Janney CAPITAL MARKETS

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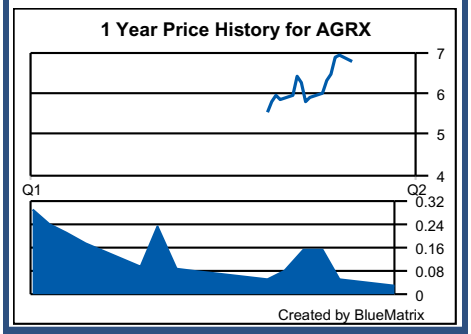
Biotechnology

Agile Therapeutics, Inc.
(AGRX) - BUY

Price:	**$6.78**
Fair Value Estimate:	$18.00
52-Week Range:	$5.05-$6.92
Market Cap (MM):	$126
Shr.O/S-Diluted (mm):	18.6
Average Daily Volume:	NA



Equity Research
Basic Report

AGRX: Initiating With a Buy Rating, $18 FV

A De-Risked Program Targeting an Unmet Market Need

INVESTMENT CONCLUSION:

We view Agile's main value driver, Twirla (AG200-15), as a validated, combined hormonal contraceptive (CHC) patch that should improve patient compliance and provide efficacy and safety similar to low-dose oral contraceptives while targeting an unmet need for a patch contraceptive option. Its value proposition lies in its once-weekly delivery of low-dose estrogen via a proprietary transdermal patch technology, which does not carry the additional safety risks associated with higher estrogen levels. AGRX's near-term success will be correlated with a successful Phase 3 study outcome and is fairly de-risked, in our view, given several recent contraceptive approvals along with the additional clarity received from the FDA on study design following a Complete Response Letter (CRL). We estimate that Twirla does not need to garner significant market share in the $4.2 billion CHC market to become a blockbuster product and we estimate peak sales of $1.0 billion under conservative assumptions. We consider AGRX a compelling investment based on its proprietary transdermal technology, its differentiated and burgeoning pipeline, experienced management team and attractive valuation. As such, we are initiating with a Buy rating and $18 fair value estimate, which is based on a DCF analysis that examines free cash flow through 2021.

KEY POINTS:

- **Twirla – A differentiated contraceptive in a validated market that is attractive to physicians and patients.** Twirla is a Phase 3-ready, low-dose CHC patch that provides convenience and facilitates compliance while delivering contraceptive efficacy and safety comparable to approved low-dose oral contraceptives in a market that has already been validated by Ortho Evra. Feedback from OB/GYNs indicate that the daily delivered estrogen dose is important to them given the safety concerns of deep vein thromboses (DVTs) associated with high estrogen levels. They also rank convenience and compliance highly. Surveyed consumers cite that Twirla's selling propositions include non-daily dosing, ease of use, comfort and less breakthrough bleeding while affording an active lifestyle.
- **Regulatory pathway de-risked.** Following a CRL, AGRX received clear guidance from the FDA regarding a new Phase 3 study design that would be acceptable for approval. We assign a 70% probability of success for the Phase 3 outcome based on the straightforward and simple study design, the robust powering of the study, an experienced clinical research organization and improved study conduct. Lastly, we believe several recent approvals in the space provide regulatory clarity.
- **A blockbuster opportunity in a meaningful market under most conservative assumptions.** In 2013, total sales in the CHC market was $4.2B, with slightly more than 50% of sales generated by branded products. We conservatively estimate Twirla's market share at 9% with drug pricing at a slight discount to a generic patch and currently branded oral contraceptives, which translates into $1.0B in peak sales. By comparison, Ortho Evra, the first contraceptive patch, garnered 10% market share 1.5 years after its launch and peaked at 11% share when it received a black box warning. Based on its distinguished profile, we believe Twirla can command greater market share and premium pricing to Xulane, the generic CHC patch, which we view as upside to our estimates.

Research Analyst Certifications and Important Disclosures are on pages 20 - 22 of this report

Summary and Investment Highlights

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, Twirla (AG200-15), is a once weekly contraceptive patch currently in Phase 3 clinical trials. Other pipeline candidates include AG200-ER, which is an extended cycle regimen that allows women to extend the time between episodes of withdrawal bleeding, and AG200-SP, a 28-day regimen that includes a shortened hormone-free interval which results in shorter, lighter withdrawal bleeds and potentially improved contraceptive efficacy (Exhibit 1).

Exhibit 1: Pipeline

Drug Candidate	Indication	Stage of Development
Twirla™ (combined hormone)	Transdermal patch for perscription contraception (once weekly dosing)	Phase 3
AG200-ER (combined hormone)	Transdermal patch for perscription contraception (extended cycle between withdrawal bleeds)	Phase 2
AG200-SP (combined hormone)	Transdermal patch for perscription contraception (28-day regime with shorter hormone free interval)	Pre-Clinical
AG890 (Progestin-only)	Transdermal patch for perscription contraception (unable/unwiling to take estrogen, higher risk patients	Pre-Clinical

Source: Company reports

We are initiating coverage of Agile Therapeutics with a Buy rating and $18 fair value estimate. We view AGRX as a reasonable investment for small-cap investors for the following reasons:

1) **Twirla is a differentiated contraceptive in a validated market that is attractive to physicians and patients.** Twirla is a low-dose, Phase 3-ready CHC patch that should provide convenience and facilitate compliance based on its weekly application while delivering contraceptive efficacy and safety comparable to approved low-dose oral contraceptives. This market is one that has already been validated by a successful Ortho Evra launch so there has been market experience with the patch. Feedback from OB/GYNs indicate that the daily dose of estrogen delivered is important to them given the safety concerns of deep vein thromboses (DVTs) associated with high estrogen levels. Physicians also rank convenience and compliance highly. Surveyed consumers cite that Twirla's selling propositions include non-daily dosing, ease of use, less breakthrough bleeding and comfort while affording an active lifestyle.
2) **Twirla's development and regulatory pathways are de-risked.** Following a CRL in February 2013, the manufacturing validation was completed. Importantly, the company received clear guidance from the FDA regarding a new Phase 3 study design that would be acceptable for approval. We assign a 70% probability of success for the Phase 3 outcome based on the straightforward and simple study design, the robust powering of the study, an experienced

clinical research organization and improved study conduct. Lastly, we believe several recent approvals in the space provide regulatory clarity.

3) **Twirla can reach blockbuster status in a meaningful market under most conservative assumptions.** In 2013, total sales in the CHC market was $4.2 billion, with slightly more than 50% of sales generated by branded products. We conservatively estimate Twirla's market share at 9% with drug pricing at a slight discount to a generic patch and currently branded oral contraceptives, which translates into $1.0 billion in peak sales. By comparison, Ortho Evra, the first contraceptive patch, garnered 10% market share 1.5 years after its launch and peaked at 11% share when it received a black box warning. Based on its distinguished profile, we believe Twirla can command greater market share and premium pricing to Xulane, the generic CHC patch, which we view as upside to our estimates.
4) **Experienced management team leads the charge.** Alfred Altomari, CEO, has over 20 years of experience in the development and commercialization of specialty pharmaceutical products, with executive roles at Barrier Therapeutics and Johnson & Johnson. Elizabeth Garner, MD, is the company's Chief Medical Officer and a trained gynecologic oncologist with highly relevant experience overseeing successful clinical trial programs and regulatory approval. She has nearly 20 years of experience in women's health, including overseeing the global Phase 3 endometriosis programs at Abbott Laboratories and developing the human papillomavirus (HPV) vaccine program at Merck. Katie MacFarlane, Pharm D., is Chief Commercial Officer, with prior executive roles at SmartPharma, Warner Chilcott and Parke-Davis.

