

# Mallinckrodt

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GUIDANCE RELEASE

May 3, 2013

# Forward-Looking Statements

- › This presentation contains certain “forward-looking statements” within the meaning of the United States Private Securities Litigation Reform Act of 1995. These statements are based on management’s current expectations and are subject to risks, uncertainty and changes in circumstances, which may cause actual results, performance or achievements to differ materially from anticipated results, performance or achievements. All statements contained herein that are not clearly historical in nature are forward-looking and the words “anticipate,” “believe,” “expect,” “estimate,” “plan,” and similar expressions are generally intended to identify forward-looking statements.
  
- › The forward-looking statements in this presentation may include statements addressing the following subjects, among others: future financial condition and operating results and economic, business, competitive and/or regulatory factors affecting our business and the terms and effect of the anticipated spin-off of the Pharmaceuticals business from Covidien. Any of the following factors, among others, may cause actual results to differ materially from those described in the forward-looking statements:
  - Our ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration
  - Our ability to obtain and/or to timely transport molybdenum-99 to our technetium-99m generator production facilities
  - Customer concentration
  - Cost-containment efforts of our customers, purchasing groups, third-party providers and governmental organizations
  - Our ability to successfully develop or commercialize new products
  - Our ability to protect our intellectual property rights
  - Competition

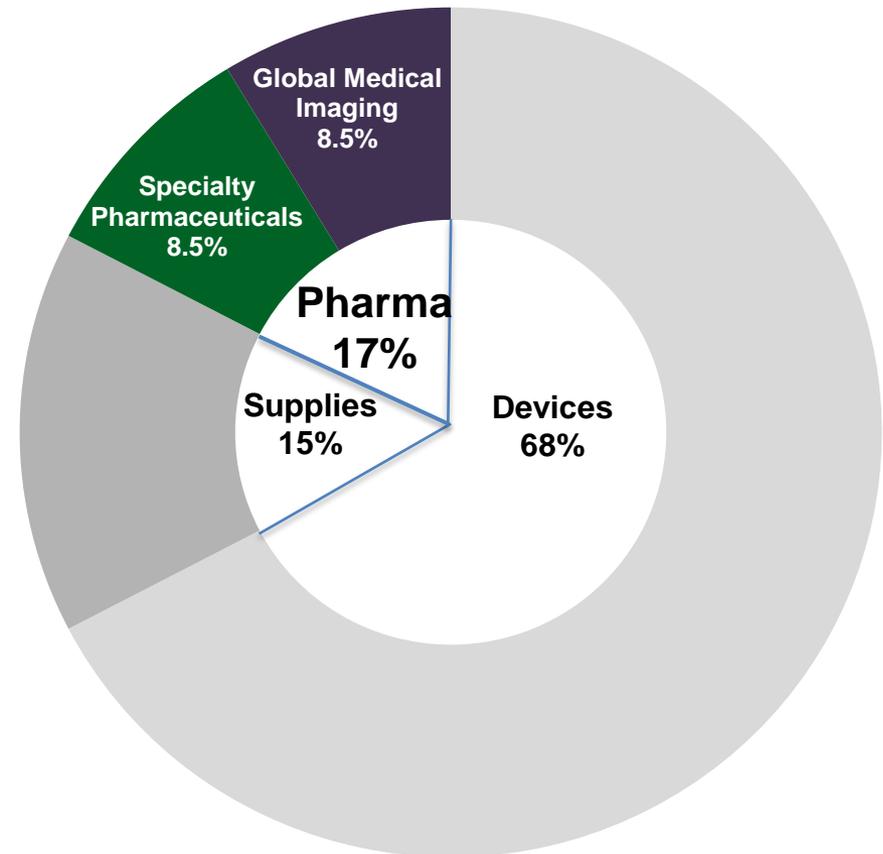
# Forward-Looking Statements (continued)

