William Blair

Agile Therapeutics, Inc.

Finding a Pearl in Twirla; Initiating Coverage With an Outperform Rating and $18 Price Target

June 17, 2014
Basic Report (14-080)

Stock Rating:	**Outperform**
Company Profile:	**Aggressive Growth**
Price Target:	$18.00
Symbol:	AGRX (NASDAQ)
Price:	$6.78 (52-Wk.: $5.05–$6.92)
Market Value (mil.):	$126
Fiscal Year End:	December

Estimates	**2013A**	**2014E**	**2015E**
EPS FY	NA	-$1.02	-$0.88
EBITDA (mil.)	-$12.7	-$25.3	-$19.0

Valuation			
P/E	NM	NM	NM

Trading Data	
Shares Outstanding (mil.)	20.2
Float (mil.)	5.95
Average Daily Volume	355,447

Financial Data	
Long-Term Debt/Total Capital	NA
Book Value Per Share	NM
Enterprise Value (mil.)	$81.4
EBITDA (mil.)	-$24.3
Enterprise Value/EBITDA	NA

Agile Therapeutics is a developer of women's health specialty products; its lead program, Twirla, is a contraceptive patch entering a Phase III study, which should report out in late 2015. The company is conducting the current Phase III study for Twirla following a negative FDA review of the initial new drug application (NDA) in 2013. We believe the first Phase III study for Twirla, while suggesting efficacy, had many flaws stemming from study design, enrollment, and conduct. However, we have confidence in the company's new clinical leadership and believe that this setback provided an entry point for investors in what we view as a relatively low-risk Phase III product.

New Twirla Phase III study should hold relatively low risk. While the prior Phase III program included an active control arm and over-enrolled, high-risk patient populations, we believe the second Phase III study holds a relatively low clinical risk, and Agile and the FDA have agreed that it will be the basis for the reply to the company's complete response letter. Specifically, the Phase III study will be an open-label, single-arm study, enrolling roughly 2,000 women, with the primary endpoint being the standard measure for pregnancy risk in contraception studies: the Pearl Index. We believe new management including new Chief Medical Officer Elizabeth Garner, M.D., who has prior FDA experience at Merck with Gardasil and an impressive women's health pedigree, should be able to run a trial focused on achieving an approvable Pearl score of less than 3.16 (or lower) through attention to trial conduct and enrollment.

Pending clinical success, the market for contraceptives remains attractive for new product formulations. We believe the success of Ortho Evra, which reached over $400 million in annualized sales within two years of launch, suggests healthy interest in an improved patch product such as Twirla. Ortho Evra sales still exceeded $150 million in 2013 despite risks surrounding the high dose of estrogen used in the product. We project peak-year sales for Twirla of $400 million following an approval in 2016. On a prescription basis we estimate only 5% penetration into the 88 million prescription market. Total contraception sales in 2013 approximated $5.6 billion.

Twirla the main value driver. While Agile is developing several additional products, we expect Twirla will be the main value driver for shares over the next 12-16 months. We derive a net present value (NPV) for the product with a $17.90 per share value, given what we view as reasonable peak product sales assumptions and a 75% risk adjustment for approval, which may be conservative given the known efficacy of the Twirla components. Risks for Agile include the clinical risk surrounding the ongoing Phase III Twirla study as well as reimbursement and manufacturing risks.

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

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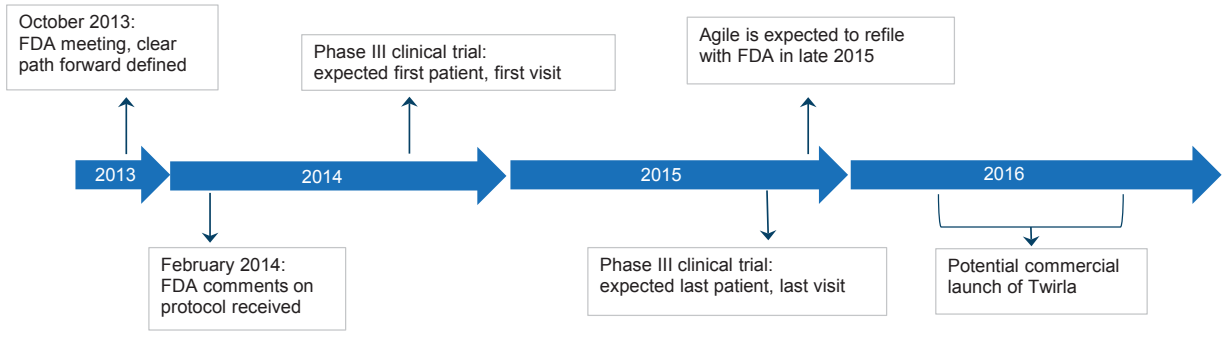
Investment Summary

Agile Therapeutics is a specialty pharmaceuticals company developing a product pipeline focused on women's health. The company's main pipeline therapy, Twirla, is a contraceptive patch that is in a pivotal Phase III study scheduled to report out by the end of 2015. Twirla will be the lowest-dose estrogen/progestin contraceptive patch in the market pending a successful development and launch in 2016. We believe the experience of contraceptive patch products to date, namely the success of Ortho Evra, suggests that a low-dose patch product free of the safety concerns surrounding Ortho Evra should bode well for the market acceptance of Twirla, pending an approval.

Twirla has previously been through a regulatory review by the FDA, and Agile received a complete response letter for the product in 2013. The product was not approved by the agency in the prior Phase III trial, despite the product showing improved contraception rates against the approved oral contraceptive product, Levlite. After it received the complete response letter, Agile management looked to bring in new clinical leadership. Dr. Elizabeth Garner joined the Agile team in January 2014, with past experience at Myriad Genetics, Abbott (now AbbVie), and Merck, where she was a key figure in the HPV vaccine development team. Shortly after Dr. Garner joined Agile, the company met with the FDA to determine the path forward for Twirla. The agency guided the company to launch another well-controlled, high-quality, single-arm, open-label study in approximately 2,000 women who will receive Twirla for up to one year—similar to the development pathways for most of the approved contraception products. Specifically, we believe the company will need to show a Pearl Index (the standardized measurement of combined hormonal contraceptives calculated as the number of contraceptive failures per 100 women divided by the years of exposure) of less than 3.19, which is the rate achieved by the Quartette product and the highest Pearl rate ever approved by the FDA for a contraceptive product. We anticipate that this study will read out in late 2015.

We assume an approval and launch of Twirla in third quarter 2016 following a successful Phase III study readout in the late 2015. Exhibit 1 includes the anticipated timelines for the development of Twirla.

Exhibit 1
Agile Therapeutics, Inc.
Timing of Events Related to Twirla Clinical Trial and Potential Launch



Sources: William Blair & Company, L.L.C. estimates and company reports

The company has several additional programs aside from Twirla in development, including an extended release product that is designed to extend the length of a woman's cycle. However, we believe the majority of the Street's focus will be on the development of Twirla over the next 12-16 months. We include the time and events calendar for Agile's disclosed development-stage pipeline in exhibit 2, on the following page.

Exhibit 2
Agile Therapeutics, Inc.
Timeline and Events

Date	Product	Event	Description/Comments
2014			
1H 2014	Twirla (AG-200)	Clinical	First patient, first visit for Phase III clinical trial
2015			
1H 2015	Twirla (AG-200)	Manufacturing	Validation of additional line (full commercial capacity)
2H 2015	Twirla (AG-200)	Clinical	Last patient, last visit for Phase III clinical trial
Late 2015	Twirla (AG-200)	Regulatory	NDA resubmission to FDA
2016			
3Q 2016	Twirla (AG-200)	Regulatory	NDA approval and potential launch

Sources: Company reports and William Blair & Company, L.L.C. estimates

Key Risks

An investment in Agile Therapeutics involves clinical, regulatory, and financial risks that are typical for development-stage biopharmaceutical companies. Moreover, the company may face manufacturing and competitive risks. We estimate that Agile will incur losses through 2017, given preparations for the Twirla Phase III trial and expenses needed to bring the product to market. In addition to the risks associated with Twirla clinical testing, development, and marketing, there are intellectual property risks to consider as well.

Agile previously failed to run a high-quality, well-controlled Phase III program, and the new Phase III trial conduct and analysis present a risk to the company's timeline and profitability. Previously, Agile conducted two Phase III clinical trials for Twirla and filed an NDA with the FDA in April 2012. The FDA issued a complete response letter in February 2013 and requested additional clinical data, quality control information, and manufacturing/control information. The company thoroughly analyzed the data from the failed program and determined several trial design flaws that likely contributed to a regulatory submission that was difficult to interpret. Some of the flaws that affected the trial include poor subject compliance, a concentration of unplanned pregnancies at a few study sites, and a disproportionately high number of subjects at higher risk of noncompliance and pregnancy. Regarding the unplanned pregnancies at a few study sites, 36% of pregnancies occurred in 4 of the 96 total locations. These locations enrolled 15% of the total patient population. Furthermore, 19% of pregnancies occurred at one site that enrolled 8% of the total trial population. The company met with the FDA in October 2013 to discuss a new Phase III clinical trial and received substantial written comments from the FDA in February 2014.

Regulatory and clinical risks, in line with other development-stage therapeutics companies. Twirla will still need to undergo another FDA review prior to launch and risks related to regulatory review exist, similar to other development-stage therapeutics companies. Delays and/or rejections of applications for approval could result in a significant risk to Agile. Regulatory delays can be attributed to requests for further data, interpretations of data and analyses, or insignificant or inconclusive results from the trial.