Catalysts:

Upcoming Catalysts:	Timeline											
	1Q14	2Q14	3Q14	4Q14	1Q15	2Q15	3Q15	4Q15	1Q16	2Q16	3Q16	4Q16
Inititation of pivotal Phase 3 trial for Twirla			Initiation of Phase 3					Data		Launch Mid-2016		
AG200-ER initiaion of clinical trials					2015 - Initiation of clinical trials				Data	IND - Mid 2016		

Source: Janney estimates

Valuation:

Our 12-month fair value estimate of $18 is based on a DCF analysis that evaluates cash flow through 2020. Based on a pro-forma fully diluted share count of 18.6M plus the impact of in-the-money options outstanding and assuming the midpoint of the discount rate at 30%, our calculated average intrinsic share value is $18 (Exhibit 2). AGRX has a pro-forma cash position of approximately $53.3M as of 2Q14, which is sufficient to support operations through 4Q15.

Exhibit 2: Discounted Cash Flow

		Assuming Discount Rates of:				
		29.0%	29.5%	30.0%	30.5%	31.0%
Present Value of Unlevered Free Cash Flow		$ 120,617	$ 116,734	$ 112,968	$ 109,316	$ 105,774
Present Value of Terminal Value Assuming	**Exit Multiple**					
	2.50x	$ 172,929	$ 166,796	$ 160,887	$ 155,194	$ 149,709
	2.75	190,222	183,475	176,976	170,714	164,680
Annualized Quarterly Revenue (as of 3/31/22) $ 605,681	**3.00**	207,515	200,155	193,065	186,233	179,651
	3.25	224,808	216,835	209,153	201,753	194,622
	3.50	242,100	233,514	225,242	217,272	209,593
Enterprise Value	**2.50x**	$ 293,546	$ 283,529	$ 273,855	$ 264,510	$ 255,484
(PV of Free Cash Flow + PV of Terminal Value)	**2.75**	310,839	300,209	289,944	280,030	270,454
	3.00	328,132	316,889	306,032	295,549	285,425
	3.25	345,425	333,568	322,121	311,069	300,396
	3.50	362,717	350,248	338,210	326,588	315,367
Net Debt (as of Q2:14 E)		$ (39,977)	$ (39,977)	$ (39,977)	$ (39,977)	$ (39,977)
Options Proceeds		5,813	5,813	5,813	5,813	5,813
Equity Value	**2.50x**	$ 339,336	$ 329,319	$ 319,645	$ 310,300	$ 301,273
(Enterprise Value - Net Debt + Option Proceeds)	**2.75**	356,628	345,999	335,733	325,819	316,244
	3.00	373,921	362,678	351,822	341,339	331,215
	3.25	391,214	379,358	367,911	356,858	346,186
	3.50	408,507	396,037	383,999	372,378	361,157
Shares Outstanding		18,592	18,592	18,592	18,592	18,592
Options Outstanding ("In-the-Money")		1,387	1,387	1,387	1,387	1,387
Diluted Shares Outstanding		19,979	19,979	19,979	19,979	19,979
Implied Price Per Share	**2.50x**	$ 16.98	$ 16.48	$ 16.00	$ 15.53	$ 15.08
	2.75	17.85	17.32	16.80	16.31	15.83
	3.00	18.72	18.15	17.61	17.08	16.58
	3.25	19.58	18.99	18.41	17.86	17.33
	3.50	20.45	19.82	19.22	18.64	18.08

Sources: Company reports and Janney estimates

Hormonal Contraception:

Hormonal contraception refers to the method of birth control that acts on the endocrine system of a woman who has begun to menstruate. Menstruation is the cycle of changes that occur in the uterus and ovaries that allow for sexual reproduction. These changes include maturation of ovarian follicles, the release of the mature egg, the formation of the corpus luteum, the growth of the lining of the uterus and lastly making the endometrium receptive to implantation. If no pregnancy occurs, the uterine lining is shed. Menstruation now typically begins around 12-13 years of age and lasts to natural menopause at approximately 51.

Hormonal contraceptives can be used to prevent pregnancy. There are two types of hormonal contraceptive formulations: combined methods which use both estrogen and a progestin and progestin-only methods which contain only progesterone or one of its synthetic analogues. In the estrogen and progestin combination, estrogen prevents the pituitary gland from producing follicle stimulating hormone (FSH) and luteinizing hormone (LH), which prevents ovulation and supports the uterine lining to prevent breakthrough bleeding mid-cycle. The progestin also works to stop the pituitary from producing luteinizing hormone in order to prevent egg release and makes the uterine lining inhospitable to a fertilized egg as well as thickens the cervical mucus to hinder sperm movement.

Exhibit 3: Oral Contraceptives

Oral CHCs	Hormones	
MONOPHASIC	**Estrogen**	**Progestin**
Alesse-28	Ethinyl estradiol	Levonorgestrel
Apri	Ethinyl estradiol	Desogestrel
Aviane	Ethinyl estradiol	Levonorgestrel
Beyaz	Ethinyl estradiol	Drospirenone
Brevicon	Ethinyl estradiol	Norethindrone
Demulen	Ethinyl estradiol	Ethinyl diacetate
Desogen	Ethinyl estradiol	Desogestrel
Genora	Mestranol	Norethindrone
Levlite	Ethinyl estradiol	Norethindrone
Levlen	Ethinyl estradiol	Levonorgestrel
Levora	Ethinyl estradiol	Levonorgestrel
Loestrin	Ethinyl estradiol	Levonorgestrel
Loestrin FE	Ethinyl estradiol	Norethindrone acetate
Lo-Ovral 28	Ethinyl estradiol	Norgestrel
Ovral 28	Ethinyl estradiol	Norgestrel
Ogestrel	Ethinyl estradiol	Norgestrel
Microgestin	Ethinyl estradiol	Norethindrone acetate
Microgestin FE	Ethinyl estradiol	Norethindrone acetate
Modicon	Ethinyl estradiol	Norethindrone
Necon	Ethinyl estradiol	Norethindrone
Nordette	Ethinyl estradiol	Levonorgestrel
Norinyl	Mestranol	Norethindrone
Nortrel	Ethinyl estradiol	Norethindrone
Orthro-Cept	Ethinyl estradiol	Desogestrel
Ortho-Novum 1/35	Ethinyl estradiol	Norethindrone
Ortho-Novum 1/50	Mestranol	Norethindrone
Ortho-Cyclen	Ethinyl estradiol	Norgestimate
Ovcon	Ethinyl estradiol	Norethindrone
Tri-Norinyl	Ethinyl estradiol	Norethindrone
Yasmin	Ethinyl estradiol	Drospirenone
Zovia	Ethinyl estradiol	Ethinyl diacetate
BIPHASIC	**Estrogen**	**Progestin**
Jenest 28	Ethinyl estradiol	Norethindrone
Mircette	Ethinyl estradiol	Desogestrel
Necone	Ethinyl estradiol	Norethindrone
Other-Novum 10/11	Ethinyl estradiol	Norethindrone
TRIPHASIC	**Estrogen**	**Progestin**
Estrostep	Ethinyl estradiol	Norethindrone
Ortho Novum 7/7/7	Ethinyl estradiol	Norethindrone
Ortho Tri-Cyclen	Ethinyl estradiol	Norgestimate
Other Tri-Cyclen LO	Ethinyl estradiol	Norgestimate
TriLevlen	Ethinyl estradiol	Levonorgestrel
Tri-Norinyl	Ethinyl estradiol	Norethindrone
Triphasil	Ethinyl estradiol	Levonorgestrel
Trivora	Ethinyl estradiol	Levonorgestrel
24-4 PREPARATIONS	**Estrogen**	**Progestin**
Yaz	Ethinyl estradiol	Drospirenone
Lo-Estrin 2-24	Ethinyl estradiol	Norethindrone acetate
EXTENDED CYCLE	**Estrogen**	**Progestin**
Seasonale	Ethinyl estradiol	Levonorgestrel
Seasonique	Ethinyl estradiol	Levonorgestrel
Quarette	Ethinyl estradiol	Levonorgestrel

Source: Company reports and Janney research

Estrogen Standard:

Currently, there are three synthetic estrogens approved for use in contraceptives: ethinyl estradiol (EE), mestranol and estradiol valerate. EE has been in use for over 40 years in FDA-approved products and is the estrogen component of nearly all combination hormonal contraceptives today, as seen in Exhibit 3. As for progestin, there are 10 different progestins currently being used on the market today.

