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## **Agile Therapeutics**

## Initiating with Outperform rating and \$12 PT - we see a "patch" toward approval

Our view: AGRX stock is significantly discounting what we think is a clear path to approval for its lead combination hormonal contraceptive (CHC), Twirla, a once-weekly patch which we think could be a >\$300 million peak opportunity. Upside to peak and potential for take-out post Phase III data add attractive optionality.

#### **Key points:**

- 1. Twirla offers a differentiated patch option that we think can deliver \$340 million in peak sales or 3% market share. The CHC market is a \$4.2 billion market growing at mid-single digits driven by eight brands generating close to 50% of revenues. The market is currently dominated by oral contraceptives with only one branded CHC patch (and its generic) available. Twirla will likely be the only patch without a black box warning, and be uniquely positioned to offer enhanced convenience and compliance, positioning it well to take solid share.
- 2. We see a clear path to approval in H2/16 which we think can be the trigger for significant upside. Agile is pursuing a new Phase III trial with proceeds from its recent IPO to address a number of FDA concerns from the prior CRL, most notably the high Pearl Index score. FDA has given clear guidance and the issues with the prior Phase III trials have been addressed in a more simplified single arm study that we think can deliver positive Phase III data in late 2015.
- 3. Our sensitivity analysis points to the potential for significant upside to our peak estimate adding favorable optionality to the story. There is potential for upside from both greater penetration and more aggressive pricing that we think leaves room for revision in our initial forecasts. Specifically, each 1% of market share adds ~\$100 million in additional peak sales driving close to \$3 in NPV per share or roughly 50% implied upside from where the stock currently trades.
- 4. The pipeline and patch technology are unlikely to command much value but do offer some incremental upside and importantly life cycle extension opportunity. We see an opportunity for Agile to further leverage its patch technology platform and advance AG200-ER, an extended regimen CHC patch. This could introduce another Phase III opportunity over the near term and importantly provide a life cycle extension opportunity to the franchise.
- 5. We think Agile could be a possible take-out, which creates a potentially interesting exit opportunity on successful Phase III results in late 2015. We see several companies with existing contraceptive franchises where a patch combination product could fit offering potential for an attractive exit opportunity on positive data and ahead of a commercial launch.

## **Outperform Speculative Risk**

NASDAQ: AGRX; USD 6.78

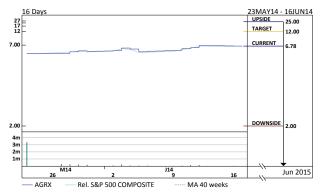
## **Price Target USD 12.00** Scenario Analysis\*

All values in USD unless otherwise noted.

Scenario	Price	Target	Scenario	
2.00 ↓ 71%	6.78	12.00 <b>↑</b> 77%	25.00 <b>↑</b> 269%	<b>—</b>
*Implied Total Returns <b>Key Statistics</b>				
Shares O/S (MM):	20.0	Market Cap	(MM):	136
Dividend:	0.00	Yield:		0.0%
<b>RBC Estimates</b>				
FY Dec	2013A	2014E	2015E	2016E
EBITDA, Adj		(26.8)	(18.4)	(25.0)
EPS, Adj Diluted		(1.23)	(0.87)	(1.14)
Revenue	0.0	0.0	0.0	14.8
P/AEPS	NM	NM	NM	NM
EBITDA, Adj	Q1	Q2	Q3	Q4
2014	(2.4)A	(3.1)E	(10.8)E	(10.4)E
2015	(6.3)E	(4.3)E	(4.3)E	(3.3)E
EPS, Adj Diluted				
2014	0.01A	(0.17)E	(0.55)E	(0.52)E
2015	(0.32)E	(0.22)E	(0.22)E	(0.13)E

#### **Target/Upside/Downside Scenarios**

#### **Exhibit 1: Agile Therapeutics**



Source: Bloomberg and RBC Capital Markets estimates for Upside/Downside/Target

#### Target price/ base case

Our base case scenario sees a \$12 share price on the following assumptions:

- Progress toward successful Phase III results and expected commercial launch by Agile in US H2/16.
- Peak US sales potential of \$340 million for Twirla reflecting 3% share of the CHC market on 4% annual pricing increases.
- Risk adjustment of 70% in our DCF while our Twirla NPV assumes a 23% discount rate on un-risk adjusted sales.
- No revenue contribution from the remainder of the pipeline and only modest benefit from existing NOLs.

#### **Upside scenario**

Our upside case scenario sees a \$25 share price on the following assumptions:

- Progress toward successful Phase III results and expected commercial launch by Agile in US H2/16.
- Peak US sales of \$617 million for Twirla reflecting 5% share of the CHC market and 5% annual pricing increases.
- Risk adjustment of 70% in our DCF while our Twirla NPV assumes a 23% discount rate on un-risk adjusted sales as the Phase III data read is expected in late 2015 (> 12 months).
- No revenue contribution from the remainder of the pipeline and only modest benefit from existing NOLs.

#### Downside scenario

Our downside case scenario sees a \$2 share price on an early unexpected halt to the Phase III study. In this scenario we assume modest value for platform technology, cash on hand, and existing NOLs.

#### **Investment summary**

Agile's lead product Twirla offers a low-dose once-weekly contraceptive patch that we believe fills an established unmet need in the market. Twirla offers both convenience and compliance benefits that we think would appeal to a core patient base once approved. Our thesis rests on four main points:

- 1) We believe Twirla can capture 3% TRx share in the sizable \$4.2 billion CHC market that is growing annually in the midsingle digits given the unique benefits that a CHC patch product without a black box safety warning could bring.
- 2) We see a clear path to market for Twirla and expect positive Phase III data in late 2015 followed by approval in H2/16.
- 3) There could be additional value from the existing pipeline and platform technology that we have not ascribed value to.
- 4) We see Agile as a logical take-out candidate by an established player in contraceptives with significant marketing resources and an established specialty sales force.

**Catalysts to focus on:** 1) Phase III data readout in late 2015,2) NDA approval and commercial launch in H2/16, and 3) Potential acquisition that could be possible post positive Phase III data.

**Risks to our thesis:** 1) New phase III data for Twirla is insufficient for an NDA filing, 2) Additional regulatory or execution delays to launch, 3) Potential for greater than expected financing needs, and 4) Lack of commercial uptake or adoption below expectations

## **Key questions**

#### Our view

1. Why did the prior Phase 3 trials fail, and why will this time be different?

A primary concern from the February 2013 Complete Response Letter (CRL) was the high Pearl Index (PI) score, which the new trial is addressing. This is the measure of efficacy and is based on the number of observed on-treatment pregnancies seen in the study. We believe several factors specific to the Twirla study drove a high PI score, including: an inexperienced contract research organization (CRO) running the trial, speedy recruitment, inappropriate patient screening and enrollment, data collection failures, and lack of proper controls. Notably, the brand comparator also saw a high PI score in the Twirla trial versus the score it achieved in its own clinical trials. Management has hired a new CRO experienced with large contraceptive studies, and is placing heavy scrutiny on patient recruitment, site selection, and data collection. We believe the new Phase III study will show efficacy in line with prior approved contraceptives.

2. How is Twirla differentiated from other combination hormonal contraceptives (CHCs)?

Twirla is a once-weekly, non-invasive contraceptive that is comparable in strength to low-dose oral contraceptives and offers better convenience and compliance against the daily pill. Close to 50% of sales are generated by eight branded products in what is a promotionally sensitive combination hormonal contraceptive (CHC) market open to new innovation. Importantly, Twirla would be the only patch CHC on the market without a black box warning around safety, which is the case with the only other branded patch, Ortho Evra. Based on Ortho Evra's peak market share of 11% before the black box warning came into effect (it has since fallen to <2% following safety concerns and generic entry), we think potential market acceptance of a safer patch alternative could be high.

3. What is the plan for Twirla's commercialization and can Agile Therapeutics gain share against established competitors?

