



darébioscience

Daré Bioscience, Inc. 3Q2023 Earnings Call

November 9, 2023; 4:30pm EST

DARÉ

IN ITALIAN, IT MEANS "TO GIVE."

IN ENGLISH, IT MEANS "TO BE BOLD."



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Advancing Products Women Want and Need

How Daré Creates Value

- **Innovative women's health pipeline** with multiple upcoming program milestones anticipated.
- Every program, if approved, represents a potential **first-line or first-in-category** product opportunity.
- **Demonstrated success in clinical and non-clinical development**, regulatory affairs, corporate strategy and strategic partnerships.
 - 7 successful Phase 1 through Phase 3 studies across multiple candidates, one FDA approval, two pharma commercial collaborations

Commercialization Collaborations with Leading Companies in Women's Health




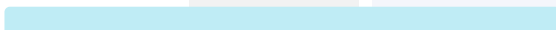
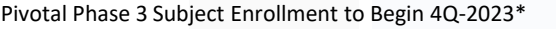

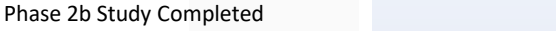
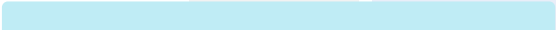
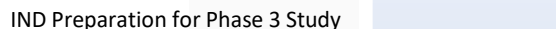

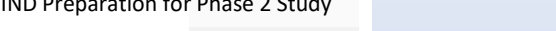

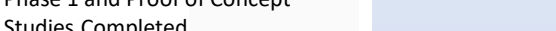


Examples of emerging and large pharmaceutical companies with branded women's health products.



GEDEON RICHTER LTD.

Advancing First-Line or First-in-Category Products – The Portfolio Snapshot*

Collaborators		PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL	REGULATORY SUBMISSION	FDA APPROVED	Updates
	XACIATO™ NDA Approved							First commercial milestone achieved October 2023
	Ovaprene® Hormone-Free, Monthly Contraception Pivotal Phase 3 Study IDE approved							On track for pivotal Phase 3 enrollment in 4Q*
	Sildenafil Cream, 3.6% ^ Female Sexual Arousal Disorder Topline Data Announced June 2023							Additional analyses of Phase 2b RESPOND study data support co-primary endpoint structure and broader population (FSAD/FSIAD) for the Phase 3 pivotal study; on track for end-of-Phase 2 meeting with FDA by end of year
	DARE-HRT₁ ^ Menopausal Hormone Therapy							IND related activities for DARE-HRT ₁ to support Phase 3
	DARE-VVA₁ ^ Vulvovaginal Atrophy						IND related activities for DARE-VVA ₁ to support Phase 2	
	DARE-CIN (formerly R-131-2) ^ Cervical Intraepithelial Neoplasia (CIN)						Phase 1 and Proof of Concept Studies Completed	

^505(b)(2) regulatory pathway anticipated

* Anticipated timing

XACIATO is indicated for the treatment of bacterial vaginosis in females 12 years and older.

See Full Prescribing Information for the safe and effective use of XACIATO.

See XACIATO selected safety information on slide 14

Sildenafil Cream, 3.6%

Late-Stage Program

Sexual Health

Sildenafil Cream, 3.6% (FSAD/FSIAD)

- **Potential first-in-category** treatment for female sexual arousal disorder (FSAD) and/or female sexual interest/arousal disorder (FSIAD).
- Investigational cream formulation of sildenafil, **the active ingredient in Viagra®**, for topical administration to treat FSAD/FSIAD.
- **Female Sexual Arousal Disorder (FSAD)** is characterized primarily by inability to attain or maintain sufficient genital arousal during sexual activity.¹
 - Of the various types of female sexual dysfunction disorders, FSAD is most analogous to erectile dysfunction in men.
- **Female Sexual Interest/Arousal Disorder (FSIAD)** is defined in the DSM-5 as a lack of or significantly reduced sexual interest/arousal.¹ There are currently no FDA-approved treatments.