Progestin Differences:

Progestins differentiate themselves via their progestational, estrogenic and androgenic activity. To date, there are four generations of progestins. Levonorgestrel (LNG) is a second-generation progestin and is the most widely prescribed contraceptive progestin worldwide. Although progestins are effective at suppressing ovulation, the high androgenic effects cause unwanted side effects like acne and weight gain and in combined hormonal birth controls, risk of venous thromboembolism (VTE), or blood clots. However, LNG has been on the US market for over 25 years, with recent studies concluding that the risk associated with VTEs is not as high with 2nd generations progestins like LNG as it is with the 3rd and 4th generations such as desogestrel and drosperinone which function to reduce those androgenic side effects such as oily skin and acne.

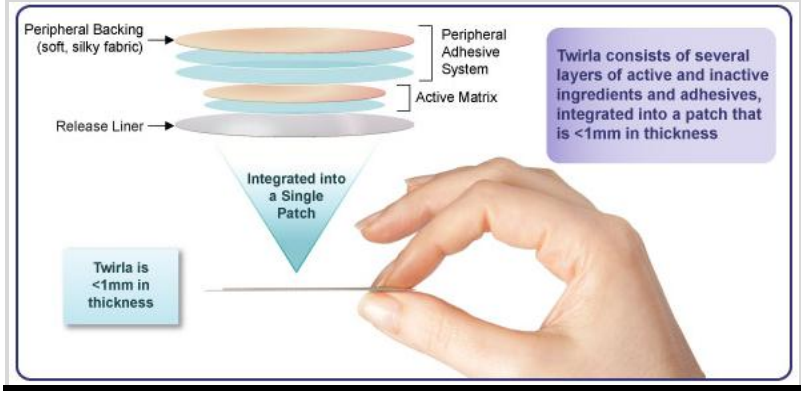
The Twirla Patch:

AGRX's lead product candidate is Twirla, a combined hormone contraceptive (CHC) patch that contains both EE and LNG delivered via a unique and proprietary Skinfusion technology, which utilizes both an inner and outer adhesive system (Exhibit 4). The inner active matrix delivers both EE and LNG at specific levels through the skin, while the peripheral system provides adherence and stability and prevents ingredients from migrating to the outer edges (Exhibit 5). Twirla 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.

Exhibit 4: Twirla Patch

Source: Company reports

Exhibit 5: Twirla Layers

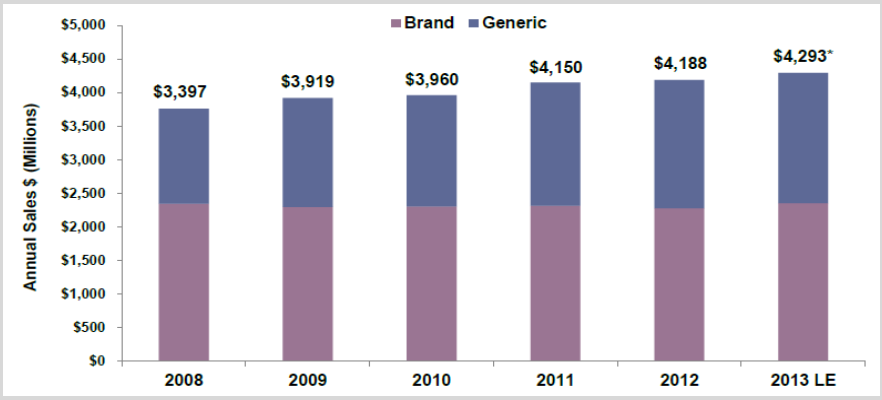


Source: Company reports

Crowded Product Marketplace But Branded Products Rule:

There are over 180 generic and brand CHC products on the market today which generate approximately $4.2B in sales every year. Currently, branded products comprise approximately 55% of total sales, as seen in Exhibit 6.

Exhibit 6: Branded Products Versus Generics



*2013 estimate based on MAT Oct1 2-Sept 13

Source: Company reports

Significantly, only eight branded products hold approximately 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 and Ortho Evra with $152M.

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 (Exhibit 7).

Exhibit 7: Significant Revenue & Market Share in Brand Products

Brand	Peak TRx Share	Sales at Peak Share (year)	Revenue at Current 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

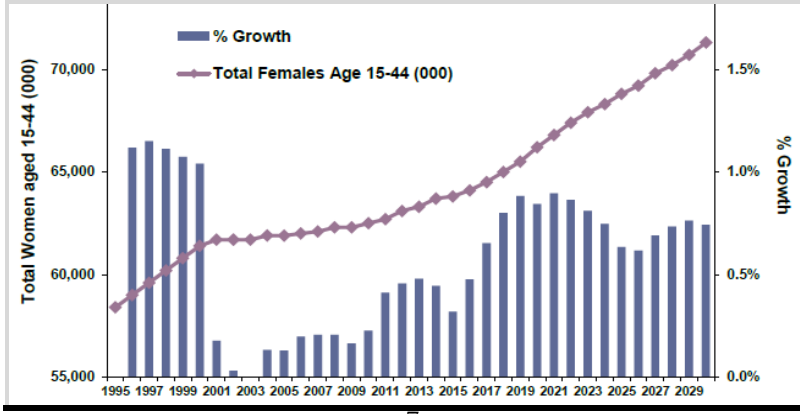
*Avg WAC price/TRx of $88/cycle of branded products of 2013
1% of TRx = $110M
Source: Company reports and Janney research

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.

A Large and Growing Market:
The whole US contraceptive market recorded sales of $5.6B in 2013, according to IMS Health. This market is segmented further into the CHC market which consists of oral contraceptives, a transdermal patch and a vaginal ring, all of which generated $4.2B in US sales. The progesterone (P-only) products which consist of IUDs, injectables, implants and P-only pills recorded $1.4B in sales in the same year.

The overall US CHC market is mature, with both branded and generic products available. Historically, the market growth has been flat to declining as measured by prescription volume. The average annual growth rate in dollar sales for the five years ended December 2013 was 2.4% for the CHC market.

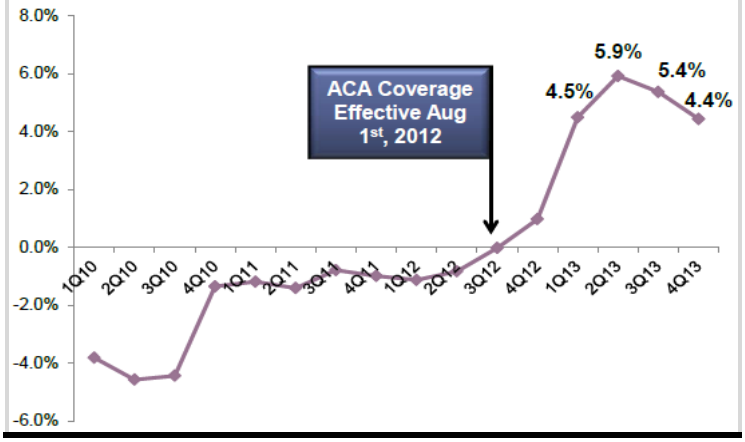
Exhibit 8: Contraceptive Population (women age 15-44 yrs)



Source: Company reports

Continual price increases amongst the branded products demonstrate healthy market growth. Recently, the CHC market has seen a 4.8% prescription volume growth YOY, likely due to a slight surge in the targeted patient population (Exhibit 8) and to the enactment of the Patient Protection and Affordable Care Act, or ACA. US Census data show that the population of women aged 15 to 44 years has been growing at a rate of approximately 0.4% to 0.5% per year since 2011, thus increasing this population by 250,000 to 300,000 women per year. Within the ACA, which became effective August 1, 2012, provisions require all health plans, with limited exception, to cover certain preventative services such as FDA-approved contraceptive methods and counseling, at no cost sharing. This means no deductible, co-insurance or co-payments. As a result, quarterly prescription growth for the CHC market has risen from negative growth year-over-year to positive growth between 4.0% and 5.0% for each of the six quarters following implementation (Exhibit 9).