Financial risks—we do not estimate the company generating profit until 2017. Agile is a development-stage biopharmaceutical company with its main product, Twirla, in the Phase III clinical trial design process. The company's ability to generate revenue and reach profitability depends

on it completing the clinical trial for Twirla, obtaining the necessary regulatory approval, and successfully launching the commercial product. In addition, the company has roughly $15 million in outstanding debt from a loan and security agreement with Oxford Finance LLC.

Competitive risks—the contraceptive market has several competitive products (both branded and generics). Generic contraceptives have been gaining market share in recent years as several brand products have lost exclusivity. As of September 2013, 73% of prescription volume and 45% of sales of combined hormonal contraceptives were generics. While there have been many successful brand launches in this drug category, the large footprint of generics will likely decrease the pricing power of new brand therapies. Specific to patch products, Mylan, Inc. introduced a generic version of the Ortho Evra patch in April 2014; while we believe Twirla holds a superior product profile, the availability of a generic contraceptive patch may constrain the pricing power of Twirla.

Manufacturing risk—the company relies on third-party manufacturer for delivery platform. Agile Therapeutics uses another publicly traded company, Corium International (CORI), to manufacture the clinical supplies for Twirla and its other product candidates. Corium facilities will be subject to approval by the FDA after the submission of an NDA by Agile. This concentration within its supply chain represents a risk for Agile, but it also presents a hurdle for generics to enter the market. According to Corium's website, its manufacturing capabilities are FDA and DEA registered with the capacity to produce over 100 million patches annually.

Company Overview

Agile Therapeutics is a women's health specialty pharmaceutical company with a focus on developing prescription contraceptives. Its lead product candidate, Twirla (AG200-15), is a contraceptive patch that uses the company's proprietary Skinfusion technology, which provides advantages over currently available patches by optimizing patient comfort, adherence, and stability. Twirla is applied once weekly, which is intended to provide greater convenience and compliance over oral contraceptive pills that need to be taken once daily.

Twirla is a combined hormonal contraceptive (CHC) that contains the active ingredients ethinyl estradiol (a synthetic form of estrogen) and levonorgestrel (a synthetic steroid hormone)—both of which have well-defined safety/efficacy profiles and are the key components in several other low-dose CHCs. The current patch products in the contraceptive market deliver ethinyl estradiol at higher doses than those delivered with low-dose oral contraceptives, which leads to black-box warnings that describe the risks associated with exposure to higher doses of estrogen. We believe there is an unmet need for a low-dose patch product as an alternative to low-dose oral contraceptives.

The hormonal contraceptive market in the United States had roughly $5.6 billion of sales in 2013; more than half of this was generated by branded products, on about 27% prescription volume compared with generics. Twirla is designed to deliver both ethinyl estradiol and levonorgestrel in combination at levels similar to low-dose oral contraceptives. In addition to Twirla, the company has three other disclosed products in its pipeline: an extended cycle regimen of Twirla (AG200-ER), a 28-day regiment with shortened hormone-free intervals (AG200-SP), and a levonorgestrel-only patch (AG890). We include the company's current pipeline in exhibit 3, on the following page.

Exhibit 3
Agile Therapeutics, Inc.
Product Pipeline

Product	Develop-ment	Phase I	Phase II	Phase III/ Pivotal	Comments/Timing
Twirla (AG200-15)					Weekly contraceptive patch containing levonorgestrel and ethinyl estradiol.
AG200-ER					Extended cycle regimen
AG200-SP					28-day regiment with shortened hormone-free interval
AG890					Levonorgestrel-only contraceptive patch

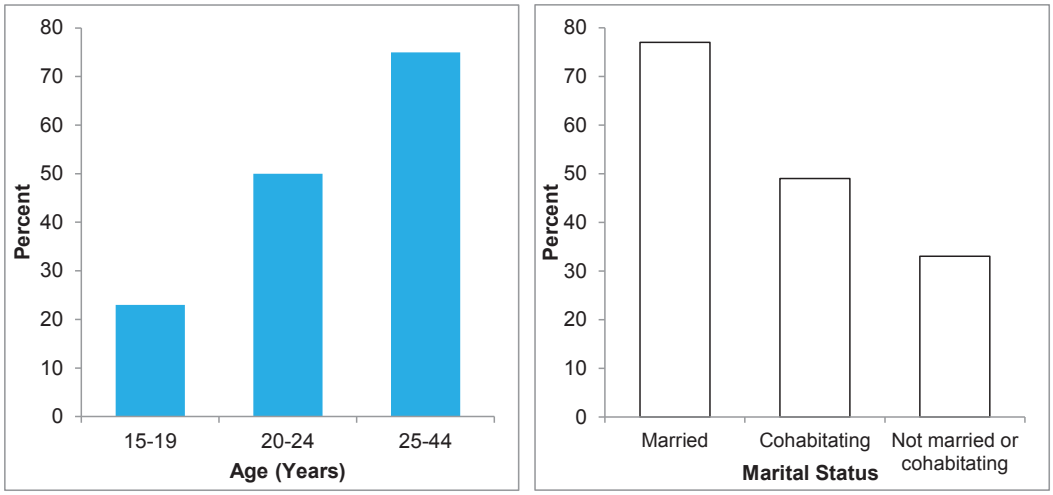
Sources: Company reports and William Blair & Company, L.L.C.

Contraception Market Overview

Women are biologically capable of pregnancy from their first menstrual cycle at an average age of 13 years to natural menopause at an average age of 51 years. According to studies published in 2011 and 2014, 51% of pregnancies in the United States were unintended in 2010, up from 49% in 2006, and 48% in 2001 (Finer and Zolna *Contraception* 2011; Finer and Zolna *Am J Public Health* 2014). As shown in exhibit 4, the National Survey of Family Growth (NSFG) conducted by the Centers for Disease Control and Prevention (CDC) estimates that the intended pregnancy rate for women is roughly 49% of intended pregnancies (51% unintended), with 33% of intended pregnancies in either not-married or not-cohabitating women (66% unintended). The lowest percentage of intended births is for women under the age of 19 (23%). In older age groups, the percentage of intended births increases to 50% in 20- to 24-year-old demographic, with that number increasing to 75% in 25 to 44 year olds. The high percentages of unintended birth rates in several age demographics create a significant need for contraceptive methods.

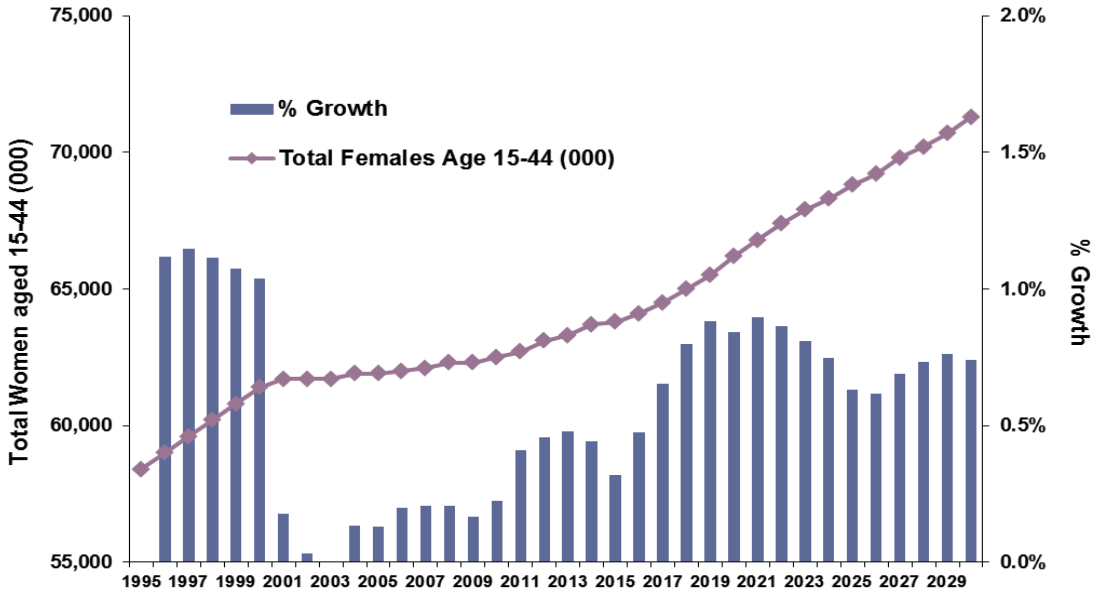
In addition to age, a large percentage of the unintended pregnancy rate was shown to be associated with women from lower-education and lower-income demographics. For example, women with incomes below 150% of the poverty level had 56% of all unintended births. In exhibit 5, according to the U.S. Census Bureau, the population of women aged 15 to 44 and eligible for contraception is about 70 million and has been growing at a rate of roughly 0.4%-0.5%. This is due to an increase in the general population, combined with an increase in women eligible for contraceptives, creating a large market.

Exhibit 4
Agile Therapeutics, Inc.
Percentage of Births Intended at Conception by Mother's Age and Marital Status at Birth



Sources: CDC—National Survey of Family Growth and William Blair & Company, L.L.C.