Recent Highlights

- **Data from additional analyses support replicating our Phase 2b approach for pivotal Phase 3 study**
 - Propose advancing Phase 2b co-primary endpoint assessing arousal sensation, and items from the other co-primary endpoint scale evaluating concern related to difficulties with sexual arousal
 - Propose advancing selected Phase 2b patient population which includes women with FSAD, as well as women with FSIAD, with primary complaint of arousal dysfunction
- **On track for end-of-Phase 2 Meeting with FDA this year***

* Anticipated timing

1. Diagnostic and Statistical Manual (DSM) 4th Edition Text Revision (DSM IV TR) defines FSAD as a persistent or recurrent inability to attain or to maintain until completion of the sexual activity, an adequate lubrication-swelling response of sexual excitement. The diagnostic criteria also state that the inability causes marked distress or interpersonal difficulty, is not better accounted for by another Axis I disorder (except another sexual dysfunction) and is not due exclusively to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition. As described in the fifth edition of the DSM (DSM 5), which was published in 2013, FSIAD is characterized as lack of, or significantly reduced, sexual interest and/or arousal for at least six months and the symptoms must be severe enough to cause clinically significant distress. Patients could meet the DSM 5 criteria for FSIAD if they predominantly have symptoms of low sexual interest, if they predominantly have symptoms of low sexual arousal, or if they predominantly have symptoms of both low sexual desire and low sexual arousal.

Ovaprene®

Late-Stage Program

Contraception

Ovaprene® *Collaborator & Grant funding*  
Investigational Hormone-Free, Monthly Contraceptive
Pivotal Phase 3 Study to Commence 2023*

Potential first-in-category hormone-free contraception

- Self-administered intravaginal drug/device.
- Designed to be an easy-to-use monthly option with effectiveness approaching hormonal methods. There are currently no FDA-approved monthly, hormone-free contraceptives.
- Commercial license agreement with Bayer. Pivotal study collaboration with NICHD.

Recent Highlights

- Continued progress toward patient enrollment for the anticipated start of our pivotal Phase 3 study.
 - Multi-center, single arm, non-comparative, pivotal Phase 3 contraceptive study to evaluate Ovaprene's effectiveness as a contraceptive device along with its safety and usability.
 - On track to start enrolling patients in this fourth quarter of 2023.*
- Based on our communications to date with the FDA, if successful, we believe **only this single registration study will be required to support a premarket approval** application submission with the FDA.

XACIATO™ (Clindamycin Phosphate) Vaginal Gel 2%



Commercialization Collaborator

FDA Approved – XACIATO

- XACIATO [zah-she-AH-toe] (clindamycin phosphate) vaginal gel 2% is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis (BV) in females 12 years of age and older*
- **Daré's first FDA-approved product**
- Organon leveraging the knowledge and experience of its established NEXPLANON sales team to accelerate XACIATO uptake.
- Organon believes there is roughly a 95% overlap of those healthcare providers who prescribe NEXPLANON and who diagnose and treat BV. Because of the strong relationships the sales team has with these providers, we expect Organon to be well-positioned to inform them about XACIATO, ultimately providing benefits to patients.

