

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**Current Report
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 5, 2020

ANI PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-31812
(Commission File Number)

58-2301143
(I.R.S. Employer
Identification Number)

**210 Main Street West
Baudette, Minnesota**
(Address of principal executive offices)

56623
(Zip Code)

Registrant's telephone number, including area code: **(218) 634-3500**

(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class:</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered:</u>
Common Stock	ANIP	Nasdaq Stock Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On November 5, 2020, ANI Pharmaceuticals, Inc. (“ANI”) issued a press release announcing its financial and operating results for the three and nine months ended September 30, 2020. A copy of the press release is furnished as Exhibit 99.1 to this report.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

No.	Description
99.1	Press release, dated November 5, 2020, issued by ANI
104	Cover Page Interactive Data File. The cover page XBRL tags are embedded within the inline XBRL document (contained in Exhibit 101).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey

Stephen P. Carey

Vice President, Finance and Chief Financial Officer

Dated: November 5, 2020



FOR IMMEDIATE RELEASE

ANI Pharmaceuticals Reports Third Quarter 2020 Results

- Third quarter 2020 net revenues of \$53.0 million; net income of \$0.4 million and diluted eps of \$0.04 -
- Third quarter adjusted non-GAAP EBITDA of \$17.0 million and adjusted non-GAAP diluted eps of \$0.97 -
- Cortrophin[®] Gel sNDA re-filing on track; commercialization and operational launch readiness plan underway -
- New CEO and Board members add breadth of experience and strengthen capabilities to drive business growth -

Baudette, Minnesota (November 5, 2020) – ANI Pharmaceuticals, Inc. (“ANI” or the “Company”) (NASDAQ: ANIP) today announced business highlights and financial results for the three and nine months ended September 30, 2020.

Business and Recent Highlights:

- Company’s supplemental New Drug Application (“sNDA”) for lead product, Cortrophin Gel, re-filing on track; driving commercial and operational readiness for a successful launch;
- Welcomed Nikhil Lalwani as President and CEO, on September 8, 2020; and
- Broadened Board of Directors’ scope of experience with addition of two pharmaceutical industry leaders, Jeanne Thoma and Tony Pera.

Third Quarter 2020 Financial Highlights:

- Net revenues for Q3 2020 were \$53.0 million compared to \$51.3 million in Q3 2019 and \$48.5 million in Q2 2020.
- GAAP net income for Q3 2020 was \$0.4 million, and diluted GAAP earnings per share was \$0.04.
- Adjusted non-GAAP EBITDA for Q3 2020 was \$17.0 million.
- Adjusted non-GAAP diluted earnings per share for Q3 2020 was \$0.97.
- Cash and cash equivalents were \$17.9 million, net accounts receivable was \$83.7 million, and debt was \$187.9 million as of September 30, 2020.

“My initial two months as CEO of ANI Pharmaceuticals have been rewarding, as I have set forth to evaluate the state of the business and begun to build plans for the next phase of ANI’s growth. I have completed tours of our manufacturing facilities, conducted dozens of one-on-ones and small group discussions with our team, commercial customers, CDMO clients, key suppliers and external stakeholders. All of these interactions have contributed to understanding our challenges, and importantly, our opportunities and what we need to do to realize their full potential. These include the significant opportunity with Cortrophin Gel, a strong North American manufacturing footprint that can be leveraged further and a robust portfolio of ANDAs, several of which have limited competition. In addition, the target-rich acquisition environment will enable us to build on our strong track record of pursuing accretive in-organic opportunities to enhance scale and capabilities in our company. I am excited to lead ANI at this important time in the company’s journey,” stated Nikhil Lalwani, President and CEO.