Exhibit 5
Agile Therapeutics, Inc.
Total Potential Contraceptive Population (Women Ages 15-44 years)

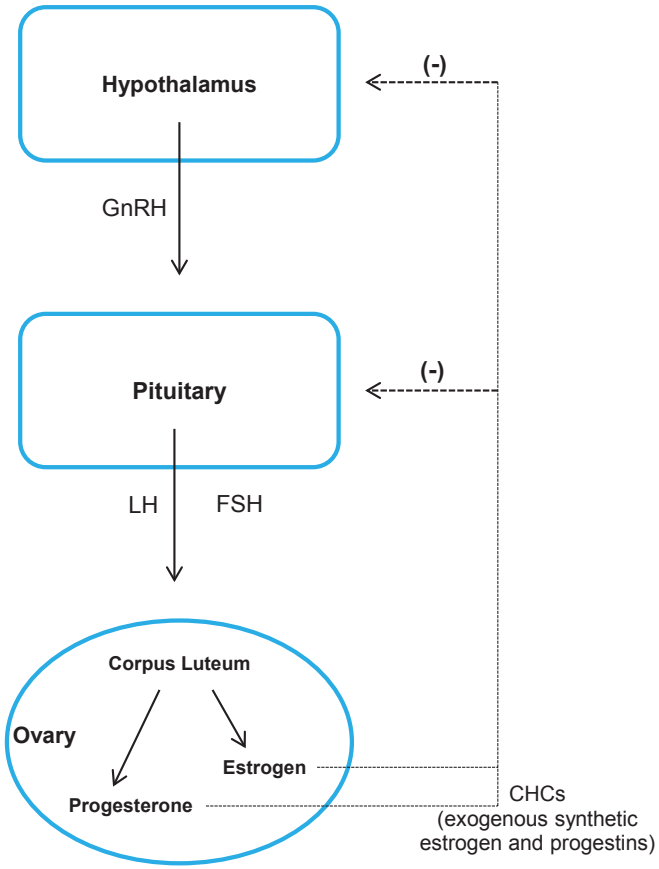


Sources: U.S. Census Bureau and company reports

The efficacy of birth control methods is identified by the CDC as critically important for reducing the risk of unintended pregnancies. The hormones estrogen and progesterone have significant roles in the menstrual cycle. Estrogen builds up the endometrium of the uterus and progesterone increases after an ovary releases an egg (ovulation) at the middle of the cycle. A drop in progesterone and estrogen correspond with the menstrual bleeding. In 1961, the FDA approved a hormonal combination

drug for use in contraception with Enovid 10 mg a combination of 9.85 mg of norethynodrel and 150 mcg of mestranol (Bahamondes and Bahamondes *Int J Women's Health* 2014). As shown in exhibit 6, the mechanism of action of CHC involves the delivery of synthetic estrogen and progestins. CHCs are able to suppress the secretion of the hormones from the pituitary follicle stimulating hormone (FSH) and luteinizing hormone (LH). This occurs through a negative feedback loop that prevents the rise in FSH for the initiation of follicle development, due to increased levels of estrogen, and the rise in LH for ovulation, due to increased levels of progesterone provided by CHCs.

Exhibit 6
Agile Therapeutics, Inc.
Mechanism of Action of Combined Hormonal Contraceptives



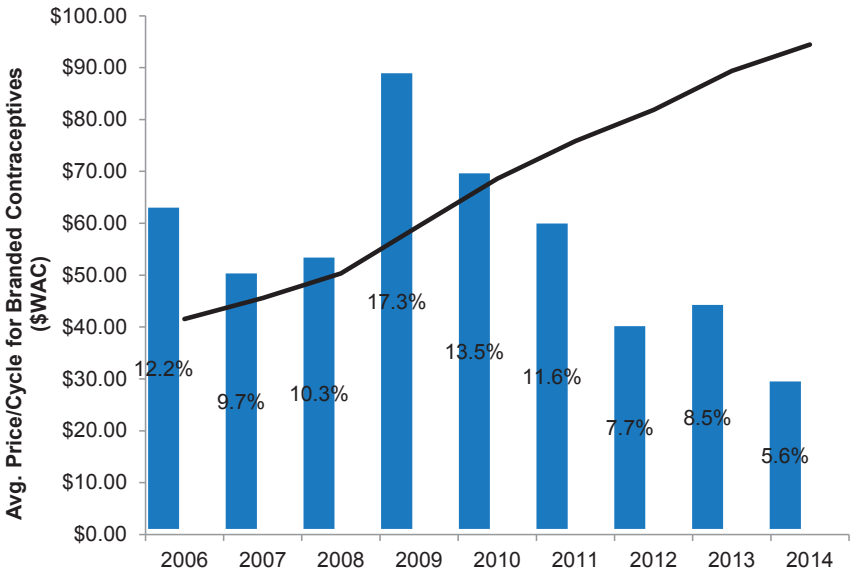
Sources: William Blair & Company. L.L.C.

Combined Hormonal Contraceptive Industry Is a $5.6 Billion Market With Increasing Growth Potential

According to a study published in the *BMJ*, an average of 75.8% of U.S. women ages 25-74 were sexually active during the past six months of the study time frame (Lindau and Gavrilova *BMJ* 2010). According to IMS Health, the U.S. hormonal contraceptive market recorded annual sales of $5.6 billion in 2013. The CHC portion of the market includes pills, two transdermal patches (available as a brand and generic), and one vaginal ring. The progestin-only portion of the market consists of intrauterine contraceptive devices (IUDs), injectables, implants, and progestin-only pills. According to 2013 IMS Health data, CHCs claimed roughly 75% of the total market and progestin-only contraceptives comprised 25% of the total market. In addition, branded products have maintained a significant share of the CHC market, with 55% of retail sales and 27% of prescriptions for the 12 months ended September 2013. As detailed in exhibit

7, the average annual price increase from 2006 thru 2013 was about 11.4% with the average price per cycle for branded contraceptives at wholesale acquisition cost (WAC) at $41.53 in 2006 to $94.44 as of February 2014. According to Agile's S-1, the branded and generic forms of the CHC patch are $110.22 and $95.12 per cycle, respectively, with the vaginal ring priced at $91.69 per cycle.

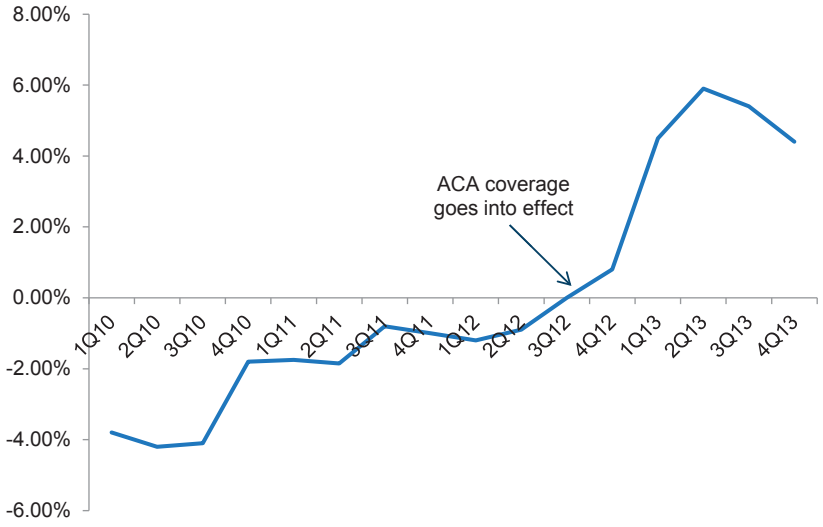
Exhibit 7
Agile Therapeutics, Inc.
Average Price/Cycle and Price Increases of Branded Contraceptives



Percentages refer to average annual price increase, 2014 only includes price increases thru February
Sources: Company reports and William Blair & Company, L.L.C.

Currently, the majority of women who use contraceptives primarily choose the pill form because of familiarity, promotion, noninvasive nature of the products, and ease of reimbursement with public and private healthcare plans. The 2010 Patient Protection and Affordable Care Act (ACA) now requires all health plans (with exceptions) to cover certain preventive services for women with no cost sharing, deductible, co-insurance, or co-payments by the patient as of August 2012. As a result, the prescription for CHCs has grown roughly 4.0% to 5.0% in the six quarters following the healthcare law's implementation, as shown in exhibit 8, on the following page. The growth in the female 15- to 44-year-old demographic, CHC wholesale acquisition cost increases year-over-year, and the ACA's female preventive service reimbursement all contribute to an expanding market.

Exhibit 8
Agile Therapeutics, Inc.
CHC Prescription Growth Before and After ACA Implementation



Sources: Company reports and IMS Health

Contraceptive Efficacy Is Most Commonly Measured by Pearl Index

The efficacy of a contraceptive is assessed by the rate of unplanned pregnancies during the time of exposure. Two methods are currently used to measure efficacy, the Pearl Index and life table analysis. The Pearl Index, originally introduced by Raymond Pearl in 1933, is defined as the number of contraceptive failures per 100 women divided by the years of exposure. The numerator in the index is the number of pregnancies, and the denominator is the cumulative number of months or cycles of exposure from the start of the method until the completion of the study, discontinuation of the method, or pregnancy. The quotient is multiplied by 1,200 if the denominator is reported in months or by 1,300 if the denominator is reported in cycles (Trussell *Stat Med* 1991). Life table analysis provides the contraceptive failure rate for each month of use and can provide a cumulative failure rate for any specific length of exposure (U.S. FDA Advisory Committee for Reproductive Health Drugs Meeting).

The pregnancy rates in clinical trials appear to have increased through the years, particularly in the past decade and have been attributed to several factors. Increased method failures could be caused by effective lower doses of estrogen and progestins being delivered because of heavier test subjects, due to general obesity trends. Another potential cause for increased pregnancy rates could be higher user compliance failure and improved pregnancy detection. The primary clinical trials used to support approval of all oral contraceptives from 1960 to 1970 had failure rates of less than 1.0 (overall Pearl Index). As shown in exhibit 9, in the past decade, some oral contraceptive products have been approved with overall Pearl rates of about 2.0. The Pearl Index for the Twirla patch was 5.76 pooling both Phase III trials; however, the combined oral contraceptive control Pearl Index score was 6.72. The potential causes for these numbers are discussed later in this report. The highest approved upper bound of the 95% confidence interval was 5.03 for Seasonale in 2003. The most-recent approval of a contraceptive was Quartette, which had a Pearl rate of 3.19.