We expect approval and launch in H2/16 by a newly built sales force but do think take-out is possible. Given the concentration of oral contraceptive providers in the United States, we believe Agile could hit close to 80% of all prescribers with a sales force of 90 reps. The oral contraceptive space is sensitive to promotion, which means the advertising and promotional campaign, including social media, will be instrumental to the rollout and market share gains. While we have modeled a commercial launch for Twirla, we do believe the potential for an acquisition of Agile exists given possible interest in the company's patch product from one of several different companies that compete in this market.

4. What is the peak potential of Twirla and what kind of duration does it have? We model peak year sales of \$340 million in 2022E, which reflects 3% TRx market share of the CHC market. Twirla has patents expiring from 2021-2028 and AGRX has an extended regimen patch CHC product in the pipeline that could serve to extend the life cycle. Each 100 basis points of additional market share could add roughly \$100 million in sales, and potential for more aggressive pricing assumptions could also drive upside to our initial peak sales forecast.

5. Will Agile have to access the public market again for capital before Twirla's launch? We believe Agile has raised enough funds to carry it through the Phase III data read in late 2015. We have modeled a raise in Q4/15 off assumed Phase III data intended to bolster funds ahead of the commercial build-out and launch that we expect will come in late 2016.



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## Differentiation targeting the CHC space – Initiating on Agile Therapeutics with an Outperform rating and \$12 price target

We have initiated coverage with an Outperform rating and a \$12 price target implying 77% upside.

Each +100 basis points in market penetration drives ~\$100 million in annual sales or roughly \$3 in NPV per share.

We think potential for an Agile take-out exists with focus likely to pick-up in late 2015 post Phase III data.

## Five key reasons why we would be buyers of Agile Therapeutics

- 1) Twirla offers a differentiated CHC patch option that we think can deliver \$340 million in peak sales. Our peak sales forecast reflects a 3% TRx market share of the CHC market in 2022E with an assumed 4% annual pricing increase. Importantly, we could see upside from both greater market share and more aggressive pricing. Each 100 basis points of market share adds ~\$100 million in revenue to annual sales while each additional 100 basis points of annual pricing increase boost our peak estimate by \$30 million.
- We see a clear path to approval in H2/16, which we think can be the trigger for significant upside. Agile is pursuing a new Phase III trial to address a number of FDA concerns from the prior CRL, most notably the high Pearl Index score. FDA has given clear guidance, and issues with the prior Phase III trials are being addressed in a more simplified single arm study to be conducted by PAREXEL, an industry leading CRO.
- 3) We like the upside optionality that we see based on our sensitivity analysis. There is potential for upside from both greater market penetration and aggressive pricing increases that we think leaves room for revision in our initial forecasts. Each \$100 million in additional peak sales adds close to \$3 in NPV per share or implied upside of close to 50% from current stock levels.
- 4) The pipeline and technology are unlikely to command much value initially but do offer some incremental upside and more importantly, a life-cycle extension opportunity. We assign no value to the pipeline, and view it as a source for upside. Specifically, AG200-ER is an extended regimen contraceptive that plays an important role in life-cycle management beyond patent reliance. Our NPV in the 2020E to 2022E time frame average \$40 million at a 22% discount rate (~\$2 per share), underscoring the importance of out-year franchise protection to the overall Agile value equation.
- 5) We think Agile is a logical take-out, which creates a potentially interesting exit opportunity on successful Phase III results in late 2015. We see several companies with existing oral contraceptive franchises where a patch combination product could fit offering potential for an attractive exit opportunity on positive data and ahead of commercial build out. Our analysis of acquisitions of single/lead product pre-revenue companies implies valuations of 1-3x expected peak revenue versus 0.4x for Agile.

## Four primary risks to our Outperform rating and price target

### We see four primary risks to AGRX shares

- 1) Regulatory risk: Getting the current Phase III single arm study right with a Pearl Index score below three is going to be key to FDA approval. Given the importance of Twirla to the overall value of Agile, further FDA delays or concerns would have a material impact on the stock. There are several angles to this beyond a lack of success in the trial as any significant delay could impact the timing and ability to go back to market to raise additional funds. Even on approval, having a clean label relative to Ortho Evra's black box warning will be key in market uptake and differentiation.
- 2) Commercialization risk: The contraceptive category is promotion sensitive and dominated by several large established companies. While we have assumed that Agile creates and builds out a commercialization platform, execution risk is something that needs to be considered. It will be particularly important to sell competitive differentiation between its patch product and the other eight leading brands that comprise roughly half of the market. The cost to do so will be an added consideration given what has, in many cases, been aggressive new launch spending to bring new contraceptives to market. This adds some uncertainty around what level of spend is the most appropriate for the best return on investment in order to drive the highest market share gains.
- 3) Financing risk: We expect another raise will be needed to fund commercialization efforts in the US and could likely come in late 2015 or early 2016. The company completed its IPO on May 23, 2014, which raised net proceeds of ~\$49 million. Agile has indicated that it expects the Twirla Phase III trial to cost \$31 million in total and given start-up costs we expect some greater cash burn in 2014. However, we have modeled \$18 million and \$19 million in cash burn in 2015E and 2016E followed by profitability in 2017E. In other words, based on our current commercialization forecasts we think Agile can get by with one more moderately sized raise to fund itself through 2016E though other capital raising options do exist.
- Competitive risk: Market acceptance for Twirla could face greater than expected headwinds and see slower than expected uptake as there are multiple branded and generic contraceptive alternatives already on the market. Additionally, the prior issues surrounding Othro Evra, a competitor contraceptive patch, could potentially hamper adoption as it has been linked to safety concerns including higher levels of estrogen absorption with elevated risks for deep-vein thrombosis (blood clots) - though we believe, Twirla is differentiated with a label we expect to be more favorable. In PK studies, Twirla EE concentration levels were within range of daily oral contraceptives, but no head-to-head study with Ortho Evra was run. The other competitive risk that could emerge is the approval of another CHC patch product at some point targeting the same market as Twirla, for example, if Bayer's CHC patch product was to re-emerge and ultimately make it to market. This could impact market share assumptions but also a potential for a competitive take-out, as we have highlighted. We think AGRX is a takeout opportunity post Phase III data in late 2015E.

Our model reflects an additional financing in late 2015 to fund launch costs and commercialization with breakeven in 2017.

## Our "Buy" case for shares in more detail – five reasons we like AGRX shares

Agile completed its IPO on May 23, 2014, which raised net proceeds of ~\$49 million after issuing 9.2 million shares at \$6 per share. The initial IPO range was \$12 - \$14 per share. Agile plans to used \$31 million towards the Phase III study for its lead product, Twirla.

## 1) Twirla offers a differentiated product that we think can deliver \$340 million in peak sales

Our \$340 million peak forecast assumes Twirla captures 3% peak TRx share in 2022E.

Our peak sales forecast of \$340 million still implies ~\$11 in NPV for Twirla discounting back at a 22% rate per Exhibit 2. Our model assumes a H2/16 launch and 3% market share of the CHC market in 2022E with pricing growth of 4% annually off of an initial 2016E WAC price of \$99. We have assumed no generic competition until 2023E at which point our terminal growth is -30%, leaving little value for an authorized generic, life-cycle extension or patents that run to 2028 - all which can add upside. Importantly, we could see upside from both greater market share and more aggressive pricing. Each 100 basis points of market share adds \$114 million in revenue to our peak estimate while each additional 100 basis points of annual pricing increase boosts our peak estimate by \$30 million.

Differentiation and promotion will be the two key factors driving market penetration and we expect Twirla to be the only once-weekly combination hormonal contraceptive (CHC) patch on the market without a black box warning. The only other approved CHC patch products are Ortho Evra and its associated generic launched by Mylan in April 2014. Ortho Evra received peak market share of 11% in the first two years of launch before its black box warning was added taking share down to below 2% by 2009. We think this points to demand for a safe and effective patch product in the market and could indicate that our peak market share assumption is conservative.