Exhibit 9: CHC Market TRx Growth (%) vs. Prior Year



Source: Company reports

Ortho Evra, The First CHC Patch, Validates the Market:

Ortho Evra was approved in 2002 as the first contraceptive patch available in the US. The initial approved label for Ortho Evra indicated that it delivered a daily EE dose of 20 micrograms, which was lower than most oral contraceptives of 35 micrograms. Its early success was unparalleled and Ortho Evra achieved a 10% share of the CHC market by September 2003. However, there were numerous reports from Ortho Evra users of thrombotic and thromboembolic events. This culminated in April 2004 when a 19 year old fashion student collapsed while waiting for the subway in New York City and later died. A study was published in 2005 that revealed that Ortho Evra had higher EE levels than Nuvaring and low-dose pills. In November 2005, Johnson & Johnson revised the Ortho Evra label to include information that the EE exposure with Ortho Evra was 60% higher than that of an oral contraceptive containing 35 micrograms of EE. The company stopped active promotion of the product. Johnson & Johnson was later sued and settled for $68.7M in 2008. Ultimately, Ortho Evra received a black box warning and bolded warnings unique to Ortho Evra's profile. The fallout was swift and Ortho Evra's market share declined rapidly from peak share of 11% in 2005, 4% in 2006 and 1.4% by 2013.

Twirla Has a Different Profile From Ortho Evra:

Several key characteristics differentiate Twirla from Ortho Evra. Importantly, Twirla uses a safer, 2nd generation progestin whereas Ortho Evra uses a 3rd generation progestin. Also, the EE concentrations from Twirla are substantially less than Ortho Evra over a 3-week cycle. Lastly, AGRX's Skinfusion

technology allows for the application and removal of the patch without a darkened ring of residue, which is common cosmetic complaint.

Progestins: 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 CHCs, there are others who claim that CHCs with 3rd and 4th generation progestins can significantly increase the risk of developing a VTE. Twirla uses Levonorgestrel (LNG), a 2nd generation progestin, while Ortho Evra uses Norelgestromine, a 3rd generation progestin (Exhibit 10).

Exhibit 10: Generations of Progestins

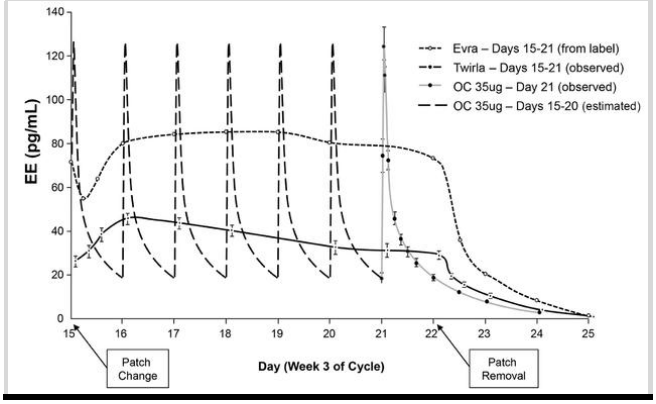
Generation	Progestins
First Testosterone derived estranes	Norethindrone Norethynodrel Norethindrone acetate Ethynodiol diacetate
Second Testosterone derived gonanes	Levonorgestrel Norestrel
Third Levonorgestrel derivatives	Desogestrel Gestodene Norgestimate/Norelgestromine Etonorgestrel
Fourth Non-ethylated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

Source: Janney research

To keep things in perspective, *any* woman on a CHC has an increased risk of a VTE (from 4-5/10,000 to 8-9/10,000). 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 0.5%, 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, a low dose EE CHC must be taken daily otherwise 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 at higher doses. Though no direct head-to-head comparisons have been done between Twirla and Ortho Evra, a pharmacokinetic (PK) study with Twirla has been run similar to one with Ortho Evra had that provided the EE concentration information for the Ortho Evra package insert. The chart below combines the results. Twirla clearly shows a decreased and lower dose of EE at 30 mcg compared to Ortho Evra at 56mcg (Exhibit 11).

Exhibit 11: EE Concentrations (pg/ml)



Source: Company reports

Cosmetic Improvements: Twirla 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 Ortho Evra which has a smooth plastic film. Twirla is specially designed to adhere to the skin for a full seven-day 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 Ortho Evra users.

The Twirla Clinical Program:
The company has completed a comprehensive clinical program that has enrolled over 2,100 patients. More than 1,500 patients have received Twirla with 485 patients having received Twirla in the past 12 months. The company completed two Phase 2 studies that demonstrated a pregnancy rate comparable to oral contraceptives and the patch was well tolerated.

The Completed Phase 3 Trials:
AGRX completed a 407-patient and 1,504-patient Phase 3 study for 6 and 12 months, respectively. Both studies were open-label with a Twirla-treated arm and an approved low-dose oral contraceptive arm. The primary endpoint was the Pearl Index (PI), which is the rate of unintended pregnancies experienced by women over the course of the study and 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.

Results: The pooled PI value for Twirla was 5.76 compared to 6.72 for the CHC contraceptive control arm. Twirla's PI was outside the historical range of 1.34-3.19 from pivotal studies conducted on approved products in the past 10 years. From a safety perspective, Twirla was generally well-tolerated, with levels of adverse events comparable to those of low-dose oral contraceptives. In the larger trial, approximately 3% of patches became completely detached from the skin over the 7-day period. Of the combined trials, there were 16 serious adverse events (SAEs) from the Twirla cohort which had 2.3 times as many subjects as the oral contraceptive group. Of these, there was one upper extremity deep vein thrombosis in a higher-risk patient who was a weight lifter and kick boxer. Other non-serious adverse events included nausea, headache, application site irritation and breast tenderness. As such, the company believes that Twirla's potential label should be consistent with all marketed low-dose CHC products.

In February 2013, the FDA issued a CRL for Twirla that indicated the completed Phase 3 studies were not sufficient for approval. Feedback from the FDA indicated that an additional Phase 3 trial was required for a potential approval.

What went wrong?
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.

- *Rapid Enrollment:* Rapid enrollment led to the inadequate 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 approximately 8% of the randomized subject population. Thirty-six percent of on-treatment pregnancies were reported from four out of 96 sites, which represented 15% of the randomized subject population.

- *Disproportionally high number of new users:* Experts agree 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 Phase 3 study, 56% of patients were new users with 17.8% of patients being current users within 6 months of enrollment. 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.

- *Disproportionally high number of subjects at higher risk of non-compliance and pregnancies, including a high number of minorities:* Another factor that contributed to the outcome of the trial was the higher proportion of black and Hispanic subjects (Exhibits 12, 13). Within these patient groups, high contraceptive failure rates have been well documented. In the larger Twirla Phase 3 study, rates of lab-verified 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.

