

Current Status of The U.S. Business

米国事業の現状について

Rusty Field – President & CEO
Upsher-Smith Laboratories, LLC

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The U.S. Generic Price Trends

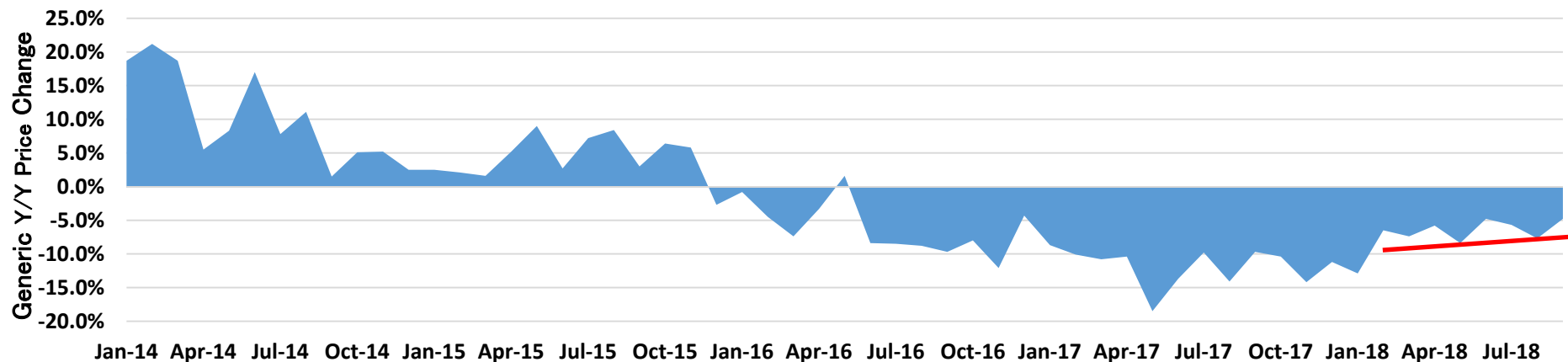
(ジェネリック医薬品の価格動向)

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◆ The U.S. market has rebounded from historic lows in price deflation and we have seen it return to low single digit levels
(米国市場は価格下落傾向が緩和しており、下落率が1桁台に戻っている)

Generic Price Deflation appears to be have stabilized at mid single digit price decreases when compared to pricing from the same period last year