Exhibit 2: Our NPV model derives ~\$11 in value for Twirla alone without any explicit credit for ex-US contribution, pipeline, NOLs or technology

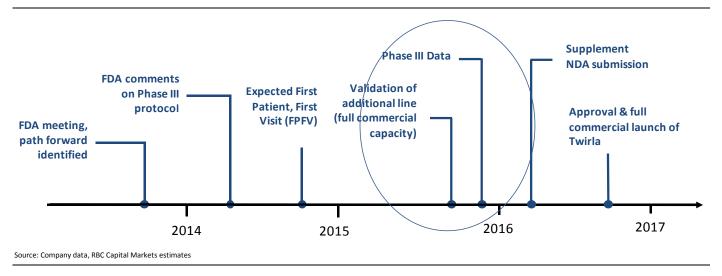
US P&L Build	01100445	20455	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Comments
110	2H2014E		2016E	2017E	2018E	2019E	2020E	2021E	2022E	
US sales	0	0	21	97	171	248	290	325	340	Assume late 2016 Launch
Gross profit	0	0	19	89	156	227	267	300	315	COGS @ \$6 per cycle + 0.5% for warehousing
Gross margin			92%	92%	92%	92%	92%	92%	93%	
SG&A	3	5	32	43	40	38	39	40	41	
R&D	19	13	7	4	7	9	9	6	7	Expect Phase III data in late 2015
US EBIT	(21)	(18)	(19)	42	110	181	220	254	267	
EBIT margin	NM	NM	NM	43%	64%	73%	76%	78%	79%	
Tax %	0%	0%	0%	0%	20%	35%	35%	35%	35%	Assume some NOL benefit initially
Net Income	(\$21)	(\$18)	(\$19)	\$42	\$88	\$118	\$143	\$165	\$173	
NPV	(\$21)	(\$15)	(\$13)	\$23	\$40	\$44	\$43	\$41	\$35	No credit for follow-on pipeline / No R&D
Terminal value									\$45	Assume generic entry after 2022E
Total NPV	\$222									
NPV per share	\$11.09									
NPV assumptions			Commen	ts on assu	umptions					
NPV 2016E to 2022E	\$177		Assumes	6 years of	market op	portunity b	efore gene	eric entry		
Terminal NPV	\$45		We assur	ne generic	entry after	2022E bu	t potential	for (1) life	cycle exter	nsion (2) authorized generic could drive upside
Terminal growth	-30%					M in NPV				
Discount rate	22%		Reflects a	ssumed ris	sk from on	going Pha	se III trial a	and comme	ercial unce	rtainty
Normalized tax rate	35%		We expec	t some ea	rly benefit	from use o	f NOLs an	d have fac	tored in tax	x savings through 2018E
Share count	20.0				ent IPO - o					

We expect data in late 2015 with potential approval in H2/16.

## 2) We see a clear path to approval in H2/16, which we think can be a trigger for significant upside

We think the prior Phase III FDA Complete Response Letter concerns have been addressed and see a high likelihood of approval in H2/16. FDA has given clear guidance and issues with the prior Phase III trials, most notably the higher Pearl Index score, are being addressed in a more simplified single arm study to be conducted by PAREXEL, an industry leading CRO. We have risk adjusted approval in our model at 70%, which reflects likelihood of a favorable outcome. As detailed in Exhibit 3, we expect Phase III data to come in late 2015 and, importantly, believe that management will look to provide progress updates along the way.

Exhibit 3: The Twirla "timeline" and what to focus on relative to the stock

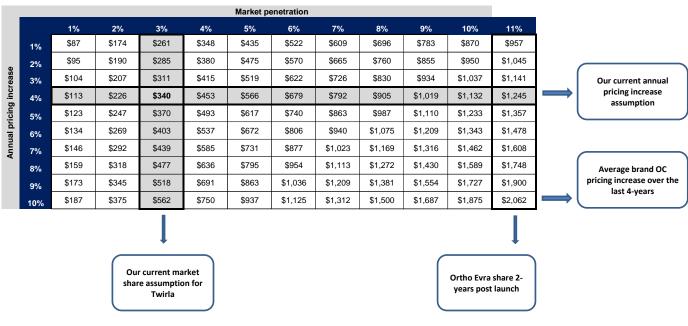


Our assumptions around penetration and pricing leave significant upside potential around peak sales.

## 3) There is potential for significant upside based on our sensitivity analysis

We see two very sizable avenues to a much bigger peak sales realization - penetration and pricing. Given Twirla's importance to the overall value of Agile, this is where most of the debate around upside/downside will rest. Our \$340 million peak sales estimate reflects only 3% TRx market penetration and 4% annual pricing increases – both of these are arguably conservative creating what we think is a very favorable upside scenario. In Exhibit 4, we have taken a closer look at the sensitivity analysis around each. By way of sensitivity, for each 100 basis points in TRx penetration, we see roughly \$114 million in additional peak sales and that translates into close to \$3 in NPV per share or ~50% higher than where the stock currently trades. However, there is support to suggest that both could be meaningfully higher. First on the pricing side, we have seen support for branded oral contraceptive pricing over the last several years with a three-year average increase of 10%, well above our forecast. It is not clear where pricing will be by the time Twirla makes it to market but we do think there is some potential pricing flexibility at levels above what we have modeled. Currently, we assume a WAC price of \$99 in 2016, which we believe would still put it at a discount to Ortho Evra even on today's pricing. Second, our 3% peak penetration estimate is reasonable but does leave us with potential for upside.

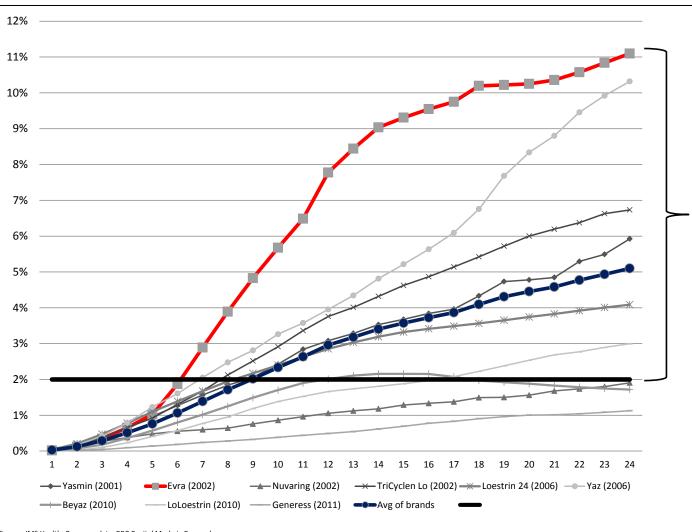
Exhibit 4: We could see significant peak sales upside potential on greater market share or penetration assumptions versus what we have built into our model – and there are data points to support the upside case (\$ millions)



Source: RBC Capital Markets estimates

Performance of new branded oral contraceptive launches has been variable, but as Exhibit 5 details, well-funded key launches have broken through the 3% market share barrier within 24 months post-launch. For comparative purposes, we still have Twirla below 2% after 24 months post-launch, which again, is another data point in support of what could be greater upside relative to our forecast.

Exhibit 5: Most branded oral contraceptive launches have seen penetration of 3% or greater within the first 24 months of launch - each 100 basis points of market share for Twirla is equal to roughly \$100 million



Source: IMS Health, Company data, RBC Capital Markets Research

Focus on AG200-ER as a possible life cycle extension strategy to the Twirla franchise.

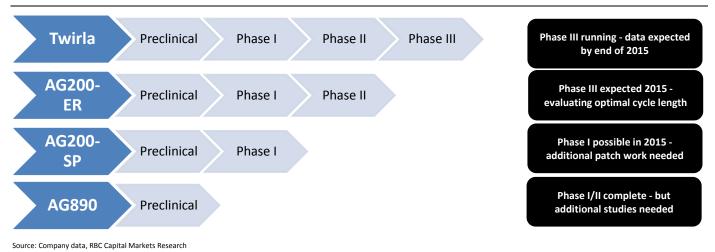
## 4) Pipeline and technology unlikely to command much value initially but do offer incremental upside and franchise protection

We assigned no value to the pipeline but it does represent realistic upside opportunity and more importantly, the potential to add NPV value through life-cycle extension of key product Twirla. The pipeline candidates below use Agile's Skinfusion transdermal delivery technology. To us, the most interesting opportunity is AG200-ER, which is an extended regimen oral contraceptive patch that we think could serve as a life cycle extension **opportunity.** Exhibit 6 details the stage of development for each product.