- Our ability to integrate acquisitions of technology, products and businesses
  - Product liability losses and other litigation liability
  - The reimbursement practices of a small number of large public and private issuers
  - Risks associated with complex reporting and payment obligation under healthcare rebate programs
  - Changes in laws and regulations
  - Risks associated with conducting business internationally
  - Fluctuations in currency exchange rates
  - Risks associated with material health, safety and environmental liabilities, litigation and violations
  - Information Technology infrastructure
  - Unanticipated developments that may prevent, delay, alter the terms of or otherwise negatively affect the planned spin-off.
- › These are examples of factors, among others, that could cause actual results to differ materially from those described in the forward-looking statements. In addition, there can be no assurances as to the timing of the contemplated spin-off, or whether it will be completed. We are under no obligation to (and expressly disclaim any such obligation to) update or alter our forward-looking statements whether as a result of new information, future events or otherwise. More detailed information about these and other factors is set forth in Mallinckrodt's Registration Statement on Form 10, as amended, which has not yet been declared effective by the SEC, and Covidien's Annual Report on Form 10-K and other periodic filings with the SEC.

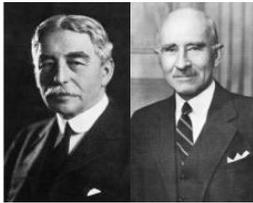
# Spin will create incremental value for Mallinckrodt

- › Covidien and Mallinckrodt Pharmaceuticals have different business models and product lifecycles
- › Mallinckrodt has opportunity to unlock potential
  - Focused R&D, strategic and operational plans
  - Improved flexibility for infrastructure investment and business development
- › Separation provides investors with distinct investment alternatives
- › Anticipated spin: June 28, 2013

**Covidien - FY2012 Sales**  
**\$12 billion**



# A proud 145-year history of growth



**1867**  
Formed API<sup>1</sup>  
business in St. Louis,  
MO

**1996**  
Entered  
controlled  
substance  
generics

**2001**  
Acquired  
branded portfolio

**EXALGO**  
(hydromorphone HCl) <sup>Ⓒ</sup>  
Extended-Release Tablets

**PENNSAID**  
(diclofenac sodium topical solution) 1.5% w/w

**2010**  
Expanded sales  
force; launched  
pain products

**2012**  
Announced co-promotions with  
Sumavel DosePro<sup>®</sup> and Duexis <sup>®</sup>  
Launched Exalgo<sup>®</sup> 32mg  
Acquired CNS Therapeutics &  
Roxicodone<sup>®</sup>  
Launched methylphenidate ER<sup>2</sup>



**Spin-off from  
Covidien Mid-2013**

**1920**  
Launched  
first  
contrast  
media



**1966**  
Launched  
Radio-  
pharmaceutical  
business

**1989**  
Launched  
Optiray<sup>®</sup>



**2000**  
Launched  
Optimark<sup>®</sup>



**2008**  
Launched  
generic  
Cardiolite<sup>®</sup>

**2010**  
Divested Baker  
Chemicals and  
Radiopharmacies

<sup>1</sup> Active Pharmaceutical Ingredients

<sup>2</sup> Methylphenidate (HCL) Extended Release, the generic form of CONCERTA, is a registered trademark of ALZA Corporation

\* Reflects Calendar Year

SUMAVEL and DosePro are registered trademarks of Zogenix, Inc.

