

The Impact of Downstream Inventory on Gross-to-Net Accounting

Contents

Inventory Data in the Gross-to-Net Process (Gross and Net)..... 3

What Can Go Wrong? 5

IntegriChain Solution for Downstream Inventory 14

Practical Use Cases..... 16

Conclusion.....20

About IntegriChain 21

♥ 2015 IntegriChain, Inc. All rights reserved. IntegriChain is a registered trademark of IntegriChain, Inc. All other trademarks are property of their respective owners.

Inventory Data in the Gross-to-Net Process (Gross and Net)

Valuation of channel inventories has direct impact in three fundamental processes: forecasting gross sales, forecasting reserves, and budget reconciliations, especially on the elements in green below.

Forecast Gross Sales	Forecast Net Reserves	Budget Reconciliations
Project demand based on syndicated Rx trends	Review historical trend and variances	Reconcile gross sales forecast-to-actuals
Adjust for product and market events	Estimate channel inventories	Identify inventory impacts
Build in assumptions about inventory changes	Adjust reserve rates by product	Evaluate reserve sufficiency based on channel inventories
Create gross sales forecast	Forecast reserves	Adjust carry-forward balances

Forecasting gross sales: Pharmaceutical suppliers typically build a demand forecast based on syndicated Rx trends (IMS and/or Symphony) along with institution purchase data, adjusting for product and marketplace lift and contraction events. This demand forecast is ultimately converted into a gross sales forecast. The delta between what demand will be and what you ultimately sell is how inventories will change. Financial analysts within each pharmaceutical supplier tracks inventory trends and distribution agreements to best forecast how wholesale and/or retail inventories will change, building them into the gross sales forecast.

Forecasting net reserves: Similar to forecasting gross sales, review historical trends and variances of gross-to-net cost item – rebates, co-pay program costs, Medicaid/Medicare, and historical returns rate – to determine a rate at which you need to reserve against sales forecasts. Estimating inventory is also an important element in this process: determining what is out in the marketplace at the beginning of the period and what are the future liabilities.

Budget reconciliation: When looking at how gross sales actuals compare with forecasts, understanding the impact of inventory and demand are important. Inventory data is also used to determine if reserves are appropriate, with many teams monitoring this on a weekly or month basis. This can lead to retuning of the carryforward or the actual reserve rate but is very dependent on inventory data to monitor the sufficiency of the reserve.

What Can Go Wrong?

Addressing Gaps in Downstream Inventory Data

The availability and quality of data is the most significant risk factor in gross-to-net accounting. Pharma manufacturers receive inventory data (EDI 852) from their direct trading partners: wholesalers, specialty distributors, specialty pharmacies. This 852 data has been proven to be a highly reliable dataset for inventory levels in direct trading partners, but it lacks visibility to inventories in indirect trading partners: retail pharmacies, retail distribution centers, mail order, indirect specialty pharmacies, and institutions.

To fill in the gaps, manufacturers depend on assumptions, anecdotal data, or extrapolations to fill in downstream data gaps:

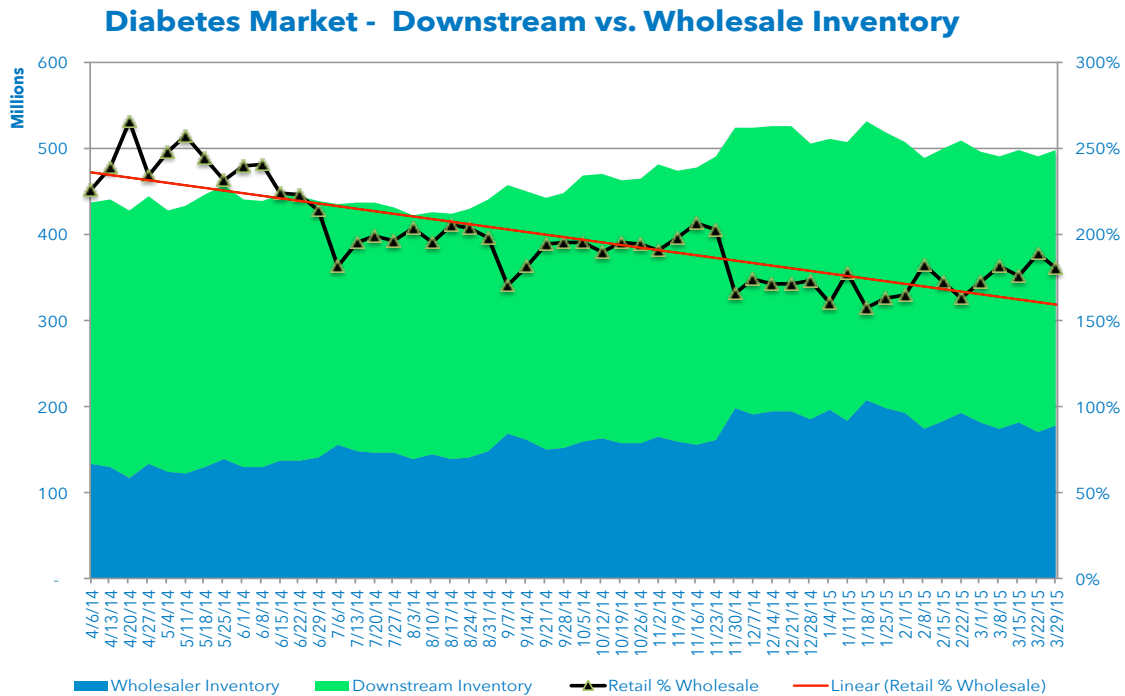
- **Assumption:** Downstream inventory = (wholesale inventory * factor)
- **Ad Hoc:** Often used by smaller manufacturers to gather insights from trade, which typically involve a call to two or three chains to query on the purchase of chain-specific data
- **Sampling:** Survey a panel of 200 pharmacists
- **Imputed:** Typically used by big pharma to derive downstream inventory by rolling forward wholesale withdrawals less syndicated Rx data

What Can Go Wrong with Assumed Factors for Downstream Inventory

Product	Actual Wholesaler Inventory (852)	Expected Downstream Inventory Ratio	Expected Downstream Inventory	Actual Downstream Inventory	Actual Downstream Ratio	Expected vs. Actual Error
Product 1	\$ 193,739,593	125%	\$ 242,174,491	\$ 257,740,541	133%	-\$15,566,050
Product 2	\$ 16,190,776	125%	\$ 20,238,470	\$ 13,189,383	81%	\$7,049,086
Product 3	\$ 92,344,538	125%	\$ 115,430,672	\$ 79,567,094	86%	\$35,863,578
Product 4	\$ 29,273,068	125%	\$ 36,591,335	\$ 63,271,424	216%	-\$26,680,089
Product 5	\$ 72,012,808	125%	\$ 90,016,009	\$ 77,300,765	107%	\$12,715,244
Product 6	\$ 153,888,210	125%	\$ 192,360,263	\$ 104,242,478	68%	\$88,117,785
Product 7	\$ 247,467,640	125%	\$ 309,334,550	\$ 126,954,490	51%	\$182,380,060
Product 8	\$ 23,134,423	125%	\$ 28,918,029	\$ 31,530,290	136%	-\$2,612,261
Product 9	\$ 8,147,708	125%	\$ 10,184,635	\$ 28,557,638	350%	-\$18,373,003
Product 10	\$ 74,634,683	125%	\$ 93,293,353	\$ 131,778,417	177%	-\$38,485,063
Product 11	\$ 1,459,023	125%	\$ 1,823,778	\$ 983,832	67%	\$839,947
Product 12	\$ 1,500,508	125%	\$ 1,875,635	\$ 4,358,166	290%	-\$2,482,531