- AG200-ER: A combination contraceptive designed to extend the length of a women's cycle with fewer episodes of bleeding. There are approved orals that offer an extended cycle, but all require daily administration. Management is in the process of preparing for a Phase III study and anticipates to start the study in 2015.
- AG200-SP: A 28-day combination contraceptive designed to provide a shortened hormone-free interval that could provide users with shorter and lighter withdrawal

- bleeding. AG200-SP uses a smaller, lower-dose path in week 4, and delivers declining doses of hormones. Management anticipates Phase I studies to initiate in 2015.
- AG890: A levonorgestrel (LNG) progestin-only patch for women intolerant or unwilling to take estrogen, which may include women who are breastfeeding, at higher risk of VTE, smokers, and/or obese. Development is still early with a completed Phase I/II study and still pending data. As we previously mentioned, a progestin-only contraceptive patch from Actavis may enter the market in 2015. This patch targets the \$1.4 billion progestinonly market as part of the overall \$5.6 billion US hormonal contraceptive market.

Exhibit 6: Agile's pipeline utilizing its patch technology could add to upside potential



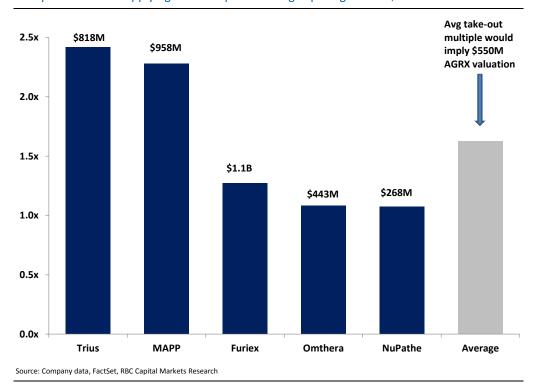
If we apply a 1.6x price to revenue take-out valuation to AGRX we get an implied value of ~\$550 million or more than 4x the current valuation.

## 5) We think Agile could be a logical take-out target creating an interesting exit opportunity for late 2015 post Phase III data

There are several companies we think could have an interest in acquiring Agile once favorable Phase III data is presented. Agile will hold what we think will be a unique position in the market as the only combination patch oral contraceptive product without a black box warning (i.e. Ortho Evra) and we think that could draw strategic interest. It may also present management and investors with an exit option ahead of having to build up sizable commercial infrastructure in 2016 - though for now that is what our model assumes. Exhibit 7 lays out the competitive landscape and specifically who we think the most plausible possible buyers could be.

Recent acquisitions of pre-revenue lead/single product companies have been in the range of 1.1x to 2.4x expected peak sales and well above the 0.4x implied valuation of Agile currently. Per Exhibit 7, we have looked at five select recent transactions as possible comparisons to AGRX, based on: 1) a lead pre-revenue product that was the primary driver of the acquisition; 2) regulatory and/or commercial risk, which factored into the take-out valuation; and 3) a technology platform that brought incremental value. The caveats here are that each deal had its own specific attributes and we have also assumed full earn-out realization which for all may not be the case, in effect lowering our assumed take-out price. The key point here is that if we applied the average 1.6x take-out valuation to our \$340 million peak sales forecast for Agile, we would get a valuation of \$550 million, which is more than 4x where the stock currently trades.

Exhibit 7: Recent acquisitions of pre-revenue single/lead product companies have averaged 1.6x price to sales – applying this multiple to our Agile peak gets us a \$550 million valuation



We see several potential buyers of Agile down the road. In Exhibit 8, we have detailed the leading contraceptive players with some of the more important on-market and pipeline products in development. The key here is that, outside of Johnson & Johnson (JNJ) and Bayer, we do not believe there are any late stage CHC patch products in current development. It is not clear if Bayer's CHC patch (with active ingredient gestodene) is being progressed. Additionally, JNJ's Ortho Evra has a black box warning and saw generic entry this past April.



Exhibit 8: There is a competitive need for a patch combination product amongst competitors that we think is an easier "buy" versus "build" – we highlight below the leading manufacturing and some of the key US products and pipeline

	Actavis	Teva	Bayer	Merck	JNJ	Pfizer
Key	Lo Loestrin Fe	Quartette	Mirena (IUD)	Nuvaring (Ring)	Ortho Tri Cyclen Lo	Depo-Provera (Injection)
Marketed	Minastrin 24 Fe	PlanB OneStep	BeYaz	Nexplanon (Implant)	Ortho Evra (Patch)	
Products	Generess Fe	Seasonique	Yaz	Cerazette		
	Loestrin 24 Fe	LoSeasonique	Natazia	Zoely		
		Zoely	Jadelle (Implant)			
		ParaGard (Implant)	Essure			
_						
Key	Progestin-only (Patch)	LeCette	FC-Patch Low (Patch)	MK-8342 (IUS)		
Pipeline	Levosert (IUD)		Yaz Flex	MK-8175A (Ring)		
Products	E4/Progestin		LCS-16 (IUD)	MK-8342B (Ring)		
	Etonogestrel (Ring)					
Est. \$ market share *	28%	13%	15%	15%	12%	4%

<sup>\*</sup> Total company contraceptive sales of all product (brand and generic)

Source: Company data, RBC Capital Markets research

## Background on Agile and the key aspects of the story

Twirla's value proposition comes from both the convenience of a once weekly patch and potentially better adherence than pills.

# The Twirla differentiation – Why we think there is an attractive opportunity for a new novel patch product in the OC market

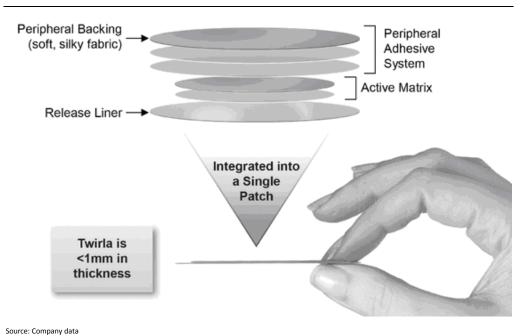
We expect Twirla to be approved in 2016 as the only once-weekly combination hormonal contraceptive (CHC) patch on the market without a black box warning. Twirla contains active ingredients Ethinyl Estradiol (EE), a synthethic estrogen, and levonorgestrel (LNG), a progestin, or type of synthetic steroid hormone, as detailed in Exhibit 9. Both ingredients have an established history of use in currently marketed contraceptives. There are three different synthetic estrogens approved for use in contraceptive products and 10 progestins. In general, the progestin component provides the contraception, while the estrogen provides spotting and bleeding control between cycles, and both are generally well tolerated. Twirla is designed to deliver 30 micrograms of EE per day consistent with low-dose contraceptives (FDA defines low dose as any contraceptive delivering ≤35ug of EE). The active ingredients are released over a seven-day period. The patch is applied once a week for three weeks followed by a week without a patch. This provides significant convenience over taking a daily pill. In general, the patch is most frequently applied to: 1) buttock 49%, 2) abdomen 39%, or 3) upper torso 12%.

Exhibit 9: The Twirla combination hormonal contraceptive patch



Agile's proprietary transdermal patch technology is called Skinfusion and is designed to improve patch adherence, stability and comfort. Twirla is a matrix patch with several layers of active ingredients (EE and LNG), contained by a top layer designed to be comfortable to the touch. There is a barrier that separates the inner and outer portion of the patch and is designed to prevent ingredients from migrating to the peripheral portion of the patch and breaking down the adhesive as detailed in Exhibit 10. Clear advantages of a weekly patch with improved convenience and compliance over orals is a compelling proposition. Real world failures are typically higher than contraceptive study results mostly due to noncompliant use. The patch is manufactured by Agile's partner, Corium, which holds the ability to ramp capacity to meet the most aggressive upside scenarios around patch volume. Corium has had a successful pre-approval inspection in relation to Twirla.

