

# Agile Therapeutics (AGRX)

November 2020 Corporate  
Presentation

# Forward-Looking Statements

Certain information contained in this presentation and other matters discussed today or answers that may be given in response to questions may include “forward-looking statements.” We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements.

In particular, the Company’s statements regarding the market availability of Twirla®, our projected cash position, the expected effects of COVID-19 on our business and the expected timing and status of our commercialization plan for Twirla are examples of such forward-looking statements. These forward-looking statements are subject to important factors, risks and uncertainties, including, but not limited to, risks related to our ability to maintain regulatory approval of Twirla, our ability along with our third-party manufacturer, Corium, to complete successfully the scale-up of the commercial manufacturing process for Twirla, the performance and financial condition of Corium or any of its suppliers, the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully commercialize Twirla, the successful development of our sales and marketing capabilities, the accuracy of our estimates of the potential market for Twirla, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla, our strategy, business plans and focus, the effects of the COVID-19 pandemic on our operations and the operations of third parties we rely on as well as on our potential customer base, unforeseen market factors or events in our clinical, regulatory and manufacturing development plans, and other factors, including general economic conditions and regulatory developments, not within the Company’s control.

These factors could cause actual results and developments to be materially different from those expressed in or implied by such statements. These forward-looking statements are made only as of the date of this presentation and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances. For additional information about the risks and uncertainties that may affect our business please see the factors discussed in “Risk Factors” in the Company’s periodic reports filed with the SEC.



A champion for healthcare choices women deserve, headquartered in Princeton, NJ

Dedicated to building a robust Women's Health Franchise

Twirla is our first FDA-approved product & on track for commercial launch in December 2020

 <p>Twirla™ (levonorgestrel/ethinyl estradiol) 120/30 mcg/day transdermal system</p>	<p><b>Weekly Contraceptive Patch</b></p> <hr/> <p><b>\$4.1B</b> <b>Addressable Market</b></p>	
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TWIRLA is indicated as a method of contraception for use in women with a BMI < 30 kg/m<sup>2</sup> for whom a combined hormonal contraceptive is appropriate. Consider TWIRLA's reduced effectiveness in women with a BMI ≥ 25 to < 30 kg/m<sup>2</sup> before prescribing TWIRLA. TWIRLA is contraindicated in women with a BMI ≥ 30 kg/m<sup>2</sup>.

# Agile's Corporate Strategy: Become a Leader in Women's Health

**Short-Term Goal** - Establish Agile in the prescription contraceptive market with Twirla, our first FDA-approved product

**Long-Term Mission** - Broaden our women's health portfolio, including in areas of unmet medical need



Establish Agile in  
Contraceptive Market  
with Twirla

Become  
Contraceptive Market  
Leader

Broaden Women's  
Health Portfolio in  
Areas of Unmet Need

# Agile's Women's Health Mission Starts with Contraception

## WHY CONTRACEPTION?

Women use contraception for an average of 30 years, and nearly all women use contraception at some point<sup>1,2</sup>

Nearly half of pregnancies in U.S. women are unintended<sup>3</sup>

## WHY DO WOMEN NEED MORE BIRTH CONTROL OPTIONS?

Nearly half of unintended pregnancies are due to inconsistent and/or improper use of contraception<sup>4</sup>

Women's individual preferences for contraceptive methods vary and change across their lifetimes as their needs change<sup>5</sup>

Women are more consistent with contraceptive use and stay with a method for longer when using a method of their choosing<sup>4</sup>

# Nearly All US Women Will Use Contraception at Some Point in Lifetime<sup>1</sup>

Women weigh various factors when selecting a contraceptive method<sup>2</sup>

- Effectiveness
- Dose
- Hormonal vs non-hormonal methods
- Delivery route and level of invasiveness
- Frequency of administration

No single method for all women<sup>3</sup>

- Choices vary person-to-person, within a woman's reproductive years

Consistency more likely when contraceptive choice fits a woman's lifestyle<sup>4</sup>

References: 1. CDC National Survey of Family Growth 2011-2015; 2. Chen et al., 2019; 3. Mansour, 2014; 4. Grady et al., 2002

# What is Missing From Available Hormonal Birth Control Options?

*“Some women are just not good at remembering to take a pill at the same time every day...Others don’t want something in their vagina while others don’t want an injection.”*  
- Ob/Gyn

LOWER  
ESTROGEN  
DOSE

The dose of estrogen in CHCs is believed to be the primary factor contributing to unwanted side effects<sup>1</sup>  
The only other non-daily transdermal patch currently available delivers a high dose of estrogen<sup>2</sup>

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NON-  
DAILY  
OPTIONS

Potential to reduce burden associated with daily pills  
**49%** of contraception users prefer non-daily method<sup>3</sup>  
**52%** are frustrated with taking the pill daily<sup>3</sup>

