

A Specialty Pharmaceutical Company

NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS



Corporate Presentation



March 7, 2018

Forward-Looking Statements

To the extent any statements made in this presentation deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about price increases, the Company's future operations, products financial position, operating results and prospects, the Company's pipeline or potential markets therefore, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words and the use of future dates.

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More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. All forward-looking statements in this presentation speak only as of the date of this presentation and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.



Corporate Overview

- U.S. based specialty pharmaceutical company (NASDAQ: ANIP) with a commercial portfolio of 35 brand and generic Rx products
- Differentiated generic strategy including acquisition and re-commercialization of previously approved products, as well as traditional development
- Baudette, MN manufacturing footprint comprised of two sites and ~165 of our ~180 employees
- 2018 Financial Guidance: \$212M \$228M Revenues / \$90M \$100M Adjusted non-GAAP EBITDA

Generic Drug	S
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- 24 commercial products
- 70 pipeline products; 40 previously approved
- Addressable market of pipeline = \$1.7B

11 commercial products

- 4 pipeline products previously approved
- Addressable market of pipeline = \$1.4B

Branded Drugs

CMO / Manufacturing

- 4 CMO clients representing 7 SKUs
- 177,000 ft² of US based facilities
- Significant capacity
- Capabilities: Solid oral, liquids, extended release, high containment

Core Strategic Focus

Create long term shareholder value by:

- Building a sustainable and growing portfolio of Brand and Generic Rx products via internal development and acquisition
- Leverage tech transfer team and manufacturing facilities to move acquired products to ANI sites
- Advancing a transformational opportunity to re-commercialize Cortrophin[®] Gel

Experienced Senior Management Team

Name	Role	Industry Experience	Joined ANI	Previous Affiliation
Arthur Przybyl	President and CEO	25+ years	2009	
Stephen Carey	VP, Finance and CFO	20	2016	PHARMACEUTICAL
Robert Schrepfer	SVP, BD and Specialty Sales	15	2013	Healthcare Value Capital
James Marken	SVP, Operations & Prod. Development	20	2007	Solvay
David Sullivan, PhD	VP, Quality Operations	20	2014	Scientific
Ellen Camos	VP, Regulatory Affairs	15	2012	SANDOZ
Mark Ginski, PhD	VP, Corticotropin Development	20	2016	Mallinckrodt
Karen Quinn, PhD	VP, Corticotropin Regulatory Affairs	30	2017	Takeda



Financial Highlights - 4Q and Full Year 2017

(\$ in millions, except per share data)	-	hree Mon <u>Decem</u> 2017	ber 3		Year E <u>Decem</u> 2017	ber 3	
Net revenues	\$	47.3	\$	38.2	\$ 176.8	\$	128.6
Net (loss) / income	\$	(9.6)	\$	(1.1)	\$ (1.1)	\$	3.9
GAAP (loss) / earnings per diluted share	\$	(0.83)	\$	(0.09)	\$ (0.09)	\$	0.34
Adjusted non-GAAP EBITDA (1)	\$	19.7	\$	17.9	\$ 74.2	\$	61.1
Adjusted non-GAAP diluted earnings per share (1)	\$	1.08	\$	0.90	\$ 3.91	\$	2.96

Posted record annual Net Revenue, Adjusted non-GAAP EBITDA and Adjusted non-GAAP EPS

Net revenues increased 24% from prior year in 4Q and 37% on a full year basis

• Adjusted non-GAAP EBITDA increased 10% from prior year in 4Q and 21% on a full year basis

• 2017 GAAP loss due to \$13.1M 4Q tax charge due to implementation of Tax Cuts and Jobs Act



Strong Capital Position

- \$31.1 million of cash as of December 31, 2017
 - 2017 cash flow from operations of \$39.4 million
 - 2017 free cash flow of \$29.0 million
- Net leverage of 2.0x based upon mid-point of 2018 guidance
- New \$125 million senior secured credit facility includes undrawn \$50 million revolver
- Beneficiary of 2017 Tax Cuts and Jobs Act
 - Favorable impact of reduced cash tax burden worth approximately \$10 - \$13 million

Improved ability to continue to invest in:

- value generating business development opportunities
- our U.S. based manufacturing and development capabilities
- research and development