Exhibit 10: Twirla proprietary transdermal patch design



A once-weekly patch offers an easily reversible contraception option that gives women additional convenience over a daily pill. The contraceptive category has seen minor innovation over time with longer acting methods such as the IUD becoming more popular. However, oral contraceptives still remain the predominant method of birth control, as they are easy to obtain, come with a plethora of generic options, and are easily reversible without implants or surgery. Studies have shown that real world usage of the pill results in higher pregnancies than clinical literature, and that a significant driver of failures arise from noncompliant and inconsistent use. Non-compliance generally arises from failure to consistently follow the daily pill regimen and this is precisely what Twirla addresses.

Prior studies indicate that Twirla is well tolerated with a favorable side effect profile relative to other approved options. In the combined data from two studies, there were 22 series adverse events, with 16 from the Twirla cohort and one instance of deep vein thrombosis. Non-adverse events included symptoms that are associated with estrogen, such as nausea, headache, and breast tenderness, which we detailed in Exhibit 11 below. The key point here is that we think Twirla may offer an improved side effect profile relative to other approved options based on comparisons taken from prescribing information literature.

Exhibit 11: Adverse events comparisons show Twirla is very tolerable

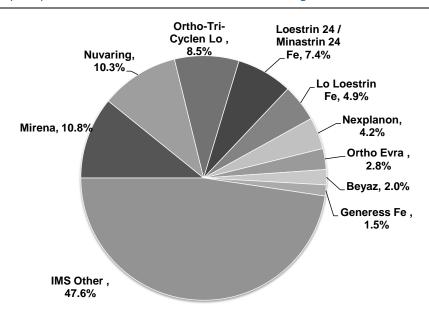
Twirla	%pts	Ortho Evra	%pts	Nuvaring	%pts	Lo Loestrin Fe	%pts
Nausea	3%	Breast Symptoms	22%	Vaginitis	14%	Nausea/vomiting	7%
Application Site Irritation	2%	Headache	21%	Headache & migraine	11%	Headache	7%
Breast Tenderness	2%	Application site disorders	17%	Mood swings	6%	Bleeding irregularities	5%
Headache	2%	Nausea	17%	Device-related events	6%	Dysmenorrhea	4%
Source: Company data, FDA.gov							

The CHC market that Twirla is targeting saw ~\$4.2 billion in sales in 2013 and is growing in the mid-single digit range.

## Sizable market – sizable oral contraceptive market that is promotion sensitive = opportunity for well positioned brands

The US hormonal contraceptive market was roughly \$5.6 billion in 2013 with the combined hormonal contraceptive (CHC) market about \$4.2 billion (Progestin only is ~\$1.4 billion). The market is growing in the mid single digits annually with flat to modest overall TRx growth combined with brand pricing growth of close to 10% offset by price erosion from generics. This CHC market has been dominated by orals with ~65% of sales volume, and ~90% of TRx volume. Nearly half of the market is driven by 10 branded contraceptives (see Exhibit 12 below). Notably, five of the top eight branded products are pills, which still remain the dominant form of contraception as they are easily reversible, have a plethora of low cost generics, and are non-invasive, which are all characteristics of Twirla.

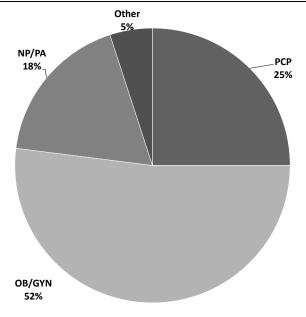
Exhibit 12: We see an attractive market opportunity for Twirla as the only combination oral contraceptive patch on the market without a black box warning



Source: IMS, RBC Research

We have assumed that Agile launches in late 2016 with a 90 person sales force targeting 80% of US CHC TRx. Agile plans to commercialize Twirla itself should it see approval. While we think positive data and a Twirla approval would make Agile strategically interesting from a take-out perspective, we have for now, assumed that the company will launch the product on its own. We think Agile can target close to 80% of TRx by focusing on the OB/GYNs who write close to half of all scripts, as well as higher prescribing Nurse Practitioners (NP), Physician Assistants (PA), and primary care physicians (PCP) per Exhibit 13 who comprise the remainder. In our model, we have assumed the company will utilize a sales force of 90 representatives. If we did ultimately see Agile launch on its own, the question would ultimately shift to platform strategy and pipeline in order to leverage a full specialty sales force. The one caveat here is that given the promotion sensitive nature of oral contraceptives, we think a more aggressive launch strategy may require significant spend.

Exhibit 13: OB/GYNs write just over half of contraceptive volume



Source: IMS

## Complete response letter – what went wrong the last time and why we think it is addressable this time around

Agile previously submitted an NDA in April 2012, but it returned with a Complete Response **Letter in February 2013 identifying the following issues:** 

- Requiring an additional Phase III study as efficacy (measured by the Pearl Index) appeared to be worse compared to approved hormonal contraceptives.
- Improvements in study conduct including site monitoring, data collection, information on in-process controls, and other product related information.
- Laser etching of label information on each patch to ensure there is no adverse performance to the patch from etching.

The Pearl Index is a standard measure of contraceptive effectiveness in clinical trials.

The biggest issue in the CRL was a low Pearl Value (efficacy), which we believe is the result of a greater pregnancy rate. Overall, the Pearl value of the pooled intent-to-treat population showed Twirla at 5.76 versus the control oral contraceptives at 6.72. Twirla demonstrated better efficacy, though the Pearl values were both high compared to trial results of approved contraceptives in the past decade (1.34 - 3.19). The two comparator OCs used in the trials, Levlite and Nordette, far exceeded the values that were originally presented in trials for their approvals at 1.8 and 0.5, respectively.

The Pearl Index represents the number of unintended pregnancies based on number of cycles. Approved contraceptives in the past decade have generally seen values between 1.34-3.19 (TEVA's Quartette approval in April 2013 had a Pearl value of 3.2). FDA guidance states that the PI calculation includes all pregnancies, but only includes cycles where a woman has engaged in sexual activity without using backup contraception (e.g. condom), and where she has completed a study diary. Factors that may impact PI values include: study design, location, weight and body mass of patients, experience in prior contraceptive use, incorrect use of contraceptives, and incomplete data collection.

From an analysis of prior Phase III data and the path ahead, we note several takeaways:

- 1) Several sites were responsible for an overwhelming portion of failures. From the 96 sites previously that were chosen, a handful was responsible for 36% of all pregnancies. Notably, two-thirds of all the sites had zero pregnancies. This leads us to believe there were likely execution issues in those locations that likely included poor training by investigators, data collection issues, and lack of controls. Management has hired a new CRO, PAREXEL, with extensive experience in running large contraceptive trials, and is implementing new technologies for real-time monitoring and data collection. The new Phase III will have fewer sites and be more simplistic in design. Management has indicated it would not use any site new to contraception studies.
- 2) Substantially over-represented groups of inexperienced patients. Data showed that Twirla trials enrolled far fewer patients that were immediate switchers from other hormonal contraceptives. Current users, or patients who have used a hormonal contraceptive within seven days of enrollment, had a zero Pearl value. Experienced users (or patients that have used a hormonal contraceptive within six months of enrollment), had a 3.0 Pearl value, which is still inline with what management is looking for (see Exhibit 14 below). Overall, ~58% of patients enrolled in Twirla's Phase III were new users of contraception (see Appendix). Percent of new users in prior contraceptive studies include Quartette 17% new users, Seasonale 8% new users, Nordette 6% new users, and Levlite 9% new users.
- 3) Agile has hired a new chief medical officer to oversee the trials and has a clear path ahead with commentary from the FDA. Management feels they have sufficient guidance to move forward in the next Phase III study. The new single-arm study is expected to recruit ~2,000 females in 50-70 sites, which will receive Twirla for up to one year. We expect new Phase III data to fall in line with approved contraceptives, which have shown PIs between 1.34 to 3.19. Management is targeting a PI within the high end of that range to be acceptable for an NDA filing.
- 4) We do not believe laser etching will be an issue for efficacy as the outer portion of the patch, which will have the Twirla etching, has no active ingredients. The overlay in Twirla is a commercially available silk-like polyester fabric. The upper barrier only prevents active and inactive ingredients from migrating to the peripheral portion of the patch and from breaking down the adhesive.
- 5) Labeling discussions with the FDA had not occurred, though we believe Twirla would not receive the black box warning that Othro Evra per its PK study results. The study was similar in design to the study conducted in Othro Evra's package insert, which showed a warning of higher EE levels against approved OCs. Estrogen concentrations for Twirla were around half the levels for Othro Evra.