Exhibit 9
Agile Therapeutics, Inc.
FDA-Approved Combined Hormonal Oral Contraceptives,
Clinical Trial Length, Pearl Index Score

Year Approved	Product Name	Study Length	Pearl Index
2013	Quartette	1 year	3.19
2010	Natazia	Up to 2.2 years	1.64 (US), 1.04 (EU)
2008	LoSeasonique	1 year	2.74
2007	Lybrel	Up to 1 year	2.38
2007	Yaz	1 year	1.41
2006	Seasonique	1 year	1.34
2006	Loestrin 24 Fe	6 cycles	1.82
2003	Seasonale	1 year	1.98
2001	Yasmin	2 years	<1.00
1998	Levlite	6 cycles	0.29
1997	Alesse	13 cycles	0.84

Sources: Company reports and William Blair & Company, L.L.C.

There is a continuing debate over whether or not efficacy in the clinical trial should be defined by a set limit on the overall Pearl Index. Limitations include the fact that the Pearl Index generally decreases with the duration of the clinical trial because the likelihood of pregnancy decreases over time, therefore Pearl rates of different time lengths cannot be meaningfully compared. In addition, individual women become more proficient with the use of contraceptives with increased experience; therefore, longer studies will have lower Pearl rates.

Because of the limitations in the Pearl rate listed above, life table analysis has been suggested as an appropriate alternative, due to the ability to measure early contraceptive failure and efficacy over time. According to the European Medicines Agency (EMA) and Committee for Medicinal Products for Human Use's guideline on the clinical investigation of steroid contraceptives in women, regulatory agencies now require both analyses in drug development studies. For Pearl Index calculations, 13 total 28-day cycles constitute one woman year. With non-cycle methods, one woman year equals one calendar year. While life table analysis may lead to more comparable scores, we believe the Pearl Index remains the primary tool used by the FDA in its analysis of contraceptive products, and reducing this score will be the key to Twirla's potential approval.

CHCs With 30-35 mcg of Estrogen Still Account for the Majority of Total Prescriptions
As stated earlier, the branded CHC market has withstood the introduction of generics, with oral contraceptives continuing to be the most-popular product form. Exhibit 10, on the following page, shows the individual product revenue of select contraceptive brands along with their revenue over the last two years. NuvaRing has continued to be the market leader with roughly $515 million in 2012 sales and $569 million in 2013 sales, followed by Lo Loestrin 24 and Ortho Tri-Cyclen Lo. However, in October 2013, a generic of Lo Loestrin 24 was released, which decreased brand prescriptions.

Exhibit 10
Agile Therapeutics, Inc.
CHC Product Retail Sales and Percent Market Share of CHCs in Last 12 Months

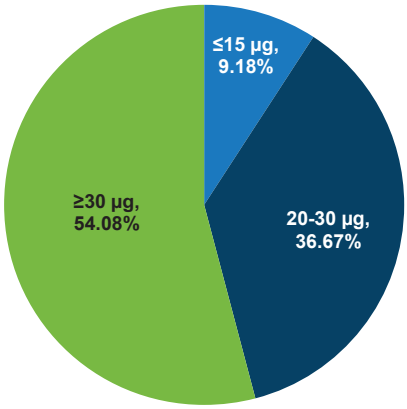
Leading Brands	2012 Sales ($MM)	2013 Sales ($MM)
NuvaRing (Merck)	515	569
Loestrin 24 (Actavis/Warner Chilcott)	540	300
Tri-Cyclen-Lo (Ortho)	433	454
LoLoestrin (Actavis/Warner Chilcott)	163	272
Evra (Ortho)	139	152
Beyaz (Bayer)	129	111
Yaz (Bayer)	76	53
Generess (Actavis)	41	82

Sources: IMS sales retail + nonretail, company reports, and William Blair & Company, L.L.C. estimates

The market for CHCs can be stratified by estrogen dose because of the risk of cardiovascular adverse events associated with high-estrogen doses that has been highly debated. These risks include venous thromboembolism (VTE), deep vein thrombosis, and pulmonary embolism. Several controlled case studies showed that oral contraceptive use with high-estrogen doses (50-150 mcg) was associated with an increased risk of VTE (Drill *JAMA* 1972). As a result of these studies, the estrogen doses in CHC were reduced to 35 mcg and below. According to our analysis in exhibit 11, the majority of total CHC prescriptions were for products with 30-35 mcg of ethinyl estradiol. Agile's main product, Twirla, contains an average of 30 mcg of estrogen delivered per day, which puts it in the low-dose range of the products which account for 54.08% of CHC market share.

With approximately 54% of all 88 million total prescriptions (TRx) written for CHCs with estrogen concentrations between 30-35 mcg within the last 12 months, the estimated 2014 WAC of $94.44 per cycle, and 1.4 cycles/TRx, only 1% of TRx share in the 30-35 mcg ethinyl estradiol CHC market yields approximately $63 million, a significant value for such small market share.

Exhibit 11
Agile Therapeutics, Inc.
Percentage of CHC Prescriptions by Dose of Estrogen

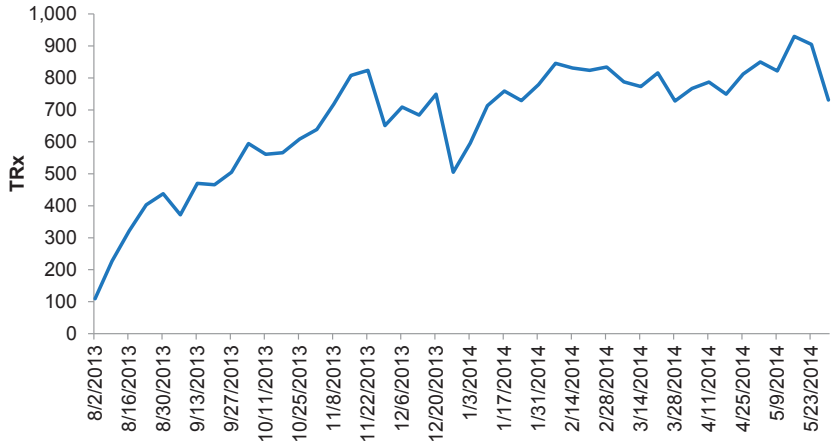


Sources: IMS Health and William Blair & Company, L.L.C.

The most recently approved branded CHC was Quartette by Teva Pharmaceuticals, which launched in August 2013 with a Pearl Index score of 3.19—the highest mean Pearl Index for an approved contraceptive. Exhibit 12 shows the weekly prescriptions since the launch of Quartette into the well-defined

market. Within the last 12 months, Quartette had roughly 25,599 prescriptions and about $7.5 million in sales, with a sequential growth rate of 13% from fourth quarter 2013 to first quarter 2014. Quartette's dosing regimen is a one pill per day, 91-day cycle involving 42 doses of 0.15 mg levonorgestrel and 20 mcg of ethinyl estradiol, followed by 21 doses of 0.15 mg levonorgestrel and 25 mcg of ethinyl estradiol, followed by 21 doses of 0.15 mg levonorgestrel and 30 mcg of ethinyl estradiol, and completed by 7 doses of 10 mcg ethinyl estradiol alone. The launch and continued growth of Quartette will be monitored to forecast the potential penetration of newer branded contraceptives into the market.

Exhibit 12
Agile Therapeutics, Inc.
Quartette Weekly Prescriptions Since Launch



Sources: IMS Health and William Blair & Company, L.L.C.

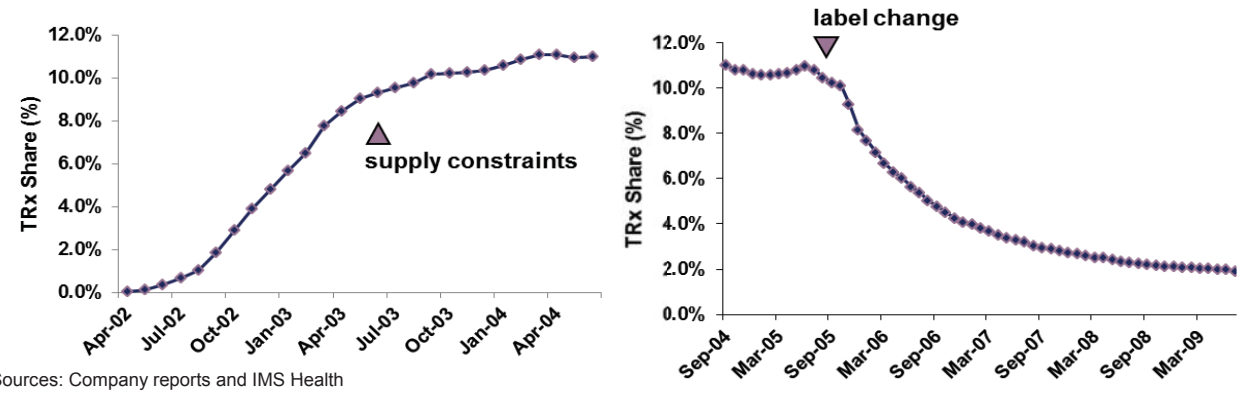
Strong Ortho Evra Launch Suggests Interest in Contraception Patches, Until Safety Concerns Dampened Product

The advantages of the patch form of CHCs are the reduction in plasma hormone level fluctuation as well as the reduced risk of noncompliance, since the patch needs to be changed only once per week instead of taken daily as with the pill. In addition to Twirla from Agile, there is another patch under investigation being produced by Bayer called FC-Patch Low, which is a combination of ethinyl estradiol and gestodene. According to a published clinical trial, the patch containing 0.9 ethinyl estradiol and 1.9 mg gestodene was tested in 199 volunteers throughout two menstrual cycles and showed ovulation inhibition in all subjects. Further, no alterations were observed in prothrombin fragments 1 + 2 or D-dimer when compared with a combined oral contraceptive containing 0.03 mg ethinyl estradiol and 0.15 levonorgestrel (Junge et al. *Drugs R D* 2013). As gestodene has not yet been approved in the United States, we would not expect the FC-Patch Low to be a significant competitor to Twirla, given the likely regulatory barriers to approval and—if approved—unfamiliarity with the product's components by physicians.