Exhibit 12: Study Population Demographics in Selected Contraception Trials

Contraceptive Product with Year of Approval - % of Subjects in category*							
Parameter		Twirla	Seasonique (2006)	Yaz (2006)	Lo-Seasonique (2008)	Natazia (2010)	Quartette (2013)
Hormonal contraception use							
Current Users		18[a]	0	60[b]	0	59[c]	0
Within 6 months of enrollment	Yes[d]	44	68	0	61	0	44
	No[e]	56	32	0	3	0	56
Race/ethnicity	Hispanic	15	5	5	10	13	11
	Black	22	11	4	12	7	18

* Randomized Twirla subjects from the larger Phase III clinical trial
a - Used a hormonal contraceptive withn 7 days of enrollment
b - Used an oral contraceptive at screening, just prior to study start
c - Using oral contraceptives prior to study start
Use within 6 months of enrollment definitions:
d - Twirla: recent and current users; Quartette/Seasonique/Lo-Sesonique: continuous users
e - Twirla: new users, Seasonique/Lo-Seasonique: fresh start and prior users; Quartette: new start and prior users

Source: Company reports

Exhibit 13: Twirla Pearl Indices Stratified By New Users and Minority Subjects

Twirla Pearl Indices Stratified By New Users and Minority Subjects		
Parameter	Demographic	Pearl Index*
Race/ethnicity	White (not Hispanic)	3.6
	Hispanic	5
	Black	15.1
Previous contraceptive use status	New users[a]	8.7
	Experienced users[b]	3
	Current users[c]	0
Race/ethnicity and Previous contraceptive use status	Hispanic subjects who were new users	7.5
	Black subjects who were new users	16

* Table includes the pooled PI values for subjects in the primary efficiacy analysis population to Twirla
a - New users = never used hormonal contraception or had not used hormonal contraception in the 6 months prior
b - Experienced users = recent (used a hormonal contraceptive within 6 months of enrollment) and current users
c - Current users = subjects who used a hormonal contraceptive within seven days of enrollment

Source: Company reports

The Path Forward: A New Phase 3 Clinical Trial

In October 2013 and February 2014, the FDA met with AGRX and provided further guidance on the requirements for the Phase 3 trial. The Agency suggested a more simplified, single-arm registration study testing Twirla in approximately 2,000 subjects for up to one year.

What will be different? Several aspects of the trial will differ from the previously run Phase 3 studies (Exhibit 14).

- Single-arm trial: 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. There will not be 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.

- Fewer clinical sites and increased oversight: The new trial will use between and 50 and 70 sites compared to 96 sites previously. 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. Fewer sites should allow for more focused oversight and facilitate more individualized attention to study subjects. There will be ongoing trial monitoring. There will be the potential to discontinue sites with high loss to follow-up or non-compliant patients and to discontinue these patients. Lastly, there will be an independent pregnancy review committee (PRC) to adjudicate all pregnancies.

- Loss to follow-up: In prior studies, there was a significant loss of patients to follow-up. The company intends to address this issue by extensive training of study coordinators to screen for the appropriate subjects, 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 studies, the new study utilizes 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. Once uploaded, the data will be available in the CRO's database, allowing for real-time review by the CRO and study monitors.

Exhibit 14: ATI-CL12 and ATI-CL23 Comparison and Risk Mitigation

	Study ATI-CL12	Study ATI-CL23	Risk Mitigation Factor
STUDY DESIGN			
Overall Study Design	CL12 was an open-label, randomized, parallel group, Phase 3 study of the contraceptive efficacy and safety of Agile transdermal contraceptive delivery system (TCDS) in comparison to a low-dose oral contraceptive (COC) containing 0.02 mg ethinyl estradiol and 0.1 mg levonorgestrel in a 21-day regimen.	Study CL23 will be a single-arm open-label study	Not having a comparator substantially reduces the complexity of statistical analysis and reduces uncertainty around interpretation of any unexpected differences in observed Pearl indices. Study design will increase the number of cycles collected for the primary efficacy population. The straightforward protocol design should be easier for sites to understand and implement. Having no COC comparator will also attract subjects who are interested in participating in the transdermal method as opposed to subjects who prefer COC and are therefore higher risk for early discontinuation if randomized to patch--as seen in study 12.
Sample Size Considerations	Sample size CL12: Up to 1500 1125 AG200-15 375 oral contraceptive (OC)	Sample size CL23: Up to 2100 1900 age ≤ 35 200 women age > 35	A greater number of subjects in the primary efficacy population will elicit a larger number of cycles and mitigate the risk of loss of cycles due to discontinuations, lack of sexual intercourse within a given cycle and use of back-up method in the case of administration noncompliance.
Study Population	Sexually active women, age 17 - 40 years.	Sexually active women (in heterosexual relationships) seeking contraception. No upper age limit. At least 18 years old; or, if less than 18 years old, a subject may participate if applicable laws are followed	Removal of age limits was requested by FDA. The additional patient selection measures will contribute to a sudy population with greater rates of compliance with study drug and the overall study protocol. Exclusion of patients who are unlikely to be sexually active or who are likely to use back-up methods with lead to fewer discarded cycles.
Study Evaluation	The following in-treatment office visits will be scheduled: Days 8-11 on Cycle 2, 4,6,9 and 13. All subjects who complete or discontinue will be required to return to the clinic 14 days (±2 days) after removal of the last patch or last pill taken for	The following in-treatment office visits will be scheduled: on Days 8-20 on Cycle 1, 3, 5, 7, 9, and 13 Exit Visit, 14 days (±3 days) after removal of the last patch (either after Cycle 13 for completers or after the last use of the patch for early discontinuations) scheduled:	Study visits were changed to maximize subject follow-up and monitor compliance: -A visit during the first cycle was added to identify any potential issues in the first cycle. -Telephone contacts between visits as well as an additional interim study visit were added to lessen the time between visits and provide ongoing subject education; this will serve to keep subjects more engaged in the study, helping to minimize loss to follow up and assist in early identification of compliance issues.
Definition of Previous Contraceptive Use	Hormonal Contraceptive User status definitions: New-users of hormonal contraceptive therapy were defined as never-users or subjects with no exposure to hormonal contraceptives for at least 6 months.	Hormonal Contraceptive User status definitions: -Never-users of hormonal contraception -Former users (previous use but not in the 6 months prior to enrollment) -Recent users (not current users, but used within 6 months of enrollment) -Current users of another hormonal method at enrollment.	In the new protocol, a more detailed contraceptive history will be collected which will assist in measuring subject experience and allow tailored subject teaching and follow-up.
Definition of ON-Treatment Pregnancy	On-treatment pregnancies were defined as those with an estimated date of conception (EDC) from the date of first study patch application or first active study pill taken through Day 14 after the last study patch removal or the last active study pill	On-treatment pregnancies will be defined as those with an EDC from the date of first study patch application through Day 7 after the last study patch removal.	The shorter EDC window related to patch removal will reduce the incidence of on-treatment pregnancies. This definition has been accepted by the FDA.
Subject Compliance	No specific discontinuation rules applied for non-compliant subjects.	In the new study subjects will be closely monitored by the investigator, study coordinator, the CRO and the sponsor. Subjects with a pre-determined level of repeated non-compliance with study drug, ediary entry, and/or study visits will be discontinued from the study. Patient education (videos, brochures, one-to-one education with study coordinator) regarding the importance of compliance will be provided at repeated intervals throughout the study. Reminders to patients regarding patch application, ediary entry, and study visits will be delivered via SMS, email,	Non-compliance with study drug administration is a major risk factor for pregnancy. Discontinuing subjects who demonstrate repeated non-compliance may help reduce the number of subjects who become pregnant due to non-compliance with the protocol. Poor compliance with ediary use leading to incomplete compliance data would lead to challenges around adjudication of any pregnancies that occur. Discontinuation of these subjects will reduce this risk. Patient non-compliance with ediary data entry would also compromise ability to assess use of back-up contraception and sexual activity, leading to increased numbers of cycles being discarded from the PEARL index analysis. Poor patient data entry and study visit compliance would also lead to poorer quality of overall study data.
Loss to Follow-Up	Significant issues with loss to follow-up led to FDA co	Early indicators of patients at increased risk of loss to follow-up (poor ediary compliance, miss visits) will be tracked for early intervention. Patient informed consent will include permission to utilize publicly available records/information to locate patient (phone directories, likely family contacts,	Utilizing real-time data to intervene early will reduce loss to follow-up in the new study. Including upfront permission to utilize all available methods to locate patients will substantially reduce loss to follow-up.
Patch Adhesion	Patch adhesion was captured by subjects on the pape	Patch adhesion will be captured by subjects daily in their electronic diaries. A new, more detailed patch adhesion scale has been developed for the new study.	Per FDA request, patch adhesion will now be captured daily. The new scale will improve adhesion data quality, which will allow demonstration that any pregnancies are not related to adhesion issues, and facilitate early identification and correction of any adhesion issues related to inappropriate patch application.
Pharmacokinetic/Hormone Evaluations	Plasma concentration levels of EE and LNG were done.	No PK analyses will be conducted.	Eliminating PK and SHBG/CBG analyses will reduce the complexity of data collection and simplify the study visit process.
Patient Format	Paper diaries were used.	Electronic diaries (ediaries) will be used.	The use of ediaries will greatly assist in the monitoring of compliance with patch use and diary completion, as well as offer real time data for review. This technology will also allow for built-in reminders for patch application and diary completion as well as built-in edit checks for data entry. A detailed subject teaching plan regarding ediary completion will be developed. Safe guards will be put in place to identify incidences where additional subject teaching may be required.
# of Study Centers	Up to 125 study centers in the United States	Up to 70 study centers in the United States	Fewer investigators will enable more focused oversight of the participating sites and more individualized attention to enrolled subjects. Sites being considered for study participation will be evaluated extensively for their prior hormonal birth control trial experience, performance on previous Agile/CRO studies, staffing (in particular for experienced study coordinator with longevity at the site), demographics of potential study subjects, and audit history.
Subject Enrollment per site	Sites were allowed to enroll up to 150 subjects.	Sites will be allowed to enroll a substantially lower number of subjects; after enrollment of the initial 3-5 subjects, a brief enrollment hiatus will be enforced to allow assessment of study conduct at the site with respect to patient follow-up and communication, protocol deviations, data entry, etc.	Patient enrollment (with attention to study population demographics) will be closely monitored in real time using an electronic data collection system; adjustments will be made early as needed to ensure enrollment of the appropriate patient population (i.e. avoiding over-representation of new users, low SES minority patients). Having lower site enrollment caps will reduce risk around poor follow-up of non-compliant patients, loss to follow-up, data entry, protocol deviations, safety follow-up, pregnancy follow-up, etc.