Third Quarter 2020 Financial Results

Net Revenues

(in thousands)

	Three Months Ended	
	September 30	
	2020	2019
Generic pharmaceutical products	\$ 37,712	\$ 31,753
Branded pharmaceutical products	12,411	16,605
Contract manufacturing	2,152	2,376
Royalty and other income	704	603
Total net revenues	<u>\$ 52,979</u>	<u>\$ 51,337</u>

Net revenues for generic pharmaceutical products were \$37.7 million during the three months ended September 30, 2020, an increase of 18.8% compared to \$31.8 million for the same period in 2019, primarily due to the January 2020 launch of Miglustat, Penicillamine, and Paliperidone, all products acquired from Amerigen. The increases were tempered by declines in revenues of Ezetimibe Simvastatin, Vancomycin Capsules, and Methazolamide.

Net revenues for branded pharmaceutical products were \$12.4 million during the three months ended September 30, 2020, a decrease of 25.3% compared to \$16.6 million for the same period in 2019, primarily due to lower unit sales of Inderal XL and Innopran XL and a decline in revenues of Atacand.

Contract manufacturing revenues were \$2.2 million during the three months ended September 30, 2020, a decrease of 9.4% compared to \$2.4 million for the same period in 2019, due to a decreased volume of orders from contract manufacturing customers in the period.

Royalty and other revenues were \$0.7 million during the three months ended September 30, 2020, an increase of \$0.1 million from \$0.6 million for the same period in 2019, primarily due to an increase in product development revenues earned by ANI Canada and an increase in royalty revenues.

Operating expenses increased to \$50.2 million for the three months ended September 30, 2020, from \$44.0 million in the prior year period.

Cost of sales, excluding depreciation and amortization, increased by \$5.1 million to \$20.1 million in the third quarter of 2020, primarily as a result of increased volumes related to a shift in product mix toward generic products and increased sales of products subject to profit-sharing arrangements.

Research and development expense decreased by \$2.1 million in the third quarter of 2020 to \$2.9 million compared with \$5.0 million in the third quarter of 2019, primarily due to a decrease in expense related to the Cortrophin re-commercialization project. The Company currently anticipates that Cortrophin-related expenses in the fourth quarter of 2020 will be moderately higher than those of the third quarter, as we continue to focus on our sNDA resubmission efforts.

Selling, general and administrative expenses rose by \$1.3 million in the third quarter of 2020 to \$15.7 million compared to \$14.4 million in the comparable quarter in 2019. The increase primarily reflects increased pharmacovigilance compliance costs in continued support of the expansion of our commercial portfolio, and increased legal, insurance and other professional fees.

Depreciation and amortization increased by \$1.9 million in the third quarter of 2020 to \$11.4 million compared to \$9.5 million in the comparable quarter in 2019 due to amortization of the Abbreviated New Drug Applications (“ANDAs”), and marketing and distribution rights acquired in January 2020 from Amerigen and the ANDA acquired in July 2020.

Net income for the third quarter of 2020 was \$0.4 million as compared to net income of \$3.9 million in the prior year period. Diluted earnings per share for the three months ended September 30, 2020 was \$0.04, compared to diluted earnings per share of \$0.32 in the prior year period.

Adjusted non-GAAP diluted earnings per share was \$0.97 in the third quarter of 2020 compared to adjusted non-GAAP diluted earnings per share of \$1.23 in the prior year period.

For reconciliations of adjusted non-GAAP EBITDA and adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure, please see Table 3 and Table 4, respectively.

Liquidity

As of September 30, 2020, the Company had \$17.9 million in unrestricted cash and cash equivalents plus \$83.7 million in net accounts receivable. The Company had \$187.9 million in outstanding debt as of September 30, 2020.

Conference Call

As previously announced, ANI Pharmaceuticals management will host its third quarter 2020 conference call as follows:

Date	Thursday, November 5, 2020
Time	10:30 a.m. ET
Toll free (U.S.)	(866) 776-8875

Webcast (live and replay) www.anipharma.com, under the “Investors” section

A replay of the conference call will be available within two hours of the call’s completion and will remain accessible for one week by dialing (800) 585-8367 and entering access code 7454258.