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LESS  
INVASIVE  
METHODS

May be preferred by some women<sup>4</sup>  
Some women prefer to avoid injections, implants, and intrauterine devices

# Twirla Designed to Fill A Hormonal Birth Control Market Need

Twirla™



HORMONE  
PROFILE

30µg/day Ethinyl Estradiol (EE)  
120µg/day Levonorgestrel (LNG)

NON-  
DAILY

Patch Regimen: Once-a-week

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

7 days no patch

Pill Regimen: Once-a-day

SUN	MON	TUE	WED	THU	FRI	SAT
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

LESS  
INVASIVE

Less invasive than some methods  
(vaginal ring, IUDs, injections, implants)

*"I want to eliminate the forgetfulness... but I don't want to lose that control either."*

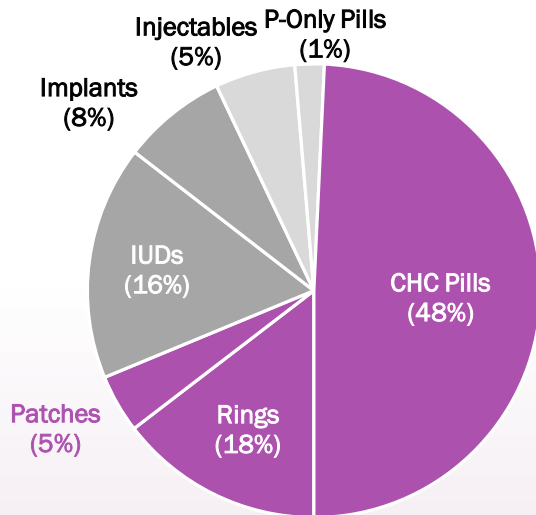
– Consumer, October 2016



# U.S. Hormonal Contraceptive Market is a Significant Opportunity

\$5.7 Billion U.S. Contraceptive Market (2019 Estimates)

Combined Hormonal Contraception (CHC)	Progestin-Only (P-Only)	Long Acting Reversible Contraception (LARC)
CHC Pill, Ring, Patch	P-only Pill, Injection	IUD, Implant
<b>\$4.1 Billion</b>	\$300 Million	\$1.3 Billion



CHC Pills + Ring + Patch =  
**\$4.1 Billion**  
 Potential Addressable Market for  
 Twirla™

**Twirla WAC of \$159.75**  
 vs Top-16 branded CHC products of approximately \$169 avg. per unit or month of contraception

# Twirla has the Potential for Significant Market Share

Peak TRx Share Estimate Based on Consumer & Physician Market Research and Market Analogs

HCP Market Research (% CHC Market TRx)		
Study Year	Stated Share	Calibrated for Overstatement
2019	20%	14%
2016	23%	14%