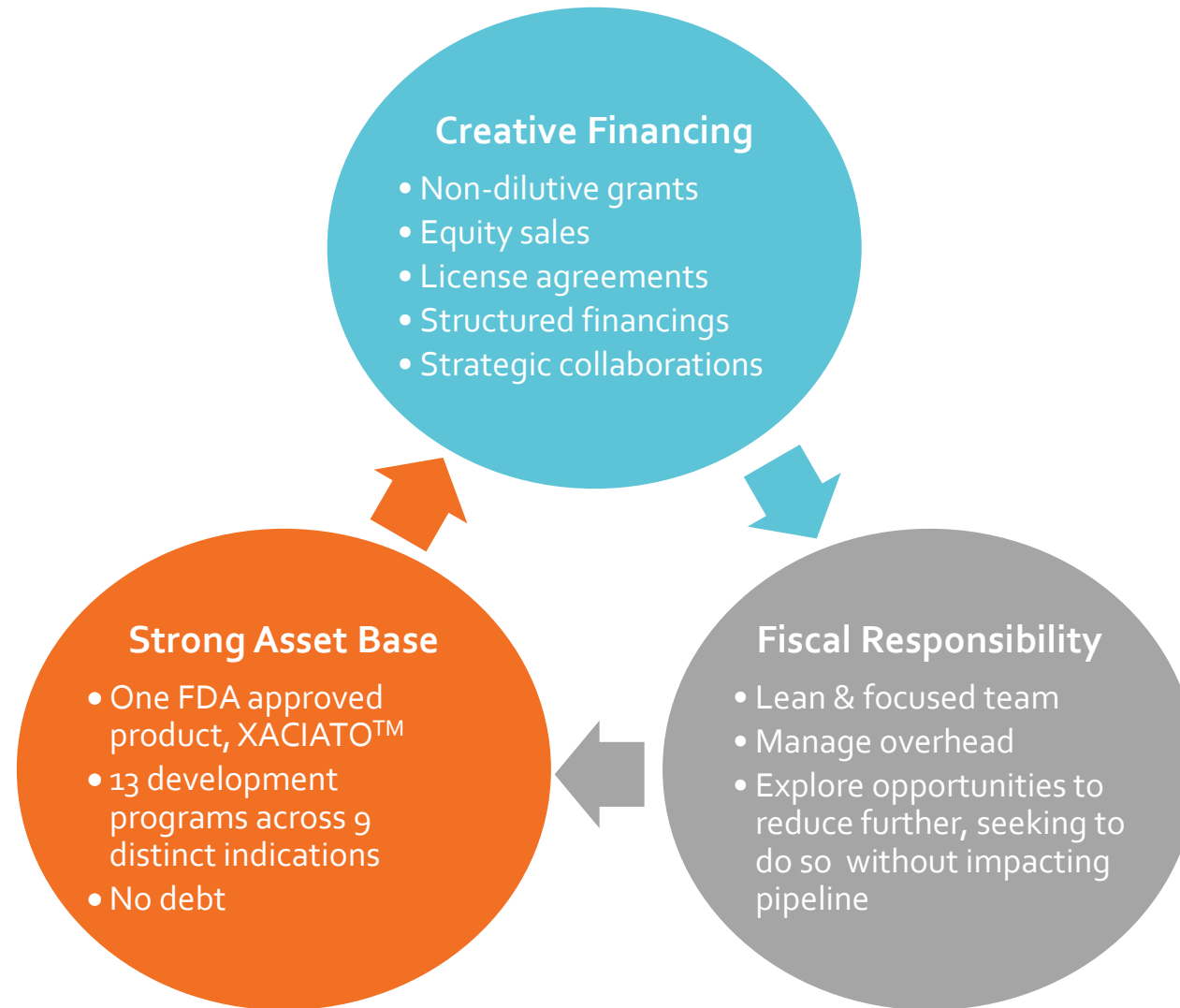
Recent Highlights

- **\$1.0 million milestone received July 2023**
- **\$1.8 million first commercial milestone achieved October 2023**
- Eligible to receive **tiered double-digit royalties** and potential milestone payments of **up to \$180 million**

*In less than five years since licensing the technology, Daré advanced a **pivotal clinical trial**, gained **FDA approval**, and **ensured product supply** to support the U.S. launch of **XACIATO***

*See Full Prescribing Information for the safe and effective use of XACIATO.
See XACIATO selected safety information on slide 14.

Focused on Driving Long-Term Shareholder Value



Executing on our mission to accelerate innovative treatments that women want and need

What to Expect for Remainder of 2023*

- **XACIATO™**: Receipt of \$1.8 million triggered by achievement of first commercial milestone under license agreement with Organon.
- **Ovaprene®**: Commencement of pivotal Phase 3 contraceptive efficacy study.
- **Sildenafil Cream, 3.6%**: End-of-Phase 2 meeting with FDA.
- **DARE-PDM1**: Phase 1 clinical study topline data.