Non-GAAP Financial Measures

Adjusted non-GAAP EBITDA

ANI’s management considers adjusted non-GAAP EBITDA to be an important financial indicator of ANI’s operating performance, providing investors and analysts with a useful measure of operating results unaffected by non-cash stock-based compensation and differences in capital structures, tax structures, capital investment cycles, ages of related assets, and compensation structures among otherwise comparable companies. Management uses adjusted non-GAAP EBITDA when analyzing Company performance.

Adjusted non-GAAP EBITDA is defined as net income, excluding tax expense or benefit, interest expense, (net), other expense, (net), depreciation, amortization, the excess of fair value over cost of acquired inventory, non-cash stock-based compensation expense, CEO transition expenses, expense from acquired in-process research and development, transaction and integration expenses, Cortrophin pre-launch charges, and certain other items that vary in frequency and impact on ANI’s results of operations. Adjusted non-GAAP EBITDA should be considered in addition to, but not in lieu of, net income or loss reported under GAAP. A reconciliation of adjusted non-GAAP EBITDA to the most directly comparable GAAP financial measure is provided below.

Adjusted non-GAAP Net Income

ANI’s management considers adjusted non-GAAP net income to be an important financial indicator of ANI’s operating performance, providing investors and analysts with a useful measure of operating results unaffected by the excess of fair value over cost of acquired inventory sold, non-cash stock-based compensation, CEO transition expenses, non-cash interest expense, depreciation and amortization, Cortrophin pre-launch charges, acquired in-process research and development (“IPR&D”) expense, transaction and integration expenses and certain other items that vary in frequency and impact on ANI’s results of operations. Management uses adjusted non-GAAP net income when analyzing Company performance.

Adjusted non-GAAP net income is defined as net income, plus the excess of fair value over cost of acquired inventory sold, non-cash stock-based compensation expense, CEO transition expenses, transaction and integration expenses, non-cash interest expense, depreciation and amortization expense, expense from acquired in-process research and development, Cortrophin pre-launch charges and certain other items that vary in frequency and impact on ANI’s results of operations, less the tax impact of these adjustments calculated using an estimated statutory tax rate, and tax benefit related to the ANI Canada transfer pricing agreement. Management will continually analyze this metric and may include additional adjustments in the calculation in order to provide further understanding of ANI’s results. Adjusted non-GAAP net income should be considered in addition to, but not in lieu of, net income reported under GAAP. A reconciliation of adjusted non-GAAP net income to the most directly comparable GAAP financial measure is provided below.

Adjusted non-GAAP Diluted Earnings per Share

ANI's management considers adjusted non-GAAP diluted earnings per share to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by the excess of fair value over cost of acquired inventory sold, non-cash stock-based compensation, CEO transition expenses, non-cash interest expense, depreciation and amortization, Cortrophin pre-launch charges, acquired IPR&D expense, transaction and integration expenses and certain other items that vary in frequency and impact on ANI's results of operations. Management uses adjusted non-GAAP diluted earnings per share when analyzing Company performance.

Adjusted non-GAAP diluted earnings per share is defined as adjusted non-GAAP net income, as defined above, divided by the diluted weighted average shares outstanding during the period, as adjusted for the dilutive effect of the convertible debt notes (in 2019), when applicable. Management will continually analyze this metric and may include additional adjustments in the calculation in order to provide further understanding of ANI's results. Adjusted non-GAAP diluted earnings per share should be considered in addition to, but not in lieu of, diluted earnings or loss per share reported under GAAP. A reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure is provided below.

About ANI

ANI Pharmaceuticals, Inc. is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit our website www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release relate to 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 the Company's future operations, products, financial position, operating results and prospects, including plans for growth, the Company's pipeline or potential markets therefor, plans for existing ANDAs, timing for submission of a sNDA for Cortrophin Gel and commercialization plans, 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.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that the Company may face with respect to importing raw materials; the use of single source suppliers and the time it may take to validate and qualify another supplier, if necessary; increased competition and strategies employed by competitors; the ability to realize benefits anticipated from acquisitions; costs and regulatory requirements relating to contract manufacturing arrangements; delays or failure in obtaining product approvals from the U.S. Food and Drug Administration; general business and economic conditions, including the ongoing impact of the COVID-19 pandemic; market trends for our products; regulatory environment and changes; and regulatory and other approvals relating to product development and manufacturing.