Consumers “Extremely Likely” to Ask for Twirla

15%

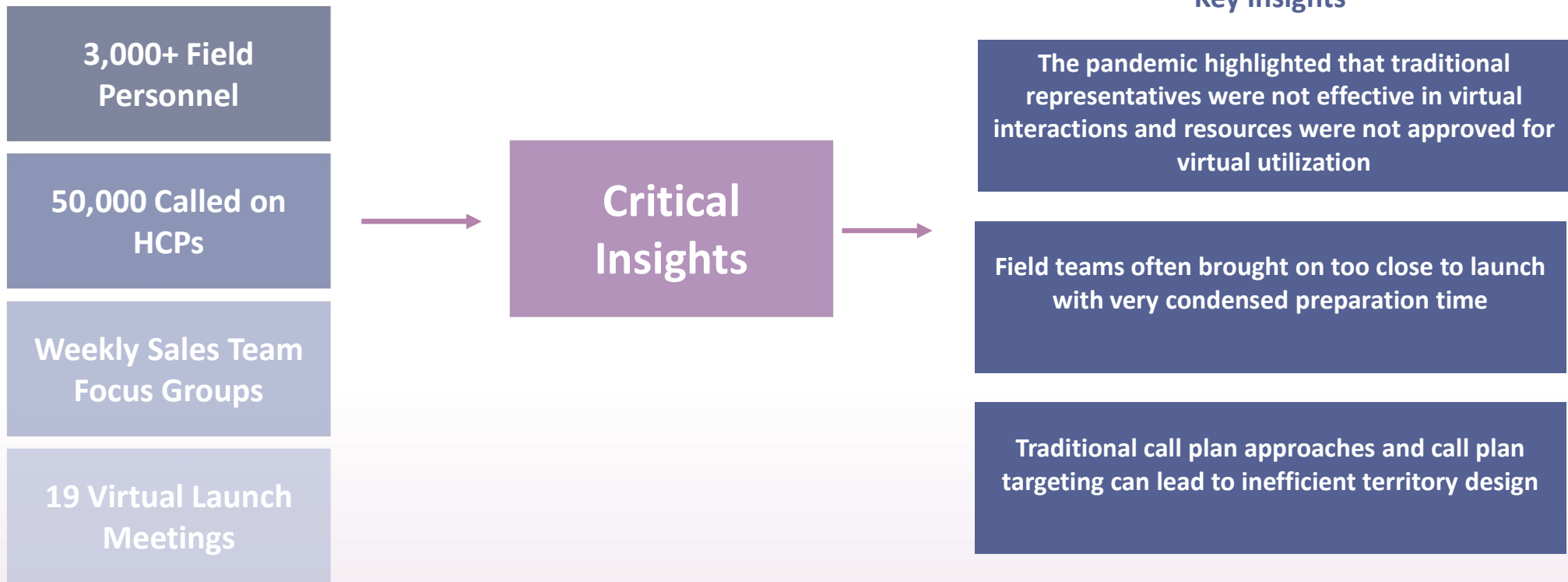
Average of Analog Brands

9.6%



\* Will continue to analyze market and update market research based on approved labeling

