase III trial, several aspects of the trial will differ from the previous Phase III.

The new Phase 3 trial is a single arm study with less clinical sites, more experienced sites and the use of 21<sup>st</sup> century data collection methods.

- <u>Single-arm trial:</u> First and foremost is the trial design. The new trial will be a simpler single-arm study, which is expected to start enrolling the first subject in the 3Q14, completing the trial by the end of 2015. This study will not have a comparator arm which will lead to more cycles for the primary efficacy analysis and an easier protocol to understand and implement for the clinical sites.
- <u>Less clinical sites:</u> The original trails utilized a total of 96 sites. The new trial will use between and 50 and 70 sites. These sites will be evaluated on their prior experience with hormonal birth control trials, staffing experience, longevity of the study coordinators, and the demographics of potential study subjects among other things. Fewer sites should allow for more focused oversight and facilitate more individualized attention to study subjects.
- Loss to follow-up: One aspect of the previous study that should also be improved upon is loss to follow-up. This is addressed by extensive training of study coordinators to screen for the appropriate subjects and to recognize data trends early and to interject on behalf of the study. The sites will screen subjects on the ability, motivation and willingness to comply with the demands of the study. Having no competitor arm also means that only individuals with true interest in a transdermal patch will be likely participants. Multiple methods of contact will also be asked of each subject, including contact information for family members and the use of public records in order to locate the subjects. Each site will provide real-time

recruitment information to the CRO throughout the recruitment process, which will facilitate enrollment of the appropriate subject population.

• 21st century data collection: Instead of the usual paper diary utilized in the previous Phase III trial, the additional trial will be using an e-diary. Subjects will be trained on the use of this application which is available on multiple platforms such as smartphones and tablets. The e-diary will allow for personal reminders via text and email for patch application, diary completion and study visits. It will also allow for improved data quality as subjects will be able to record bleeding patterns and patch adherence as well as sexual activity and use of back-up contraception. The data, once uploaded from the e-diary will be available in the CRO's database, allowing for real-time review by the CRO and study monitors.

There is significant competition in the marketplace

# **Competitive Marketplace:**

AGRX does face significant competition from currently marketed products that already have established name recognition and brand loyalty. In comparison to some of the other, more popular CHC options, Twirla has several commercial advantages.

The advantages of Twirla are the safety profile, better side effects profile and once-weekly dosing. The use of the second generation progestin, LNG can potentially bolster the safety profile. As Twirla is a once-weekly dosing regimen, the convenience of not having to take an oral pill every day at the same time is commercial benefit. Lastly, the potential side effect

Figure 7

profile is unlike most products on the market, with significantly less side effects observed through the Phase III trials.

Price Comparisons

### 2014 WAC Price **Product** Per 28 Day Cycle Nuvaring 87.32 Loestrin 24 82.88 LoLoestrin 82.88 Gianvi (generic YAZ) 56.56 Beyaz 85.40 Mirena 13.00 Ortho Evra 110.22 Xulane (generic patch \$ 95.12 OrthoTriCyclenLo

Source: Company presentation

# Mylan generic – Xulane

Recently, Mylan launched a generic version of the Ortho Evra path. Even though this is generic patch, it is a generic equivalent which means that it still has all the safety risks that are associated with Evra, including the higher risk of VTE due to the higher doses of EE. Also, pricing for Xulane is currently at \$95.12 which is a premium to where we expect Twirla to be priced.

Though there is a generic patch, it is comparable to Ortho Evra, including the increased safety risks.

Figure 8

# **Price Comparisons**

Characteristics	Twirla		Ortho Evra		NuvaRir	ng .	Loestrin 24 fe (Minast	rin 24 fe)
	Transdermal patcl	Transdermal patch Transdermal patch		Polymetric vaginal ring		Oral pill - chewa	ble	
Form of product	Round, ~28 sqcm	n	Square, ~20 sqcm					
	Soft, silky, stretchy fabric		Smooth, plastic	film				
Active Ingredients	EE, LNG		EE, norelgestro	omin	EE, etonoge	strel	EE, norethindrone acetate, fe	errous fumarate
Daily EE dose	~30 micrograms		~56 microgra	ms	15 microgra	ams	20 microgram	5
Regimin	One patch weekly	у	One patch wee	ekly	One ring for 3	weeks	One oral tablet every day at	the same time
weRillilli	21 active days /7 patch fr	ree days	21 active days /7 patch	h free days	3 weeks active, 1 w	eek ring free	24 active pills/ 4 in	active
Package configurations	1 box of 3 patches = 1	cycle	1 box of 3 patches	= 1 cycle	1 ring per o	cycle	1 blister card = 28 ta	ablets
T deliage configurations	1 box with 1 patch = repla	acement	1 box with 1 patch = re	eplacement	reclosable aluminium	laminate sachet	Carton of 5 card	is
	Nausea	3.0%	Breast symptoms	22.4%	Vaginitis	13.8%	Headache	6.3%
Too Form AFe to Astale	Site irritation	2.4%	Headache	21.0%	Headache	11.2%	Vaginal candidiasis	6.1%
Top Four AEs in trials	Breast tenderness	2.1%	Site disorder	17.1%	Mood Changes	6.4%	Nausea	4.6%
	Headache*	2.0%	Nausea	16.6%	Device related ev	ents 6.3%	Menstral cramps	4.4%

\* AEs deemed dinitley, probably or possibly related to Twirla in completed Phase 3 trials Source: Janney estimates

# **Clinical Timeline:**

AGRX initiated its Phase 3 in late September of 2014. The expectations are that the trial will enroll quickly with full enrollment by 1Q15. The trial is expected to run for twelve months which leaves top-line data read-out expectations in 1Q16.