Source: Company reports and Janney research

Commercialization Strategy:
OB/GYNs write more than half of the CHC scripts and inclusion of nurse practitioners (NPs) and physician assistants (PAs) who are either affiliated with an ObGyn practice or who are in the primary care space account for nearly 70% of all total CHC prescriptions.

AGRX intends to focus the promotion of Twirla around these key prescribers and customer groups, including consumers themselves and commercial managed care plans. The company believes that a 70- to 100-person specialty sales force should adequately detail the 22,000 prescribers who are responsible for approximately 80% of the total branded CHC prescriptions.

Target marketing will be done both in the physician's office and through media campaigns. Both branded and unbranded campaigns will be used to create awareness but not via a mass-market direct-to-consumer television campaign. Instead, the target demographic of 18-34 year olds will be optimized for a more technology savvy group who will be more likely to seek health information online and through social networks. As such, the company plans to utilize a more focused digital media route to generate Twirla awareness.

As for managed care plans, AGRX plans to utilize free product samples, co-pay vouchers and coupons to gain use by patients in private health care plans while negotiations are finalized with select commercial health care plans.

Competitive Landscape:
Marketed competitors: AGRX faces significant competition from currently marketed products that already have established name recognition and brand loyalty. Merck's Nuvaring, the only marketed contraceptive ring, has been the top selling CHC product but its market share has flattened, which may indicate maxed interest. The oral contraceptive competitors include Warner Chilcott's Loestrin 24 and LoLoestrin, Teva's Seasonique, Lo Seasonique and Quartette, Bayer's Yaz, BeYaz, Natazia and Safyral, Actavis' Generess and Pfizer's Alesse. Competition from IUDs includes Bayer's Skyla and Mirena and Teva's non-hormonal copper IUD, ParaGard. Other contraceptive methods include Merck's subdermal implant, Nexplanon and Implanon, and Pfizer's Depo Provera, a shorter acting injection.

Additionally, several generics manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz, Glenmark, Lupin, Amneal and Mylan. In April 2014, Mylan launched a generic version of the Ortho Evra patch. Although we believe existing demand for a unique transdermal contraceptive patch remains, we highlight that Xulane will still have the safety risks associated with Ortho Evra, including the higher risk of VTE due to the higher EE doses.

Competitors in development: There are other contraceptive products in various stages of development that could compete directly with Twirla, if approved. Bayer has a contraceptive patch, Bay86-5016, that completed Phase 3 development but the company has not yet filed its NDA. Oral contraceptives currently in Phase 3 development include DR-102 (Teva; Phase 3 completed in Feb 2013), Yaz Flex (Bayer; Phase 3 completed in Dec 2009) and NOMAC E2 (Merck; Phase 3 completion expected in Jul 2014). Actavis' Estelle is an oral contraceptive that completed Phase 2 development and is expected to advance into Phase 3 studies this year with a global launch anticipated in 2018. Watson and Pop Council are is developing a Nesterone and EE vaginal ring (Phase 2 initiated Mar 2012) in the US. Antares Pharma and Pop Council are conducting Phase 2 studies for Nestragel, a transdermal gel contraceptive. Bayer is developing a CHC transdermal patch that contains EE and gestodene, a 3rd generation progestin. Bayer has stated that its patch delivers a daily EE dose comparable to a 20 microgram EE oral

contraceptive. The company completed Phase 3 studies in the US/EU and Latin America and received approval in the EU in February 2014. It remains unknown whether or not the company filed for US approval. In our view, even if Bayer's patch is approved in the US, its label will likely include the fact that the patch contains a 3rd generation progestin with at least twice the risks of VTEs.

Why Twirla will be competitive: We believe Twirla has several commercial advantages over some of the other popular CHC options, namely ease of use, the use of the 2nd generation progestin, LNG, and a better safety profile (Exhibit 15).

The use of 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 a commercial benefit, from the consumer's perspective. Lastly, the potential side effect profile is unlike most products on the market, with significantly less side effects observed in the Phase 3 trials.

Exhibit 15: Competitor Comparisons

Characteristics	Twirla	Ortho Evra	NuvaRing	Loestrin 24 fe (Minastrin 24 fe)
Form of product	Transdermal patch Round, ~28 sqcm Soft, silky, stretchy fabric	Transdermal patch Square, ~20 sqcm Smooth, plastic film	Polymetric vaginal ring	Oral pill - chewable
Active Ingredients	EE, LNG	EE, norelgestromin	EE, etonogestrel	EE, norethindrone acetate, ferrous fumarate
Daily EE dose	~30 micrograms	~56 micrograms	15 micrograms	20 micrograms
Regimin	One patch weekly 21 active days /7 patch free days	One patch weekly 21 active days /7 patch free days	One ring for 3 weeks 3 weeks active, 1 week ring free	One oral tablet every day at the same time 24 active pills/ 4 inactive
Package configurations	1 box of 3 patches = 1 cycle 1 box with 1 patch = replacement	1 box of 3 patches = 1 cycle 1 box with 1 patch = replacement	1 ring per cycle reclosable aluminium laminate sachet	1 blister card = 28 tablets Carton of 5 cards
Top Four AEs in trials	Nausea 3.0% Site irritation 2.4% Breast tenderness 2.1% Headache* 2.0%	Breast symptoms 22.4% Headache 21.0% Site disorder 17.1% Nausea 16.6%	Vaginitis 13.8% Headache 11.2% Mood Changes 6.4% Device related events 6.3%	Headache 6.3% Vaginal candidiasis 6.1% Nausea 4.6% Menstral cramps 4.4%

*AEs deemed definitely, probably or possibly related to Twirla in completed Phase 3 trials
Source: Company reports and Janney research

Manufacturing:

Currently, AGRX does not own any manufacturing facilities. Instead, AGRX relies on a third party manufacturer, Corium. AGRX has an exclusive agreement to develop Twirla using the Skinfusion technology. The agreement with Corium is exclusive until Corium has commercially produced a significant, agreed-upon quantity of patche, currently projected to occur no earlier than five years following Twirla's commercial launch. To date, Agile shares equipment with Corium for clinical supply manufacturing. This equipment can supply approximately 1.7M patches (50% usage) annually.