# Partnership with Syneos Provides Ability to Launch with an Insight-Driven Innovative Sales Approach

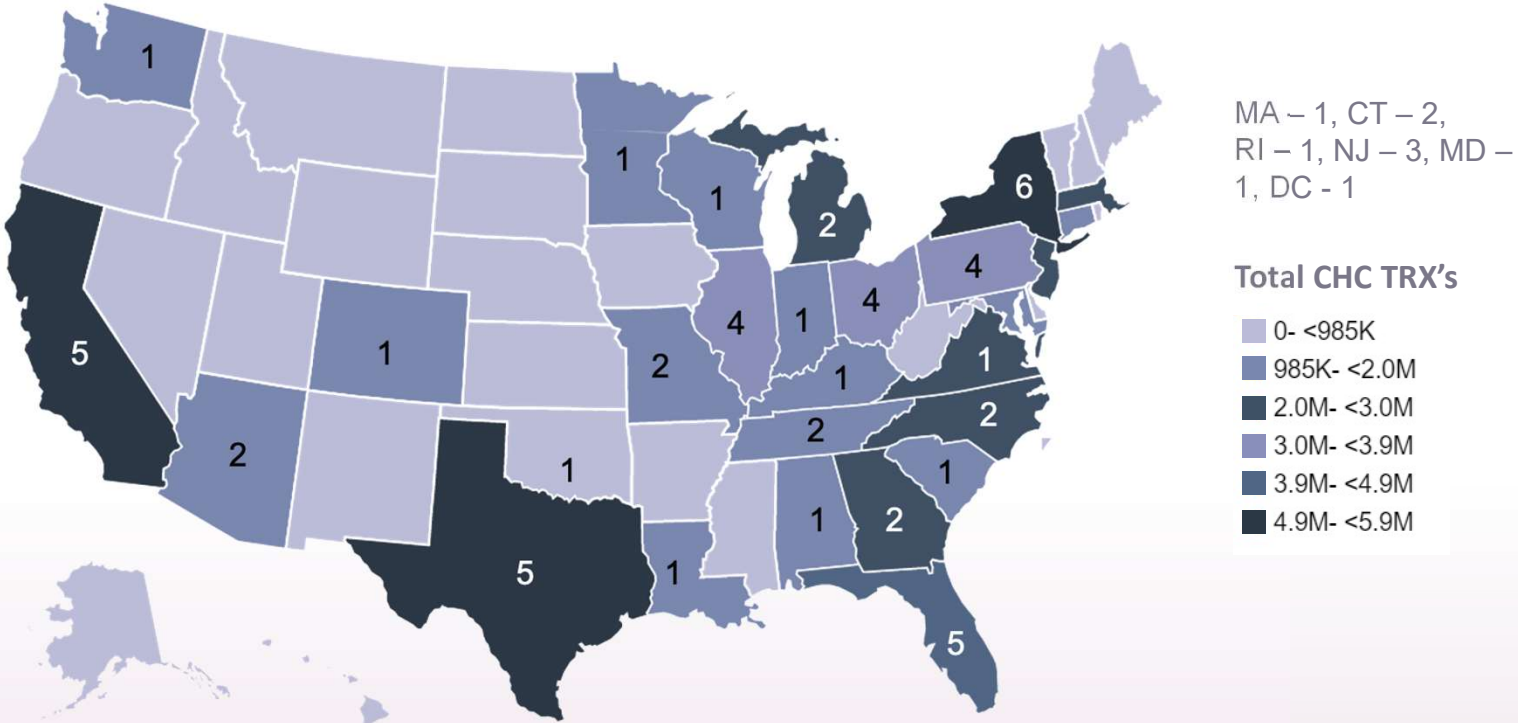


# Partnership with Syneos Provides Ability to Launch with an Insight-Driven Innovative Sales Approach

<p><b>Key Insights</b></p>	<p>The pandemic highlighted that traditional representatives were not effective in virtual interactions and resources were not approved for virtual utilization</p>	<p>Field teams often brought on too close to launch with very condensed preparation time</p>	<p>Traditional call plan approaches and call plan targeting can lead to Inefficient territory design</p>
<p><b>Strategies</b></p>	<ul style="list-style-type: none"> <li>• New Recruiting Profile: effective virtual interaction</li> <li>• Enhanced training on effective virtual interactions</li> <li>• All materials approved for virtual/F2F interactions</li> <li>• Upgraded technology for virtual interactions</li> </ul>	<ul style="list-style-type: none"> <li>• Leadership team hired/engaged early. Field teams hired/trained/engaged several months prior to launch in mid-October</li> <li>• Territories/targets profiled to understand office protocols/COVID-19 policies/appointments secured</li> <li>• 8-week virtual training program: best in class clinical knowledge, virtual selling skills, competitive/reimbursement landscape understanding</li> </ul>	<ul style="list-style-type: none"> <li>• Targeting based on office decile vs individual HCP's</li> <li>• Virtual representatives aligned/reporting to region leaders with aligned goals/incentives</li> <li>• Region Sales Leaders empowered to allocate resources to ensure most effective coverage within geographies</li> </ul>

# 65 Sales Professionals Aligned to Highest-Volume Geographies and Target Provider Offices

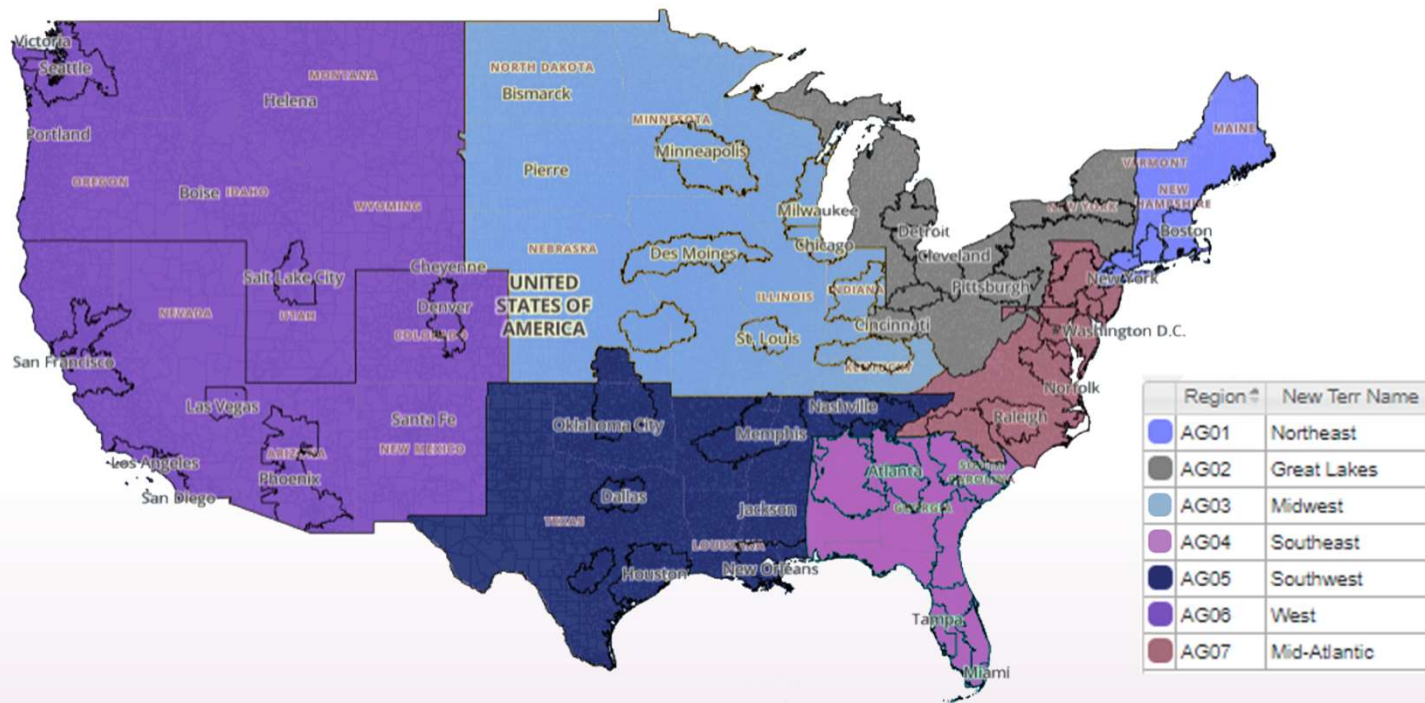
(CHC Market 12 Months Ending December 2019)