Appendix

FSAD/FSIAD – The Clinical Issue & Prevalence

- **Female Sexual Arousal Disorder (FSAD)** is characterized primarily by inability to attain or maintain sufficient genital arousal during sexual activity.¹
 - Of the various types of female sexual dysfunction disorders, FSAD is most analogous to erectile dysfunction in men.
- **Female Sexual Interest/Arousal Disorder (FSIAD)** is defined in the DSM-5 as lack of, or significantly reduced, sexual interest/arousal.¹
- Arousal disorders in women should be distinguished from a general loss of interest in sexual activity and from other sexual dysfunctions, such as orgasmic disorder (anorgasmia) and hypoactive sexual desire disorder (HSDD), which is characterized in DSM-IV-TR as lack or absence of sexual fantasies and desire for sexual activity for some period of time.^{2,3}
- Meta-analysis of 95 studies from 2000-2014 indicated prevalence of Female Sexual Dysfunction in premenopausal women worldwide is 41%, and difficulty with arousal alone is 23%.⁴
- Market research estimates:
 - 33% of US women aged 21 to 60 (~ 20 million women), experience symptoms of low or no sexual arousal.^{5,6}
 - 10 million women are considered distressed and actively seeking treatment.⁵

There are no FDA-approved treatments for FSAD/FSIAD

1. Diagnostic and Statistical Manual (DSM) 4th Edition Text Revision (DSM IV TR) defines FSAD as a persistent or recurrent inability to attain or to maintain until completion of the sexual activity, an adequate lubrication-swelling response of sexual excitement. The diagnostic criteria also state that the inability causes marked distress or interpersonal difficulty, is not better accounted for by another Axis I disorder (except another sexual dysfunction) and is not due exclusively to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition. As described in the fifth edition of the DSM (DSM 5), which was published in 2013, FSIAD is characterized as lack of, or significantly reduced, sexual interest and/or arousal for at least six months and the symptoms must be severe enough to cause clinically significant distress. Patients could meet the DSM 5 criteria for FSIAD if they predominantly have symptoms of low sexual interest, if they predominantly have symptoms of low sexual arousal, or if they predominantly have symptoms of both low sexual desire and low sexual arousal.

2. <https://labs.la.utexas.edu/mestonlab/female-sexual-interestarousal-disorders/>, accessed 8 August 2023

3. <https://my.clevelandclinic.org/health/diseases/24640-anorgasmia>, accessed 8 August 2023

4. McCool et al. Sex Med Rev 2016;4:197-212. DOI: 10.1016/j.sxmr.2016.03.002

5. Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC.

6. Based on US Census projections for 2016.

Contraception: Large Market Opportunity

Women in the Reproductive Health & Contraception Market Segment
(over 60 million women)

Population of women 15-44 years by age: US, 2020

Age (years)	US (Percent)	US (Count)
15-19 yrs	15.9	10,266,332
20-29 yrs	34.0	21,918,026
30-39 yrs	34.3	22,159,866
40-44 yrs	15.8	10,199,608
Total	100.0	64,543,832

Sources: US Census Bureau.
Population estimates based on bridged race categories released by the National Center for Health Statistics.
Retrieved June 15, 2023, from www.marchofdimes.org/peristats.

Successful Contraceptive Brands Peak Sales:



- Mirena® Hormone IUD**
(levonorgestrel-releasing intrauterine system) 52mg.
- Physician inserted, long-acting, low/locally delivered hormone IUS
 - **2020 worldwide sales: €1.2 billion (Bayer)**¹