Financial Highlights - 2017 Net Revenues

(\$ in millions)		Year I <u>Decem</u>		Variance to Prior Year			
	-	<u>2017</u>	<u>2016</u>	<u>\$</u>	<u>%</u>		
Generic pharmaceutical products	\$	118.4	\$ 95.2	\$ 23.2	24%		
Branded pharmaceutical products		50.9	26.4	24.5	93%		
Contract manufacturing		7.0	5.5	1.5	27%		
Contract services and other income		0.4	1.4	 (1.0)	-70%		
Total net revenues	\$	176.7	\$ 128.5	\$ 48.2	37%		

Generic sales gains driven by 2017 and annualization of 2016 launches

Brand sales gains reflect the late February 2017 introduction of InnoPran XL[®] and Inderal[®] XL as well as increased sales of Inderal[®] LA which launched in Q2 2016

Contract manufacturing reflects timing and volume of customer orders



2018 Guidance

(\$ in millions except EPS figures)

	2017 <u>Actual</u>		2018 Guidance				% Increase		
			-	Low		High	Low	<u>High</u>	
Net Revenues	\$	176.8	\$	212.0	\$	228.0	20%	29%	
Adjusted non-GAAP EBITDA (1)		74.2		90.0		100.0	21%	35%	
Adjusted non-GAAP diluted earnings per share (1)	\$	3.91	\$	5.43	\$	6.08	39%	55%	

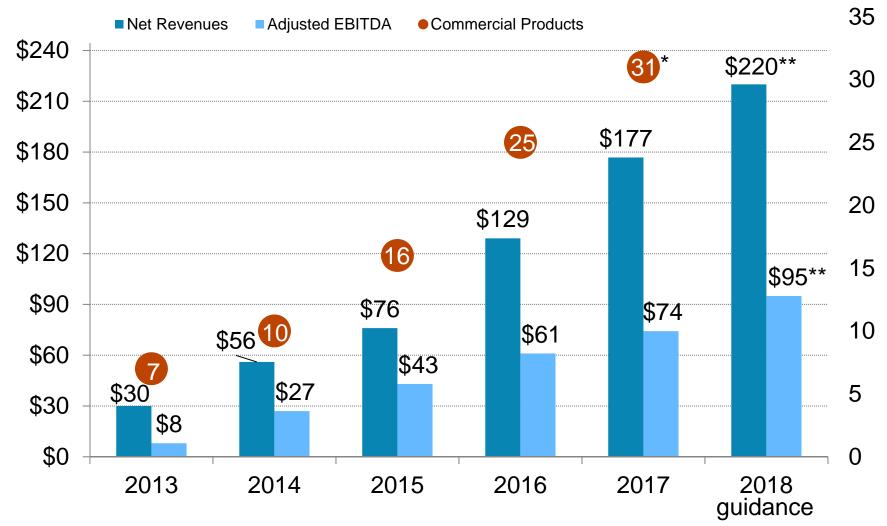
Forecast results assumes:

- Revenues and expenses related to our December 29, 2017 acquisition of the NDAs and U.S. product rights for Atacand®, Atacand HCT®, Arimidex® and Casodex®
- Maximizing the potential of our currently commercialized product portfolio and 2018 generic launches
- Increased investment in R&D driven by our commitment to the Cortrophin® Gel re-commercialization program
- Combined Federal and State effective income tax rate of 23%
- Approximately 11.7 million shares outstanding



Growth Led by New Product Introductions

(\$'s in millions)





* 2017 products do not include the four products acquired from AstraZeneca on December 29, 2017, as net revenues from these products commenced in 2018.
** Midpoint of 2018 annual guidance, as presented in February 27, 2018 Earnings Release

Sales and Marketing Overview





Generic Rx Product Portfolio 2016 & 2017 Product Introductions

- Diphenoxylate HCL and Atropine Sulfate
- Erythromycin
 Ethylsuccinate
- Fenofibrate Capsules (AG)
- HC Cream, for rectal use
- Indapamide

- Lithium Carbonate ERImage: Propranolol ER(AG)Capsules (AG)
- Mesalamine Enema (AG)
- Nilutamide Tablets
- Oxycodone Capsules
- Oxycodone Oral Solution (100 mg/5 mL)
- Pindolol



Continued broadening of our product offerings

- Twenty-four generic product families encompassing 47 SKUs
- \$118.4 million of full year 2017 net sales, up 24% vs. prior year