Source: Symphony Health Metys

# In Addition, 8 Virtual Sales Professionals Aligned to Sales Leaders to Drive Region Success

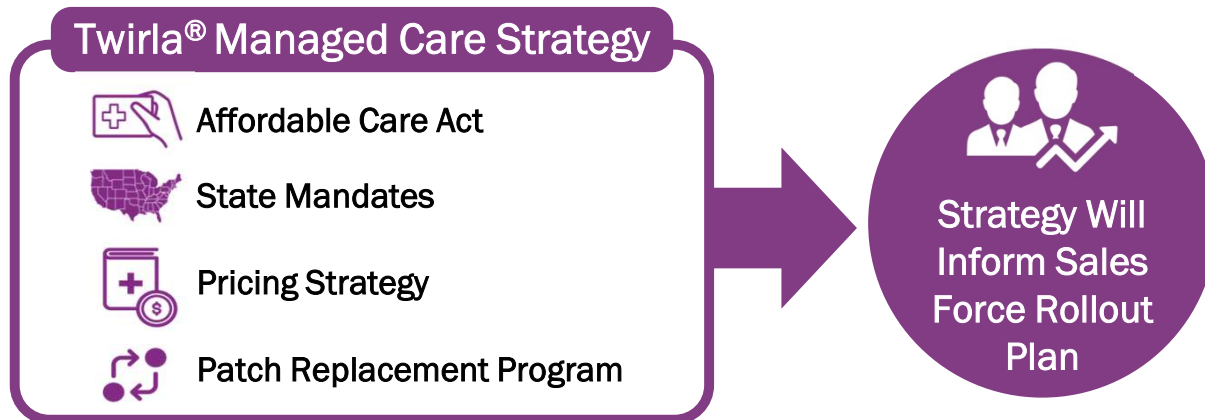
One virtual representative per region except for the West, which has 2 virtual representatives



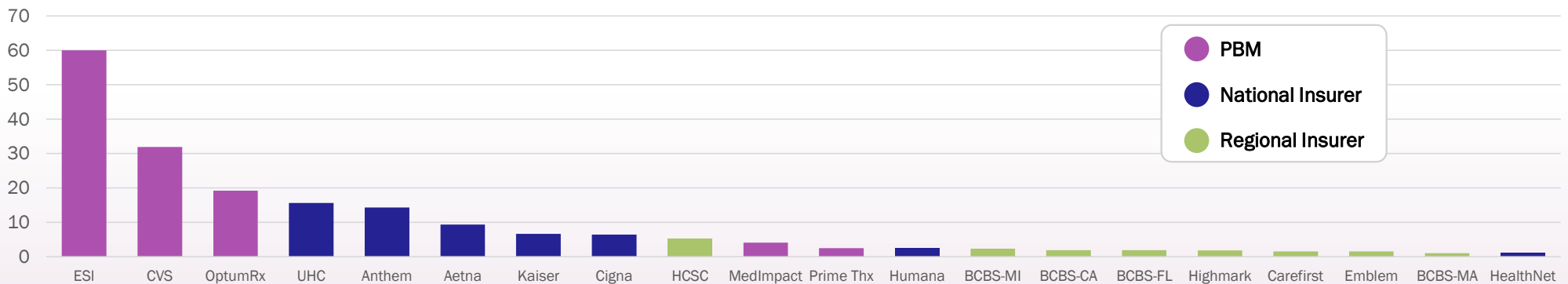
# Strong Sales Team with Deep Experience and Commitment to Success

Experience	National Sales Leader	Region Leaders	Region Virtual Representatives	Territory Representatives
Pharmaceutical Industry	34 years	AVG 16 years	AVG 25.3 years	AVG 9.5 years
Leadership	30 years	AVG 17.2 years		
Women's Health	18 years	AVG 8.2 years	AVG 8.1 years	AVG 4.8 years
Launch	>15 launches	>60 launches	90% with a minimum of one launch	>85% with a minimum of one launch

# Managed Care Strategy: Minimize Access Barriers



Top 20 Commercial Payers (MM Lives)