The most well-known contraceptive patch in the market is Ortho Evra, which was the first patch approved by the FDA in 2002. By September 2003, Ortho Evra had 10% of CHC market share; however, users reported cardiovascular adverse events despite a label of ethinyl estradiol daily dose of 20 mcg. The manufacturer, Johnson & Johnson, revised the label in 2005 to include information that ethinyl estradiol exposure is 60% higher than oral contraceptives with 35 mcg of ethinyl estradiol on the label in a specific black-box warning. The adverse events and labeling deteriorated the Ortho Evra market share from a peak of 11% in 2005 to roughly 1.4% in 2013, as shown in exhibit 13, on the following page. An advisory committee for the FDA stated that the benefits of Ortho Evra outweigh

the risks and declined a citizen petition calling for withdrawal of Ortho Evra. Despite these labeling issues and the cessation of promotion by Johnson & Johnson, Ortho Evra's retail sales within the last 12 months were roughly $160 million and 2013 U.S. sales were about $152.9 million.

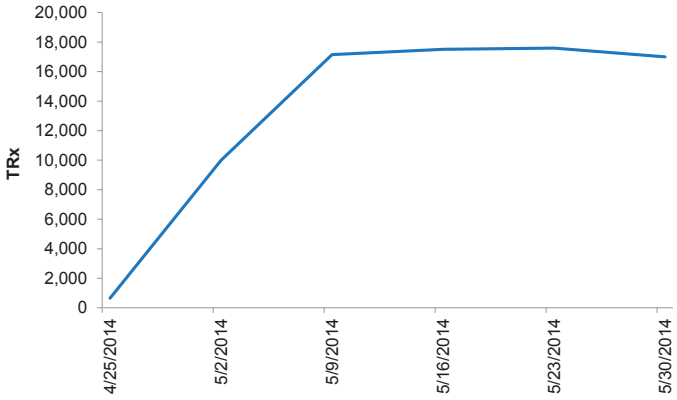
Exhibit 13
Agile Therapeutics, Inc.
Ortho Evra Launch, Adverse Event Reporting, and Subsequent Decline



Sources: Company reports and IMS Health

Recently, Mylan launched a generic version of Ortho Evra called Xulane. Exhibit 14 shows the weekly prescriptions of Xulane after launch in April 2014, which sum to 45,301 after the first four weeks. Under state-governed pharmacy dispensing rules, a pharmacist may dispense either the prescribed product or have the option of replacing it with a generic or another brand without being required to inform the patient or healthcare professional. Xulane contains 150 mcg norelgestromin and 35 mcg of ethinyl estradiol in a transdermal patch, so we expect a similar bioavailability of ethinyl estradiol to Ortho Evra. As Xulane carries the same label and warnings as Ortho Evra, we expect the product to carry the same negative stigma as the original product and while the launch of Xulane was impressive, prescription trends have flattened. And given the higher bioavailable doses of ethinyl estradiol in Xulane and Ortho Evra, we expect Twirla to compete well against the product.

Exhibit 14
Agile Therapeutics, Inc.
Xulane (Mylan's Ortho Evra Generic) Launch—Weekly Prescriptions



Sources: IMS Health and William Blair & Company, L.L.C.

Exhibit 15 notes the differences in characteristics between Twirla and Ortho Evra. Twirla provides a lower average dose of ethinyl estradiol per day in a soft, stretch fabric patch compared with Ortho Evra's dose and plastic feel for the user. Further, adverse events in clinical trials are lower with Twirla compared with Ortho Evra.

Exhibit 15
Agile Therapeutics, Inc.
Comparison of Twirla and Ortho Evra

Characteristic	Twirla	Ortho Evra
Product Form	Transdermal Patch, Round ~ 28 square centimeters, soft, stretchy fabric	Transdermal Patch, Square ~ 20 square centimeters, smooth, plastic film
Active Ingredients	Ethinyl Estradiol/Levonorgestrel	Ethinyl Estradiol, Norelgestromin
Pharmacokinetic profile (Average ethinyl estradiol dose/day)	~30 mcg	~56 mcg compared to oral contraceptive containing 35 mcg (Ortho Evra package label indicates 35 mcg/day)
Regimen	One patch weekly, 21 days active, 7 days patch-free	One patch weekly, 21 days active, 7 days patch-free
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
Top Four Adverse Events/Reactions in Clinical Trials to Date	Nausea = 3.0%, Application site irritation = 2.4%, Breast tenderness = 2.1%, Headache = 2.0%	Breast symptoms = 22.4%, Headache = 21.0%, Application site disorders = 17.1%, Nausea = 16.6%

Sources: Company reports and William Blair & Company, L.L.C.

Pipeline Overview

Twirla is the main product in Agile Therapeutics' pipeline; however, it is not the only product. The company is also developing three other CHC products, possibly moving into a Phase III trial following Twirla.

Twirla (AG200-15)

Agile's proprietary Skinfusion technology produces a best-in-class transdermal contraceptive patch. The Twirla patch is a CHC containing both ethinyl estradiol and levonorgestrel. A single patch delivers both active ingredients over a seven-day dosing interval, which presents a potential benefit compared with oral contraceptives with one-pill-per-day dosing intervals. Similar to other patch contraceptives, Twirla's 28-day regimen consists of one patch applied weekly for three consecutive weeks and the fourth week patch-free. In previous studies, Twirla's application was primarily on the buttock, abdomen, or upper torso.

Exhibit 16
Agile Therapeutics, Inc.
Twirla Application Regimen

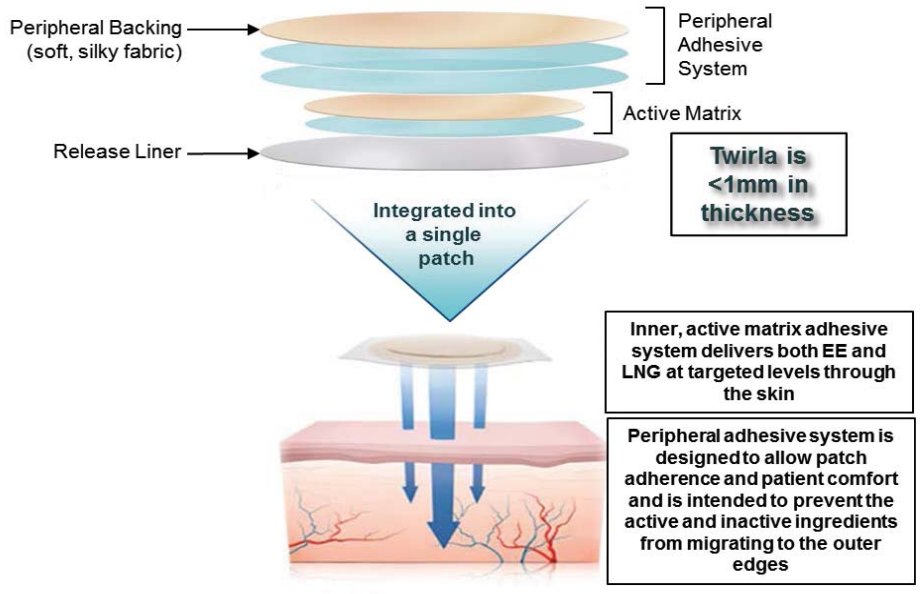
Twirla Anatomical Placement in Previous Studies

Buttock	Abdomen	Upper Torso
48%	40%	12%

Sources: Company reports

The Skinfusion technology provides hormone delivery using an inner active matrix adhesive system. The patch is a round, soft, flexible fabric that is designed to flex with body movement (exhibit 17). The matrix patch consists of the two active ingredients as well as inactive ingredients of dimethylsulfoxide, ethyl lactate, capric acid, lauryl lactate, and adhesives. The matrix patch sits inside of an outer portion that contains only adhesives and provides a physical barrier to prevent migration. In total, there are six layers of the patch, which integrates safety of hormonal delivery over the course of seven days with flexibility and a focus on patient comfort. Agile has tested the active ingredient delivery in various conditions, including heat, humidity, exercise, and exposure to water, as well as in obese versus non-obese women, and results have shown that the patch was safe and well tolerated under all conditions, and it achieved efficacy of active ingredient delivery in all groups (Archer et al. *Contraception* 2013, Foegh et al. *Contraception* 2013).