Brand Rx AstraZeneca Transaction



anastrozole 1 mg





Acquired the NDAs and U.S. rights to four brands including two hypertension and two hormone based chemotherapy drugs

- Purchased on December 29, 2017, for approximately \$46.5 million
- Generated combined sales of \$19.0 million in U.S. gross market sales during the trailing twelve months ended October, 2017 according to IMS Health data
- Opportunity to further leverage our IDC road (hormone containment) facility



Brand Rx InnoPran XL[®] and Inderal[®] XL





Two additional hypertension brands acquired in first quarter 2017:

- Purchased on February 23, 2017, for approximately \$51 million
- Generated combined sales of \$23.3 million in 2016 according to IMS Health data (gross sales basis)
- Second quarter of 2017 was first full quarter of sales and gross profit contribution



Brand Rx Product Portfolio

Inderal [®] LA
(propranolol hydrochloride)
Long-Acting Capsules

Inderal[®] LA Capsules

Hypertension



Lithobid[®] Tablets

Bipolar Disorder



Vancocin[®] Capsules

C. difficile-Associated Diarrhea



Cortenema®

Ulcerative Colitis



Reglan[®] Tablets Gastroesophageal Reflux

 Total full year 2017 Brand Rx net revenues of \$50.9 million, up 93% vs. prior year



Contract Manufacturing and Other

- Contract manufacturing
 - \$5.5 million of 2016 and \$7.0 million of 2017 net revenues
 - Four customers
 - Seven products and seventeen SKUs
 - Contract manufacturing and contract packaging
- Contract services and other
 - \$1.4 million of 2016 and \$0.4 million of 2017 net revenues
 - Product development services, laboratory services, and royalties received





Business and Product Development Overview





Business Development Activity – Generic Products

		NOTES	DATE	ANI MANUF	APPROVED	COST (\$M)
	Rowasa® AG (Partnership with Meda)	Commercial	May-16	\checkmark	\checkmark	\$0.0
G e	Lipofen® AG & 1% and 2.5% HC Cream	Commercial	Jan-16		\checkmark	\$10.0
n	IDT Partnership (18 previously approved ANDAs)	to date, 1 product commercialized	Aug-15	\checkmark	\checkmark	\$1.0
e r	ANDA Basket 2 (22 previously approved ANDAs)	to date, 3 products commercialized	Jul-15	\checkmark	\checkmark	\$25.0
i	Flecainide (flecainide tablets)	Commercial	Mar-15	\checkmark	\checkmark	\$4.5
C S	ANDA Basket 1 (31 previously approved ANDAs)	to date, 3 products commercialized	Jan-14	\checkmark	\checkmark	\$12.5
2	Nimodipine & Omega (Partnership with Sofgen)	Nimodipine Commercial Omega in pipeline	Aug-13 and Apr-14			\$1.1
					Total	\$54.1



Business Development Activity – Brand Products

		NOTES	DATE	ANI MANUF	APPROVED	COST (\$M)
	Atacand®, Atacand HCT®, Casodex®, Arimidex® (candesartan cilexetil, candesartan cilexetil- hydrochlorothiazide, anastrozole, bicalutamide)	Commercial	Dec-17		\checkmark	\$46.5
В	Inderal® XL (propranolol ER capsules)	Commercial	Feb-17		\checkmark	\$20.0
r	InnoPran XL® (propranolol ER capsules)	Commercial	Feb-17		\checkmark	\$31.0
a n	Brethine® (terbutaline tablets)	Pipeline	Dec-16	\checkmark	\checkmark	\$0.0
d	Inderal® LA (propranolol ER capsules)	Commercial	Apr-16		\checkmark	\$60.0
S	Cortrophin® Assets (corticotropin)	Pipeline	Jan-16		\checkmark	\$75.0
	Vancocin® Assets (vancomycin HCl capsules, injectable, solution)	Capsules Commercial Inj & Solution in Pipeline	Aug-14		\checkmark	\$11.0
	Lithobid® (lithium carbonate tablets)	Commercial	Jul-14	\checkmark	\checkmark	\$12.0
					Total	\$255.5



Product Development Pipeline

- 74 products in development
- ANI believes 44 can be commercialized via CBE30 or PAS
- Total combined market value: \$3.1 billion⁽¹⁾