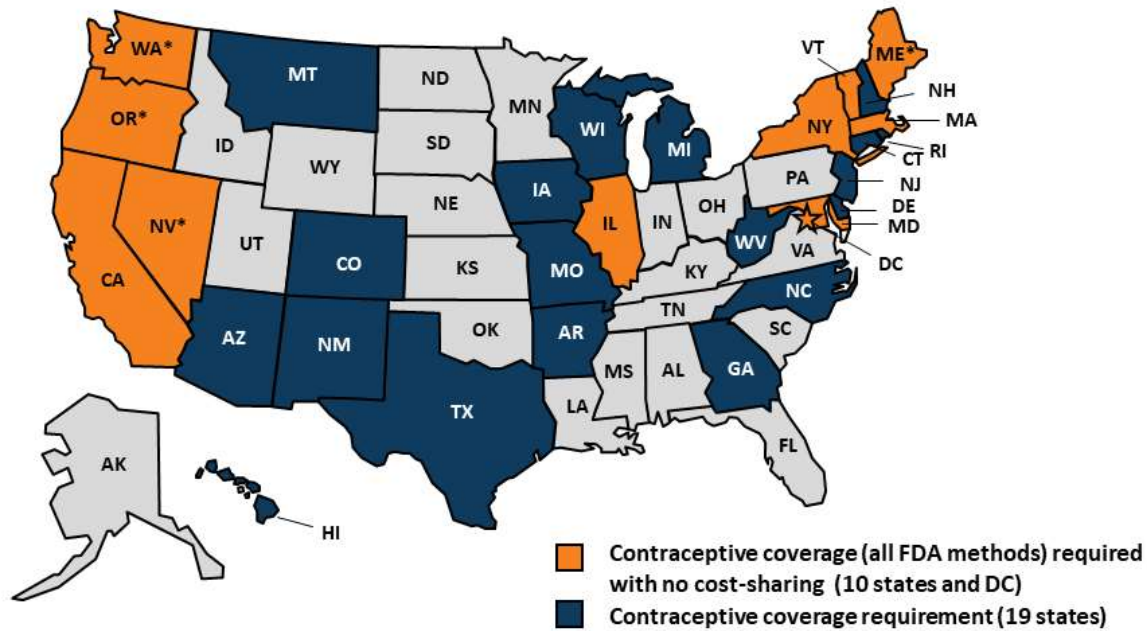




# Partnership with Ashfield Market Access to Support Reimbursement Strategies and Execution

- Contraceptive class behaves differently than most other categories as a result of contraceptive mandates at both the federal and state levels
- A limited number of PBMs and their associated health plans control the majority of prescriptions for contraception
- Limited management within the category, however each PBM/plan has its own processes and policies in place related to timing of formulary reviews for new products
  - Approximately 90-180 days from product availability to review

# Ten States Require Contraceptive Coverage of All FDA Methods and Prohibit Restrictions and Delays



NOTES: \*ME, OR, and WA laws go into effect January 2019.  
SOURCE: Kaiser Family Foundation, [State Requirements for Insurance Coverage of Contraceptives](#), State Health Facts, as of March 21, 2018.  
\*\*\* Texas Insurance Code Section [1369.004](#)



Source: Kaiser Family Foundation State Health Facts

# Minimize Access Barriers for Patients and Providers by Obtaining Rapid Formulary Positions (\$0 Co-Pay)

- Current negotiations underway with all key PBMs/health plans to secure rapid formulary reviews
- Target goals:
  - 40-50% formulary access at/near launch
  - 85% formulary access by end of 2021
- Market access support at launch
  - Education and third-party support to assist HCPs with immediate submission of medical need requests for no-cost coverage
  - Co-Pay card reimbursement assistance for limited/no out-of-pocket costs
  - Full-month sample supplies for patient trial