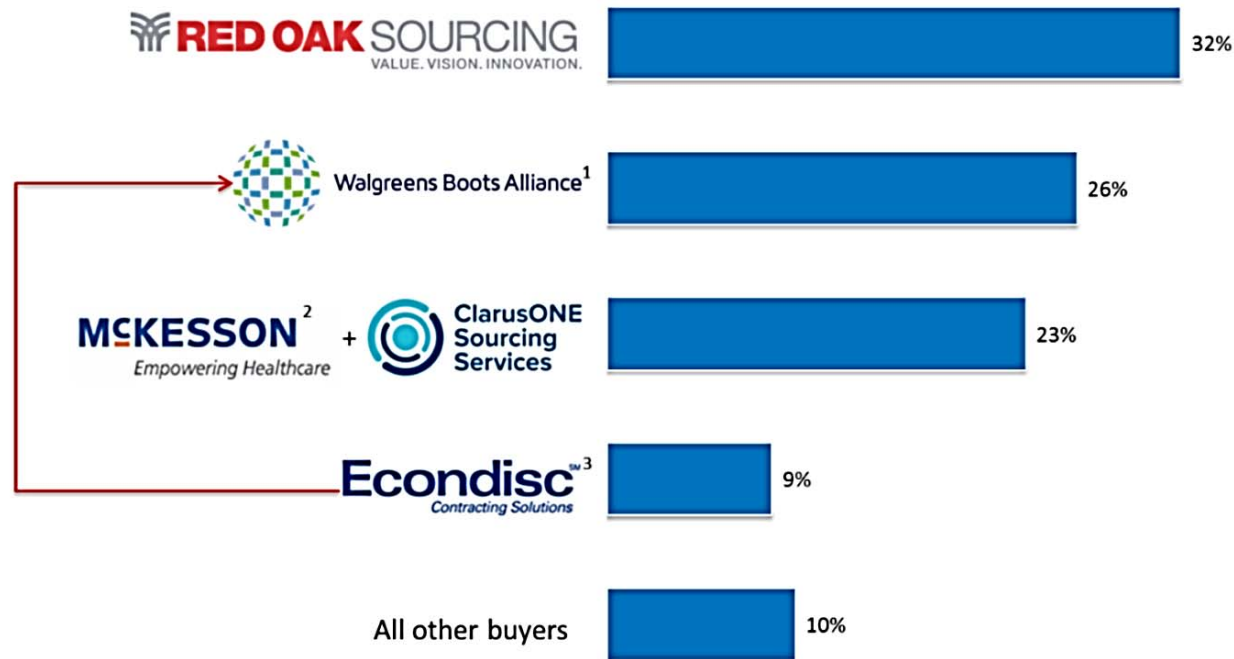


Key Driver in Price Deflation #1

(価格下落の主な原因①)

◆ Key Driver #1 in price deflation is consolidation of the generic buyers in the U.S., with top three controlling ~ 90% of the generic buying
(価格下落の主な原因①: 卸・薬局等の統合により3大購買グループが全GE医薬品の90%のシェアを占めている)

Red Oak Sourcing is almost 1/3 of US generic purchasing in 2017



Source: Drug Channels, Meet The Power Buyers Driving Generic Drug Deflation, February 2018

1. WBAD = Walgreens Boots Alliance Development GmbH. Includes U.S. volume only. Includes Amerisourcebergen volume and pro forma volume from Prime Therapeutics.

2. McKesson OneStop figures include Rite Aid and Albertsons. Excludes Colicis and other non-U.S. volume.

3. Econdisc Contracting Solutions includes Express Scripts, Kroger, SuperValu, and other retail chains. In May 2017, Econdisc agreed to partner with WBAD to purchase generic drugs.

Key Driver in Price Deflation #2

(価格下落の主な原因②)

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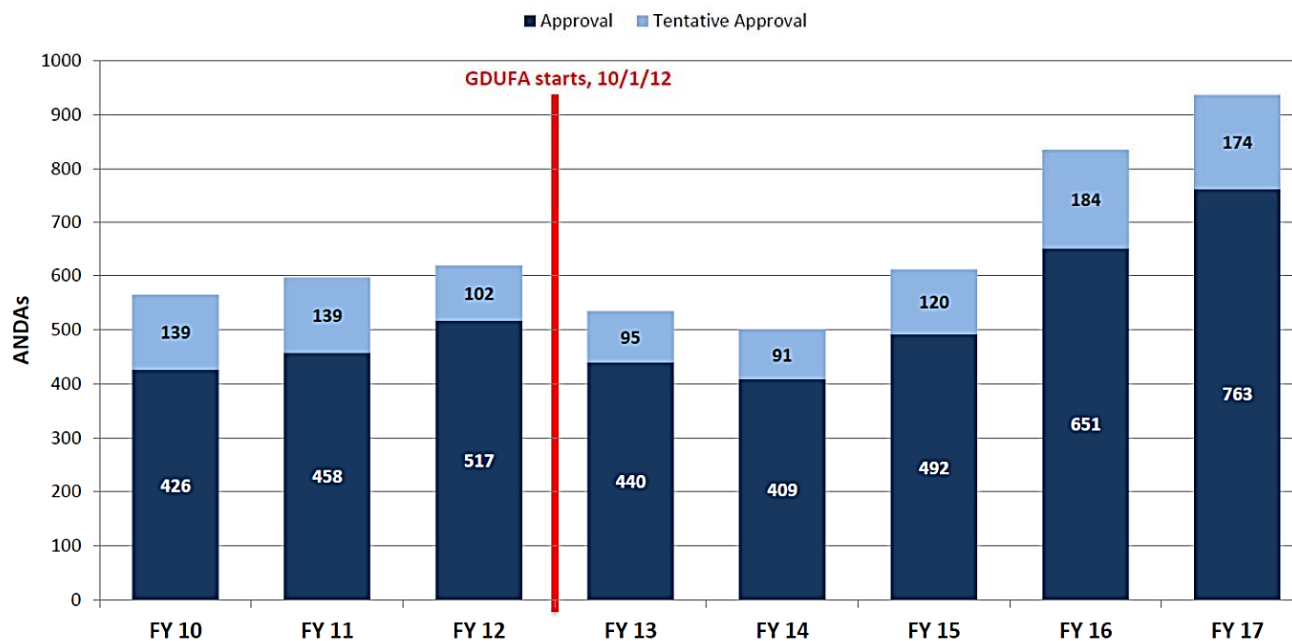
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◆ Key Driver #2 in price deflation is the record levels of ANDA approvals and focus on molecules with low competition

(価格下落の主な原因②: ANDA承認件数が過去最高水準を記録しており、競合が少ない成分に集中している)

Annual Approvals & Tentative Approvals



*Updated 10/1/2017. Numbers are based on preliminary data that will be reviewed and validated for official reporting purposes.