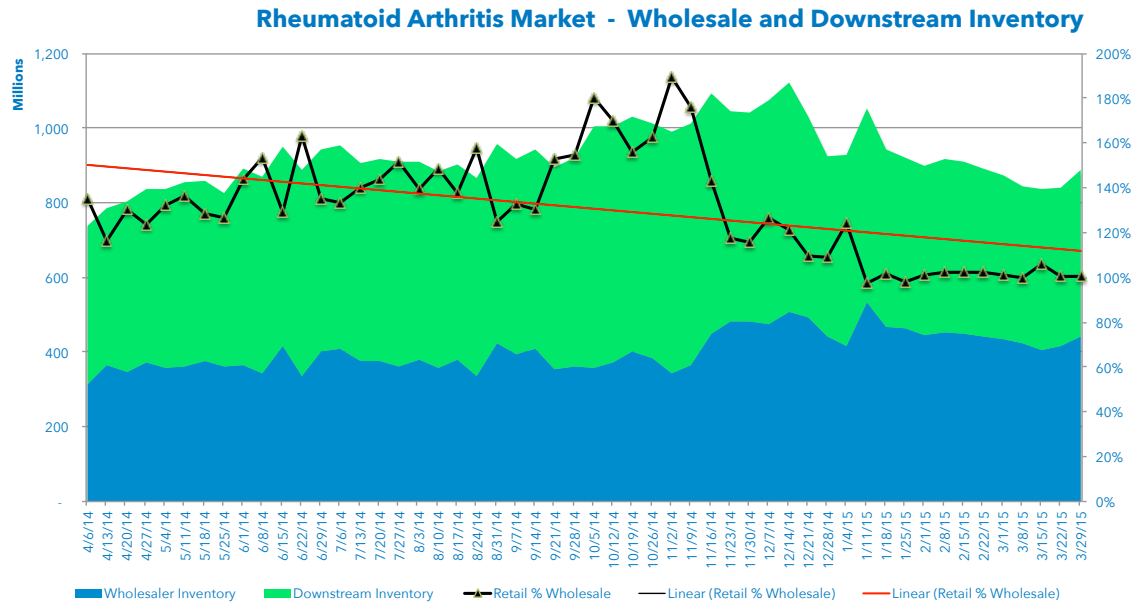
The assumption-based approach often involves setting a ratio of expected downstream revenue to wholesale inventory. However, as shown in the table above (which uses actual, blinded data from multiple pharma suppliers), this assumption can be vastly different than reality, resulting in significant error. Sometimes, this is a huge assumption error, as illustrated with Product 7, resulting in \$182 million in over-reserves.

