



Drug Pricing Investigation

Mallinckrodt—*H.P. Acthar Gel*

Selected Investigation Documents

Staff Report
Committee on Oversight and Reform
U.S. House of Representatives
October 2020
oversight.house.gov

Mallinckrodt Selected Documents

Document #	Citation	Short Description
MNK 61	MNK_InCamera-000000127369, at Page 1	June 2018 Emails
MNK 62	MNK_InCamera-000000123912, at Slides 2 and 3	January 2017 Presentation Excerpt
MNK 63	MNK_InCamera-000000104743, at Page 1	December 2017 Emails
MNK 64	MNK_InCamera-000000128172, at Slide 9	March 2014 Presentation Excerpt
MNK 65	MNK_InCamera-000000131863, at Slide 22	March 2014 Presentation Excerpt
MNK 66	MNK_InCamera-000000142599, at Slides 3 and 4	March 2014 Presentation Excerpt
MNK 67	MNK_InCamera-000000142599, at Slide 16	March 2014 Presentation Excerpt
MNK 68	MNK_InCamera_Prod-000000045618, at Slide 9	September 2018 Presentation Excerpt
MNK 69	MNK_InCamera-000000128109, at Slide 9	February 2014 Presentation Excerpt
MNK 70	MNK_InCamera-000000128109, at Slide 12	February 2014 Presentation Excerpt
MNK 71	MNK-COR-00001275, at Slide 17	October 2014 Presentation Excerpt
MNK 72	MNK-COR-00001333, at Slide 20	December 2015 Presentation Excerpt
MNK 73	MNK_InCamera-000000051322, at Slide 10	June 2017 Presentation Excerpt
MNK 74	MNK_InCamera-000000030207, at Slide 10	July 2017 Presentation Excerpt
MNK 75	MNK_InCamera-000000124918	January 2017 Emails
MNK 76	MNK_InCamera-000000128109, at Slide 6	February 2014 Presentation Excerpt

*The document numbers for Mallinckrodt begin at 61 to avoid confusion with documents for another company.

Mallinckrodt Document 61

Message

From: O'Neill, Hugh M [Redacted]
Sent: 6/8/2018 1:17:54 PM
To: Romano, Steven J [Redacted]
Subject: Re: Acthar vial size

I know ..we had the same conversation. I get it but we already did this work and this could end up just being a distraction

On Jun 8, 2018, at 1:11 PM, Romano, Steven J <[Redacted]> wrote:

Mark's discussion w me was all about being able to say "Acthar cost 25k not 38K" kind of thing. I said that the commercial team had previously evaluated everything between single injection and 5ml and there was NOT a strong desire for 2 or 3. He was razor focused on being able to say the above...

Sent from my iPhone

On Jun 8, 2018, at 2:05 PM, O'Neill, Hugh M <[Redacted]> wrote:

I would ask that you let us build this into our lifecycle plan to determine ultimate strategic fit and value

On Jun 8, 2018, at 12:53 PM, Romano, Steven J <[Redacted]> wrote:

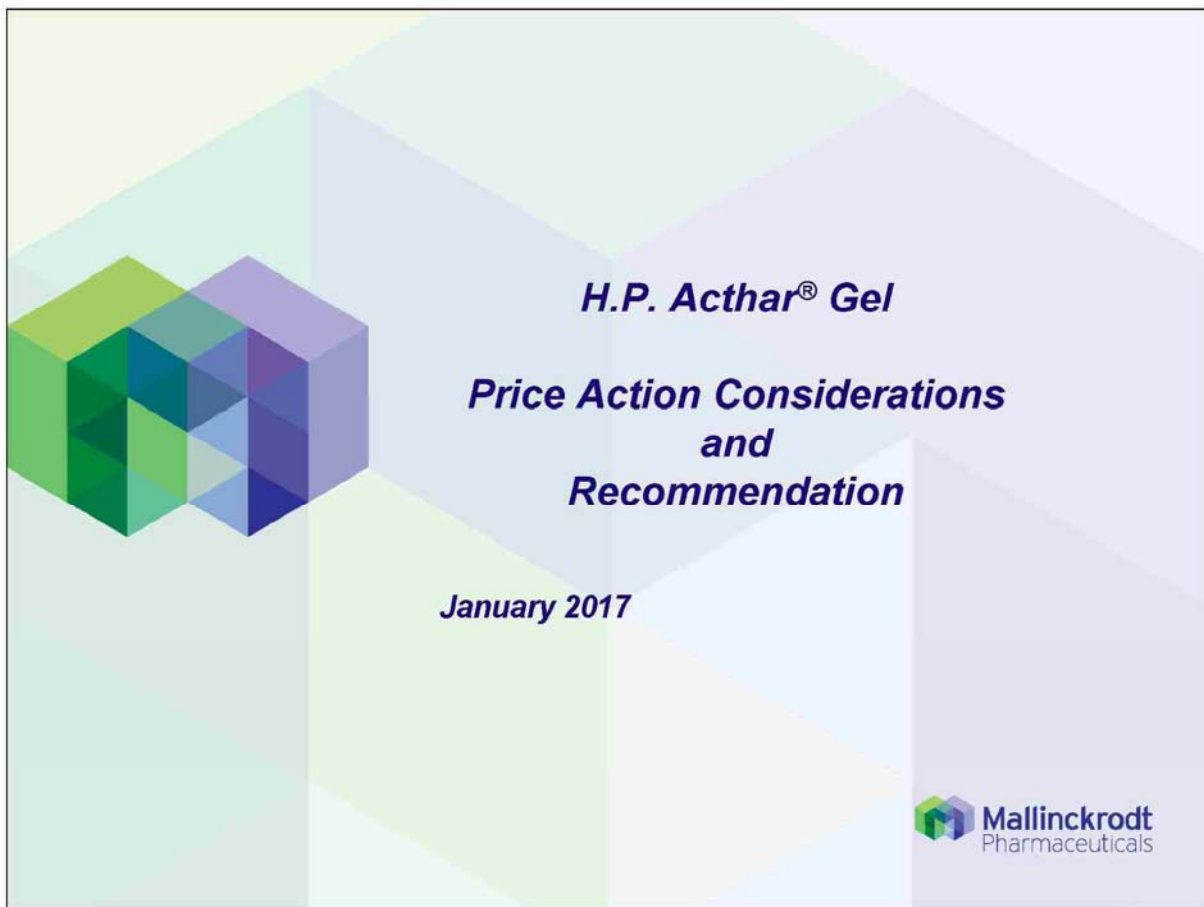
Agree

Sent from my iPhone

On Jun 8, 2018, at 1:51 PM, Trudeau, Mark C <[Redacted]> wrote:

As we discussed, in my mind speed to market is likely more important than other considerations

Sent from my iPhone



Acthar Price Increase Considerations and Recommendation

- ▶ Recommendation
 - ▶ Implement 6.9% price change
 - ▶ Effective date: Close of Business Thursday, January 26, 2017
- ▶ Impact
 - ▶ Revised vial price \$36,382
 - ▶ Increase of \$2,348 per vial
 - ▶ \$33MM positive impact over budget* (details on next slide)

*Does not consider potential impact of volume decreases resulting from an increase in price

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2

Price Action Financials

CY 2017	Q1	Q2	Q3	Q4	Total	CY 2017	Q1	Q2	Q3	Q4	Total
\$M						\$M					
Wholesaler Vials - Budget ¹	9,600	10,900	11,320	11,480	43,300	Wholesaler Vials - Budget ¹	9,600	10,900	11,320	11,480	43,300
Gross Sales - Budget	326.7	385.8	400.7	406.3	1,519.5	Gross Sales - Budget	326.7	385.8	400.7	406.3	1,519.5
Gross Price	34034	35395	35395	35395		Gross Price	34034	35395	35395	35395	
Price with 6.5% PI 1/31	36246	36246	36246	36246		Price with 6.9% PI 1/31	36382	36382	36382	36382	
New Gross Sales	342.0	395.1	410.3	416.1	1,563.5	New Gross Sales	342.9	396.6	411.8	417.7	1,569.0
Variance:	15.26	9.28	9.64	9.77	44.0	Change from Budget	16.20	10.76	11.18	11.33	49.5
Medicaid						Medicaid					
Utilization:	0.145	0.14	0.14	0.14		Utilization:	0.145	0.14	0.14	0.14	
RPU Budget:	12,500	14,100	14,100	14,100		RPU OLD:	12,500	14,100	14,100	14,100	
RPU Adjusted	11,852	13,408	13,452	13,430		RPU Adjusted	11,676	13,497	13,497	13,497	
RPU New	14,524	14,436	14,480	14,458		RPU New	14,689	14,601	14,645	14,623	
Medicaid price change impact ²					8.6	Medicaid price change impact ²					9.5
Other Rebates:					2.4	Other Rebates:					2.6
Contracted Price Protection:					2.7	Contracted Price Protection:					3.9
Net Impact:					30.3	Net Impact:					33.4

¹Model does not take into account potential volume changes

²Medicaid impact calculated on budgeted rates:

Changes to budgeted rates will have an additional impact

Summary:	
Net Impact 5% PI:	17.1
Net Impact 6.5% PI:	30.3
Net Impact 6.9% PI:	33.4

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Mallinckrodt Document 63

Message

From: O'Neill, Hugh M [Redacted]
Sent: 12/21/2017 9:44:38 AM
To: [Redacted]; [Redacted]
Subject: RE: Price increase slide

[Redacted]

I believe we placed a 6.9% in the budget for 2018 effective January 1st.

Based on the excellent analysis completed by [Redacted] I would stay with that recommendation.

[Redacted] do you concur?

Let's finalize and circle back with Finance to lock it down.

Hugh

From: [Redacted]
Sent: Wednesday, December 20, 2017 7:24 PM
To: [Redacted]; O'Neill, Hugh M <[Redacted]>
Subject: FW: Price increase slide
Importance: High

Guys – below are the GTN numbers based on [Redacted] work and synced up with [Redacted] and [Redacted] Bottom line is any price increase obviously has positive results. Really comes down to what we are comfortable with externally. Personally I would go high. We will receive the same press regardless within these ranges and key customers are protected with price protection. Let me know what you would like to do and we will implement.

[Redacted]
Mallinckrodt Pharmaceuticals, Inc.

1425 U.S. Route 206

Bedminster, NJ 07921 | 3rd Floor

O: [Redacted] C: [Redacted]

[Redacted]

| www.mallinckrodt.com

From: [Redacted]
Sent: Wednesday, December 20, 2017 4:03 PM
To: [Redacted]
Cc: [Redacted]
Subject: RE: Price increase slide
Importance: High

[Redacted] below is summary and attached includes further detail on gross to net categories. I have reviewed with [Redacted]

Price Scenarios - Base, 7 through 9.9 Scenarios reflect the ESI contract proposal impact.
I've included the budget in column I (last column) as reference which reflects 7% price increase.

Gross sales per % point is \$12.5M but as you can see diminishes as increase price due to price protection impact and increasing Medicaid RPU.

For 7%, scenario, we get \$8.4M (67%) of the \$12.5M though net sales return on gross from 9 to 9.9% scenario is only 34%.