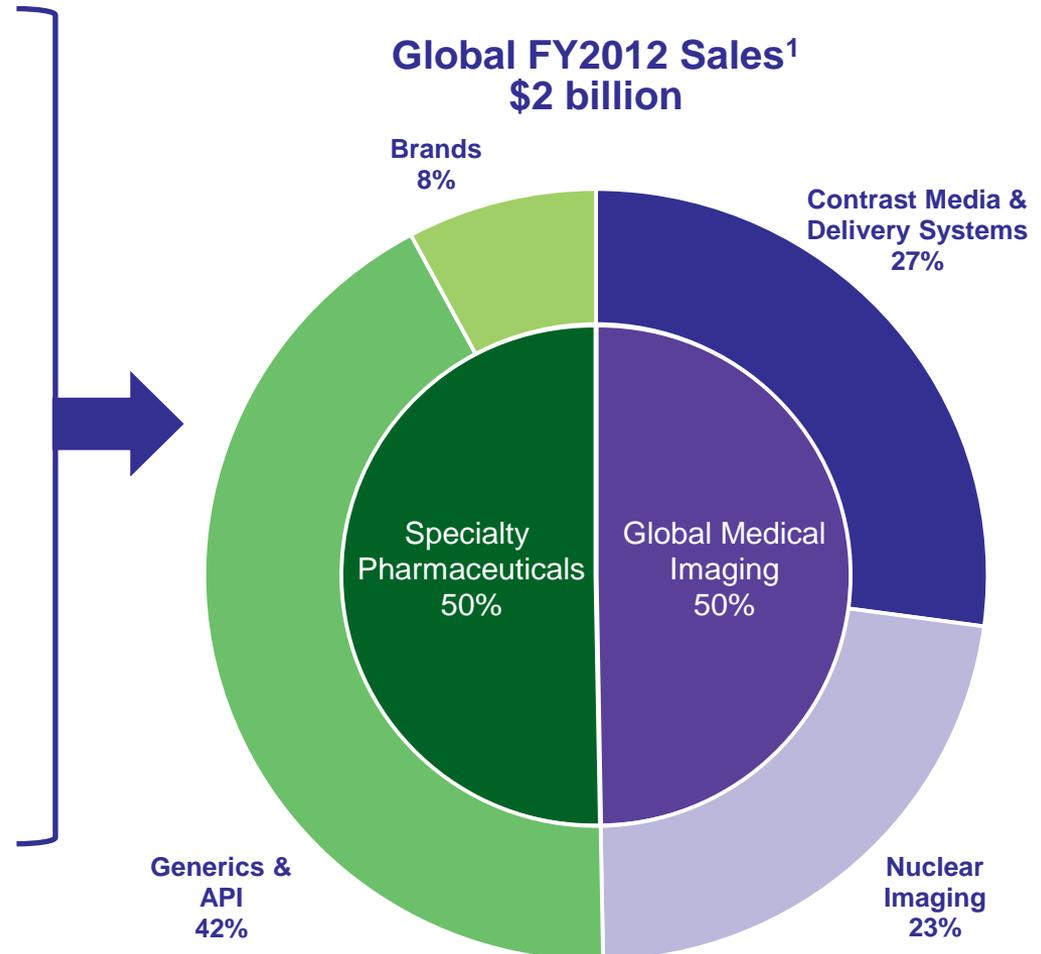
DUEXIS is a registered trademark of Horizon Pharma

Cardiolite is a registered trademark of Lantheus Medical Imaging, Inc.

# A leading diversified specialty pharmaceutical company

*We make complex products simpler, safer and better for patients*

- › Specialty Pharmaceuticals and Global Medical Imaging segments
- › Expertise in controlled substances and pain
- › Focused, lower-risk R&D strategy
- › Experienced in formulation
- › Strong regulatory relationships
- › Focus on attractive markets
- › Fuel Brands growth via core cash generating businesses



<sup>1</sup> Excludes sales of \$54M to related parties

# Mallinckrodt operates in two segments

## Specialty Pharmaceuticals

### Brands



- › Develop products across pain and spasticity
- › Sell via direct sales force of over 200 representatives
- › Distribute to wholesalers and retail pharmacy chains
- › Focus on abuse-deterrent characteristics

### Generics/API



- › Develop controlled substance ANDAs<sup>1</sup> with focus on long-acting and hard-to-formulate products in the pain and ADHD<sup>2</sup> markets
- › Sell to wholesalers, retail pharmacies and mail order
- › Sell API to competitors and supplies Generics business

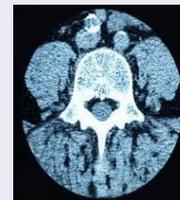
## Global Medical Imaging

### Contrast Media & Delivery Systems (CMDS)



- › Sell and distribute injectable products for diagnostic applications to hospitals, GPOs<sup>3</sup>, and imaging centers

### Nuclear Imaging



- › Develop and market nuclear agents
- › Sell to nuclear pharmacies and hospitals

<sup>1</sup>ANDA = Abbreviated New Drug Application  
<sup>2</sup>ADHD = Attention Deficit Hyperactivity Disorder  
<sup>3</sup>GPO = Group Purchasing Organization

# What makes us different

## Core Capabilities

- › Skills in acquisition and management of highly regulated raw materials
- › Deep regulatory knowledge, reputation and relationships
- › Distinctive manufacturing/logistics skills where vertical integration is an advantage
- › Leadership position in nuclear diagnostics
- › Expertise in specialized chemistry, development and formulation
- › Global commercial reach