Downstream vs. Wholesaler Inventory Levels in the Diabetes Market



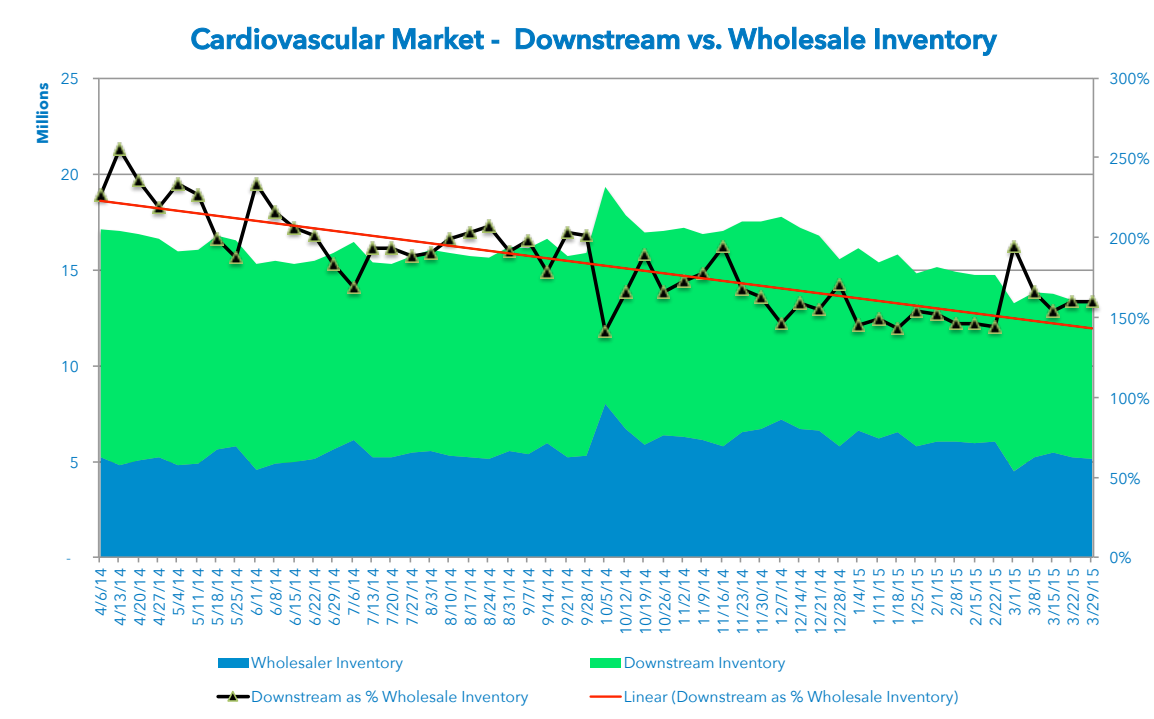
Real-world benchmark data also show trends for downstream and wholesale inventory. In the diabetes segment above, the red ratio line indicates that the channel has evolved, with more just-in-time delivery models for retailers that puts more inventory with wholesalers and less with retailers.

Downstream vs. Wholesaler Inventory Levels in the Rheumatoid Arthritis Market



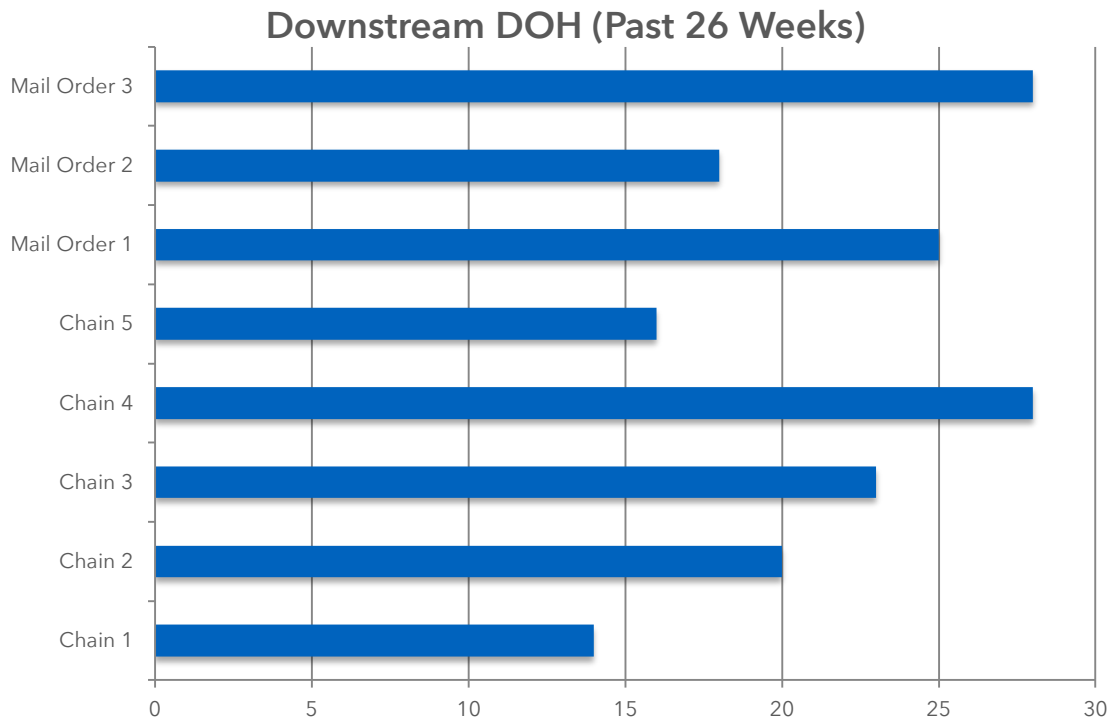
The rheumatoid arthritis market is characterized by less unit volume and higher prices and thus have a different ratio. Fewer retailers are willing to carry these products in their inventories and inventory is concentrated in specialty pharmacies. Overall inventories are much leaner. Although changing over the past year, the ratio of downstream to wholesaler inventory level for this segment remains 1:1.