Exhibit 14: What is different this time around – several changes have been made that should de-risk the current trial and lower the Pearl Index score

#### What went wrong with prior Phase III

#### **Study Design**

• Active comparators with Pearl Index higher than expected made results difficult for FDA to interpret

- Lack of experience with large contraceptive trials
- Logistical and technological capabilities did not allow real-time assessment of study procedure adherence
- Clustering of pregnancies at 5 study sites with poor oversight

#### **Trial Population**

· Pearl Index driven by pregnancies in over-represented portion of new users

#### **Data Collection Issues**

- Missing/incomplete data and lost cycles
- Lost cycles increased the Pearl Index

#### Why a new Phase III will work

#### **New Chief Medical Officer (CMO)**

 Extensive experience and demonstrated success in contraceptive approvals

#### Simplified Study Design (per FDA recommendation)

- Single-arm, non-comparative trial
- · Consistent with typical contraceptive studies

#### **New Top-Tier CRO**

- CRO with extensive experience in running large contraceptive trials
- Selection of experienced study sites
- Better patient screening
- Study coordinators experienced in training participants

#### Use of technology to assist and monitor trial conduct

- Reminders to subjects such as texts and phone calls
- Real-time data collection an daily updates to Agile from CRO regarding status of study
- Early detection of retention and documentation problems at individual sites

Source: Company data, RBC Capital Markets

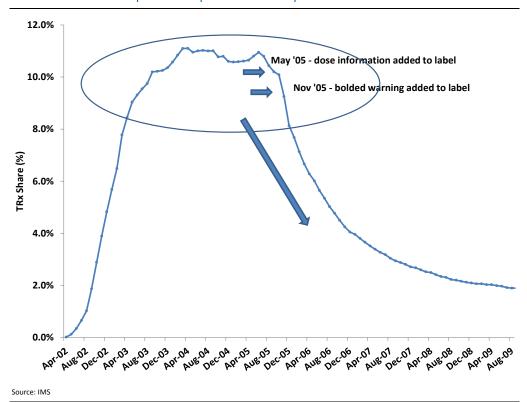
## Competitive landscape – Big market with little "direct" competition but focus on Ortho Evra

We do not think there will be much by way of direct patch competition when Twirla enters the market but we do expect focus from two angles: 1) Ortho Evra and the recently launched generic version, and 2) Bayer's Phase III patch pipeline product that has seemingly stalled in development, though has been approved in Europe.

Ortho Evra's peak market share of ~11% suggests that there is patient demand for a CHC patch with a favorable safety and side effect profile.

Competitor Othro Evra demonstrated that there is significant market demand for a onceweekly patch - but that reversed once the label changed. Otho Evra launched in 2002 and quickly became the most successful US contraceptive launch in history, reaching \$400 million annual sales and a peak TRx market share of 11% in its second year per Exhibit 15. Growth was actually constrained because production was not able to keep up with demand. In 2005, safety issues emerged following several cases of thrombosis, and a label that was revised to include a bolded black box warning that stated Evra users are exposed to 60% more estrogen versus a 35ug oral pill. Multiple deaths were linked to higher hormone levels, which increased the risks of blood clots and stroke. JNJ eventually settled hundreds of lawsuits regarding Ortho Evra, and discontinued marketing of the product. Evra remained on the market over the years with its bolded warning label, but has declined to 1.4% TRx market share, generating ~\$150 million in annual sales before seeing generic competition from Mylan in April 2014.

Exhibit 15: The rise and fall of Ortho Evra – but importantly what this means for Twirla relative to market acceptance and potential market penetration



We think that demand for a CHC patch remains and that Twirla would have a significant competitive advantage to Ortho Evra. As Exhibit 18 details, there are significant differences between Twirla and Ortho Evra though no head-to-head studies have been completed. Venous Thromboembolism (VTE), a life-threatening adverse event is unlikely to be an issue with Twirla as it was with Ortho Evra. VTE is the formation of blood clots in the vein, and has been linked to the use of Estrogen in hormonal contraceptives. The overall chances of VTE is low, and historically, the use of combination OC's have only slightly increased the incidences. PK data suggests that Twirla exhibits EE and LNG serum concentration levels consistent with combination oral contraceptives with the same active ingredients. Twirla delivered an EE dose of ~30ug per day.

Exhibit 16: There are several important differences between Twirla and Ortho Evra

Characteristic	Twirla	Ortho Evra*
Product Form	Transdermal patch centimeters Soft, silky, stretchy fabric	Transdermal patch centimeters Smooth, plastic film
Active Ingredients	EE, LNG	EE, norelgestromin
PK profile of EE (per day)	~30 micrograms	60% higher than that of an oral contraceptive containing 35
Regimen	One patch weekly 21 days active / 7 days patch-free	Same as Twirla
Package configurations	1 box of 3 patches = 1 cycle 1 box with 1 patch = replacement	Same as Twirla
Top four adverse events in trials	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%

<sup>\*</sup>Source of Ortho Evra data is U.S. prescribing information or package insert.

Source: Company data, RBC Capital Markets Research

Mylan's generic Ortho Evra "Xulane" launched in April 2014, though we do not expect any impact on the market potential for Twirla. Xulan has the same black box warning as Othro Evra, and initial pricing indicates a modest ~14% discount to branded WACC. IMS trends in Exhibit 17 indicate that Xulane has captured nearly 71% of branded TRx, but importantly has not grown overall TRx volumes. There are two things we think are important to note from this. First, having a generic Ortho Evra patch in the market at a modest discount is not drawing new patients of any significance and thus we do not think will have much competitive relevancy to Twirla. Second, generics are targeting this part of the contraceptive market with patch technology, and that has to be considered relative to competitive threats over time.

<sup>\*\*</sup>The Ortho Evra package insert indicates a strength of 35 micrograms of EE per day.

<sup>\*\*\*</sup>Adverse events deemed definitely, probably or possibly related to Twirla in completed Phase 3 trials.

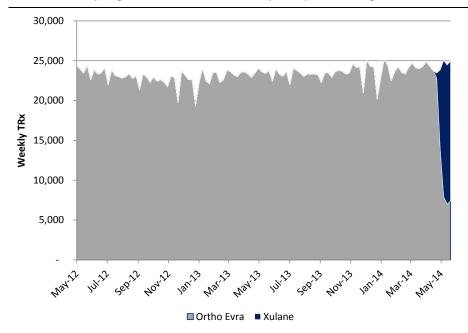


Exhibit 17: Entry of generic Ortho Evra is unlikely to expand existing market share

Source: IMS Health, REC Capital Markets

Potential competitor patches from Bayer and Actavis are unlikely to be direct competitors to Twirla. Bayer has a combination patch approved in the EU and had last completed a US Phase III trial in December 2010. The patch uses the active ingredient Gestodene, which has never been approved as a contraceptive in the US. There have been no indications of a US NDA submission, and we do not view it to be a significant competitor in the US, though our visibility as to whether it will ultimately be progressed is low. Additionally, Gestodene is a third generation progestin that had been tried before in the US, and it appeared to come with a higher risk of Venous Thromboembolism (VTE).

Actavis is in the process of preparing a resubmission for their progestin-only patch with approval expected in 2015, but targeting a different patient base. Actavis management indicated on its Q1/14 earnings call that it needs to run an additional small study related to patch size as per the FDA, and expects to submit the data in H2/14. This progestin-only patch will not be a direct competitor to Twirla, as estrogen is a key component to controlling breakthrough bleeding which is a notable differentiator. The progestin-only patch is generally designed for women that are unable or unwilling to take estrogen, including those breastfeeding, at greater risk of VTE such as those who smoke, are over the age of 35 or obese. On its Q1/14 earnings call, Actavis has indicated the market opportunity would be more limited than what we are currently seeing for Ortho Evra, recognizing that Actavis' product is not a combination patch.