Mallinckrodt Document 63



Project Quincy Preliminary Forecasts - US

Global Business Insights and Forecasting

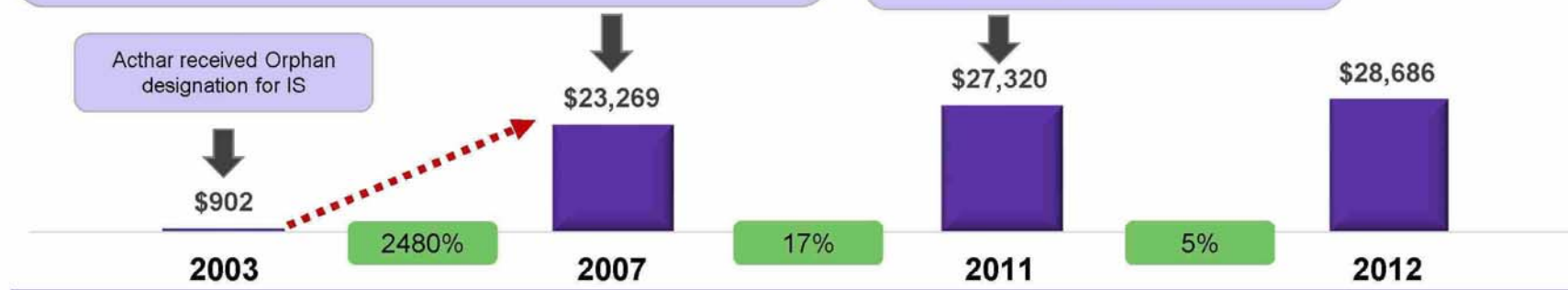
March 5th , 2014

Pricing and Reimbursement

Acthar Pricing Action¹

- Non approval of Acthar in IS (Orphan designation)
- Change in management of Quincy (CEO)
- New CEO adopted aggressive pricing strategy based on Orphan designation
- Pricing strategy contributes to company's growth
- Price increment due to orphan designation for IS; same leveraged for other indications (MS and NS)

- In 2010 Acthar got approval for IS and Orphan drug exclusivity (7 years)
- There after in Q1 2001 price increases by 5% after every 6 months



Reimbursement Update¹

Payers	% Share for IS	IS	Non IS
Health Plan of Nevada	45%	Covered	Covered
United Healthcare		Covered	Covered
BlueCross BlueShield*		Covered	Covered
Aetna	5%	Covered	Not Covered
Cigna	50%	Covered	Covered
CMS		Covered	Covered
Emblem		Covered	Covered

- In Sep 2012, Aetna announced it would no longer be covering Acthar beyond IS
 - It stated there is no clinical evidence that the Acthar is more effective than steroids
 - Quincy estimates ~5% of its prescriptions are sold through Aetna
- Quincy reduced subsidy for Medicaid prescriptions for 100% to 23%

Price growth %

* Regions covered – Kansas, Michigan, Arizona, Montana, North Carolina, Tennessee

Please check note section for sources



Preliminary review of opportunity “Quincy”

Prepared exclusively for Mallinckrodt Pharmaceuticals by
Strategic Clinical Development, LLC

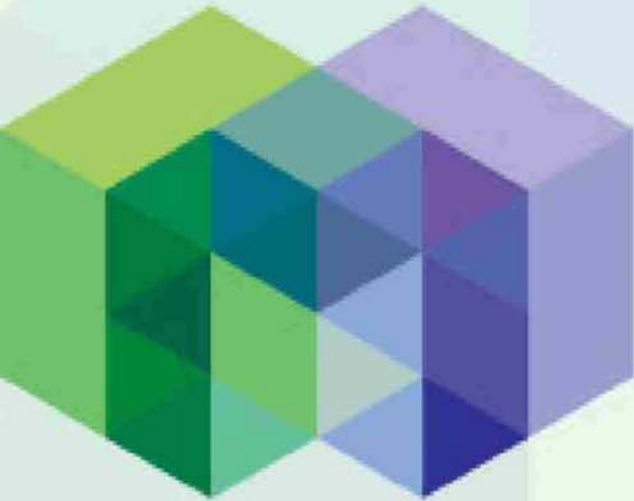


Draft 31 March, 2014 **CONFIDENTIAL**

1

Sociopolitical

- Public, turned to political, reaction to high prices of drugs in general, and drugs for rare, life-threatening, diseases in particular, amplified by “over night” price escalation of Acthar.
- Questcor’s defense: price was necessary solely to insure supply for IS, but was then followed by an unforeseeable expansion in use. Once successful at high price-point, fiduciary responsibility to shareholders precluded price reduction.
- The same narrative cannot be used with the same degree of plausibility by an acquirer of Questcor.
- Third party payers using Affordable Health Care Act as cover for jettisoning policies and programs they have begrudgingly accepted before – distributing the high cost of orphan drugs amongst these



Mallinckrodt Pharmaceuticals: BD&L strategy

Project Quincy

Board Discussion

March 11, 2014



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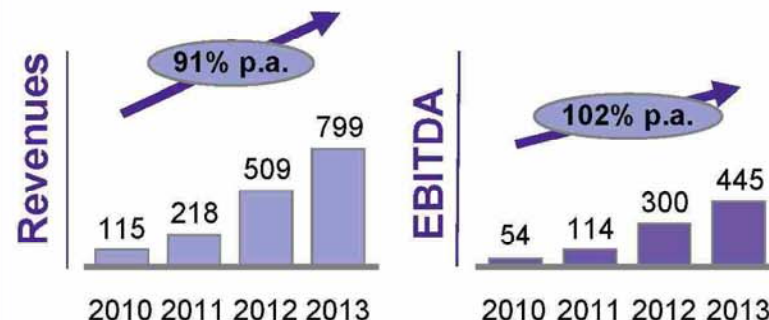
Quincy is a rapidly growing specialty pharmaceutical company with a premium-priced product

Company overview

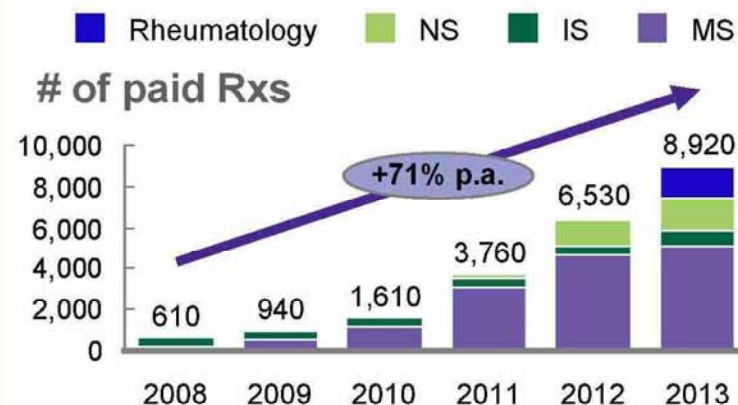
- Quincy is focused on serious, difficult-to-treat **autoimmune and inflammatory disorders**
- H.P. Acthar Gel** is a repository corticotropin injection with 19 approved indications in 4 markets:
 - Acute exacerbations of **multiple sclerosis (MS)**
 - Proteinuria in idiopathic types of **Nephrotic Syndrome (NS)**
 - Infantile spasms (IS)** in children < 2 years old
 - Rheumatology** related conditions; polymyositis (PM) and dermatomyositis (DM), with potential for new on-label indications
- Manufacturing process** is a trade secret
- Employees:** ~560 as of Jan 31, 2013 (sales force of ~230)