Downstream vs. Wholesaler Inventory Levels in the Cardiovascular Market



In theory, the cardiovascular market appears similar to diabetes. However, this is only true in the aggregate for the entire category. Drilling in by therapeutic type or individual products, however, shows that variances are abundant. There are slow movers and fast movers, and the products vary by price point, pricing strategy, benefits hurdles, prior authorization requirements, and stocking strategies for launch. With the amount of potential impact from these variables, forecasters are typically overly conservative in their assumption-based models.

What Can Go Wrong with Sampling and Anecdotal Data



Anecdotal- and sampling-driven models often do not present an accurate indication of investment. For example, the graph above illustrates blinded real-work data for a major brand from major retailers such as Rite Aid, CVS, or Express Scripts. As shown above, however, each chain and mail order pharmacy varies widely. Reaching out to a limited number of retailers will provide a very skewed view of the channel as the days on hand varies by each retailer, not accounting for the variability. The same is true for a survey of pharmacists, which often might not accurately represent the entire supply chain.

What Can Go Wrong with Imputing Downstream Inventory for Syndicated Rx Data

Syndicated Rx datasets are projected and designed for the purposes of physician targeting and incentive compensation. As such, these datasets are simply not designed to support an inventory balance process as there are significant gaps in mail order, specialty pharmacy, government, and HMO inventory.

Syndicated datasets offer good *overall* coverage in retail, BUT capture rate varies heavily by therapeutic category, leading to mistakes in gross up assumptions by the data syndicators. Projection errors of 2-3% are pervasive, and errors of >5% are commonplace.

Syndicated Rx data, while reliable for incentive compensation and directional forecasting, was never designed to support fine-tuned calculations of channel inventory.

The graph below illustrates an imputed inventory approach.

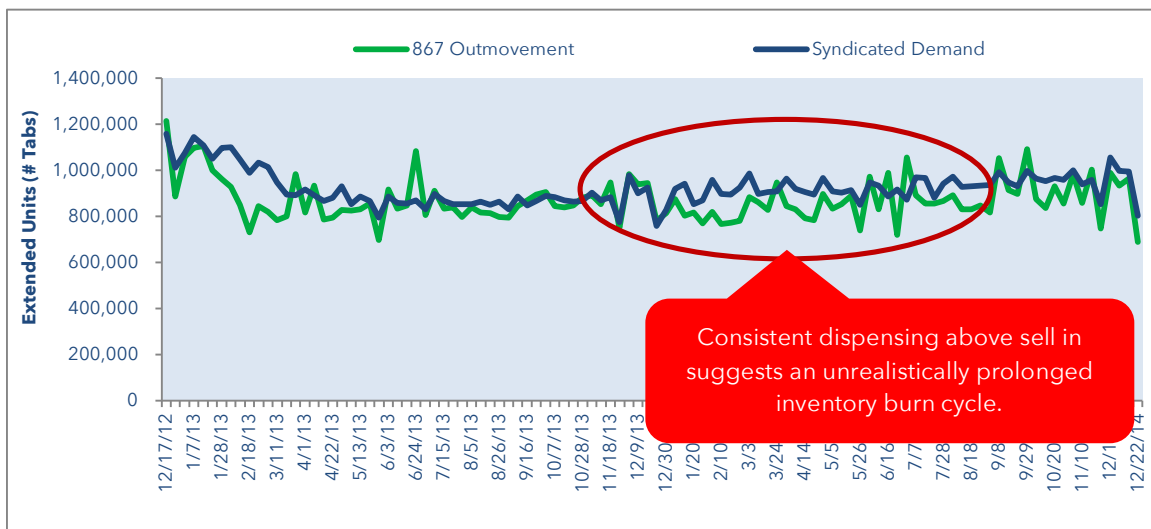
Wholesale inventory levels are stable, but the imputed retail inventory levels show this continuous trend of lowering inventory levels. It either creates fear of massive returns or stock outages, while neither is reality as this is merely a projected dataset (slightly over projected that compounds week over week).