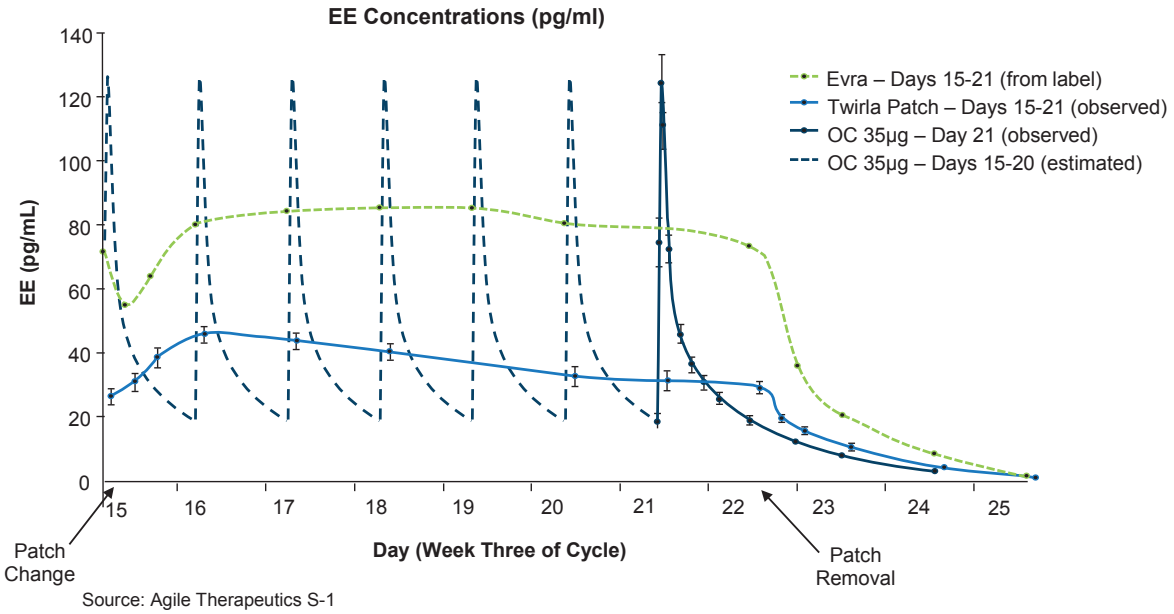
Exhibit 17
Agile Therapeutics, Inc.
Twirla Design and Adhesion



Source: Agile Therapeutics S-1

Aside from the once-per-week application, another perceived benefit of using transdermal contraceptive patches over oral contraceptives is the dosage of active ingredients. Exhibit 18 shows the differences in the pharmacokinetic profile between Twirla, Ortho Evra, and a 35 mcg oral contraceptive with respect to ethinyl estradiol concentration during week three of the respective regimen. The use of oral contraceptives results in an initial peak during absorption followed by a sharp decrease until the next dose is taken. Ortho Evra, as estimated by the label, maintains a very high level of ethinyl estradiol after patch change in comparison to the lower level seen with Twirla. It should be noted that these values were not compared head-to-head. Adverse events related to the use of contraceptives have been thought to be due to the troughs in estrogen levels. The reduced ethinyl estradiol dosage measured after Twirla administration may assuage some of the prior concerns with Ortho Evra, which led to the black-box labeling regarding the increased bioavailability of synthetic estrogen.

Exhibit 18
Agile Therapeutics, Inc.
Ethinyl Estradiol Concentrations with Twirla, Evra, and 35 mcg Oral Contraceptive



Source: Agile Therapeutics S-1

Twirla's clinical trial program: substantial experience, previous setbacks, and a pathway for potential FDA approval. Twirla's clinical trial program includes three Phase I studies, one Phase II study, and two previous Phase III studies in addition to a supporting study. Agile is planning a third Phase III study in reply to its complete response letter and guidance from the FDA; the study is expected to begin in third quarter 2014. The company's two prior Phase III trials enrolled more than 1,900 women combined to evaluate the safety and efficacy of Twirla. As mentioned, the adverse event profile of the subjects in the Phase III clinical studies with Twirla was substantially below those reported for Ortho Evra. In addition, the Pearl rate of Twirla in the pooled Phase III studies was 5.76, with the combined oral contraceptive control arm Pearl Index at 6.72. In exhibit 19, potential causes for the high Pearl rate are identified, including subjects of certain demographics and subjects without familiarity with contraceptive use contributing to abnormally high scores. In addition to demographics, of the 96 sites enrolling patients in the previous Phase III study, 4 accounted for 36% of pregnancies with 15% of the population, and 1 site accounted for 19% of the pregnancies with 8% of the population.

Exhibit 19
Agile Therapeutics, Inc.
Flaws From Previous Phase III Trial

Parameter	Demographic/Trial Arm	Pearl Index
Race/Ethnicity	White (not Hispanic)	3.6
	Hispanic	5.0
	Black	15.1
Previous Contraceptive Use Status	New users - never used or not within six months of enrollment	8.7
	Experienced users - recent (within six months of enrollment) + current users	3.0
	Current users - used within seven days of enrollment	0.0
Race/Ethnicity + Previous Contraceptive Use Status	Hispanic subjects who were new users	7.5
	Black subjects who were new users	16.0
Pearl Index Score	Twirla	5.76
	Combined oral contraceptive	6.7

Sources: Company reports and William Blair & Company, L.L.C.

Based on the guidance received from the FDA, Agile has put together a comprehensive new Phase III clinical trial plan, as detailed in exhibit 20. Furthermore, we believe the addition of Dr. Garner as chief medical officer is a positive for the company as it commences with patient enrollment, data collection, and analysis. In addition to the focus on clinical trial design, patient enrollment, and compliance, Agile has also retained a quality contract research organization in Parexel to assist in the completion and analysis of the study. By not having a comparator with a single-arm design, the company expects the number of cycles collected for primary efficacy analysis to increase and reduce the complexity of statistical analysis. In addition, the simplified trial design will allow for easier implementation from the 50 to 70 trial sites. We believe these changes should allow the company to achieve a lower Pearl rate in this Phase III trial versus the previous one, and we expect the trial to commence by the end of 2015, with a revised NDA submission in the first half of 2016.

Exhibit 20
Agile Therapeutics, Inc.
Twirla New Phase III Trial Design

Summary of Trial Design
Single-arm trial
2,000 female patients receiving Twirla for up to one year
50-70 sites located in U.S. with experience conducting contraceptive studies
Enroll significant population of subjects experienced in contraceptive trials
Electronic diary for subjects to record data critical for Pearl Index calculation
Subject teaching plan with videos, brochures, and one-on-one training
Ongoing trial monitoring with frequent communication
Potential to discontinue noncompliant subjects from trial

Source: Agile Therapeutics S-1

Agile's other pipeline candidates will provide alternative timing and hormonal contraception methods, further capitalizing on Skinfusion technology. The company's other pipeline candidates (shown in exhibit 3, on page 6) include Twirla line extensions and other transdermal candidates.

AG200-ER
This is an extended cycle regimen using the current patch product to extend the time between episodes of withdrawal bleeding, the bleeding experienced during the week the patch is left off. The company is evaluating optimal cycle length to use in clinical development.

AG200-SP
This pipeline candidate has a 28-day cycle as well, but it uses a shortened hormone-free interval. This may provide benefits to patients with sensitivity to shifts in hormone levels. Currently, the only approved products with the shortened interval are oral contraceptives, and they compose 44% of U.S. prescription volume.

AG890
This candidate is a levonorgestrel-only contraceptive patch for women who are unable to take estrogen due to adverse events, risk profiles, and other complications. This fills an unmet need for a nondaily, reversible form of contraception for non-estrogen users. The NIH has conducted a Phase I/II trial with AG890 to evaluate the pharmacokinetics, safety, and mechanisms of efficacy with data being compiled.

505(b)(2) Approval Pathway

Agile filed a section 505(b)(2) NDA for the approval of Twirla by the FDA. As shown in exhibit 21, the clinical development time frame of 505(b)(2) products is shorter, and in general the total cost of development is much less than what is required for the development of new molecular entities by traditional pharmaceutical or biotechnology companies. The clinical risk is also normally reduced because of the well-characterized nature of the base compound, which by definition of qualifying for a 505(b)(2) filing must have already been approved, suggesting a prior positive review for safety and efficacy in at least one indication. In Agile's case, it has relied on previous data on the safety and efficacy for approved products containing ethinyl estradiol and levonorgestrel.

While the clinical risk is normally less than that of new chemical entities, commercial risk is often more in question. In general, peak-year sales of such products are less than the original brand products; however, there are examples of blockbuster or near-blockbuster 505(b)(2) products. The most-common disease areas for which 505(b)(2) products are developed include pain, ADHD, and gastroenterology. Within these areas, the peak-year sales of many 505(b)(2) products have exceeded $500 million, and some have surpassed $1 billion.

The life cycle of a 505(b)(2) product will vary, depending on the IP surrounding the technology or formulation. Agile's main product Twirla is covered by five issued patents that the company intends to list in the Orange Book, the last of which expire in 2028. The intellectual property behind its Skinfusion technology and other pipeline candidates is wholly owned. Development of therapies using the 505(b)(2) pathway has accelerated over the past several years, with 2005 marking the last year that more traditional NDAs were approved than 505(b)(2) applications. During 2013, 38 therapies were approved in the United States using 505(b)(2) filings, compared with the 27 new molecular entities that were approved.