Trends in the Number of Products Approval Launched **sawai**

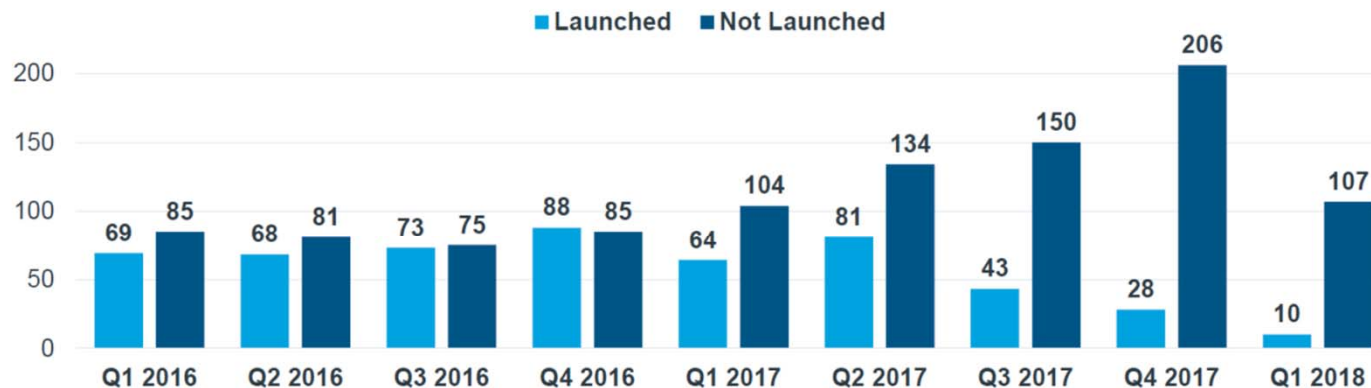
(ANDA承認数と発売数の推移)



- ◆ Current market trends suggest “over-supply” in the U.S. market as less than 10% of products approved launched in Q1
(第1四半期に発売されたGE数は承認されたGE数の10%未満となっており、現在の市場動向は“供給過剰”を示唆している)
- ◆ Upsher-Smith has launched 85% of our approved ANDAs
(Upsher-Smithは、ANDA承認されたうちの85%を発売)

From January 2016 through March 2018, only 34% (524 of 1551) of ANDA final approvals were launched; 66% (1027 of 1551) were not launched

ANDA Final approvals launched vs. non launched as of May 1, 2018



The percentage of launched approvals is getting lower:

- In 2016, nearly half, 48% (298 of 624) of approvals, were launched and 52% (326 of 624) were not launched
- In 2017, only 27% (216 of 810) of approvals were launched and 73% (594 of 810) were not launched
- In the 1st quarter of 2018, only 8.5% (10 of 117) of approvals were launched

Source: Barclays Research, FDA, IQVIA



Situation of Major Generics manufacturers **sawai**

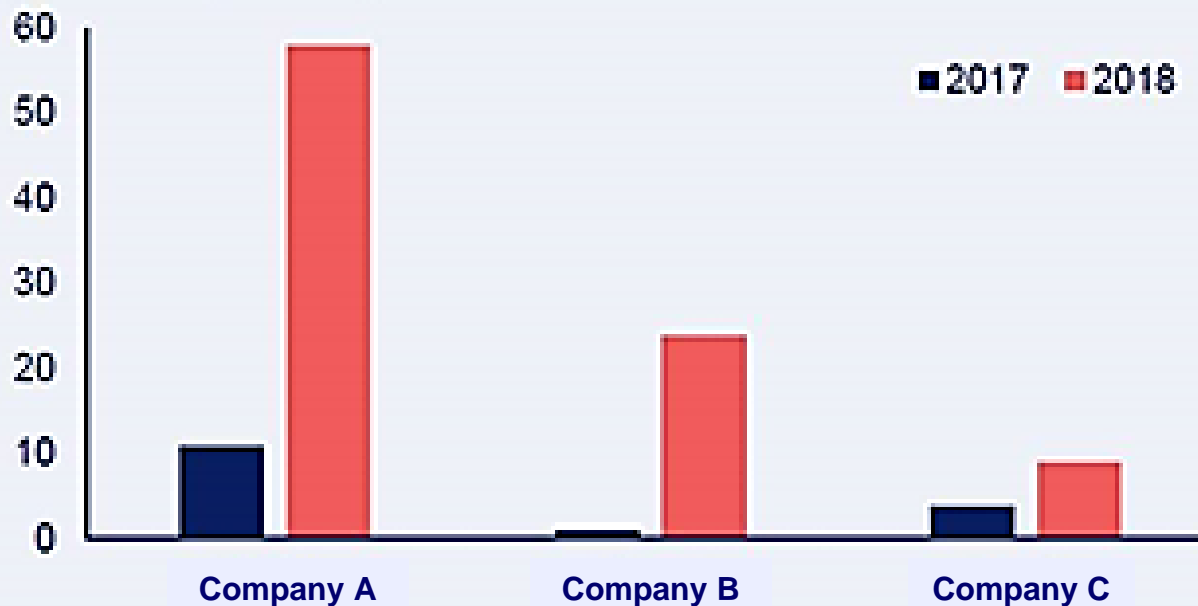
(大手ジェネリックメーカーの状況)