Downstream Inventory = (Syndicated Demand Units) - (Wholesaler Inventory Units)

Syndicated Demand Outpaces Wholesaler Withdrawals over Extended Periods

For the product below, solid weekly syndicated Rx numbers tend to be 1.5% to 3.0% higher than wholesaler withdrawals, yielding the imputed (and not at all credible) retail inventory trend.



IntegriChain Solution for Downstream Inventory

IntegriChain utilizes unprojected retail dispensed data, enriched 867 data, and third-party returns data to quantify total downstream exposure at an NDC level. This dataset is used by finance teams to create gross-to-net reserves especially at key product lifecycle milestones such as launch, LOE, and other market events. It provides weekly visibility to retail inventory builds and burns so that finance teams can monitor gross-to-net reserves on a weekly/monthly basis and thereby land quarterly reserves more predictably.

This dataset also provides a secondary QA/QC on projected syndicated prescription data, and is consistently accepted by the top audit firms as best practice for their customers.

The Details

IntegriChain delivers a weekly inventory retail dataset, utilizing actual units filled at 45,000+ pharmacies and supported by the industry’s largest pharmacy call program.

Inventory Retail Methodology = (Sales-In) - (Returns) - (Demand)
Sales-In = (Direct Sales) + (Indirect Sales)
Returns = (Returns for Credit) + (Wholesaler Returns)
Demand = (Unprojected Prescription Units) * (Package Size)

IntegriChain provides insights to downstream channels:

Weekly data, metrics and trends	Breaks down by channel type
Total downstream inventory	Pharmacy shelf
Total channel purchases	Chain distribution centers
Multiple UOM options in Extended Units or Pack Units, WAC Dollars and Days on Hand	Mail order/specialty pharmacy
	3PL morgue
	Non-retail/LTC/hospital

Practical Use Cases

Pharmaceutical manufacturers use this data in a variety of ways for the following business processes.

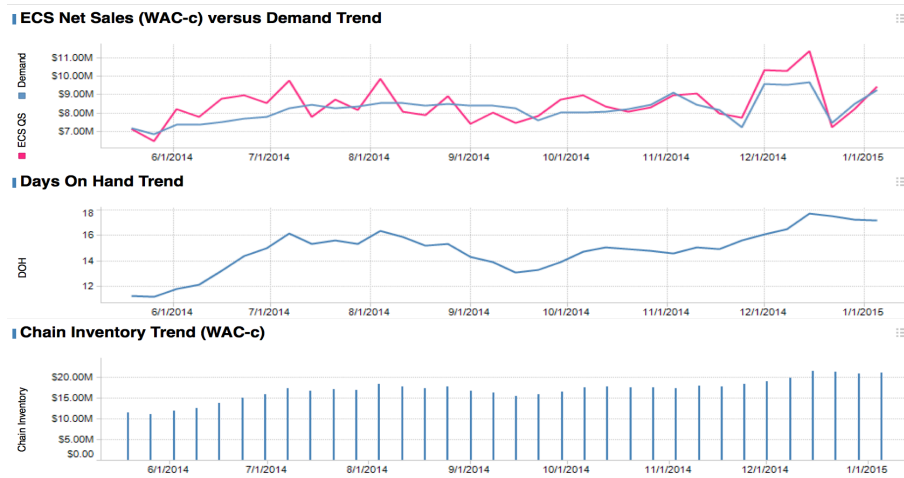
Weekly and monthly data: used to monitoring wholesale and downstream pipeline fluctuations, to assess temporary/cyclical builds and burns vs. demand trend break, and to evaluate reserve drawdown and sufficiency.