Historical revenues and earnings

USD millions



Prescription trends show historical growth in existing and new indications



Source: Barclays analysis; Quincy Earnings Conference, February 25, 2014

Quincy transaction would increase our scale and support key strategic initiatives for the combined portfolio

A broad-based specialty pharmaco with a differentiated growth strategy

NewCo

- Scale: potential **market cap exceeding \$9B** with **EBITDA approaching \$1B** and greater capacity to grow organically and inorganically
- **Strong, double-digit growth** on both top and bottom lines with competitive positions through (at least) the end of the decade
- **Irish domicile and global footprint**
- **Multiple growth platforms** in inflammation/immunotherapies, specialty generics/API, hospital products, and office-based pain/controlled substances
- Combined management team and board that can **craft and execute strategy**

Mallinckrodt and Quincy have complementary strengths

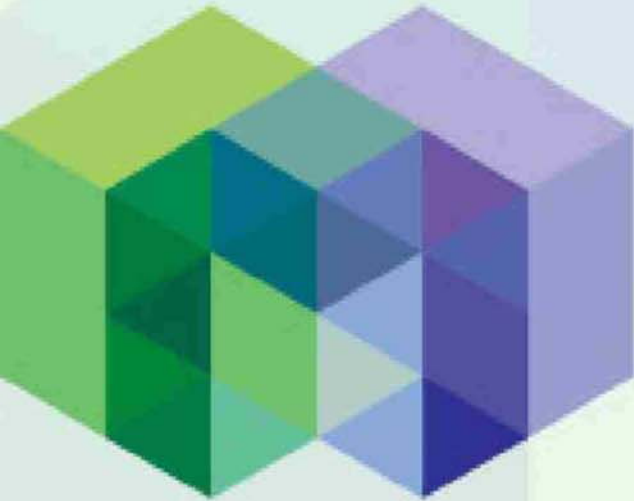


Mallinckrodt
Pharmaceuticals

- **Specialty focus** in difficult to manufacture and controlled substances
- **Optimal tax structure**
- **Global footprint**
- **Integrated supply chain**

Quincy

- **Protected franchise** with significant growth potential
- Robust **cash flow** profile
- **Strong record of execution**



Mallinckrodt Pharmaceuticals: BD&L strategy

Project Quincy

Board Discussion

March 11, 2014



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The possible transaction with Quincy is a unique opportunity

Quincy**Mallinckrodt**
Pharmaceuticals

Why Quincy?

- **Highly profitable company** with **unrivaed growth prospects** among peers
- **Good strategic fit**
- Excellent **size match** with Mallinckrodt
- **Achieve aspirational goals** with a **single transaction**
- **Best use of tax advantage** of domicile
- Social issues straightforward

Why now?

- **Willingness to strike an immediate deal**
- Highly active and competitive M&A environment with a **dwindling number of mid-sized targets**
- Deal would provide **rapid revenue and earnings growth**
- **Debt markets** are currently very attractive