Generic Product Pipeline

- 70 products 40 can be re-commercialized via CBE30 or Prior Approval Supplement
- Addressable market of pipeline = $$1.7B^{(1)}$

Brand Product Pipeline

- 4 products Cortrophin® Gel, Cortrophin-Zinc®, Vancocin® Oral Solution, and Brethine® tablets; all are approved and can be re-commercialized via sNDA filing
- Addressable market of pipeline = \$1.4B⁽¹⁾

Cortrophin® Assets

- NDA #008975 Purified Cortrophin® Gel, 40 units/mL and 80 units/mL
- NDA #009854 Cortrophin-Zinc®, 40 units/mL
- Drug Master File 4181 for corticotropin (withdrawn); API Process "know-how"



Cortrophin® - A Compelling Strategic Opportunity

Regulatory and Development Considerations

- Approved NDAs/Discontinued Marketing: Clear and abbreviated pathway to re-commercialization
- Acquired: NDAs, DMF* and other documentation (e.g. batch records, historical data)

Commercial Considerations

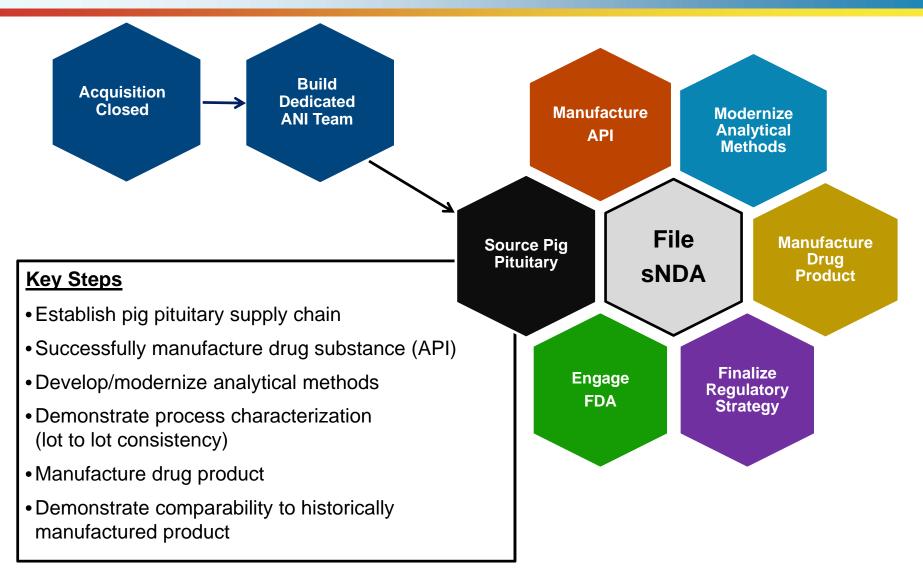
- \$1.2B U.S. market opportunity today
- Provides patients, prescribers and payors with valuable therapeutic alternative
- Broad label / concentrated prescriber base
- Durable assets: high barrier to generic entry, ANI's products represent the last of the dormant corticotropin filings that were not withdrawn via Federal Register

Value Creation

- Provides patients, payors and physicians with valuable therapeutic option
- Potential to generate substantial revenues and cash flow
- High risk-adjusted ROI and NPV



Cortrophin® - Path to Re-Commercialization





Key Re-commercialization Milestones

	Duration	Status	Additional Details
Manufacture small-scale batch of corticotropin API	4 mos.	Complete	 Initial batch yields similar to historical yields Analytical method development and testing ongoing
Select drug product CMO	6 mos.	Complete	Drug product CMO has been selected
Manufacture intermediate- scale batches of corticotropin API	4-6 mos.	Complete	 Three intermediate-scale batches successfully completed Further refined/modernized analytical methods & process Demonstrated lot-to-lot consistency
Type C meeting with FDA		FDA Response March 2018	 Meeting Request submitted 4Q17; FDA granted as Type C Meeting Information provided on ANI's regulatory plan for re-commercialization FDA response scheduled for March 2018
Manufacture demo batches of Cortrophin® Gel	TBD	Target Q2 2018	 Initiate formulation / fill / finish of drug product
Manufacture commercial- scale batches of corticotropin API	2-3 mos. per batch	Target H1 2018	 Scale-up manufacturing process 5x Manufacture API under cGMPs Finalize API manufacturing process in preparation for process validation/registration batches
Manufacture registration batches of Cortrophin® Gel	2-3 mos. per batch	Target end 2018	 Process validation Registration / Commercial batches Initiate registration-enabling ICH stability studies
Initiate registration stability for sNDA	6 mos.	TBD	 Six months of accelerated stability from drug substance and drug product batches at time of submission
sNDA submission	TBD	TBD	PAS filing - PDUFA four month review time