# Critical Customer Insights: Patient



**Her life is full by design** and she desires a birth control method that enables her to remain active and on-the-go.

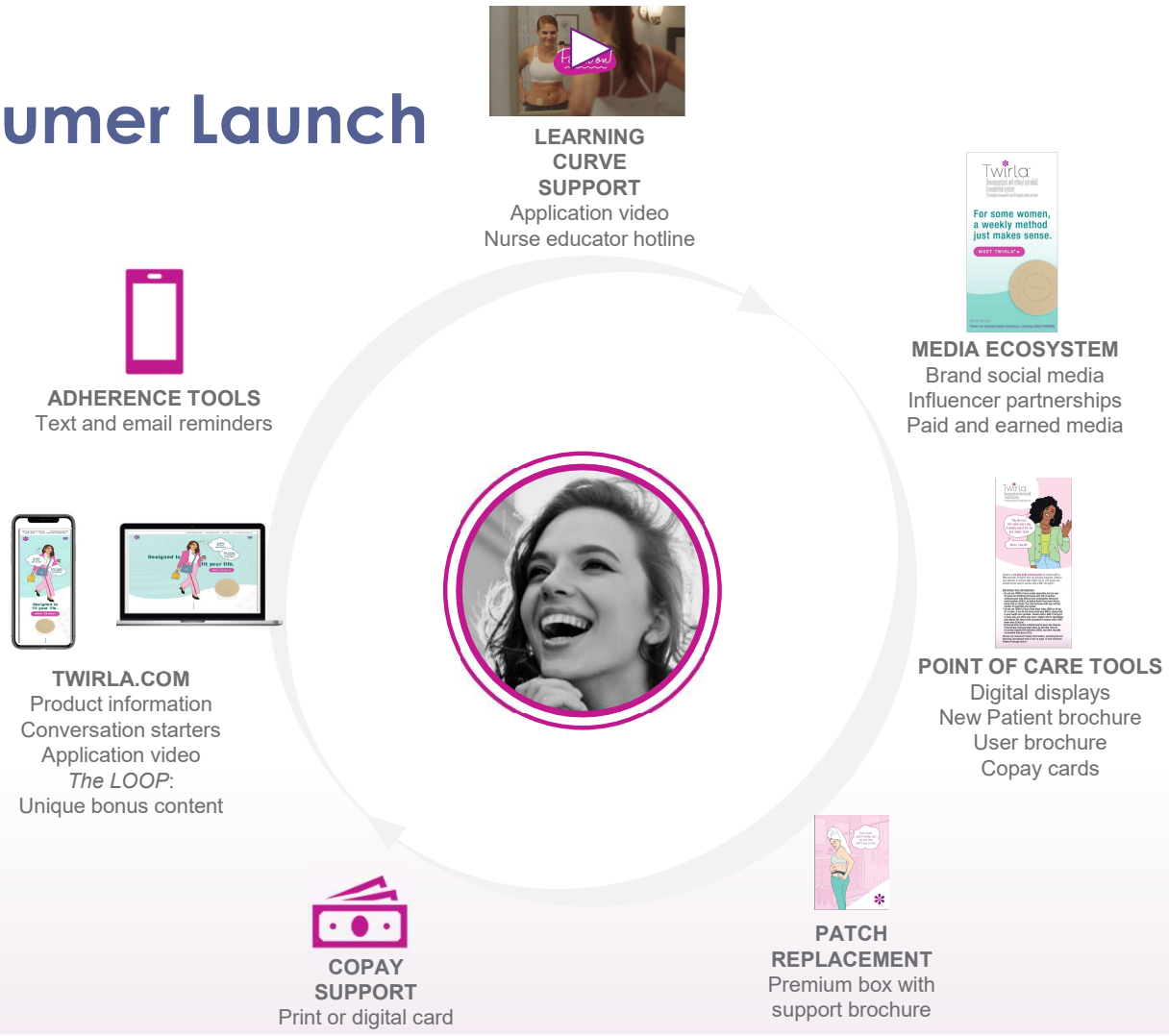


**She has birth control discussions with her trusted friends** — a key source for her information about various methods and side effects.

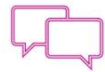


She is hindered by the **same-time-every-day pill burden** and **finds invasive methods unsettling**.

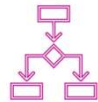
# 360° Consumer Launch



# Critical Customer Insights: HCP



**OB/GYNs and NPs/PAs invest significant time into contraceptive counseling** to inform patient shared decision-making approach.



**There is a “method gap” between OCPs and LARCs** where Twirla can fit in.



**The TWIRLA clinical trial design and diverse study population help overcome historic “Patch Baggage”** and skepticism because they allow them to provide representative data to more of their patients (including “overweight” women).