Once the data is announced, we expect that AGRX will file its complete response letter with the FDA with the standard approval timeline. Our expectations are that if approved, Twirla would enter the market in mid/late 2017.

Phase 3 clinical trial should have a quick enrollment with top-line data in 1Q15. Figure 9

# | Agile Therapeutics | Branded drugs trial timelines | 2015E | 2016E | 2017E | 102 | 202 | 302 | 402 | 102 | 202 | 302 | 402 | 103 | 203 | 302 | 403 | 103 | 203 | 303 | 403 | 403 | 103 | 204 | 303 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 | 403 |

Source: Janney estimates

# **Financials and Valuation:**

\$000 except per share)	2012A	2013A		2014E			2014E		2015E			2015E
	<u>Year</u>	<u>Year</u>	<u>1QA</u>	2QA	3QA	4QE	<u>Year</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>	Year
Revenue	0	0					0					
Twirla												
Other Products												
Total Revenue	0	0	0	0	0	0	0	0	0	0	0	
Expenses												
COGS												
Gross Prfofit									0	0	0	
R&D	17,387	9,154	1,394	2,391	4,603	6,100	14,488	6,100	6,100	5,500	4,500	22,2
K&D G&A	5,930	3,575	1,053	1,104	1,446	1,500	5,104	1,615	1,615	1,600	1,600	
G&A	3,550	5,575	1,033	1,104	1,440	1,300	3,104	1,015	1,015	1,000	1,000	6,43
Total Expenses	23,317	12,729	2,448	3,495	6,049	7,600	19,591	7,715	7,715	7,100	6,100	28,6
·												
Operating Income/Loss	(23,317)	(12,729)	(2,448)	(3,495)	(6,049)	(7,600)	(19,591)	(7,715)	(7,715)	(7,100)	(6,100)	(28,6
Interest Expense/Income	(114)	(1,511)	(378)	(403)	(391)	(345)	(1,517)	(345)	(345)	(345)	(345)	(1,3
Change in Fair Value of Warrants	171	(81)	13	180	86	180	459	180	180	180	180	7
Other	0	0					0					
												, .
Income/Loss Before Taxes		(14,321)	(2,813)	(3,718)	(6,353)	(7,765)	(20,650)	(7,880)	(7,880)	(7,265)	(6,265)	(29,29
Income Tax Expense	78	0	(3,652)	0			(3,652)					
Net Gain / Loss	(23,338)	(14,321)	839	(3,718)	(6,353)	(7,765)	(16,997)	(7,880)	(7,880)	(7,265)	(6,265)	(29,29
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GAAP EPS	(\$0.59)	(\$1.59)	\$0.09	(\$0.46)	(\$0.34)	(\$0.41)	(\$1.25)	(\$0.42)	(\$0.41)	(\$0.38)	(\$0.32)	(\$1.5
Non-GAAP Adjusted EPS												
Weighted Average S/O (000)	39,518	8,992	9,029	8,000	18,593	18,743	13,591	18,893	19,043	19,193	19,343	19,1
Fully diluted S/O (000)	39,518	8,992	9,745	8,000	18,593	18,743	13,770	18,893	19,043	19,193	19,343	19,

SOP Analysis: AGRX			
Segment		Valuation	Per share
		(000's)	value
Twirla Patch		\$293,654	\$15.5
Cash (end '15) & tech value		\$22,861	\$1.5
	SUM	\$316,516	\$17
Shares out '15E (000)			19,118

Source: Janney estimates

# IMPORTANT DISCLOSURES

# **Research Analyst Certification**

I, Chiara Russo, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

# Janney Montgomery Scott LLC ("Janney") Equity Research Disclosure Legend

Agile Therapeutics, Inc. currently is, or during the past 12 months was, a Janney Montgomery Scott LLC client. Janney Montgomery Scott LLC, provided investment banking related services.

Janney Montgomery Scott LLC currently acts as a market-maker in the securities of Agile Therapeutics, Inc..

Janney Montgomery Scott LLC managed or co-managed a public offering of securities for Agile Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC received compensation for investment banking services from Agile Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Agile Therapeutics, Inc. in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

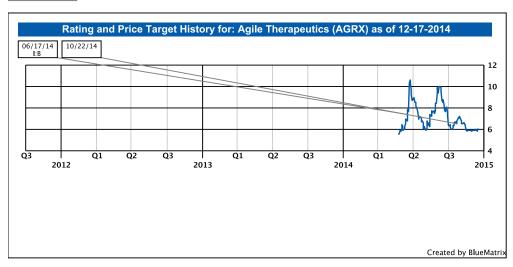
# **Definition of Ratings**

BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

NEUTRAL: Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

SELL: Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

# **Price Charts**



# Janney Montgomery Scott Ratings Distribution as of 9/30/14

IB Serv./Past 12 Mos.	ΙB	Serv.	/Past	12	Mos.
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Rating	Count	Percent	Count	Percent
BUY [B]	169	52.81	24	14.20
NEUTRAL [N]	150	46.88	18	12.00
SELL [S]	1	0.31	0	0

\*Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.

# Other Disclosures

Janney Montgomery Scott LLC, is a U.S. broker-dealer registered with the U.S. Securities and Exchange Commission and a member of the New York Stock Exchange, the Financial Industry Regulatory Authority and the Securities Investor Protection Corp.

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Investment opinions are based on each stock's 6-12 month return potential. Our ratings are not based on formal price targets, however, our analysts will discuss fair value and/or target price ranges in research reports. Decisions to buy or sell a stock should be based on the investor's investment objectives and risk tolerance and should not rely solely on the rating. Investors should read carefully the entire research report, which provides a more complete discussion of the analyst's views. Supporting information related to the recommendation, if any, made in the research report is available upon request.





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