## Valuation and how we get to our \$12 per share price target

Our \$12 price target is an equal blend of 1) net present value (NPV) for lead product Twirla of just over \$11 and 2) discounted cash flow analysis of ~\$12. Collectively this gets us to a \$12 per share target. The rationale for a blended approach is that we expect the stock to trade on the lead product Twirla but also use DCF in looking at the vast majority of our coverage. Our DCF reflects risk adjusted sales while our NPV model captures uncertainty via a higher discount rate – both of which we'll look at adjusting over time as the risk to approval is lowered.

- Net present value (NPV): We arrive at just over \$11 per share based on a peak sales forecast of \$340 million, which reflects 3% TRx market share penetration. We assume generic competition comes in 2023E at which point we apply a -30% terminal growth rate. We have provided only modest benefit from existing NOLs, no value for sales outside the US, and no additional assumed pipeline conversion. Our 22% discount rate captures both regulatory and commercial risk and will move lower as Twirla progresses through development and approval and risk moves lower. Our Twirla NPV is detailed in Exhibit 2.
- Discounted cash flow analysis (DCF): Our DCF model reflects a 70% risk adjustment to our peak sales forecast of \$340 million and also no sales from ex-US, modest benefit from NOLs and no additional pipeline conversion. We have assumed a 14% discount rate and -30% terminal growth. Our DCF captures some incremental cash value, which our NPV product model does not.

Exhibit 18: Our DCF derives a value of \$12 per share and reflects a 70% risk adjustment to sales

AGRX DCF	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Free Cash Flow	(\$20)	(\$27)	\$18	\$50	\$73	\$91	\$106	\$112
		PV of	Terminal \	/alue				
		Per	petuity Gro	wth		Ent	terprise Va	lue
WACC		-35.0%	-30.0%	-25.0%		-35.0%	-30.0%	-25.0%
10%		\$75	\$91	\$112		\$286	\$302	\$323
12%		\$63	\$75	\$92		\$249	\$262	\$278
14%		\$52	\$62	\$75		\$217	\$227	\$240
16%		\$44	\$52	\$62		\$190	\$198	\$209
1070								
18%	]	\$37	\$43	\$52		\$166	\$173	\$181
	J		\$43 al Equity Va	·		·	\$173 Value per	·
	]		·	·		·	·	·
18%		Tota	al Equity Va	alue		Equity	Value per	Share
18% WACC		Tota	al Equity Va -30.0%	alue -25.0%		Equity -35.0%	Value per -30.0%	Share -25.0%
18% WACC 10%		Tota -35.0% \$298	al Equity Va -30.0% \$314	alue -25.0% \$334		Equity -35.0% \$15	Value per -30.0% \$16	Share -25.0% \$17
18%  WACC 10% 12%	 	Tota -35.0% \$298 \$260	al Equity Va -30.0% \$314 \$273	<b>-25.0%</b> \$334 \$290		Equity -35.0% \$15 \$13	Value per -30.0% \$16 \$14	Share -25.0% \$17 \$14



## **Financial statements**

Exhibit 19: Agile Therapeutics P&L 2012 to 2017E

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Agile - Income Statement (\$ in millions)	FY2012 Actual	FY2013 Actual	Mar-14	Jun-14E	Sen-14F	Dec-14E	FY2014 Est.	Mar-15E	lun-15E	Sen-15F	Dec-15E	Est.	FY2016 Est.	Est.	Comments
1. ,	Actual	Actual	IVIGIT-1-7	Juli-14E	00p-14E	DCC-14L	Lot.	Mai-10L	Juli-13L	00p-10L	DCC-13L	Lot.	LJI.	Lot.	Comments
Revenue	0.0	0.01	0.0	0.0		0.0	0.0	0.0	0.0	0.0	0.0	0.01	440	00.0	A
Twirla Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	14.8 0.0	68.0	Assume a 2H2016 launch - no generics through '22E  Pipeline potential for lifecycle and upside
														0.0	
Total revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	14.8	68.0	Each 100 bps Twirla share ~\$100M in revenue
Cost of goods sold	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	5.6	
Total gross profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	13.6	62.4	GM 90-92% - no royalty commitments
Research and development (R&D)	17.4	9.2	1.4	2.0	9.5	9.1	22.0	5.0	3.0	3.0	2.0	13.0	7.0	3.9	
General and administrative (G&A)	5.9	3.6	1.1	1.1	1.3	1.3	4.8	1.2	1.2	1.2	1.2	4.9	5.1	5.2	Should be relatively stable
Sales and marketing (S&M)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.5	26.5	37.8	Based on 90 reps, promo, social media, ad spend
Operating income (adjusted)	(23.3)	(12.7)	(2.4)	(3.1)	(10.8)	(10.5)	(26.8)	(6.4)	(4.4)	(4.4)	(3.4)	(18.4)	(25.0)	15.5	
Interest expense & other	(0.7)	(1.5)	(0.4)	(0.2)	(0.2)	(0.1)	(0.9)	(0.1)	(0.1)	(0.1)	(0.1)	(0.4)	(0.2)	0.0	
Interest income and other income (expense)	0.2	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Total interest & other	(0.5)	(1.6)	(0.4)	(0.2)	(0.2)	(0.1)	(0.9)	(0.1)	(0.1)	(0.1)	(0.1)	(0.4)	(0.2)	0.0	
Earnings before income taxes (adj)	(23.9)	(14.3)	(2.8)	(3.3)	(11.0)	(10.5)	(27.7)	(6.4)	(4.4)	(4.4)	(3.4)	(18.8)	(25.1)	15.5	
Income tax (adjusted)	0.0	0.0	(3.7)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Net earnings to Agile	(23.9)	(14.3)	0.8	(3.3)	(11.0)	(10.5)	(27.7)	(6.4)	(4.4)	(4.4)	(3.4)	(18.8)	(25.1)	15.5	
EPS (pro-forma), diluted	(\$603.8)	(\$289.4)	\$0.01	(\$0.17)	(\$0.55)	(\$0.52)	(\$1.23)	(\$0.32)	(\$0.22)	(\$0.22)	(\$0.13)	(\$0.87)	(\$1.14)	\$0.70	
Diluted shares outstanding	0.0	0.0	9.7	20.0	20.1	20.2	17.5	20.3	20.4	20.5	25.6	21.7	22.0	22.3	
EBITDA	(23.3)	(12.7)	(2.4)	(3.1)	(10.8)	(10.4)	(26.8)	(6.3)	(4.3)	(4.3)	(3.3)	(18.4)	(25.0)	15.5	
EBITDA margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	22.8%	
Growth analysis Y-O-Y	FY2012	FY2013					FY2014					FY2015	FY2016	FY2017	
Revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	361%	We assume 2H16 launch with peak year 2021
COGS	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	400%	
Gross profit	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	358%	
Research and development (R&D)	NM	NM	NM	NM	NM	NM	140%	259%	50%	-68%	-78%	-41%	-46%	-44%	
General and administrative (G&A)	NM	NM	NM	NM	NM	NM	34%	17%	12%	-5%	-8%	3%	3%	2%	
Sales and marketing (S&M)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	5206%	43%	
Operating income (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-162%	
Net earning (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-162%	
EPS (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	
Margin analysis	FY2012	FY2013					FY2014					FY2015	FY2016	FY2017	
Gross margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	92%	92%	
R&D	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	47%	6%	R&D growth could be higher - depends on pipeline
SG&A	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	35%	8%	
Sales and marketing (S&M)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	180%	56%	
Operating income (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-169%	23%	
Interest expense	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-1%	0%	
Interest income and other income (expense)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0%	0%	
Tax rate	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0%	0%	0%	NOLs could reduce tax burden
Net earnings (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-170%	23%	