Exhibit 21
Agile Therapeutics, Inc.
Regulatory Pathway Overview

	505(b)(1)	505(b)(2)	505(j)
Description	Full-blown NDA with extensive preclinical and clinical package	NDA normally includes less clinical work than full NDA; Pharmakokinetic, safety, or potentially efficacy data may be required	Abbreviated NDA (ANDA) including only small PK study
Development Time Frame	5-10 years (or more)	3-6 years	1-3 years
Exclusivity	Depending on IP, normally 10-plus years; 30-month stay for generic litigation with 180-day exclusivity	3 years Hatch-Waxman, potential extension through IP, 30-month stay for generics but no 180-day exclusivity	None
Market Potential	May be first to market or need to compete within class or other classes	Competition from both brands and generics depending on timing	Heavy competition from other generics
International	Global opportunity	Normally difficult to receive pricing outside U.S.	Global opportunity

Source: William Blair & Company, L.L.C.

Key Management

Agile Therapeutics' management team brings many years of experience in the contraceptive space. The company is led by Alfred (Al) Altomari, who serves as the president and chief executive officer. Mr. Altomari has more than 20 years of experience on the development and marketing of commercialized products as well as product launches, in particular with Johnson & Johnson and its Ortho Evra product. Key personnel have joined the company from companies such as Warner Chilcott (a company with a focus in women's health), Myriad Genetics, and Medarex. The joint expertise of management in the contraceptive/specialty pharmaceutical field as well as the recent appointment of Dr. Elizabeth Garner in January 2014 positions the company well as it works to test its lead product, Twirla, in Phase III clinical trials and potentially bring it to market. We include further information of key personnel in the profiles below.

Al Altomari, president and chief executive officer. Mr. Altomari has been involved with Agile Therapeutics since 2008. From 2008 to 2010 he served as a consultant and then transitioned to executive chairman in 2010. He has served as president, CEO, and as a member of the board of directors since 2010. Before his work at Agile, Mr. Altomari held several management positions at Barrier Therapeutics, Inc., including chief executive officer. In 2008, as CEO of Barrier and a member of its board of directors, he orchestrated the successful sale of Barrier Therapeutics to Stiefel Laboratories, which was subsequently acquired by GlaxoSmithKline. Mr. Altomari holds an M.B.A. from Rider University and a B.S. from Drexel University. He also serves on the board of directors of Insmed, Inc. and Recro Pharma, Inc.

Elizabeth Garner, M.D., M.P.H., chief medical officer. Dr. Garner recently joined Agile Therapeutics in January 2014. Most recently, she served as the vice president or women's health and preventative care at Myriad Genetics Laboratories and managed the women's health clinical research, publication, and Key Opinion Leader (KOL) development program; provided medical and scientific input for the company's marketing and new product strategies; and served as media spokesperson from 2012 to 2014. Before Myriad, she was the senior medical director of women's health at Abbott Laboratories. She also worked at Merck Research Laboratories from 2007 to 2011. Dr. Garner holds joint M.D. and M.P.H. degrees from Harvard Medical School and School of Public Health. Her residency in obstetrics and gynecology was completed at Brigham and Women's/Massachusetts Hospitals, with her subspecialty fellowship in gynecologic oncology. She is board certified in obstetrics and gynecology and gynecologic oncology.

Scott M. Coiante, vice president and chief financial officer, Mr. Coiante joined Agile in December 2010 and initially served as the vice president of finance until June 2011 when he transitioned to his current position. From 2002, Mr. Coiante served several roles in finance at Medarex, Inc., a publicly listed company that was acquired by Bristol-Myers Squibb in September 2009. He has several years of experience in financial preparation and reporting for client offerings, both initial and follow-on, as well as with SEC registration filing statements for both public and private companies. Mr. Coiante received his B.S. in accounting from Villanova University.

Katie MacFarlane, Pharm.D., chief commercial officer. Ms. MacFarlane has been a commercial advisor for Agile since 2009 and recently became chief commercial officer in March 2014. From 2001 to 2006, Ms. MacFarlane served as vice president of women's health and new product planning at Warner Chilcott, a pharmaceutical company focused on women's healthcare which was recently acquired by Actavis in 2013. In addition, Ms. MacFarlane serves as a managing partner of SmartPharma Inc., a pharmaceutical consulting firm specializing in new product commercialization since 2007. Before her position at Agile, Ms. MacFarlane served as president and CEO of a start-up company from 2006 through 2008 called Xintria Pharmaceutical Corporation, which focused on treatments for type II diabetes and dyslipidemia. Ms. MacFarlane holds a B.S. in pharmacy and a Pharm.D. from Purdue University, and she completed a postdoctoral fellowship in industrial pharmacy practice at Rutgers University/Hoffman-LaRoche.

Valuation and Financial Overview

Valuation

Shares of Agile have traded in line with the pricing of the company's IPO at $6 per share. We believe the shares hold a strong risk/reward profile, given the well-defined efficacy of ethinyl estradiol/levonorgestrel products and the clear pathway for approval of contraception products. However, shareholders will likely have to be patient for several months when news flow regarding the company's main product may be scarce, and share prices of development-stage therapeutics companies tend to trade in line with the markets until a clear catalyst approaches. We ultimately believe in the strong management at Agile and view the current Phase III study for Twirla as very achievable. We believe the company's shares hold a reduced development risk compared with many small-cap development-stage specialty pharmaceutical companies.

We are establishing a price target of $18, based on an NPV of the company's lead development program, Twirla. In this calculation, we assume a launch of Twirla in mid-2016, after Agile responds to the complete response letter with data provided by the just initiated Phase III study. We assume Twirla peak sales will approach $400 million, which we project as only a 5.0% penetration into the total prescription contraception market. We include our launch assumptions and our Twirla model in exhibit 22.

Exhibit 22
Agile Therapeutics, Inc.
Twirla Market Model

	2016	2017	2018	2019	2020	2021	2022	2023
Total Prescriptions in U.S. Market	88,000,000	88,000,000	88,000,000	88,000,000	88,000,000	88,000,000	88,000,000	88,000,000
Twirla Penetration into U.S. Rx Market	0%	1.5%	2.3%	3.5%	4.0%	4.0%	4.0%	4.0%
Total Prescriptions for Twirla in U.S. Market	242,000	1,166,000	2,046,000	3,080,000	3,520,000	3,520,000	3,520,000	3,520,000
WAC per cycle of treatment ($)	88	88	88	88	88	88	88	88
Number of cycles of treatment	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
Gross to Net	9.5%	9.5%	9.5%	9.5%	9.5%	9.5%	9.5%	9.5%
Twirla Sales ($)	26,982	130,004	228,121	343,408	392,466	392,466	392,466	392,466
Growth Year-Over-Year	N/A	NM	75%	51%	14%	0%	0%	0%
Growth Quarter-Over-Quarter								

Source: William Blair & Company L.L.C. estimates

Given the development stage of Agile Therapeutics we derive our price target through an NPV calculation for Twirla, excluding value for earlier-stage candidates. We include the summary of our NPV calculation for Agile Therapeutics in exhibit 23. Our full NPV model with additional details is available from a William Blair salesperson.

Exhibit 23
Agile Therapeutics, Inc.
Sum-of-the-Parts Valuation

	Peak Sales	Discount Rate	Probability of Success	Peak Sales	Value Per Share
Twirla	$392	11%	75%	2021	$ 18.32
Cash Per Share					$ 2.44
NPV of Future Losses Per Share					$ (2.86)
NPV Value					$ 358.02
NPV Value Per Share					$ 17.90

Note: For per share numbers we use fully diluted share count of 20.7 million

Source: William Blair & Company L.L.C. estimates

In exhibit 24, on the following page, we provide the enterprise values (EV) and EV-to-sales and sales multiples of several established and smaller specialty pharmaceutical companies, many of which are marketing products that have been approved through the 505(b)(2) development pathway. The average enterprise value for Agile's specialty pharmaceutical peer group (less than $1 billion in

market capitalization) is more than five times higher than the roughly $80 million enterprise value of Agile, which we believe suggests significant room for upside from current levels if the company executes on several of its four product candidates.

Exhibit 24
Agile Therapeutics, Inc.
Comparable-Company Analysis

			Market		Revenue Multiples			
Company	Ticker	Price	Capitalization	EV	2013A	2014E	2015E	2016E
Salix Pharmaceuticals	SLXP	$111.66	$7,070	$8,635	2.8	4.4	2.1	2.1
Endo	ENDP	$68.74	$8,808	$11,523	2.5	3.4	2.4	2.4
Shire	SHPG	$191.11	$37,509	$38,858	4.4	6.3	3.9	3.9
Allergan	AGN	$159.37	$48,369	$46,908	3.8	6.5	3.2	3.2
Actavis	ACT	$210.38	$36,795	$45,176	2.2	3.4	1.7	1.7
Forest Pharmaceuticals	FRX	$94.97	$26,314	$27,161	2.7	5.7	2.4	2.4
Jazz Pharma	JAZZ	$144.14	$8,436	$9,383	4.8	6.2	3.5	3.5
Valeant	VRX	$117.75	$39,434	$56,222	4.2	4.4	3.7	3.7
Alkermes	ALKS	$47.31	$6,782	$6,593	8.1	10.1	5.9	5.9
Averages			$24,391	$27,829	3.9	5.6	3.2	3.2
Small Cap								
Pacira Pharmaceuticals	PCRX	$84.01	$2,832	$2,869	72.5	15.9	15.9	9.0
Horizon Pharma	HZNP	$14.95	$1,004	$1,326	51.1	3.7	3.7	2.4
Insys Therapeutics	INSY	$26.45	$976	$929	63.0	4.7	4.7	3.6
Depomed	DEPO	$13.17	$789	$808	8.7	3.8	3.8	3.7
Kythera	KYTH	$37.72	$855	$734	NM	NM	NM	6.2
Versartis	VSAR	$31.49	$762	$557	NM	NM	NM	15.2
BioDelivery Sciences	BDSI	$12.26	$594	$522	10.9	12.4	6.9	4.4
Auspex	ASPX	$21.42	$506	$401	NM	NM	NM	10.4
Acelryx	ACRX	$10.35	$448	$370	NM	NM	NM	4.0
Revance	RVNC	$29.64	$329	$256	NM	NM	NM	NM
Adamas	ADMS	$18.87	$315	$235	NM	NM	10.2	NM
Zogenix	ZGNX	$1.73	$251	$230	5.7	5.5	5.5	1.8
Pain Therapeutics	PTIE	$5.18	$234	$187	NM	NM	NM	NM
Egalet	EGLT	$13.83	$235	$158	NM	NM	NM	7.3
Durect Corp.	DRRX	$1.47	$162	$145	3.1	9.3	9.2	6.8
Flexion	FLXN	$13.03	$204	$130	NM	NM	NM	NM
Eagle Pharmaceuticals	EGRX	$12.22	$171	$121	NA	NM	14.4	1.2
Agile Therapeutics	AGRX	$6.78	$126	$85	NA	NM	NM	NM
Alexza	ALXA	$4.36	$75	$81	18.5	6.3	2.0	1.2
Averages			$572	$534	29.2	7.7	7.6	5.5

Market capitalizations, revenue, and enterprise value (EV) in millions
Sources: FactSet and William Blair & Company, L.L.C.