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. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. Except as required by law, the Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Contact

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SOURCE: ANI Pharmaceuticals, Inc.

Financial Tables Follow

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net Revenues	\$ 52,979	\$ 51,337	\$ 151,223	\$ 158,581
Operating Expenses				
Cost of sales (excl. depreciation and amortization)	20,118	15,002	62,617	45,359
Research and development	2,939	4,982	12,318	15,128
Selling, general, and administrative	15,725	14,357	50,621	41,829
Depreciation and amortization	11,358	9,473	33,739	35,048
Cortrophin pre-launch charges	37	195	8,275	195
Total Operating Expenses	<u>50,177</u>	<u>44,009</u>	<u>167,570</u>	<u>137,559</u>
Operating Income/(Loss)	2,802	7,328	(16,347)	21,022
Other Expense, Net				
Interest expense, net	(2,510)	(3,336)	(6,898)	(10,096)
Other expense, net	(229)	(33)	(335)	(117)
Income/(Loss) Before Benefit/(Provision) for Income Taxes	63	3,959	(23,580)	10,809
Benefit/(provision) for income taxes	<u>371</u>	<u>(64)</u>	<u>4,667</u>	<u>120</u>
Net Income/(Loss)	<u>\$ 434</u>	<u>\$ 3,895</u>	<u>\$ (18,913)</u>	<u>\$ 10,929</u>
Basic and Diluted Earnings/(Loss) Per Share:				
Basic Earnings/(Loss) Per Share	\$ 0.04	\$ 0.32	\$ (1.58)	\$ 0.91
Diluted Earnings/(Loss) Per Share	\$ 0.04	\$ 0.32	\$ (1.58)	\$ 0.89
Basic Weighted-Average Shares Outstanding	11,991	11,879	11,953	11,826
Diluted Weighted-Average Shares Outstanding	<u>12,003</u>	<u>12,085</u>	<u>11,953</u>	<u>12,060</u>

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 2: US GAAP Balance Sheets
(unaudited, in thousands)

	September 30, 2020	December 31, 2019
Current Assets		
Cash and cash equivalents	\$ 17,900	\$ 62,332
Accounts receivable, net	83,745	72,129
Inventories, net	59,195	48,163
Prepaid income taxes	1,621	1,076
Prepaid expenses and other current assets	3,358	3,995
Total Current Assets	165,819	187,695
Property and equipment, net	40,444	40,551
Restricted cash	5,003	5,029
Deferred tax assets, net of deferred tax liabilities and valuation allowance	48,130	38,326
Intangible assets, net	198,620	180,388
Goodwill	3,580	3,580
Other non-current assets	985	1,220
Total Assets	\$ 462,581	\$ 456,789
Current Liabilities		
Current debt, net of deferred financing costs	\$ 12,785	\$ 9,941
Accounts payable	13,460	14,606
Accrued expenses and other	2,534	2,362
Accrued royalties	6,088	5,084
Accrued compensation and related expenses	5,993	3,736
Accrued government rebates	11,678	8,901
Returned goods reserve	23,250	16,595
Deferred revenue	112	451
Total Current Liabilities	75,900	61,676
Non-current debt, net of deferred financing costs and current component	175,161	175,808
Derivatives and other non-current liabilities	16,420	6,514
Total Liabilities	267,481	243,998
Stockholders' Equity		
Common stock	1	1
Treasury stock	(2,246)	(723)
Additional paid-in capital	211,792	200,800
(Accumulated deficit)/retained earnings	(1,337)	17,584
Accumulated other comprehensive loss, net of tax	(13,110)	(4,871)
Total Stockholders' Equity	195,100	212,791
Total Liabilities and Stockholders' Equity	\$ 462,581	\$ 456,789