## Mallinckrodt's Position

- › 40% share, U.S. DEA quota for controlled substances<sup>1,2</sup>
- › 32% market share, U.S. DEA schedule II and III opiate oral solids<sup>1,2</sup>; long standing regulatory relationships
- › Only manufacturer of acetaminophen outside of Asia
- › 1 of 2 manufacturers of technetium-99m generators in the U.S.
- › 1 NDA and 5 ANDAs on file with FDA; 2 NDA products in development
- › Direct sales in ~50 countries

<sup>1</sup> Across the 43 controlled substances in which Mallinckrodt participates

<sup>2</sup> Estimated market shares as of Dec. 31, 2012 and reflects Watson's acquisition of Actavis

SOURCE: IMS Health National Sales Perspective (2012)

# Brands are our primary growth driver

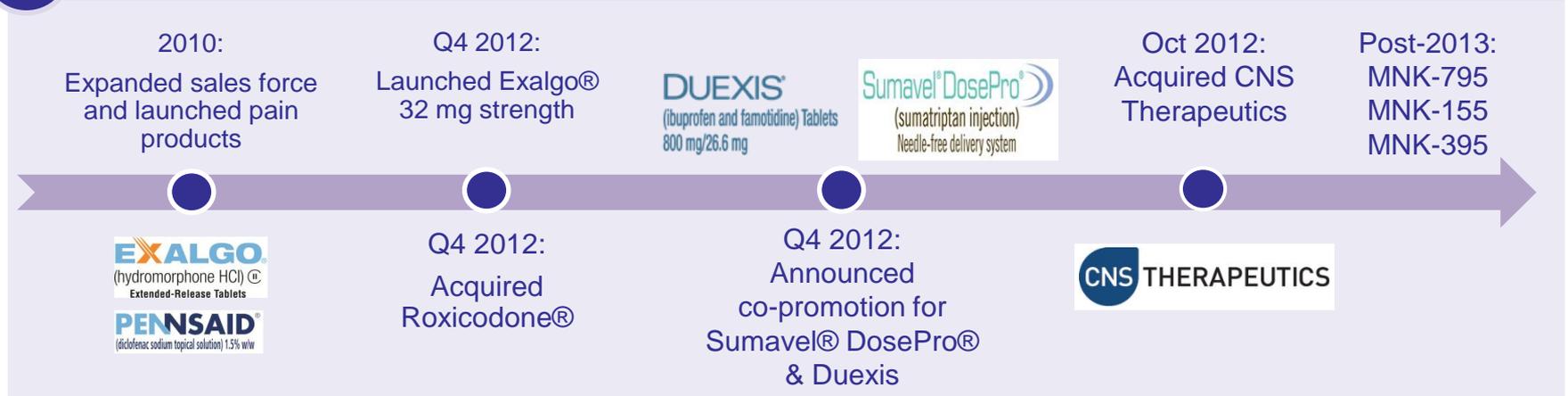


## Why Mallinckrodt?

- › Increased Brands sales almost 80% since 2010
- › Tripled number of promoted brands in the last 12 months through acquisition, licensing and co-promotions
- › Leveraged pain knowledge to launch 3 new products since fiscal 2011
- › Acquired CNS Therapeutics to expand portfolio
- › FDA Filings: 1 NDA submitted; 2 NDAs in development



## What have we done and where are we going?



# Generics / API: Strong competitive position supplements our growth and generates cash



## Why Mallinckrodt?

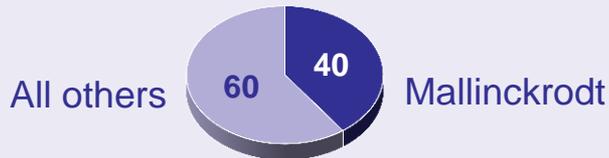
- › #1 or #2 in U.S. for our top 8 generic products / 12th largest in U.S. pharma market by total scripts<sup>1,2</sup>
- › Strong position in U.S. controlled substance generics market with growing ADHD franchise
- › Many products genericized for 20 years → Sustained high dollar value products
- › Only manufacturer of acetaminophen outside of Asia providing vertical integration for Generics
- › \$3.4B U.S. generics pain market with a 5-year projected of CAGR of ~1%<sup>2</sup>