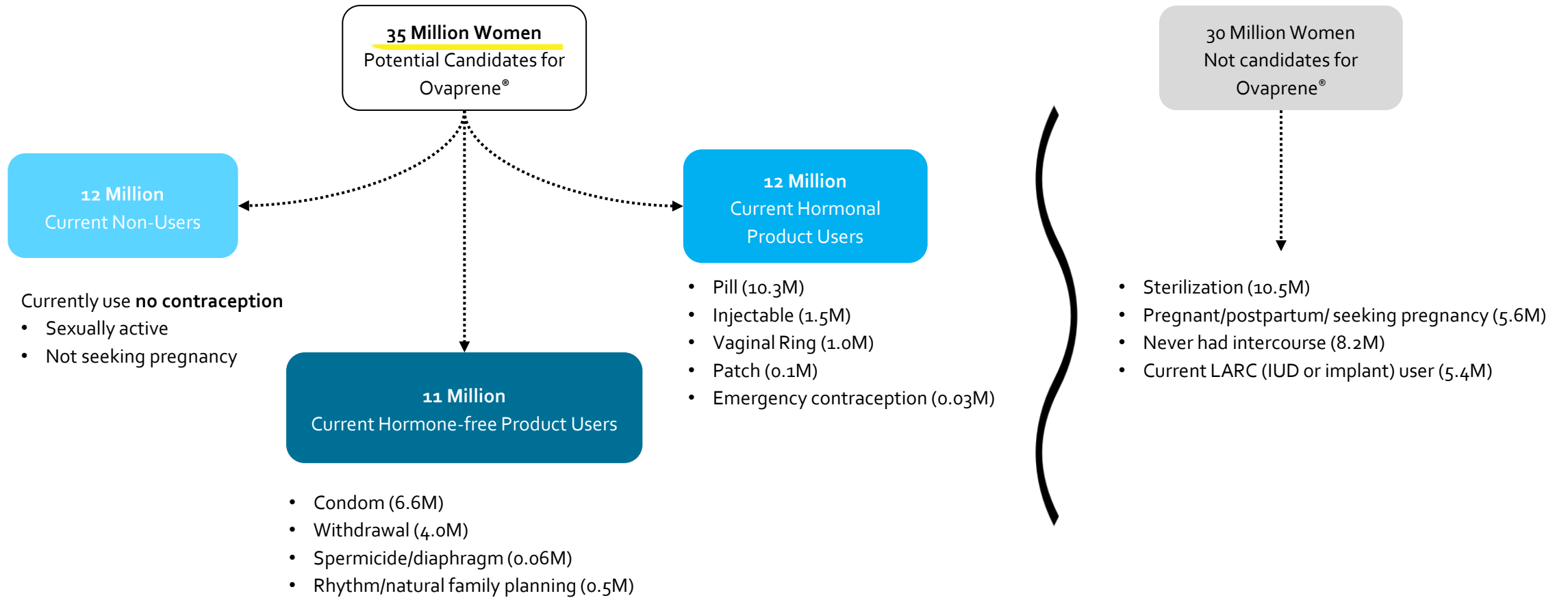
- Lo Loestrin®**
(norethindrone acetate and ethinyl estradiol, ethinyl estradiol tablets)
- Lowest amount of daily estrogen (10 micrograms) available in pill form
 - **2019 US sales: \$588 million (Allergan)**²



- NuvaRing®**
(etonogestrel/ethinyl estradiol vaginal ring)
- Monthly vaginal ring
 - **2018 worldwide sales: \$900 million (Merck)**³

1. <https://www.bayer.com/en/bayer-ag-annual-report-2019.pdf>. Includes sales for Mirena®, Kyleena® and Jaydess® / Skyla®
2. <https://www.prnewswire.com/news-releases/allergan-reports-fourth-quarter-and-full-year-2019-financial-results-301001646.html>
3. <https://www.sec.gov/Archives/edgar/data/0000310158/000031015819000014/mrk1231201810k.htm>

darébio Ovaprene® - Potential Market Opportunity^{1,2}



1. Market research study conducted in 2019 for Daré Bioscience
 2. Contraceptive use data applied to 2019 population data from US Census

XACIATO Selected Safety Information

- XACIATO is contraindicated in individuals with a history of hypersensitivity to clindamycin or lincomycin.
- Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against *C. difficile* may need to be discontinued.
- Polyurethane condoms are not recommended during treatment with XACIATO or for 7 days following treatment. During this time period, polyurethane condoms may not be reliable for preventing pregnancy or for protecting against transmission of HIV and other sexually transmitted diseases. Latex or polyisoprene condoms should be used.
- XACIATO may result in the overgrowth of *Candida* spp. in the vagina resulting in vulvovaginal candidiasis, which may require antifungal treatment.
- The most common adverse reactions reported in >2% of patients and at a higher rate in the XACIATO group than in the placebo group were vulvovaginal candidiasis and vulvovaginal discomfort.
- XACIATO has not been studied in pregnant women. However, based on the low systemic absorption of XACIATO following the intravaginal route of administration in nonpregnant women, maternal use is not likely to result in significant fetal exposure to the drug.
- There are no data on the effect of clindamycin on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for clindamycin and any potential adverse effects on the breastfed child from clindamycin or from the underlying maternal condition.
- Please see the [Prescribing Information](#), [Patient Information](#), and [Instructions for Use](#).