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 3: Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation
(unaudited, in thousands)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Net Income/(Loss)	\$ 434	\$ 3,895	\$ (18,913)	\$ 10,929
Add/(Subtract):				
Interest expense, net	2,510	3,336	6,898	10,096
Other expense, net	229	33	335	117
Benefit/(provision) for income taxes	(371)	64	(4,667)	(120)
Depreciation and amortization	11,358	9,473	33,739	35,048
Cortrophin pre-launch charges	37	195	8,275	195
Expensed FDA approval milestone payment	-	329	-	329
Stock-based compensation ⁽¹⁾	2,383	2,470	7,078	6,773
CEO transition items ⁽²⁾	204	-	7,349	-
Cortrophin team restructuring	-	-	401	-
Acquired IPR&D expense	-	-	3,784	2,324
Excess of fair value over cost of acquired inventory	111	-	4,183	-
Asset impairments ⁽³⁾	92	-	884	-
Charges related to market exits	-	-	567	-
Transaction and integration expenses	-	-	-	84
Adjusted non-GAAP EBITDA	<u>\$ 16,987</u>	<u>\$ 19,795</u>	<u>\$ 49,913</u>	<u>\$ 65,775</u>

⁽¹⁾ For the nine months ended September 30, 2020, Stock-based compensation excludes \$3.4 million of stock-based compensation expense associated with the departure of our former President and CEO. This amount is included in this table as part of CEO transition items.

⁽²⁾ CEO transition items for the nine months ended September 30, 2020 is comprised of \$3.4 million of stock-based compensation expense and \$3.1 million of expense for salary continuation, bonus and other fringe benefits associated with the departure of our former President and CEO, as well as certain legal and recruiting costs related to the search for a permanent replacement.

⁽³⁾ For the nine months ended September 30, 2020, Asset impairments is comprised of finished goods inventory reserves for Bretylium and accounts receivable reserves due to customer bankruptcy, tempered by a modest recovery of previously reserved inventory related to market exits.

ANI Pharmaceuticals, Inc. and Subsidiaries

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net Income/(Loss)	\$ 434	\$ 3,895	\$ (18,913)	\$ 10,929
Add/(Subtract):				
Non-cash interest expense	565	1,871	1,222	5,525
Depreciation and amortization expense	11,358	9,473	33,739	35,048
Cortrophin pre-launch charges	37	195	8,275	195
Expensed FDA approval milestone payment	-	329	-	329
Acquired IPR&D expense	-	-	3,784	2,324
Stock-based compensation ⁽¹⁾	2,383	2,470	7,078	6,773
CEO transition items ⁽²⁾	204	-	7,349	-
Cortrophin team restructuring	-	-	401	-
Asset impairments ⁽³⁾	92	-	884	-
Excess of fair value over cost of acquired inventory	111	-	4,183	-
Charges related to market exits	-	-	567	-
Transaction and integration expenses	-	-	-	84
Less:				
Tax impact of adjustments	(3,540)	(3,441)	(16,196)	(12,067)
Discrete tax benefit related to ANI Canada transfer pricing agreement	-	-	-	(1,653)
Adjusted Non-GAAP Net Income	\$ 11,644	\$ 14,792	\$ 32,373	\$ 47,487
Diluted Weighted-Average				
Shares Outstanding	12,003	12,085	11,953	12,060
Less: Dilutive Effect of Notes	-	(78)	-	(128)
Adjusted Diluted Weighted-Average				
Shares Outstanding	12,003	12,007	11,977	11,932
Adjusted Non-GAAP				
Diluted Earnings per Share	\$ 0.97	\$ 1.23	\$ 2.70	\$ 3.98

⁽¹⁾ For the nine months ended September 30, 2020, Stock-based compensation excludes \$3.4 million of stock-based compensation expense associated with the departure of our former President and CEO. This amount is included in this table as part of CEO transition items.

⁽²⁾ CEO transition items for the nine months ended September 30, 2020 is comprised of \$3.4 million of stock-based compensation expense and \$3.1 million of expense for salary continuation, bonus and other fringe benefits associated with the departure of our former President and CEO, as well as certain legal and recruiting costs related to the search for a permanent replacement.

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