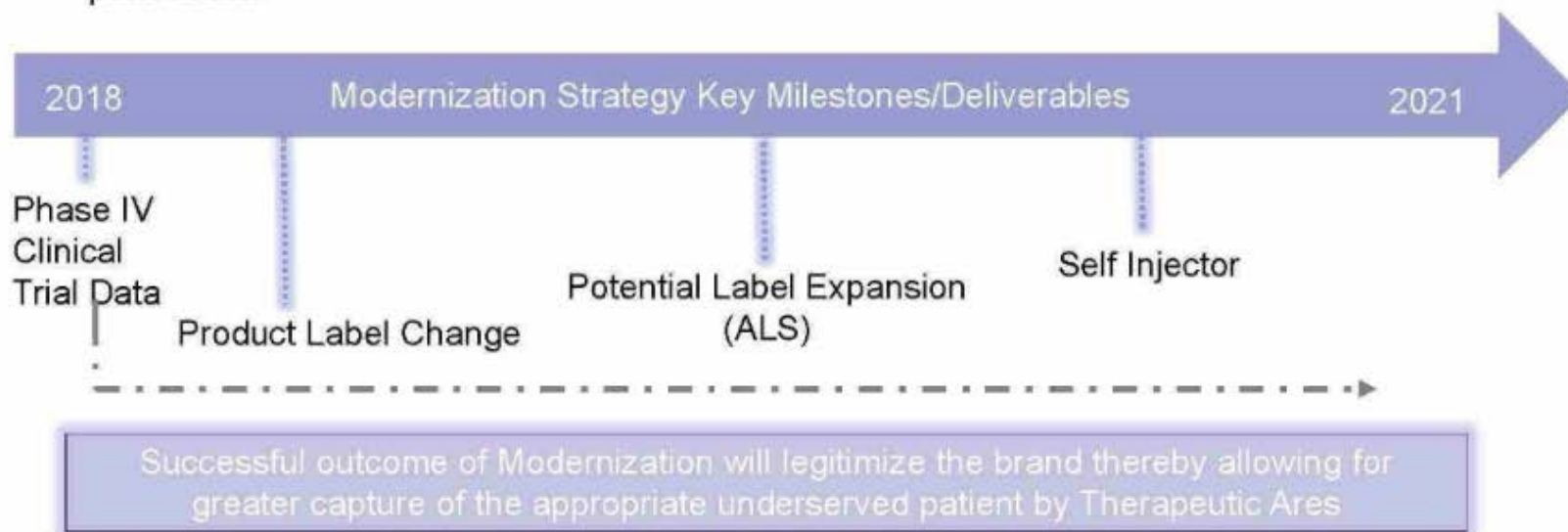


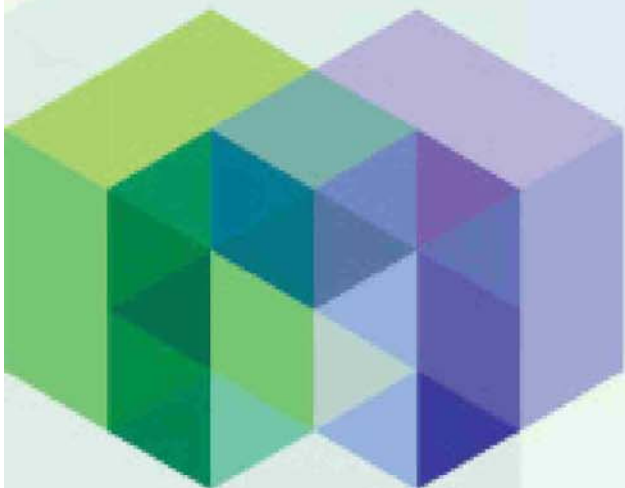
Acthar Modernization Strategy defines the Future of the Brand as either a Growth Asset or Cash Cow



Current Pressures on Acthar

- Stabilizing and Growing reimbursement for the appropriate population
- Brand Perception as overpriced steroid
- Lack of Acceptance of Academic Opinion Leaders across TAs limits product penetration





Mallinckrodt Pharmaceuticals: BD&L strategy

Meeting of the Transaction Committee

Gary Phillips / Rick Hoyt

February 27, 2014



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Quincy is a rapidly growing specialty pharmaceutical company with a premium-priced product

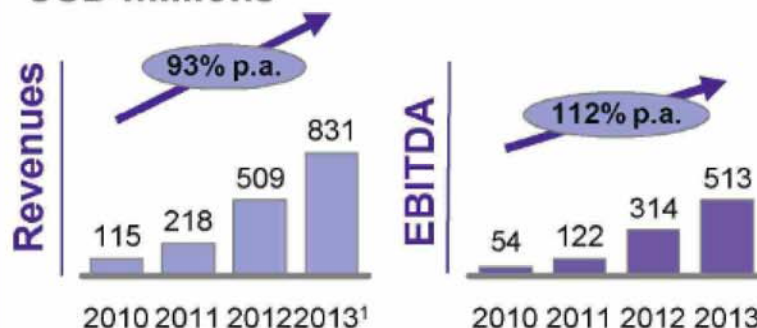
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Company overview

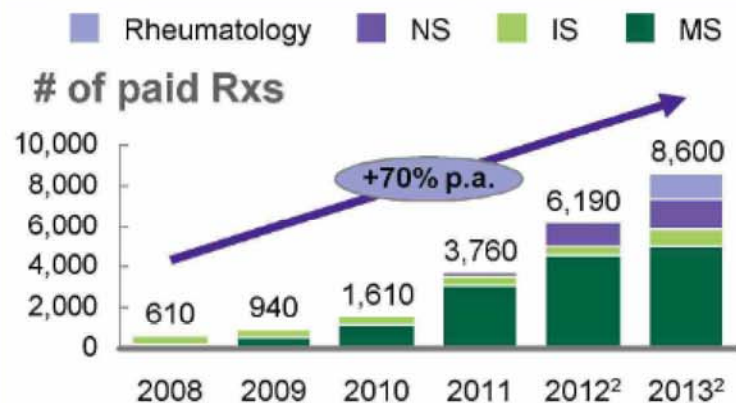
- Quincy is focused on serious, difficult-to-treat **autoimmune and inflammatory disorders**
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 - Acute exacerbations of **multiple sclerosis** (MS)
 - Proteinuria in idiopathic types of **Nephrotic Syndrome** (NS)
 - **Infantile spasms** (IS) in children < 2 years old
 - **Rheumatology** related conditions; polymyocitis (PM) and dermatomyositis (DM), with potential for new on-label indications
- **Multiple barriers to entry** related to formulation, manufacturing and regulatory
 - Quincy has 'walled off' possible weaknesses by acquiring BioVectra (API supplier) and Synacthen (synthetic analog of Acthar)
- **Employees:** ~557 as of Jan 31, 2013 (sales force of 229)

Historical revenues and earnings

USD millions



Prescription trends show historical growth in existing and new indications



¹ Expected 2013 revenue (Earnings Conference Feb 25, 2014)

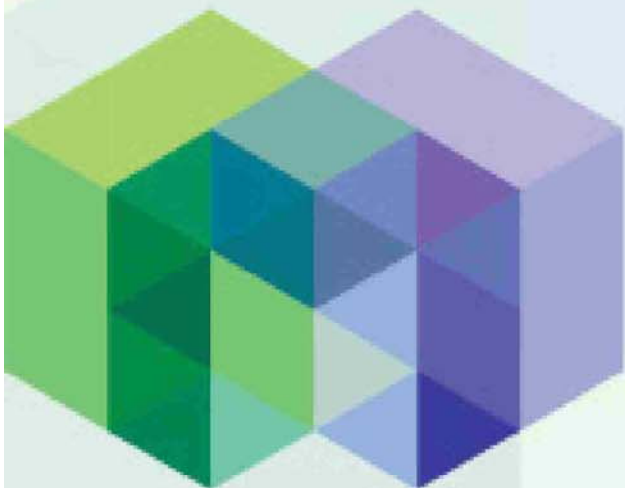
² Q4 2012 and Q4 2013 prescription detail not disclosed – number of prescriptions per segment per year annualized based on the first 3 quarters