To accommodate the anticipated commercial launch of Twirla if it is approved, Corium has completed a substantial build-out of its facilities, including a dedicated building as well as installing over $10M of equipment purchased by AGRX. This new manufacturing facility has large batch (~500k patches) capability as well as an estimated 30M patch annual capacity.

Next steps include completion of new equipment qualification, finalization of the validation strategy, protocols and process validation and notification of scale-up to the FDA.

Twirla Line Extensions and Other Products:
The hormonal contraceptive market has a long history of manufactures successfully using line extensions to extend the lifecycle of a brand, often by gaining additional exclusivity periods for the product extension under provisions of the Hatch-Waxman Act or with additional patents.

- AG200-ER – This is an extended cycle regimen which would allow a patient to extend the time between withdrawal bleeding. While there are currently several oral contraceptives on the market with the 84-91 day extended cycle regimen, there are no currently approved patch options. AG200-ER is designed to potentially minimize breakthrough bleeding which is a common concern among patients. AG200-ER would utilize the same drug product as Twirla and therefore require no further patch development. ARGX believes that AG200-ER could be presented to the FDA and a Phase 3 study started in 2015, once a protocol is developed.

- AG200-SP – This product is a 28-day regimen that includes a shortened hormone-free interval (SHFI) designed to provide users with shorter, lighter withdrawal bleeds and potentially improve contraceptive efficacy. Currently, there are several oral contraceptives built around the SHFI which comprise 44% of US total prescription volume, demonstrating high acceptability among patients and providers. AG-200 would require additional patch development work prior to initiation of a Phase I study in 2015.

- AG-890 - AG890 is a progestin-only (P-only) contraceptive patch intended for use by patients who are unable or unwilling to take estrogen, including those who are breastfeeding or who are at greater risk of VTE, such as women who smoke, are over 35 years of age, or who are obese. Currently, the P-only market consists of pills and several non-oral options, including IUDs, implants and injections. AG890 is intended to fulfill an unmet medical need for a non-daily, easily reversible form of contraception in the P-only market. AGRX has completed a Phase 1 study and data is being compiled. Early findings indicate that additional patch development work for dose selection will be required, including additional Phase 1 and Phase 2 studies to determine the optimal formulation and dose to advance to Phase 3.

Intellectual Property:
Currently, AGRX has five issued US patents that cover Twirla, the last of which expires in 2028, and the company plans to list them all in the Orange Book (Exhibit 16). All the intellectual property behind the

Exhibit 16: Intellectual Property

Patent Number	Content	Expires	Product
7,045,145	Wet formulation of the transdermal delivery system	March 2021	Twirla
7,384,650	Final dry product formulation of transdermal delivery system	March 2021	Twirla
8,221,784	Final dry product formulation of transdermal delivery system	March 2021	Twirla, AG890
8,246,978	Structure features of transdermal delivery system	August 2028	Twirla, AG890
Pending	Continuation Application	August 2028	Twirla, AG890

Source: Company reports

AGRX current product line is wholly-owned by the company (Exhibit 1).

Risks to Fair Value Estimate:
Development risk - Many of our assumptions are based on a review of clinical trial data available in the public domain. Although management seems to have taken the appropriate steps to adjust the issues of the initial Phase 3 study, this does not guarantee a successful outcome, although the risk of a negative result is significantly decreased.

Regulatory risk - The company is dependent on getting its lead product, Twirla, to market and thus, its success is dependent upon regulatory approval. There is a risk that the drug does not get approved.

Manufacturing risk – Currently, the company is dependent on a single source manufacturer and raw material supplier. The company's commercial success is dependent on successful scale-up and validation of the new equipment as well as FDA approval of the new manufacturing suite and equipment.

Commercial/Competitive risk – A large portion of the current market is comprised of generics. Generic patch entrants may make marketing Twirla challenging and difficult to gain access to reimbursement by payors. Twirla may not penetrate the contraceptive market significantly given the numerous competitive players in the market.

Management:
Al Altomari - President & CEO: Mr. Altomari is President and Chief Executive Officer of Agile Therapeutics and a member of the Company's Board of Directors since 2010. Prior to joining Agile Therapeutics, Mr. Altomari served as Chief Executive Officer of Barrier Therapeutics and was a member of the Company's Board of Directors. Preceding Barrier Therapeutics, he held several executive positions within Johnson & Johnson including Vice President / Franchise Head of Ortho-McNeil Pharmaceuticals Women's Health Care for which global product sales were in excess of $1 billion. During his tenure, Mr. Altomari led the introduction of several life cycle and new product development initiatives and successfully launched multiple products including Ortho Evra. Mr. Altomari currently serves as a member of the Board of Directors of Insmed Inc., (NASDAQ: INSM) and Recro Pharma, Inc., (NASDAQ: REPH) and was a former member of the Board of Directors at Auxilium Pharmaceuticals Inc., (NASDAQ: AUXL) and DUSA Pharmaceuticals Inc. In July 2007, PharmaVoice Magazine recognized Mr. Altomari as one of the Top 100 Most Inspirational and Influential Leaders in the Life Sciences Industry. He received a Master of Business Administration from Rider University and a Bachelor of Science degree from Drexel University with a dual major in finance and accounting.

Elizabeth Garner, MD, MPH – Chief Medical Officer: Dr. Garner serves as Chief Medical Officer since January 2014 and leads the clinical research, drug safety and medical affairs teams in the clinical development of the company's product pipeline. Dr. Garner has significant clinical development experience in the pharmaceutical industry and has highly relevant experience overseeing successful clinical trial programs and regulatory approval. She has nearly 20 years of experience in women's health and is board certified in Obstetrics and Gynecology and Gynecologic Oncology. Most recently, Dr. Garner served as Vice President, Medical Affairs, Women's Health and Preventive Care at Myriad Genetics Laboratories. Previously, she was Senior Director at Abbott Laboratories (now Abbvie), where she oversaw all clinical aspects of the global Phase 3 development program in endometriosis, including protocol development, preparation of regulatory documents, safety and risk management plans, and clinical operations including site and vendor selection. From 2007 to 2011, Dr. Garner served as Associate Director and then Director, Vaccines Clinical Research at Merck Research Laboratories, and served in roles of increasing responsibility during her tenure. She was also a key clinical development leader of the human papillomavirus (HPV) vaccine program and was instrumental in achieving successful

outcomes on important supplemental submissions to the FDA. Dr. Garner also served as the team leader and core presenter for the 2010 FDA Gardasil Advisory Committee Meeting for which she developed and delivered the key clinical presentation that resulted in committee support of FDA approval of a gender-neutral anal cancer indication. Dr. Garner received joint M.D. and M.P.H degrees from Harvard Medical School and the School of Public Health, completed her residency in obstetrics and gynecology at Brigham and Women's/Massachusetts General Hospitals and subspecialized in gynecologic oncology at Brigham and Women's and the Dana Farber Cancer Institute. She received board certification in both general Obstetrics and Gynecology and Gynecologic Oncology.

Katie MacFarlane, Pharm.D. - Chief Commercial Officer: Ms. MacFarlane serves as Chief Commercial Officer at Agile Therapeutics, where she has headed commercial operations since 2010. She is also Managing Partner of SmartPharma LLC., a pharmaceutical consulting firm specializing in new product commercialization since 2007. Ms. MacFarlane has over 20 years of pharmaceutical industry experience, including clinical research and development, marketing and sales management. Before joining Agile Therapeutics, Ms. MacFarlane served as President and Chief Executive Officer at Xintria Pharmaceutical Corporation from 2006 to 2008. Prior to that, she served as Vice President of Women's Health and New Product Planning at Warner Chilcott from 2001 to 2006 where she had marketing, sales and commercialization responsibilities in the women's health portfolio, including sales force planning and configuration. She also oversaw the sales and marketing of several contraceptive and menopause products like Ovcon, Estrostep, Femring, Femhrt, Femtrace, Sarafem and Loestrin 24. Ms. MacFarlane began her career in 1991 with the Parke-Davis in clinical research, marketing and sales management. Serving in management positions of increasing responsibility, Ms. MacFarlane had senior-level marketing responsibility for the launches of Lipitor achieving over $1 billion in sales in twelve months and Celexa. Ms. MacFarlane received her Bachelor of Science degree in Pharmacy and Doctor of Pharmacy degree from Purdue University. She completed a Postdoctoral Fellowship in Industrial Pharmacy Practice with Rutgers University and Hoffmann-LaRoche.