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- ◆ Additionally, several major U.S. market manufacturers are pulling products off the market (大手GEメーカーが製品を米国市場から撤退させている)
- ◆ And, we are hearing of products supply disruption from the “Big 3” (また、大手3社による製品供給の混乱も聞こえてきている)

ANDA discontinuations increasing

(number of products)



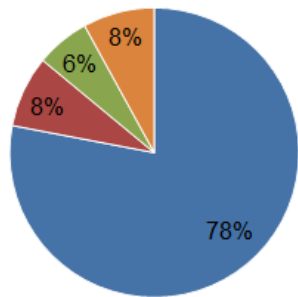
Source: FDA, Hikma analysis

Pipeline of Upsher-Smith (Upsher-Smithのパイプライン)

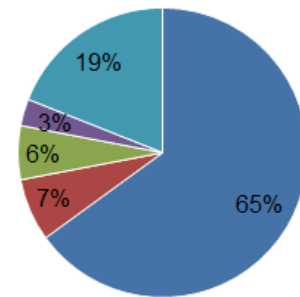
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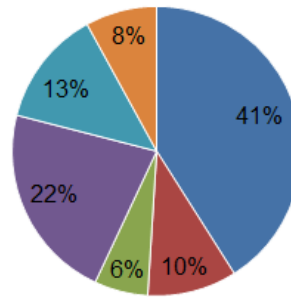
On Market



Current Pipeline



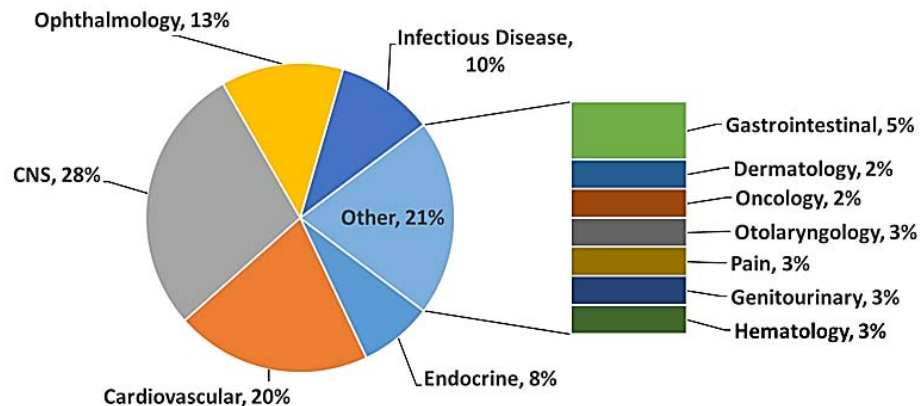
Active Opportunities



■ Solid Oral ■ Other ODF ■ Suspension/Solution ■ Injection ■ Ophthalmic ■ Other

Upsher-Smith continues to diversify dosage forms within their development portfolio

Portfolio Mix by Therapeutic Area



- Upsher-Smith Laboratories has positioned itself to succeed in this market by dramatically expanding our new product pipeline and diversifying the portfolio into more complex, niche generic products (Upsher-Smithは、パイプラインを大幅に拡大し、開発品はコンプレックスGEやニッチなGEへ多様化することで米国市場において業績を伸ばしている)
- Our product pipeline has grown to an average of around 40 programs at any given time (Upsher-Smithの製品パイプラインは、現在、約40成分へと拡大している)
- We estimate 9 submissions in FY2018 after 9 submissions in 2017 (2017年に9件のANDAを申請済み 2018年度は9件申請予定)