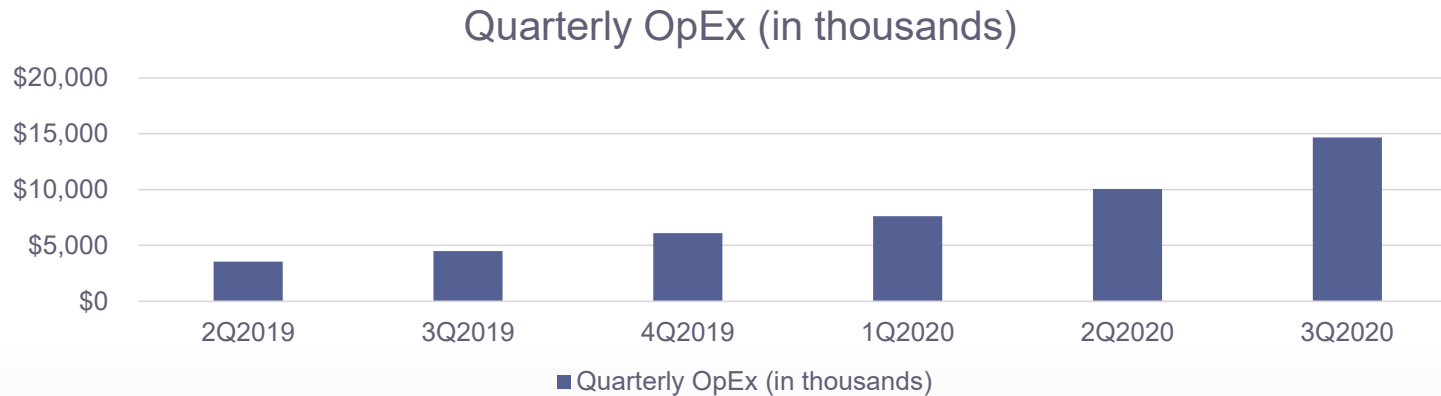
# HCP Flexible and Adaptable Launch



# AGRX 2020 Financial Guidance

## Operating Expenses

- As of November 6, 2020, The Company narrowed its operating expense guidance for the full year 2020 to be in the range of \$52 million to \$54 million, with general and administrative expenses accounting for approximately 70% of the spending as we build out our commercial infrastructure. The Company's operating expenses guidance includes \$2.7 million to \$3 million of non-cash stock compensation expense.



## 2020 Revenue

- The Company expects its gross revenue in the fourth quarter of 2020, reflecting expectations of initial stocking of Twirla by wholesalers, to be approximately \$1 million.



# Access to Capital/Cash Guidance – Reaffirm

The Company believes its \$71.9 million of cash, cash equivalents, and marketable securities as of September 30, 2020 will be sufficient to meet its projected operating requirements through the end of 2021



PERCEPTIVE  
ADVISORS  
DEBT  
FACILITY

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## **\$35.0 Million debt facility signed February 10, 2020**

- \$20 million disbursed
  - \$5 million in proceeds at signing
  - \$15 million in proceeds at Twirla® approval
- Additional \$15 million potentially available in 2021



SHARES  
OUTSTANDING

- 
- Approximately 87.4 million common shares outstanding at November 6, 2020
  - The Company filed a new universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, and debt securities

# Strategy To Enhance Shareholder Value

The Company believes that building a U.S. women's health franchise on the foundation of Twirla's commercial success can enhance the value for our shareholders. A successful launch of Twirla is our primary focus.

- Reevaluation and potential development of our internal pipeline candidates will commence in 2021
- We are open to potentially acquiring news assets to expand our reach in women's health

We have sought out and will continue to explore partnerships and opportunities that leverage our existing infrastructure:

- Co-promotion within the U.S.
- Partnerships outside of the U.S.
- Any other opportunities that will enhance shareholder value

# Deep Management Experience

<b>Al Altomari</b>	Chairman & Chief Executive Officer	 <b>Barrier Therapeutics, Inc.</b>	
<b>Dennis Reilly</b>	Senior Vice President & Chief Financial Officer	 <b>INVISIBLE SENTINEL</b> A BIOMERIEUX COMPANY	 <b>NEOSTRATA</b>  <b>Barrier Therapeutics, Inc.</b>
<b>Amy Welsh</b>	Vice President of Marketing	 <b>antares</b> pharma	 <b>AstraZeneca</b>
<b>Kimberly Whelan</b>	Vice President of Market Access		
<b>Keith Fromelt</b>	Vice President of Supply Chain		
<b>Geoffrey Gilmore</b>	Senior Vice President, General Counsel & Corporate Secretary	 <b>Amicus</b> Therapeutics	
<b>Robert Conway</b>	Senior Vice President and Chief Supply Chain Officer		
<b>Tristen Herrstrom</b>	Vice President of HR & Administration	 <b>CERTARA</b> Implementing Translational Science	
<b>Terry Herring</b>	National Sales Leader (Syneos/InVentiv)	 <b>Mission</b> PHARMACAL	 <b>NOVEN</b> PHARMACEUTICALS, INC.
<b>Paul Korner, MD, MBA</b>	Chief Medical Officer	 <b>SOLVAY</b>	 <b>Wyeth</b>  <b>BAYER</b>  <b>FERRING</b> PHARMACEUTICALS

# Continue To Follow Along

## Agile Therapeutics

- Website: [www.agiletherapeutics.com](http://www.agiletherapeutics.com)
- Twitter: @AgileTher
- LinkedIn: @Agile Therapeutics

## Investor Contact

- Matt Riley
- Head of Investor Relations & Corporate Communications
- [mriley@agiletherapeutics.com](mailto:mriley@agiletherapeutics.com)

## Twirla

- Website: [www.twirla.com](http://www.twirla.com)
- Instagram: Coming Soon
- Facebook: Coming Soon

## I'm So Done

- Website: [www.BirthControlDoneMyWay.com](http://www.BirthControlDoneMyWay.com)
- Instagram: @SoDoneClub
- Facebook: @SoDoneClub