## What have we done and where are we going?

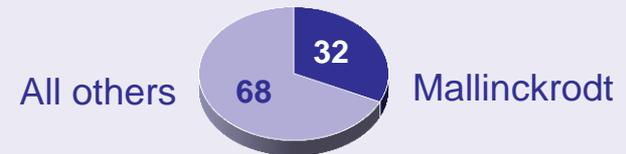
API

Established share of DEA quota for controlled substances<sup>1,3</sup>  
Percent share of kilograms



Generics

Established share of DEA schedule II and III opiate oral solids<sup>1,3</sup>  
Percent share of tablets



**We have 5 ANDAs on file with FDA**

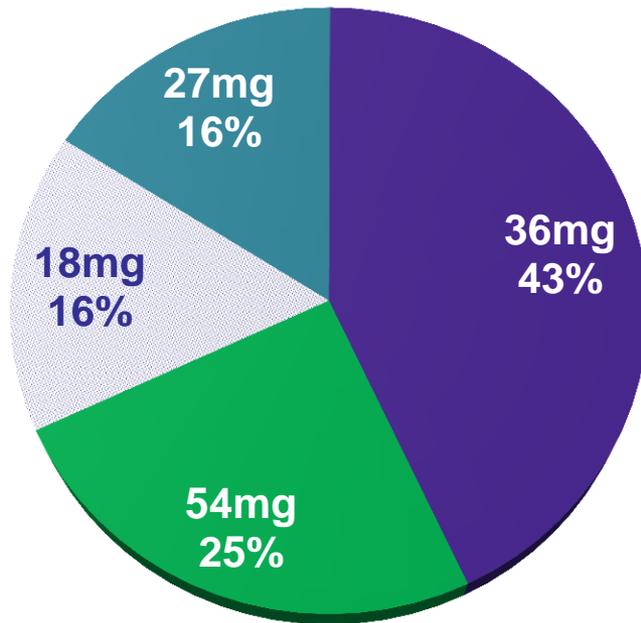
<sup>1</sup> Estimated market share as of Dec. 31, 2012 and reflects Watson's acquisition of Actavis

<sup>2</sup> SOURCE: IMS Health National Prescription Audit & National Sales Perspective (2012)

<sup>3</sup> Across the 43 controlled substances in which Mallinckrodt participates

# Generic CONCERTA® demonstrates core capabilities and contributes to sales growth

## Tablet Share by Strength<sup>1</sup>



- › ANDA approval for Methylphenidate ER<sup>2</sup>, the generic form of CONCERTA®:  
Anticipate 180-day exclusivity on three strengths approved
  - 27mg launched December 28, 2012
  - 36mg & 54mg launched in fiscal Q2 2013
  - 18mg: supplement submitted
- › Demonstrates formulation expertise and ability to manufacture complex products
  - Expands ADHD presence
- › CONCERTA® U.S. market pre-Mallinckrodt entry was \$1.6B<sup>1</sup> in sales

<sup>1</sup> SOURCE: IMS Health National Prescription Audit (2012)

<sup>2</sup> Methylphenidate (HCL) Extended Release, the generic form of CONCERTA  
CONCERTA is a registered trademark of ALZA Corporation