Exhibit 20: Agile Therapeutics balance sheet 2012 to 2017E

Agile - Balance Sheet	FY2012	FY2013					FY2014					FY2015	FY2016	FY2017	FY2018	Comments
(\$ in millions)	Actual	Actual	Mar-14	Jun-14E	Sep-14E	Dec-14E	Est.	Mar-15E	Jun-15E	Sep-15E	Dec-15E	Est.	Est.	Est.	Est.	
Assets																
Cash and cash equivalents	20.0	2.1	3.0	51.5	40.2	29.4	29.4	17.4	12.7	8.0	42.6	42.6	10.3	20.6	70.8	We assume a cash raise in 4Q2015E
Investment securities	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Total cash & marketable	20.0	2.1	3.0	51.5	40.2	29.4	29.4	17.4	12.7	8.0	42.6	42.6	10.3	20.6	70.8	
Prepaid expenses and other assets	0.3	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.7	3.4	
Total current assets	20.3	2.3	3.1	51.6	40.3	29.5	29.5	17.5	12.8	8.1	42.7	42.7	10.3	21.4	74.2	
Property, plant and equipment, net	7.0	12.0	12.0	12.3	12.6	12.9	12.9	13.1	13.4	13.7	14.0	14.0	15.5	16.9	18.4	
Deferred financing costs, net	0.2	0.2	0.1	6.0	6.0	6.0	6.0	6.0	6.0	6.0	7.6	7.6	7.6	7.6	7.6	
Other assets	0.0	0.0	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	8.0	8.0	0.8	0.8	0.8	
Total assets	27.5	14.4	16.0	70.7	59.6	49.1	49.1	37.5	33.0	28.6	65.1	65.1	34.1	46.7	100.9	
Liabilities and equity																
Accounts payable	1.1	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.4	2.0	3.6	
Accrued expenses	0.4	0.4	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.7	3.4	6.0	
Loan payable, ST	0.0	5.1	5.7	8.7	8.7	8.7	8.7	3.5	3.5	3.5	3.5	3.5	0.0	0.0	0.0	
Warrant liability	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	
Other current liabilities	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Total current liabilities	2.1	6.8	7.9	10.9	10.9	10.9	10.9	5.7	5.7	5.7	5.7	5.7	1.9	6.1	10.2	
Deferred rent	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Loan payable, LT	14.8	9.8	9.2	9.2	9.2	9.2	9.2	9.2	9.2	9.2	9.2	9.2	7.2	(0.0)	(0.0)	Oxford Term Loan \$15M
Series A-1 8% non-conv pref stock	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	
Series A-2 conv pref stock	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
Series B 8% conv pref stock	44.9	44.9	44.9	44.9	44.9	44.9	44.9	44.9	44.9	44.9	44.9	44.9	44.9	44.9	44.9	
Series C 12% conv pref stock	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9	
Total liabilities	86.1	85.8	86.3	89.3	89.3	89.3	89.3	84.1	84.1	84.1	84.1	84.1	78.2	75.3	79.4	
Common stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Additional paid-in capital	45.4	46.9	47.2	102.2	102.2	102.2	102.2	102.2	102.2	102.2	142.2	142.2	142.2	142.2	142.2	
Retained earnings	(104.0)	(118.3)	(117.5)	(120.8)	(131.8)	(142.4)	(142.4)	(148.8)	(153.3)	(157.7)	(161.2)	(161.2)	(186.3)	(170.8)	(120.7)	
Shareholders' equity	(58.6)	(71.4)	(70.3)	(18.6)	(29.6)	(40.2)	(40.2)	(46.6)	(51.1)	(55.5)	(19.0)	(19.0)	(44.1)	(28.6)	21.5	
Total liabilities and equity	27.5	14.4	16.0	70.7	59.6	49.1	49.1	37.5	33.0	28.6	65.1	65.1	34.1	46.7	100.9	
Total habilities and equity	21.3	17.4	10.0	70.7	33.0	70.1	73.1	37.3	33.0	20.0	00.1	00.1	J7.1	70.7	100.9	



Exhibit 21: Agile Therapeutics cash flow 2012 to 2017E

	FY2012	FY2013					FY2014					FY2015	FY2016	FY2017	FY2018	Comments
Agile - Statement of Cash Flows	Actual	Actual	Mar-14	Jun-14E	Sep-14E	Dec-14E	Est.	Mar-15E	Jun-15E S	ep-15E [	Dec-15E	Est.	Est.	Est.	Est.	
Net earnings	(23.3)	(14.3)	0.8	(3.3)	(11.0)	(10.5)	(24.0)	(6.4)	(4.4)	(4.4)	(3.4)	(18.8)	(25.1)	15.5	50.1	
Non-cash items included in net earnings	0.6	1.6	0.3	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Depreciation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Stock bonus	0.0	0.1	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Stock-based compensation	0.7	1.3	0.2	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Interest	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Change FV warrants	(0.2)	0.1	(0.0)	0.0	0.0	0.0	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Other non-cash items	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Changes in working capital	(0.3)	(0.3)	(0.2)	0.0	0.0	0.0	(0.2)	0.0	0.0	0.0	0.0	0.0	(0.2)	3.5	1.5	
Prepaid expenses and other assets	(0.0)	0.1	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1	(0.7)	(2.7)	
Accounts payable and accrued exp	(0.3)	(0.4)	(0.3)	0.0	0.0	0.0	(0.3)	0.0	0.0	0.0	0.0	0.0	(0.3)	1.6	1.5	
Other assets	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(0.1)	2.7	2.6	
Cash from operations	(23.0)	(13.0)	0.9	(3.3)	(11.0)	(10.5)	(23.9)	(6.4)	(4.4)	(4.4)	(3.4)	(18.8)	(25.3)	19.1	51.6	
Capital expenditures	(6.7)	(4.9)	(0.0)	(0.3)	(0.3)	(0.3)	(0.9)	(0.3)	(0.3)	(0.3)	(0.3)	(1.2)	(1.5)	(1.5)	(1.5)	
Cash used in investing	(6.7)	(4.9)	(0.0)	(0.3)	(0.3)	(0.3)	(0.9)	(0.3)	(0.3)	(0.3)	(0.3)	(1.2)	(1.5)	(1.5)	(1.5)	
Proceeds from conv bridge notes	6.0	0.0	0.0	3.0	0.0	0.0	3.0	(5.2)	0.0	0.0	0.0	(5.2)	(3.5)	0.0	0.0	
Proceeds from issuance of term loan	15.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(2.0)	(7.2)	0.0	Assumed maturity payments
Proceeds from issurance pref stock, net	19.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Cash paid for financing costs	(0.2)	0.0	(0.0)	(5.9)	0.0	0.0	(5.9)	0.0	0.0	0.0	(1.6)	(1.6)	0.0	0.0	0.0	
Proceeds from issuance of common	0.0	0.1	0.0	55.0	0.0	0.0	55.0	0.0	0.0	0.0	40.0	40.0	0.0	0.0	0.0	IPO net proceeds \$49.2 million at \$6 per share
Other items, net	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Cash from financing	40.1	0.1	(0.0)	52.2	0.0	0.0	52.1	(5.2)	0.0	0.0	38.4	33.2	(5.5)	(7.2)	0.0	
Net increase in cash	10.5	(17.9)	0.9	48.5	(11.3)	(10.8)	27.3	(11.9)	(4.7)	(4.7)	34.7	13.2	(32.3)	10.4	50.1	
Beginning cash	9.6	20.0	2.1	3.0	51.5	40.2	2.1	29.4	17.4	12.7	8.0	29.4	42.6	10.3	20.6	
Effect of exchange rate changes on cash	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Cash at year end	20.0	2.1	3.0	51.5	40.2	29.4	29.4	17.4	12.7	8.0	42.6	42.6	10.3	20.6	70.8	



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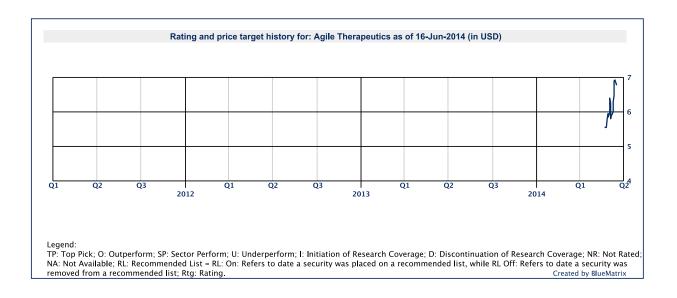
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