

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 1: US GAAP Income Statement
(unaudited, in thousands, except per share amounts)

	Three Months Ended March 31,	
	2019	2018
Net Revenues	\$ 52,887	\$ 46,483
Operating Expenses		
Cost of sales (excl. depreciation and amortization)	14,725	20,693
Research and development	4,373	2,102
Selling, general, and administrative	13,284	8,956
Depreciation and amortization	16,103	8,195
Total Operating Expenses	48,485	39,946
Operating Income	4,402	6,537
Other Expense, Net		
Interest expense, net	(3,354)	(3,634)
Other expense, net	(130)	(61)
Income Before Provision for Income Taxes	918	2,842
Provision for Income Taxes	(469)	(592)
Net Income	\$ 449	\$ 2,250
Earnings Per Share		
Basic Earnings Per Share	\$ 0.04	\$ 0.19
Diluted Earnings Per Share	\$ 0.04	\$ 0.19
Basic Weighted-Average Shares Outstanding	11,747	11,589
Diluted Weighted-Average Shares Outstanding	11,823	11,706

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Table 2: US GAAP Balance Sheets
(unaudited, in thousands)

	March 31, 2019	December 31, 2018
Current Assets		
Cash and cash equivalents	\$ 38,233	\$ 43,008
Accounts receivable, net	67,410	64,842
Inventories, net	42,032	40,503
Prepaid expenses and other current assets	4,157	4,524
Total Current Assets	151,832	152,877
Property and equipment, net	38,425	38,090
Restricted cash	5,008	5,021
Deferred tax assets, net of deferred tax liabilities and valuation allowance	28,542	27,964
Intangible assets, net	205,100	201,604
Goodwill	3,580	3,580
Other non-current assets	1,903	1,468
Total Assets	\$ 434,390	\$ 430,604
Current Liabilities		
Current component of non-current borrowing, net of deferred financing costs	\$ 3,243	\$ 3,256
Convertible notes, net of discount and deferred financing costs	114,150	112,463
Accounts payable	10,519	8,884
Accrued expenses and other	3,074	1,707
Accrued royalties	5,440	8,456
Accrued compensation and related expenses	2,454	3,524
Current income taxes payable, net	3,453	5,022
Accrued government rebates	8,552	8,974
Returned goods reserve	13,559	12,552
Deferred revenue	624	711
Total Current Liabilities	165,068	165,549
Non-current borrowing, net of deferred financing costs and current borrowing component	66,501	67,296
Other non-current liabilities	3,109	496
Total Liabilities	234,678	233,341
Stockholders' Equity		
Common stock	1	1
Treasury stock	-	(659)
Additional paid-in capital	189,971	186,812
Retained earnings	11,939	11,488
Accumulated other comprehensive loss, net of tax	(2,199)	(379)
Total Stockholders' Equity	199,712	197,263
Total Liabilities and Stockholders' Equity	\$ 434,390	\$ 430,604

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Table 3: Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation

(unaudited, in thousands)

	Three Months Ended March 31,	
	2019	2018
Net Income	\$ 449	\$ 2,250
Add back		
Interest expense, net	3,354	3,634
Other expense, net	130	61
Provision for income taxes	469	592
Depreciation and amortization	16,103	8,195
Add back		
Stock-based compensation	1,710	1,377
Excess of fair value over cost of acquired inventory	-	5,645
Transaction and integration expenses	84	-
Adjusted non-GAAP EBITDA	\$ 22,299	\$ 21,754

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Table 4: Adjusted non-GAAP Net Income and Adjusted non-GAAP Diluted Earnings per Share Reconciliation

(unaudited, in thousands, except per share amounts)

	Three Months Ended March 31,	
	2019	2018
Net Income	\$ 449	\$ 2,250
Add back		
Non-cash interest expense	1,799	1,914
Depreciation and amortization expense	16,103	8,195
Stock-based compensation	1,710	1,377
Excess of fair value over cost of acquired inventory	-	5,645
Transaction and integration expenses	84	-
Less		
Tax impact of adjustments	(4,727)	(3,940)
Adjusted non-GAAP Net Income	\$ 15,418	\$ 15,441
Diluted Weighted-Average Shares Outstanding	11,823	11,706
Adjusted non-GAAP Diluted Earnings per Share	\$ 1.30	\$ 1.32

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Table 5: Cortrophin® Gel Re-Commercialization Milestone Update

Step	Duration	Status	Additional Details
Manufacture small-scale batch of corticotropin API	4 mos.	Complete	<ul style="list-style-type: none"> • Initial batch yields similar to historical yields • Analytical method development and testing ongoing
Select drug product CMO	6 mos.	Complete	<ul style="list-style-type: none"> • Drug product CMO has been selected
Manufacture intermediate-scale batches of corticotropin API	4-6 mos.	Complete	<ul style="list-style-type: none"> • Four intermediate-scale batches successfully completed • Further refined/modernized analytical methods and process • Demonstrated lot-to-lot consistency
Type C meeting with FDA		Complete	<ul style="list-style-type: none"> • Meeting Request submitted 4Q17; FDA granted as Type C Meeting • Information provided on ANI's regulatory plan for re-commercialization • Initial FDA response received March 2018 with additional communications in 2nd Quarter 2018
Manufacture demo batch of Cortrophin® Gel	1 mo.	Ongoing	<ul style="list-style-type: none"> • Initiate non-GMP formulation/fill/finish of drug product at commercial scale
Manufacture commercial-scale batches of corticotropin API	2-3 mos. per batch	Ongoing	<ul style="list-style-type: none"> • Analytical method validation for API release/stability • Scale-up manufacturing process 5x to projected commercial scale • Manufacture API under cGMPs • Finalize API manufacturing process and initiate process validation/registration batches • Initiate viral clearance studies
Initiate manufacture of registration batches of Cortrophin® Gel	1 mo. per batch	Q2 2019	<ul style="list-style-type: none"> • Analytical method validation for drug product release/stability • Process validation • Registration/Commercial batches • Initiate registration-enabling ICH stability studies
Initiate registration stability for sNDA	6 mos.	1H 2019	<ul style="list-style-type: none"> • Six months of accelerated stability from drug substance and drug product batches at time of submission
sNDA submission		Q1 2020	<ul style="list-style-type: none"> • Filing - four month PDUFA date