Quarterly and annual data: used to reconcile prior period actuals, to document variances in reserves, to create/adjust next period reserve, and to adjust carryforward balances.

Event-driven data: used for product launch and for loss of exclusivity.

IntegriChain Inventory Dashboard

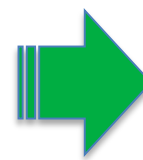
Working with these datasets are easy through the dashboards provided.



Additionally, dataset extracts are provided that can be imported to your gross-to-net system of record, be it Excel spreadsheets or automated third-party solutions including daVIZta, BPI, or Oracle Hyperion.

Dataset Extracts

Week	ExFactory Sales	Demand	Wholesaler		Downstream	
			Inventory	DOH	Inventory	DOH
12/29/14	\$12,089,094	\$9,898,355	\$35,302,968	22	\$24,354,046	14
1/5/15	\$3,830,389	\$9,680,481	\$26,293,599	16	\$26,857,376	16
1/12/15	\$12,191,590	\$11,419,105	\$28,432,996	18	\$25,517,976	15
1/19/15	\$7,520,733	\$10,442,677	\$27,045,594	17	\$23,889,612	15
1/26/15	\$6,988,742	\$10,092,912	\$23,687,848	15	\$23,758,211	15
2/2/15	\$11,439,365	\$10,425,918	\$22,932,938	14	\$25,784,520	16
2/9/15	\$12,121,958	\$11,072,983	\$24,197,922	15	\$25,239,148	16
2/16/15	\$11,891,926	\$10,173,067	\$26,235,305	17	\$24,831,089	16



Gross-to-Net System of Record

daVIZta

BPI

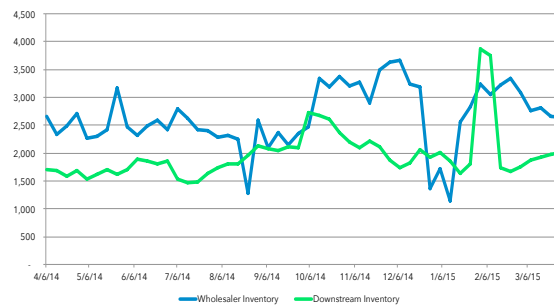
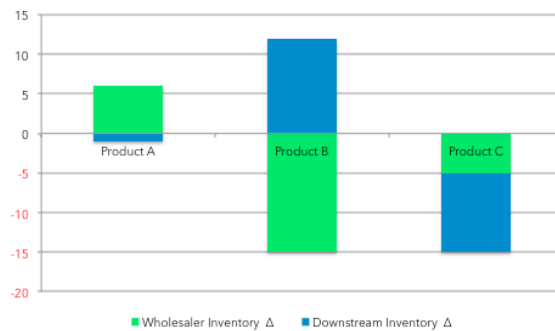
ORACLE Hyperion



Sales and Demand Reconciliation

IntegriChain offers access to plan vs. actual changes in demand, sales, and inventories. A dashboard, as shown below, is used to quickly review forecasts against actual data on an individual product basis and over time to validate and cross-validate sales demand plans.