Source: Barclays analysis

Confidential

10/18/2019 9



Mallinckrodt Pharmaceuticals: BD&L strategy

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Gary Phillips / Rick Hoyt

February 27, 2014

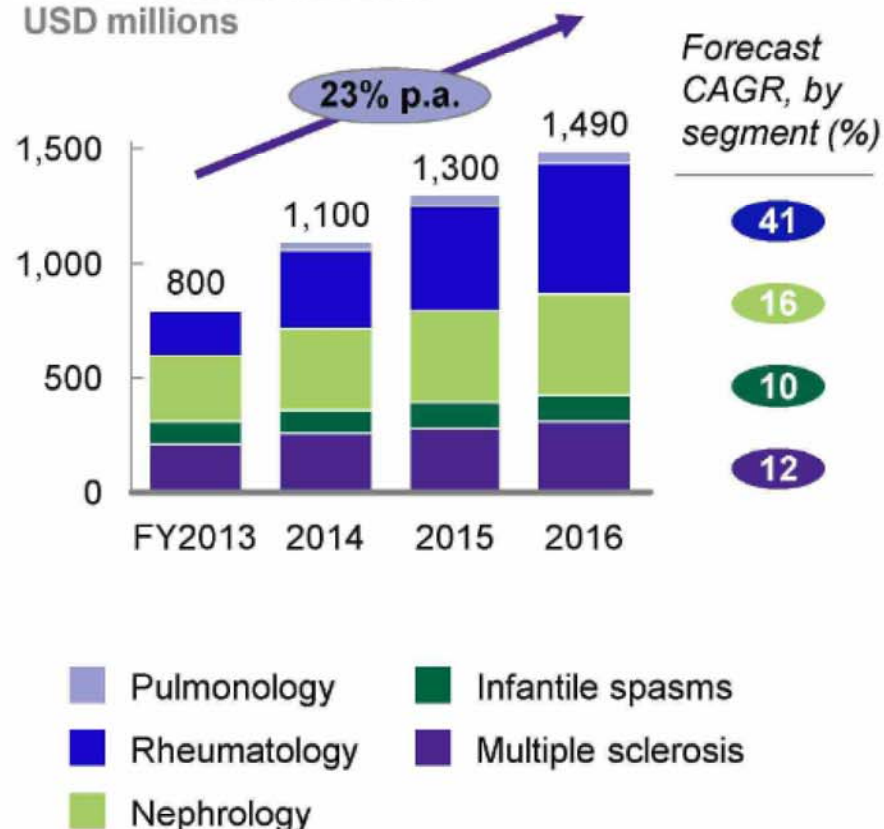


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Acthar revenue growth will be driven by new on-label indications and 'headroom' in current indications

Expansion into on-label rheumatology indications will provide ~XX% of Acthar growth over the next 3 years

Acthar revenue forecast
USD millions



	Acthar indications ¹	Market size (US patients / year)	Current penetration
Current	Infantile spasms	1,500	52%
	Multiple sclerosis flares	30,000	18%
	Nephrotic syndrome	35,000	9%
	Polymyocitis and dermatomyocitis	20,000	2%
New	Systemic lupus erythematosus	70,000	0.4%
	Rheumatoid arthritis	80,000	0.5%
	Psoriatic arthritis	30,000	0.2%
	Ankylosing spondylitis	50,000	0.04%
	Sarcoidosis (Pulmonology)	20,000	0.2%

¹ In 2010, the Acthar label was updated in connection with FDA approval of the sNDA for Acthar in the treatment of IS (with Orphan designation); prior to this update, the label included over 50 approved indications; now there are 19 listed indications



Mallinckrodt Pharmaceuticals Investor Briefing

October 14, 2014

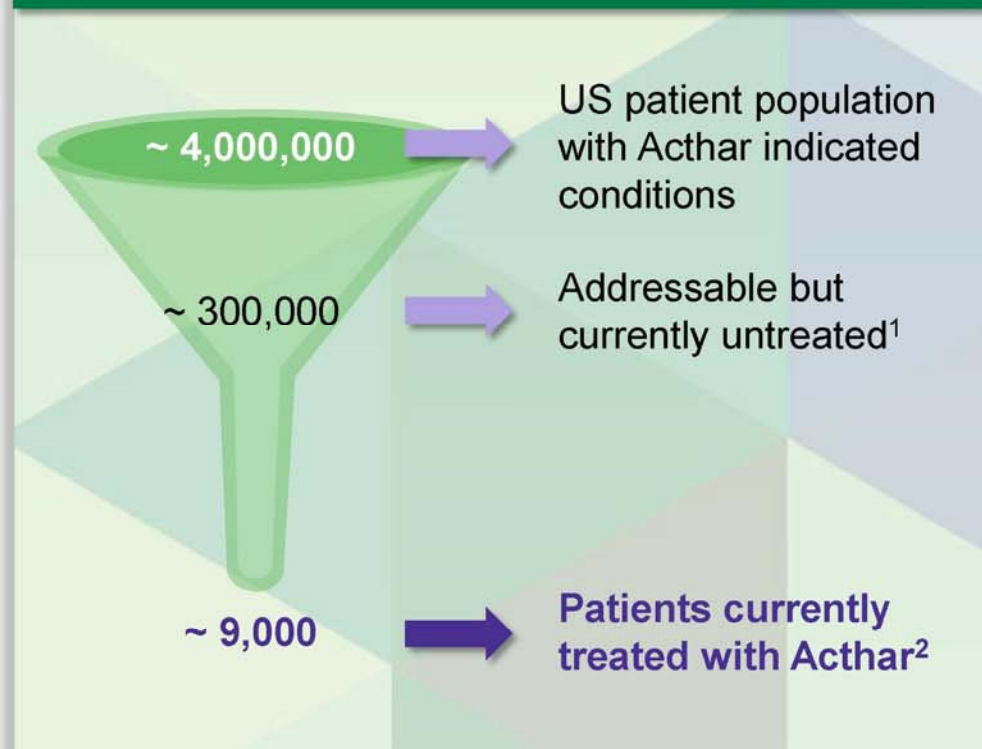


MNK-COR-00001275

Acthar is the foundation of our broad Autoimmune and Rare Diseases business



In 9 currently promoted indications, only 3% of addressable Acthar patients are now treated



Mallinckrodt's Strategy

- ▶ Document and publish clinical experience and health economic outcomes
- ▶ Grow utilization of Acthar in appropriate, but underserved, patient populations
- ▶ Initiate commercial efforts in other approved indications with high unmet medical need
- ▶ Increase payer engagement to support reimbursement
- ▶ Focus R&D investment
- ▶ We believe current regulatory guidelines drive complicated development and make a generic unlikely

¹ Source: Internal estimates

² Moving annual total (MAT) ending August 2014, 9,059 unique patients treated with Acthar