# R&D pipeline represents significant opportunity

Branded Product	Indication	Status	Market Opportunity (U.S. only)	
<b>MNK-795 &amp; MNK-155</b>	May be indicated for acute, moderate to severe pain with abuse-deterrent characteristics	MNK-795: Phase III complete NDA submission 1H2013  MNK-155: Entered Phase III clinical development 1H2013	<b>TRx volume, mm</b>  <b>Step 1</b> (Mild Pain): 49% (Short acting), 51% (Long acting), 106  <b>Step 2</b> (Moderate Pain): 100% (Short acting), 0% (Long acting), 1230  <b>Step 3</b> (Severe Pain): 47% (Short acting), 53% (Long acting), 49  <i>Target segment</i>	<b>Sales, \$bn</b>  24% (Short acting), 76% (Long acting), 3.0  10% (Short acting), 90% (Long acting), 1.8  16% (Short acting), 84% (Long acting), 6.7  Legend: Short acting (Green), Long acting (Purple)
<b>MNK-395</b>	Treatment of osteoarthritis (OA) of the knee	NDA submitted June 2012; FDA requested additional pharmacokinetic study March 2013	<b>TRx volume, mm</b>  <b>NSAIDs<sup>1</sup></b> (Mild Pain): 49% (Short acting), 51% (Long acting), 106  <b>Topical OA</b> (Mild pain): 100% (Short acting), 0% (Long acting), 3  <i>Target segment</i>	<b>Sales, \$bn</b>  24% (Short acting), 76% (Long acting), 3.0  100% (Short acting), 0% (Long acting), 0.2
<b>Intrathecal Development</b>	Management of severe spasticity through novel delivery	Products are in various stages of development	Conversion of compounds to cGMP <sup>2</sup> (Spasticity, Pain)	
<p style="text-align: center;"> <b>Pipeline of low risk programs and productive R&amp;D organization</b>  <b>➔ 10 drugs approved in the last 4 years across portfolio<sup>3</sup></b> </p>				

<sup>1</sup> NSAIDs = Non-steroidal anti-inflammatory drugs

<sup>2</sup> cGMP = current good manufacturing practice,

<sup>3</sup> Source: Orange Book on [www.fda.gov](http://www.fda.gov)

Source: IMS Health National Prescription Audit

# Mallinckrodt investment summary

**We make complex products simpler,  
safer and better for patients**

- › Global company focused on pain management and medical imaging diagnostics with 145-year history of pharmaceutical excellence
- › Strong market positions based on core strengths in manufacturing, with vertical integration, pharmaceutical formulation and regulatory relationships
- › Focus on attractive markets
- › Grow through R&D and targeted acquisitions to accelerate Specialty Pharmaceuticals expansion and increase margins
- › Unlock potential by expanding core product lines, increasing R&D investment and adding products in near adjacencies

**Achieve sales growth faster than the market in  
Specialty Pharmaceuticals**

# 2013 Mallinckrodt guidance

<b>Net Sales Growth</b> 7% to 11%	
<b>Specialty Pharmaceuticals</b> 21% to 25%	<b>Global Medical Imaging</b> -7% to -3%
<b>Methylphenidate ER net sales of at least \$125M</b> <b>Exalgo net sales of at least \$100M</b>	
<b>Adjusted EBITDA<sup>1</sup> as percentage of sales</b> 17% - 21%	
<b>Fiscal 2013 Effective Tax Rate<sup>2</sup></b> 34% to 38%	
<b>Fiscal Q4 2013 Effective Tax Rate<sup>2</sup></b> 28% to 32%	
<b>Capital Expenditures</b> \$140 million to \$160 million	

1. See following page for definition

2. Tax rates exclude the impact of one-time items.

# 2013 Mallinckrodt guidance

The guidance ranges for adjusted EBITDA and effective tax rate assume a June 28, 2013, separation date. The ranges reflect one quarter of Mallinckrodt plc operating as a standalone, public company and three quarters of financial results reflecting the business managed as part of Covidien prior to the separation. The financial results for the three quarters as part of Covidien include expense allocations for certain functions provided by Covidien. While we believe such allocations are reasonable, they may not be indicative of the actual expenses Mallinckrodt plc would have incurred had it been operating as a separate, publicly traded company. Actual costs that may have been incurred if Mallinckrodt had been a standalone company would depend on a number of factors, including the organizational structure, what functions were outsourced or performed by employees and strategic decisions made in areas such as information technology and infrastructure.

Adjusted EBITDA represents earnings before interest, income taxes, depreciation and amortization, adjusted to exclude certain items. These items include, if applicable, discontinued operations; other income, net; separation costs; restructuring charges, net; immediately expensed up-front and milestone payments; acquisition related costs; and non-cash impairment charges. We have provided this non-GAAP financial measure because it is used by management, along with financial measures in accordance with accounting principles generally accepted in the US. (“GAAP”), to evaluate our operating performance. In addition, we believe it will be used by certain investors to measure our operating results. Management believes that presenting adjusted EBITDA to investors provides useful information about our performance across reporting periods on a consistent basis by excluding items that we do not believe are indicative of our core operating performance.