Income Statement

The performance of Agile's shares will largely be driven in the near term by the development of the company's main pipeline asset Twirla. We expect the company to be cash flow negative until 2017, which will likely be the first full year of sales of Twirla. We estimate profitability of $1.48 per share in 2017, but for projections that far off this is our best attempt estimate. When the company breaks into profitability, we anticipate that it will be highly profitable, given the 90% gross margins for Twirla.

We believe SG&A expense for Agile will range between $5 million and $7 million until the company begins to incur launch costs for Twirla in 2016. During that period the company will need to build out a salesforce of roughly 50 to 60 representatives. We begin to ramp up SG&A expense beginning in 2016, with roughly $39 million in expense, which we believe will approach $50 million in 2018.

R&D expense will likely be front loaded during the 2014-2015 period, which includes the expense related to the Twirla Phase III study. We assume $22 million in 2014 and $12.5 million during 2015, with the R&D expense again ramping up for post-marketing obligations and potentially bringing an additional pipeline product forward. The income statement is included in exhibit 25.

Balance Sheet and Cash Flow
We estimate that Agile holds about $50 million in cash on its balance sheet, based on a pro forma estimate following its initial public offering. Use of proceeds from the offering includes mostly the clinical costs of the Phase III trial for Twirla and taking the product through the necessary regulatory process. Throughout its operating history, Agile has accumulated net losses of about $104 million, while cash used in operating activities over the next four quarters will approximate $7 million per quarter. We anticipate that Agile will use $38 million in cash during 2014 and 2015 until we expect an approval for Twirla in early 2016. We do not believe that Agile will need to raise additional cash before reaching profitability; however, management may raise additional funds opportunistically to strengthen the cash position of the company heading into the launch of Twirla in 2016.

Conclusion

Agile Therapeutics is developing an intriguing pipeline of four specialty products focused on women's health. The company's lead product Twirla is looking to be a best-in-class contraceptive patch, which we believe may approximate $400 million in peak sales, assuming reasonable midsingle-digit market penetration estimates. Given our belief that the Twirla development program holds a relatively straightforward clinical pathway with a strong likelihood for achieving positive results from the company's next Phase III study, we are initiating coverage with an Outperform rating and Aggressive Growth company profile. While we understand that shares will likely trade in line with the market until we approach the company's Phase III trial readout, we believe patient investors with a reasonable time frame should do well purchasing shares at current valuation levels. We derive our price target of $18 from a product-specific NPV calculation for Twirla and exclude additional pipeline opportunities.

Our income statement for Agile Therapeutics is on the following page.

Exhibit 25
Agile Therapeutics
Income Statement

($ in millions except EPS data)

	2012(A)	2013(A)	Q1(A)	Q2(E)	Q3(E)	Q4(A)	2014(E)	2015(E)	2016(E)	2017(E)	2018(E)	2019(E)
Product Revenue								-	-			
Twirla	-	-	-	-	-	-	-	-	26,982	130,004	228,121	343,408
Royalty/Milestone Revenue	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	-	-	-	-	-	-	-	-	26,982	130,004	228,121	343,408
yr/yr growth	NA	NA	NA	NA	NA	NA	NA	NA	NA	381.8%	75.5%	50.5%
incremental rev q/q												
Cost of Goods Sold	-	-	-	-	-	-	-	-	2,698	13,000	22,812	34,341
Gross Profit	-	-	-	-	-	-	-	-	24,284	117,004	205,309	309,067
SG&A	17,387	9,154	1,053	1,225	1,470	1,470	4,900	6,500	39,000	48,500	50,300	52,000
Growth							-46%	33%	40%	20%	10%	15%
R&D	5,930	3,574	1,394	5,500	6,600	6,600	22,000	12,500	7,800	21,000	39,000	48,000
Growth		-40%	-	-	-	-	516%	-43%	-38%	15%	10%	15%
Total Operating Expenses	23,317	12,728	2,447	6,725	8,070	8,070	25,312	19,000	46,800	69,500	89,300	100,000
growth			NA	NA	NA	NA	99%	-25%	146%	49%	28%	12%
Operating Income	(23,317)	(12,728)	(2,447)	(6,725)	(8,070)	(8,070)	(25,312)	(19,000)	(22,516)	47,504	116,009	209,067
EBIT Margin							NM	NM	NM	NM	51%	61%
growth y/y (%)			NA	NA	NA	NA	NM	NM	NM	NM	NM	NM
Depreciation and Amortization	-		250	250	250	250	1,000	1,000	1,000	1,000	1,000	1,000
EBITDA	(23,317)	(12,728)	(2,197)	(6,475)	(7,820)	(7,820)	(24,312.0)	(18,000.0)	(21,516.2)	48,504	117,009	210,067
							NM	NM	NM	NM	51%	61%
Interest expense	(140)	(1,592)	(366)	750.0	750.0	750.0	3,000	2,000	1,500	1,500	8,000	8,000
Interest income	26	-	-	-	-	-	-	-	-	-	-	-
Change in fair value of warrants	171.0	-	-	-	-	-	-	-	-	-	-	-
Other	-	-	-	-	-	-	-	-	-	-	-	-
Income Before Taxes	(23,260)	(14,320)	(2,813)	(5,975)	(7,320)	(7,320)	(23,428)	(17,000)	(21,016)	49,004	124,009	217,067
Income Tax Provision	-	-	(3,652)	299	225	225	(2,903)	1,000	1,000	17,641	44,643	78,144
ffective Tax Rate	0.0%	0.0%	NA	5.0%	NA	NA	NM	NA	NA	36%	36%	36%
Beneficial conversino charge	(600)	-										
Net Income (loss) Attributable to Common	$ (23,860.1)	$ (14,320.4)	839	(6,274)	(7,545)	(7,545)	$ (20,524.7)	(18,000)	(22,016)	31,363	79,366	138,923
Net income to common (basic)	$ (845.3)	$ (405.1)	839	(6,274)	(7,545)	(7,545)	(20,525)	(18,000)	(22,016)	31,363	79,366	138,923
Net loss per share (diluted)	$ (845.3)	$ (405.1)	839	(6,274)	(7,545)	(7,545)	(20,525)	(18,000)	(22,016)	31,363	79,366	138,923
Net income to common per share (diluted)			0.02	(0.31)	(0.38)	(0.37)	(1.02)	(0.88)	(1.06)	1.48	3.09	5.30
Basic avg. number of shares used in computing net income	28	35	75,953	13,651	13,751	13,851	13,751	14,101	14,501	14,901	20,424	20,424
Diluted avg. number of shares used in computing net income	28	35	587,270	15,074	15,174	15,274	15,174	15,524	15,924	16,324	20,724	21,268
Key Ratios (GAAP unless noted)												
Gross Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	90.0%	90.0%	90.0%
R&D (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	NM	16.2%	17.1%	14.0%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	NM	37.3%	22.0%	15.1%
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	36.5%	50.9%	60.9%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	24.1%	34.8%	40.5%
Revenue Growth												
Growth Yr/Yr	NM	NM	NM	NM	NM	NM	NM	NM	NM	382%	75%	51%
Growth Q/Q	NM		NM	NM	NM	NM						
SG&A Growth												
Growth Yr/Yr	NM	-47%	NM	NM	NM	NM	-46%	33%	500%	24%	4%	3%
Growth Q/Q	NM		NM	NM	NM	NM						
R&D Growth												
Growth Yr/Yr	NM	-40%	NM	NM	NM	NM	516%	-43%	-38%	169%	86%	23%
Growth Q/Q	NM		NM	NM	NM	NM						

Source: Company reports and William Blair & Company, L.L.C.

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DJIA:	16,781.01
S&P 500:	1,937.78
NASDAQ:	4,321.11

The prices of the common stock of other public companies mentioned in this report follow:

AbbVie Inc.	$54.00
Bristol-Myers Squibb Company (Outperform)	$47.27
Corium International	$8.14
GlaxoSmithKline plc	$54.39
Johnson & Johnson	$102.45
Merck & Co. Inc.	$58.07
Mylan, Inc.	$50.40
Myriad Genetics Inc. (Outperform)	$36.65
PAREXEL International Corporation (Market Perform)	$53.25
Teva Pharmaceutical Industries Ltd.	$51.70

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