MNK-COR-00001291

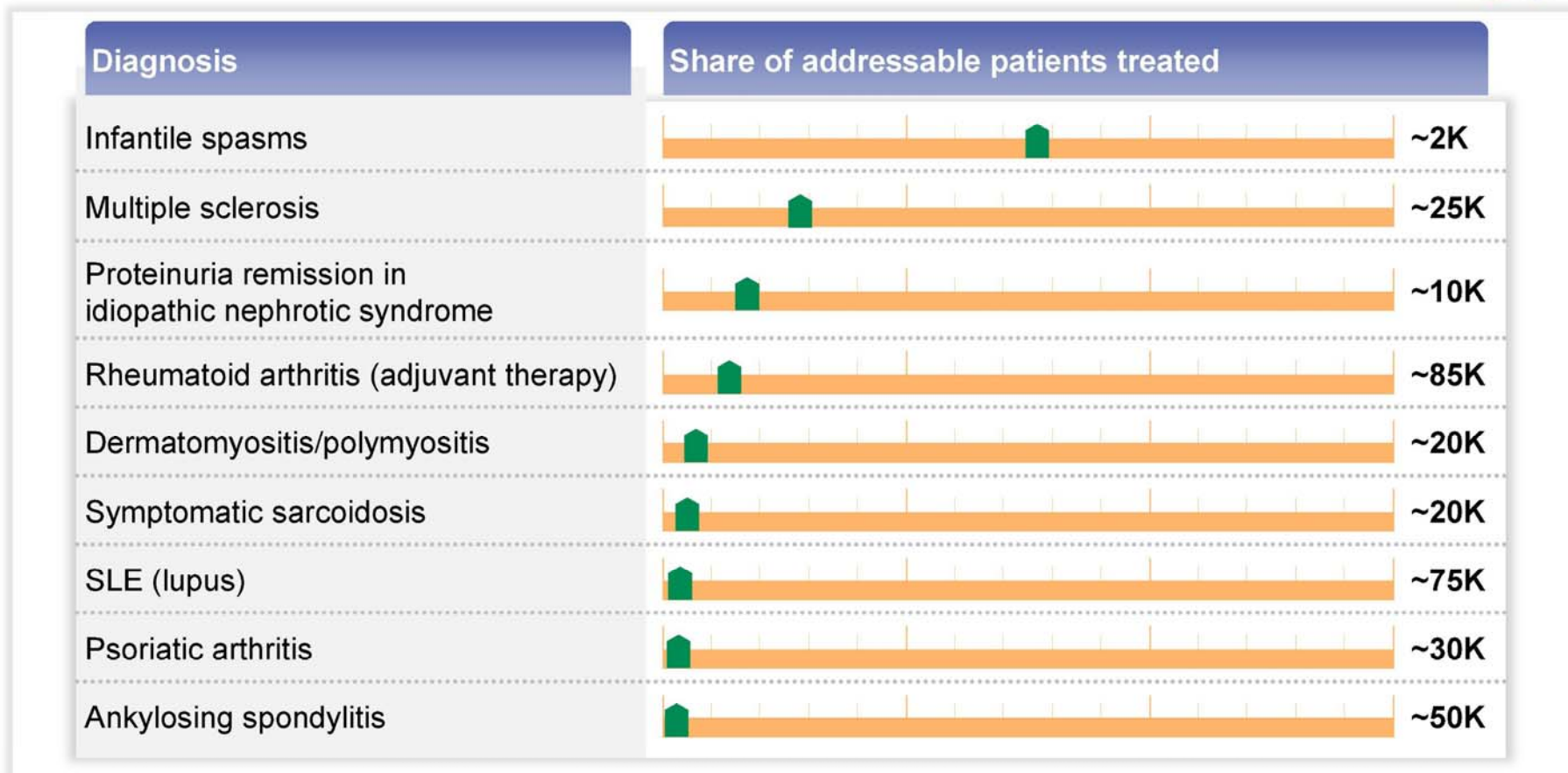


December 7, 2015



MNK-COR-00001333

Acthar has low patient penetration across majority of approved indications









Here is what payers are telling us:



- ▶ Old drug/old FDA label – high cost steroid
- ▶ Public scrutiny and negative perception of Acthar
- ▶ Pricing is egregious; payers want 30-50% rebates
- ▶ Evidence base and clinical support is lacking and doesn't support access
- ▶ Concerned about managing utilization and risk of opening access without clearly defined patient population, UM criteria and expected outcomes
- ▶ Worried about adverse selection
- ▶ Payers need to offer competitive programs that control specialty drug spend for clients

Mallinckrodt Document 75

Message

From: [REDACTED] [Redacted]
Sent: 1/23/2017 9:20:08 AM
To: O'Neill, Hugh M [Redacted]
Subject: RE: Pharmaceuticals - Quantifying "real" price growth vs. list price growth

Hugh,

Do we have all the necessary signoffs to implement at close of business Thursday? If so, will need in-writing approvals for our files and need to get process rolling today to be ready for Thursday.

Thanks!

From: O'Neill, Hugh M
Sent: Monday, January 23, 2017 9:15 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Pharmaceuticals - Quantifying "real" price growth vs. list price growth

Perfect

Thanks

From: [REDACTED]
Sent: Monday, January 23, 2017 9:00 AM
To: O'Neill, Hugh M; [REDACTED]
Cc: [REDACTED]
Subject: RE: Pharmaceuticals - Quantifying "real" price growth vs. list price growth

Hugh,

We will absolutely look into this. We did last fall and it was still showing a net increase as a result of rebate payments not being as high as originally estimated. [REDACTED] and I will take another look.

Also, if you trend the ASP that is published it was still showing a positive. This is a data point that some of the analysts will call out.

From: O'Neill, Hugh M
Sent: Monday, January 23, 2017 8:49 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Pharmaceuticals - Quantifying "real" price growth vs. list price growth

I hear you....we have the data and can certainly pull it together.

Hugh

[REDACTED] Can you guys pull together the analysis that looks at Gross and Net Price for Acthar under our ownership? Including the upcoming pricing action.