Scott Coiante – Vice President and Chief Financial Officer: Mr. Coiante joined the company in 2010. Prior to joining Agile, Mr. Coiante served as Vice President Finance, Treasurer, Principal Accounting Officer at Medarex, Inc., which was acquired by Bristol-Myers Squibb Co. in September 2009 for $2.4 billion. From 2002 through 2009, Mr. Coiante was responsible for corporate financial functions, including treasury, accounting, SEC reporting, risk management and oversight of revenue recognition for all collaborations and out-licensing agreements. During 1989 to 2002, Mr. Coiante held management positions of increasing responsibilities at Ernst & Young LLP predominantly within the life science and pharmaceutical industries. He holds a Bachelor's degree in accounting from Villanova University and is a certified public accountant.

Agile Therapeutics, Inc. (NASDAQ: AGRX)

Income Statement

(In thousands, except per share data)

	2012 A	For the Quarter Ending Q1:13 A	Q2:13 A	Q3:13 A	Q4:13 A	2013 A	For the Quarter Ending Q1:14 A	Q2:14 E	Q3:14 E	Q4:14 E	2014 E	2015 E
Revenue:												
Twirla	-	-	-	-	-	-	-	-	-	-	-	-
Other Products	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	-	-	-	-	-	-	-	-	-	-	-	-
Cost of Product Sales	-	-	-	-	-	-	-	-	-	-	-	-
Gross Profit	-	-	-	-	-	-	-	-	-	-	-	-
Cost and Expenses:												
Research and Development	17,387	3,072	-	-	-	9,154	1,394	6,737	6,737	6,737	21,604	12,561
General and Administrative	5,930	1,156	-	-	-	3,574	1,053	1,280	1,280	1,280	4,893	6,458
Total Costs and Expenses	23,317	4,228	-	-	-	12,728	2,448	8,016	8,016	8,016	26,497	19,019
Operating Income (Loss)	(23,317)	(4,228)	-	-	-	(12,728)	(2,448)	(8,016)	(8,016)	(8,016)	(26,497)	(19,019)
Other Income (Expense):												
Interest Income	(114)	(377)	-	-	-	(1,511)	(378)	(304)	(255)	(225)	(1,162)	(630)
Change in Fair Value of Warrants	171	-	-	-	-	(81)	13	13	13	13	50	50
Other	-	-	-	-	-	-	-	-	-	-	-	-
Loss Before Income Taxes	(23,260)	(4,605)	-	-	-	(14,321)	(2,813)	(8,308)	(8,259)	(8,229)	(27,609)	(19,599)
Income Taxes	-	-	-	-	-	-	(3,652)	-	-	-	(3,652)	-
Net Income	$ (23,260)	$ (4,605)	$ -	$ -	$ -	$ (14,321)	$ 839	$ (8,308)	$ (8,259)	$ (8,229)	$ (23,956)	$ (19,599)
Basic Earnings Per Share	$ (0.59)	$ (0.11)	$ -	$ -	$ -	$ (1.59)	$ 0.09	$ (0.45)	$ (0.44)	$ (0.44)	$ (1.47)	$ (1.02)
Diluted Earnings Per Share	$ (0.59)	$ (0.11)	$ -	$ -	$ -	$ (1.59)	$ 0.09	$ (0.45)	$ (0.44)	$ (0.44)	$ (1.47)	$ (1.02)
Basic Shares Outstanding	39,518	42,181	1	1	1	8,992	9,029	18,592	18,742	18,892	16,314	19,267
Diluted Shares Outstanding	39,518	42,181	1	1	1	8,992	9,745	18,592	18,742	18,892	16,314	19,267
Effective Tax Rate	0.0%	0.0%	#DIV/0!	#DIV/0!	#DIV/0!	0.0%	129.8%	0.0%	0.0%	0.0%	13.2%	0.0%
EBITDA Calculation:												
Loss Before Income Taxes	$ (23,260)	$ (4,605)	$ -	$ -	$ -	$ (14,321)	$ (2,813)	$ (8,308)	$ (8,259)	$ (8,229)	$ (27,609)	$ (19,599)
Less: Interest Income	114	377	-	-	-	1,511	378	304	255	225	1,162	630
Plus: Depreciation	-	-	-	-	-	-	3	2	2	2	9	8
EBITDA	$ (23,146)	$ (4,228)	$ -	$ -	$ -	$ (12,809)	$ (2,432)	$ (8,001)	$ (8,002)	$ (8,002)	$ (26,437)	$ (18,961)
Margins:												
Gross	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M
Operating	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M
Net Income (Loss)	N/M	N/M	N/M	N/M	N/M	N/M	#DIV/0!	N/M	N/M	N/M	N/M	N/M
EBITDA	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M
Growth Rates:												
Total Revenue						N/M	N/M	N/M	N/M	N/M	N/M	N/M
Operating Income						N/M	N/M	N/M	N/M	N/M	N/M	N/M
Net Income (Loss)						N/M	N/M	N/M	N/M	N/M	N/M	N/M
Research and Development Expense						-47.3%	-54.6%	N/M	N/M	N/M	136.0%	-41.9%
Selling, General and Administrative Expense						-39.7%	-8.9%	N/M	N/M	N/M	36.9%	32.0%

Source - Company reports and Janney Montgomery Scott LLC estimates

IMPORTANT DISCLOSURES

Research Analyst Certification

I, Kimberly Lee, 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.

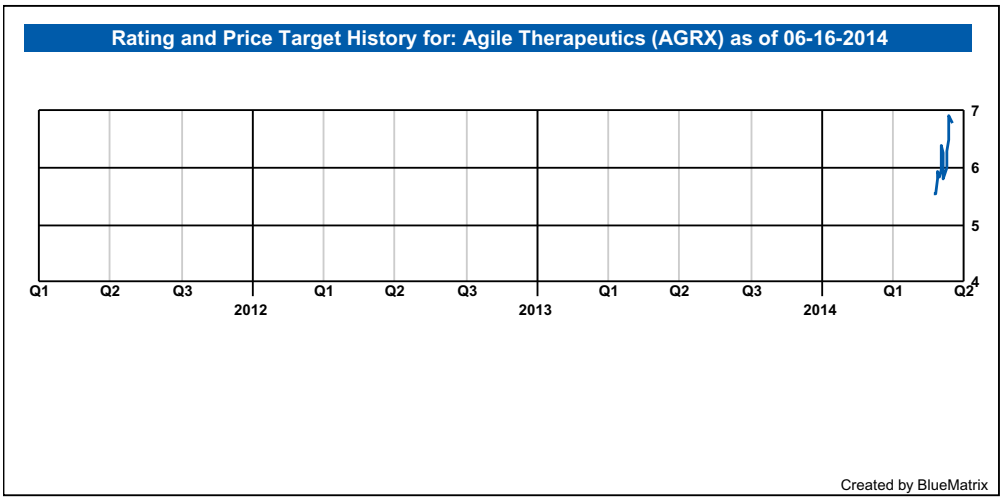
Definition of Ratings

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 3/31/14

			IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY [B]	218	51.12	44	20.18
NEUTRAL [N]	205	48.12	21	10.24
SELL [S]	3	0.70	0	0.00

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

Other Disclosures

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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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