Manufacturing Overview





Manufacturing Overview

	Main Street Facility – 130K ft ²	IDC Road Facility – 47K ft ²
Overview	 57,000 ft² of manufacturing, packaging, and warehouse Recently completed 5,500 ft² warehouse expansion includes additional schedule CII vault & CIII cage space 17,000 ft² of laboratory space for product development and analytical testing 	 32,000 ft² of manufacturing, packaging, and warehouse 100 nano-gram per eight-hour time weighted average maximum exposure limit to ensure employee safety Adding a low-humidity suite for processing and encapsulating moisture-sensitive compounds
Capabilities	 Rx solutions, suspensions, topicals, tablets, capsules and powder for suspension DEA-licensed for Schedule II controlled substances 	 Fully-contained high potency facility with capabilities to manufacture hormone, steroid, and oncolytic products DEA Schedule III capability
Capacity	 Solid Dose - ~1.2 billion doses/yr Liquids - ~53 million bottles/yr Liquid Unit Dose - ~23 million doses/yr Powder - ~12 million bottles/yr 	 Tablets - ~2.5 billion doses/yr Capsules - ~150 million doses/yr



Manufacturing and Packaging Capabilities by Site

Main Street Facility

Solid Dose Manufacturing

- Particle Size Control
 - Sieving, Oscillating Granulators, Fitzmills, Comils
- Blending / Granulating Wet and Dry capability
 - Marion Paddle Mixers, V-Blender, Gemco Slant Cone
 - Collette Gral 600 High Shear Granulator (100 200kg)
 - Collette Gral 75 (also explosion proof) (12 25kg)
 - Hobart Planetary Mixer
- Drying Gruenberg Ovens, Vector FL-3N Fluid Bed Dryer
- Encapsulating Machine (pilot scale / small batch)
 - Zanasi, MG Suprema
- Rotary Tablet Presses
 - Courtoy R100, Killian Synthesis 300
- Coating Film / Sugar coating, Solvent & Aqueous
 - ACCELA-COTA and Vector Hi Coater Pans

Liquid Manufacturing

- Liquids / Syrups
- Solutions / Suspensions / Emulsions
- Lotions / Ointments



Solid Dose Packaging – 7 to 1,000 units/container

- Tablets Mass: 60mg 1050mg
- Capsules Mass: 100mg 600mg

Liquid Dose Packaging Capabilities

Solutions, Suspensions, Enemas

Unit Dose Cup Blisters

Powder Filling Capability

• 1" - 5" Diameter containers



Manufacturing and Packaging Capabilities by Site

IDC Road Facility

Solid Dose Manufacturing

- Particle Size Control
 - Sieving, Oscillating Granulators, Fitzmills, Comils
 - Alpine Pin Mill (1Q18)
- Blending / Granulating Wet and Dry capability
 - Marion Paddle Mixers, V-Blender, Gemco Cone Blenders
 - Gemco Formulator (jacketed)
 - Collette Gral 75 (also explosion proof)
 - Vector Granumeist GMX 600L high shear granulator
 - Hobart Planetary Mixer
- Drying Gruenberg Ovens, Vector FL-N-15 Fluid Bed Dryer
- Rotary Tablet Presses
 - Two Courtoy R190
 - Korsch XL 200
 - Two Korsch XL 400
- Encapsulation
 - Bosch 1400L for hotmelt capsule filling (1Q18)

Solid Dose Packaging – 7 to 1,000 units/container

- Tablets Mass: 60mg 1050mg
- Capsules Mass: 100mg 600mg

Blister Packaging (Klockner CP-2 and Klockner CP-8)

- Physician sample / clinical size Klockner Blister Forming Machines
 - Multiple base material options
 - 4, 7, or 10 tablet blister
 - Cold form capable