Mallinckrodt Document 75

Mallinckrodt Document 75

From: [REDACTED]
Sent: Monday, January 23, 2017 7:47 AM
To: O'Neill, Hugh M
Subject: FW: Pharmaceuticals - Quantifying "real" price growth vs. list price growth

Have we recently done an analysis like this about Acthar price growth under our ownership? Not necessarily to try to make a point that price has 'declined' but to have another data point that would say, 'with our most recent increase, the list price of Acthar grew by 6.9%, but with the contractual discounts included in our payer strategy, the net effective increase is Y.Y%?

May not make a difference but I'm searching for messages. [REDACTED]

From: [REDACTED]
Sent: Monday, January 23, 2017 6:38 AM
To: [REDACTED]
Subject: Fwd: Pharmaceuticals - Quantifying "real" price growth vs. list price growth

[REDACTED]

Mallinckrodt Pharmaceuticals

T: [REDACTED] | M: [REDACTED]
[REDACTED] www.mallinckrodt.com

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Sent from my iPhone...

Begin forwarded message:

From: [REDACTED] Deutsche Bank" <[REDACTED]>
Date: January 23, 2017 at 12:08:39 AM EST
To: <[REDACTED]>
Subject: Pharmaceuticals - Quantifying "real" price growth vs. list price growth

Deutsche Bank - Equity Research - North America

Pharmaceuticals - Quantifying "real" price growth vs. list price growth
23 January 2017 (21 pages/ 478 kb)

Download the complete report: <http://pull.db-gmresearch.com/p/399-6763/266722885/0900b8c08c5be529.pdf>

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Analysis suggests that list price growth has outpaced net price growth

The market remains focused on and concerned about drug price inflation, and the potential for increasing transparency around “real” prices vs. list prices (or WAC/gross prices) is likely to create volatility for stocks in the pharma food chain. Because companies generally do not provide net prices (that is, “real” prices after discounts, rebates, etc.) for their products on an individual basis, we attempt to quantify how implied net prices (based on reported sales and IMS unit data) have changed over time relative to list prices for various drugs. For the set of drugs we chose to start with, it is clear that implied net prices have grown slower than list prices over the last several years, and in some cases have hardly grown at all. We are not attempting in this note to explain how or why this spread exists, but we thought it might be helpful to try to put some numbers around this theme.

Our methodology

We looked at 10 drugs across several therapeutic categories that are primarily retail-dispensed and for which companies report US sales – Januvia, Janumet, and Lantus (diabetes), Humira and Enbrel (biologics for rheumatoid arthritis, psoriasis, and other inflammatory disorders), Eliquis and Xarelto (anti-coagulants), Cialis and Viagra (erectile dysfunction), and Lyrica (pain). For each product we calculated the implied net price per unit using reported sales and extended units dispensed (per IMS) and compared this with the WAC per unit (per PriceRx) on a quarterly basis for the last six years (based on the availability of IMS data). We also looked at the implied gross-to-net discount (WAC sales vs. reported sales) over time.

Net price growth generally well below list price growth, but varies by product

Based on our analysis, implied net price growth has been much lower than list price growth for some drugs (eg, diabetes, anti-coagulants) and closer for others (eg, Humira, Enbrel, Lyrica), which could be related to competitive dynamics for these products (Table 1). For example, the list price for MRK’s Januvia grew by a CAGR of 13% from 2011-16, while we estimate that net price grew by 1% over that period. For ABBV’s Humira, the list price grew by a CAGR of 18% vs. estimated net price growth of 13%.

Gross-to-net has increased significantly for many of these products

The difference between gross sales (based on IMS units and list prices) and reported net sales has increased significantly for many of these products, particularly those in competitive categories. For example, we estimate the gross-to-net discount for Januvia was ~53% in 1Q-3Q16 vs. ~19% in 2011. The implied gross-to-net discounts for the other drugs are lower, but have also increased over the last several years (Table 2).

Important caveat

An important caveat is that our analysis does not take into account other factors that can influence reported sales, such as channel stocking/ destocking, which can skew implied net price growth in a given quarter. To help smooth out such influences, we look at trends by year in addition to quarters.

Redacted

Redacted

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Click/ copy this link into a browser to access the report: <http://pull.db-gmresearch.com/p/399->

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[6763/266722885/0900b8c08c5be529.pdf](#). If you have any difficulty accessing the report, please forward this email with the word 'PDF' in the subject line to GMResearch.Subscriptions@db.com. After 90 days you can access the report on our web site: <http://gm.db.com>.

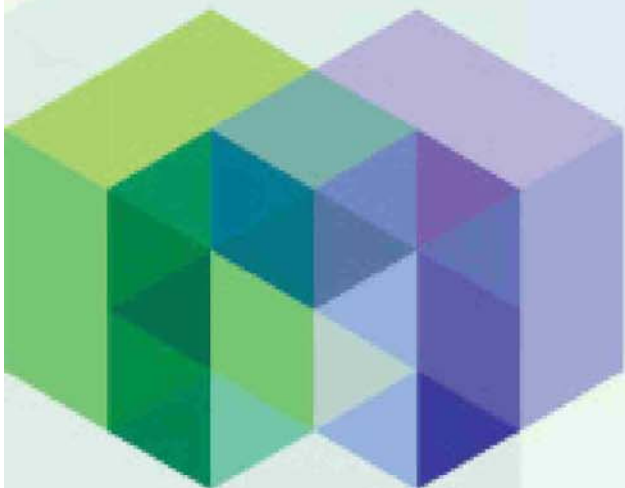
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Redacted



Mallinckrodt Pharmaceuticals: BD&L strategy

Meeting of the Transaction Committee

Gary Phillips / Rick Hoyt

February 27, 2014



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The possible merger with Quincy is a unique opportunity that should be pursued urgently



Why Quincy?

- **Highly profitable company** with **unrivalled growth prospects** among peers
- **Good strategic fit**
- Excellent **size match** with Mallinckrodt
- **Achieve aspirational goals** with a **single transaction**
- **Best use of tax advantage** of domicile
- Social issues straightforward

Why now?

- **Willingness to strike an immediate deal**
- Highly active and competitive M&A environment with a **dwindling number of mid-sized targets**
- Deal would provide **rapid revenue and earnings growth** in the short- and medium-term
- **Debt markets** particularly attractive