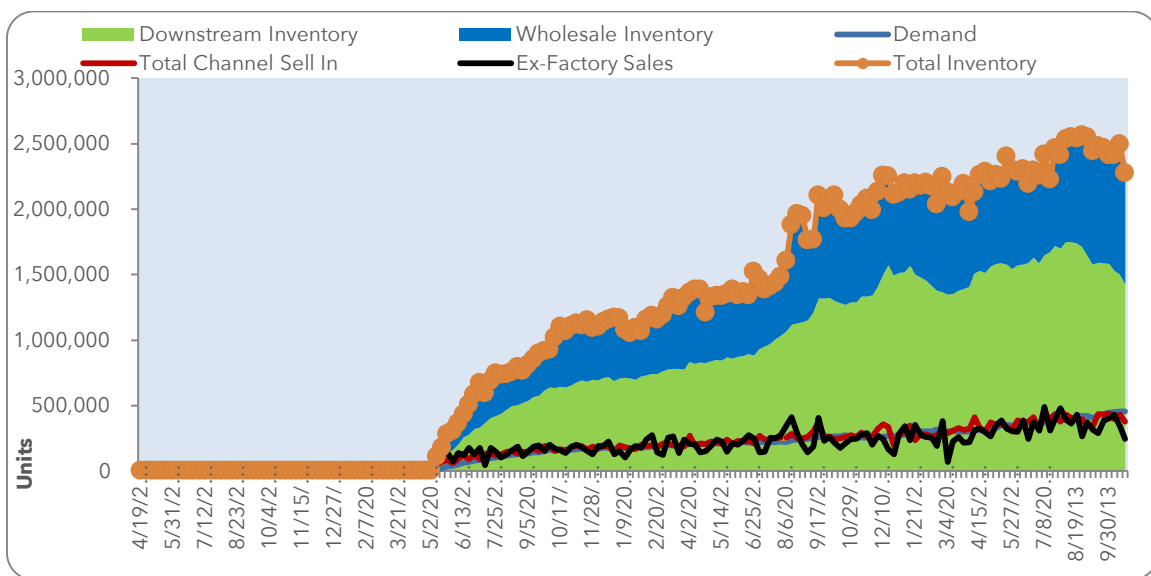
	Demand Forecast	Sales Forecast	Inventory Δ Assumption	Demand Actual	Sales Actual	Inventory Δ Actual	Sales Forecast vs. Actual	Inventory Δ Forecast vs. Actual	Demand Forecast vs. Actual
Product A	100	90	-10	100	105	5	15	15	0
Product B	125	112	-13	118	115	-3	3	10	-7
Product C	140	125	-15	145	130	-15	5	0	5



Product Launch

Total inventory dynamics views help Brand and Finance:

- Monitor draw down of launch stocking (returns risks)
- Validate/triangulate projected Rx data
- Explain noise between sales and Rx data (end-to-end view)



Similar analytics are available for LOE and other market events.

Conclusion

Pharma manufacturers of all sizes and segments – bio/pharma, generics consumer – are under increasing pressure from CFOs and external auditors to land gross and net forecasts more predictably (no more than plus or minus 5% variance) and with more insightful explanations for missed budgets. For smaller manufacturers, establishing reserves correctly is not merely a matter of compliance but of the ongoing health of the organization. Creating a forecast based on projected data introduces unacceptable levels of noise into the gross-to-net revenue accounting process. IntegriChain allows gross-to-net forecasters the ability to use actual inventories and thereby reduce inefficiency and risk.

About IntegriChain

IntegriChain is the leading channel management cloud used by healthcare suppliers, including nine of the top-10 pharmaceutical manufacturers, to improve the efficiency of how products reach customers. Pharmaceutical, biopharm/specialty pharma, generics, and consumer health suppliers use IntegriChain to manage their supply chain relationships, inventories, and orders across a vast network of retailers, ecommerce, and distributors. As a suite of informed applications and analytics built on top of aggregated channel inventory and point-of-sale (POS) data, IntegriChain provides customer operations, national accounts, and finance teams with a collaborative, agile, and mobile alternative to ERP and homegrown systems. By embedding big-data customer insights into daily business processes, IntegriChain helps control the high cost of product distribution while improving product availability, ensuring a higher level of revenue predictability and maximizing distribution investment. More than \$175 billion in annual US commerce and 1.5 billion transactions flowed through the IntegriChain Cloud in 2014. For more information, visit www.integrichain.com and follow us on Twitter @IntegriChain.