Recently Expanded Warehouse Capacity

	Pallet Spaces					
Main Street Facility						
Approved Rack Spaces	1,471					
Quarantine Rack Spaces	136					
Reject Spaces	14					
CIII (Cage Spaces)	180					
CII (Vault Spaces)	116					
Containment Facility						
Approved Rack Spaces	216					
Building 5 (Bulk Materials / Equipment Storage)						
Approved Rack Spaces	50					
Total Pallet Spaces	2,183					



New controlled substance vault expansion



Main St. warehouse



Summary

- ANI is an integrated specialty generic pharmaceutical company with:
 - Profitable base business generating organic growth
 - Strong capital position
 - Experienced management team
 - US-based manufacturing assets and expertise
 - 2018 Annual guidance⁽¹⁾
 - Net revenues of \$212 million to \$228 million
 - Adjusted non-GAAP EBITDA⁽²⁾ of \$90 million to \$100 million
 - Adjusted non-GAAP diluted earnings per share⁽²⁾ of \$5.43 to \$6.08
- ANI is focused on delivering value through:
 - Partnerships, strategic alliances and accretive acquisitions
 - Internal product development and leveraging manufacturing capabilities
 - Advancing the re-commercialization of Cortrophin[®] Gel



(1) February 27, 2018 press release(2) See Appendix A for note regarding US GAAP reconciliations

Appendix A





U.S. GAAP Reconciliations

ANI Pharmaceuticals, Inc. and Subsidiaries Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation (unaudited, in thousands)

	Three Months Ended December 31,				Year Ended December 31,				
		2017		2016		2017		2016	
Net (Loss)/Income	\$	(9,629)	\$	(1,080)	\$	(1,076)	\$	3,934	
Add back									
Interest expense, net		3,026		2,859		12,035		11,327	
Other income/(expense), net		3		43		(55)		74	
Provision/(benefit) for income taxes		13,979		(524)		17,425		4,744	
Depreciation and amortization		7,022		5,812		27,928		22,343	
Intangible asset impairment charge		903		6,685		903		6,685	
Add back									
Stock-based compensation		1,422		1,380		6,090		6,067	
Excess of fair value over cost of acquired inventory		2,946		2,758		10,448		5,938	
Expenses related to transaction not consummated		-		-		477		-	
Adjusted non-GAAP EBITDA	\$	19,672	\$	17,933	\$	74,175	\$	61,112	



U.S. GAAP Reconciliations

ANI Pharmaceuticals, Inc. and Subsidiaries

Adjusted non-GAAP Net Income and Adjusted non-GAAP Diluted Earnings per Share Reconciliation

(unaudited, in thousands, except per share amounts)

	Three Months Enc 2017		ded December 31, 2016		Year Ended D 2017		December 31, 2016	
Net (Loss)/Income	\$	(9,629)	\$	(1,080)	\$	(1,076)	\$	3,934
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Add back								
Excess of fair value over cost of acquired inventory		2,946		2,758		10,448		5,938
Non-cash interest expense		1,758		1,784		7,113		7,048
Stock-based compensation		1,422		1,380		6,090		6,067
Depreciation and amortization expense		7,022		5,812		27,928		22343
Intangible asset impairment charge		903		6,685		903		6,685
Expenses related to transaction not consummated		-		-		477		-
Less								
Tax impact of adjustments		(5,199)		(6,815)		(19,595)		(17,790)
Add back								
Impact of Tax Cuts and Jobs Act of 2017 on Deferred Tax Assets		13,394		-		13,394		-
Adjusted non-GAAP Net Income	\$	12,617	\$	10,524	\$	45,682	\$	34,225
Diluted Weighted-Average								
Shares Outstanding		11,723		11,635		11,680		11,573
Adjusted non-GAAP								
Diluted Earnings per Share	\$	1.08	\$	0.90	\$	3.91	\$	2.96



U.S. GAAP Reconciliations

Non-GAAP Financial Measures included in 2018 Guidance

The Company's fiscal 2018 guidance for adjusted non-GAAP EBITDA and adjusted non-GAAP diluted earnings per share is not reconciled to the most comparable GAAP measure. This is due to the inherent difficulty of forecasting the timing or amount of items that would be included in a reconciliation to the most directly comparable forward-looking GAAP financial measures. Because a reconciliation is not available without unreasonable effort, it is not included in this presentation.