Overview of the Financial Results

(業績概要)

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- ◆ 1st half performance has been strong in the core generic products
(主力品が順調に推移)

(Unit: Millions of yen)

	FY 2017 1H*1	FY 2018 1H	Year on Year		FY 2018 Forecasts
			Mil. yen	Growth (%)	
Net Sales	13,479	20,194	6,715	49.8%	35,900
Core Operating Income	2,461	5,252	2,791	113.4%	7,300
Operating Income	77	1,974	1,898	2,464.9%	2,700
EBITDA	2,855	5,816	2,961	103.7%	8,300

*1 Financial Results for the 1st Half of FY2017: Financial Results for 4 months (June 2017 to September 2017)

FY 2018 Q2 Quarterly Average Rate :1USD = 110 JPY

New Products of Upsher-Smith

(Upsher-Smithの新製品)

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- ◆ We had 4 products approved and launched 4 products in 1HFY2018
(2019年3月期は2Qまでで4品目が承認され、4品目を発売)
- ◆ Revenue performance may not reach expectations due to competitive entrants prior to our Vigabatrin launch
(ビガバトリンの発売前に競合他社が参入したため、収益が予想を下回る可能性がある)
- ◆ We have had 3 more approved and launched 2 in October
(10月にはさらに3品目で承認を取得し、2品目の発売を開始)

Product launched in 1HFY2018

- ▶ **May - 18 Doxazosin Tablets, USP, 1 mg, 2 mg, 4 mg and 8 mg^{*1}**
- ▶ **Jul - 18 Vigadrone™ (vigabatrin) for oral solution, 500 mg, a fully substitutable, generic version of Sabril® (vigabatrin) powder for oral solution^{*2}**
- ▶ **Aug - 18 Bexarotene Capsules, 75 mg (the branded product: Targretin®)^{*3}**
- ▶ **Sep - 18 Diphenoxylate Hydrochloride and Atropine Sulfate Tablets, USP, 2.5 mg/0.025 mg (the branded product: Lomotil®)^{*4}**

*1 Doxazosin tablets 1 mg, 2 mg, 4 mg and 8 mg are prescribed for signs and symptoms of Benign Prostatic Hyperplasia, and treatment of Hypertension in the U.S.

*2 Vigadrone™ is prescribed for Infantile Spasm or Refractory Complex Partial Seizures.
Vigadrone™ is a trademark of Upsher-Smith.

*3 Bexarotene Capsules 75 mg is prescribed for the treatment of cutaneous manifestations of cutaneous T cell lymphoma.

*4 Diphenoxylate Hydrochloride and Atropine Sulfate Tablets 2.5 mg/0.025 mg is prescribed for adjunctive therapy in the management of diarrhea in patients 13 years of age and older.

◆ USLマネジメントチーム2名が、米国ビジネス界における名誉ある賞、業界団体の要職ポジションを獲得

- Richard Fisher : SVP of Corporate Strategy

2018年のミネソタ州「最もパワフルなビジネスリーダー500名」の一人に選出



RICHARD FISHER

SVP of Corporate Strategy
UPSHER-SMITH LABORATORIES


Richard "Rich" Fisher is the senior vice president of corporate strategy for Upsher-Smith Laboratories, a Maple Grove-based pharmaceutical company that offers a broad selection of generic and branded medications. Fisher began his business career as an engineer in the aerospace industry, working for companies like General Dynamics in its space systems division in San Diego. After working with General Dynamics, Fisher worked at Brady Corp. where he led an engineering team responsible for designing electro-mechanical systems. Fisher joined Upsher-Smith in 2004 as an associate director in project management and eventually moved his way up, taking on tasks as the director of strategic portfolio management, senior director of strategy and vice president of business development before being promoted to his current role. Fisher earned his undergraduate degree in engineering from Montana State University Bozeman and his master's in business administration from the University of St. Thomas.

Source: MINNESOTA 500 2018

- Sami Yusuf : VP of Corporate Development

米国製薬業界有数の業界団体DCAT(Drug, Chemical & Associated Technologies Association)のBoardメンバーの一員に選出

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		<p>DIRECTOR Sami Yusuf VP, Corporate Development Upsher-Smith</p>



Source: DCAT News Brief November 2018