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 9, 2022**

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-31812**	**58-2301143**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

210 Main Street West **Baudette, Minnesota**	**56623**
(Address of principal executive offices)	(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:

Title of each class:	**Trading Symbol(s)**	**Name of each exchange on which registered:**
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 9, 2022, ANI Pharmaceuticals, Inc. ("ANI") issued a press release announcing its financial and operating results for the three and nine months ended September 30, 2022. 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 9, 2022 issued by ANI
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded in the Inline XBRL document)

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
Senior Vice President Finance and Chief Financial Officer

Dated: November 9, 2022

FOR IMMEDIATE RELEASE

ANI Pharmaceuticals Reports Third Quarter 2022 Financial Results; Reports Record Net Revenues

Third Quarter 2022 Results:

-- Net revenues of $83.8 million, net loss available to common shareholders of $(9.0) million and diluted GAAP loss per share of $(0.55) –

-- Adjusted non-GAAP EBITDA of $19.6 million and adjusted non-GAAP diluted earnings per share of $0.64 --

-- Year-over-year net revenue growth of 61% resulting in record quarterly net revenues --

-- Lead Rare Disease asset, Purified Cortrophin® Gel (Repository Corticotrophin Injection USP) 80 U/ml (Cortrophin) net sales of $12.6 million --

Full-Year 2022 Guidance:

-- Reiterates total Company net revenue guidance of $295 million to $315 million; adjusted non-GAAP EBITDA guidance of $54 million to $60 million; adjusted non-GAAP Earnings Per Share between $1.34 and $1.62 --

Company Highlights:

-- Achieved strong Cortrophin revenue growth with 765+ cases initiated by 380 unique prescribers; continued expansion in market access and investment in launch initiatives --

-- Launched several limited-competition new products; completed acquisition of four ANDAs from Oakrum Pharma LLC --

-- Consolidation of manufacturing network on track with expected closing of Oakville, Canada, plant by Q1 2023 --

-- Built out leadership team with the appointments of Meredith W. Cook as SVP, General Counsel and Corporate Secretary, and Krista L. Davis as Chief Human Resources Officer --

BAUDETTE, Minn.--(BUSINESS WIRE) – November 9, 2022 – ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced business highlights and financial results for the three and nine months ended September 30, 2022.

“Our third quarter results reflect clarity in our strategy and strong focus on operational execution. We are pleased to share that ANI delivered record net revenues of $83.8 million and significant sequential gains of non-GAAP EBITDA, which at $19.6 million is nearly double that of the second quarter of 2022. We continue to strengthen the foundation of our Cortrophin launch with a greater than 50% increase in the number of patient cases initiated and in new and repeat prescribers. We have also expanded market access and continue making investments in launch initiatives. Most importantly, we see evidence that our efforts are having a favorable impact on the overall number of patients receiving critical ACTH therapy,” stated Nikhil Lalwani, President and CEO of ANI.

“Our Generics business revenues grew 51% over the prior year on the strength of our acquisition execution and success in bringing several limited-competition drugs to market. We continue to invest in our Generics and 505(b)(2) R&D platform to fuel future growth. These internal efforts are supplemented through business development opportunities, such as the acquisition of four abbreviated new drug applications from Oakrum Pharma, LLC. The Oakville plant is on track to close in the first quarter of 2023, and we have made meaningful progress with prospective buyers. Our investments in R&D, business development and driving cost competitiveness keep us well positioned for sustainable growth in Generics,” concluded Lalwani.

Third Quarter 2022 Financial Highlights:

- Net revenues were $83.8 million compared to $52.1 million in Q3 2021.
- GAAP net loss available to common shareholders was $(9.0) million, and diluted GAAP loss per share was $(0.55).
- Adjusted non-GAAP EBITDA was $19.6 million compared to $16.6 million in Q3 2021.
- Adjusted non-GAAP diluted earnings per share was $0.64, compared to diluted earnings per share of $1.01 in Q3 2021.
- Cash and cash equivalents were $56.3 million, net accounts receivable was $140.4 million, and face value of debt was $297.8 million as of September 30, 2022.

Cortrophin Launch Update:

The Company is reiterating its 2022 revenue guidance for Cortrophin of between $40.0 million and $45.0 million.

Key highlights (as of November 8, 2022):

- **Launch Trajectory:** Cumulative new patient cases initiated increased by more than 50% to 765+ cases. The Company made further investments in its hub, patient support services and distribution network.
- **Physician Interest:** The prescriber base increased by greater than 50% since the Company’s last report to 380 unique prescribers and approximately one third of the prescribers have written more than one prescription. Prescriptions continue to be distributed across our targeted specialties.

- **Patient Access:** The Company remains focused on market access and bringing savings to the healthcare system. Our efforts continue to yield improved access for patients across the country.

Generics Growth Engine Update:

Sales of generic pharmaceuticals products grew 51% year-over-year in the third quarter. The Company continued to focus on bringing limited-competition products to market and driving cost competitiveness.

- **Focus on R&D Excellence:** During the first nine months of 2022, ANI filed 11 ANDAs and in the third quarter successfully launched multiple limited- competition products, including Prochlorperazine Maleate Tablets USP, 5 mg and 10 mg; and Acebutolol Hydrochloride Capsules. The Company continues to invest significantly in R&D and initiated work on several new product development projects to fuel future growth.
- **Operational Synergies:** The previously announced plan to consolidate manufacturing operations and cease operations at the Oakville, Ontario, Canada manufacturing facility in the first quarter of 2023 is on track. The Company has begun manufacturing and packaging many Oakville products in our U.S. facilities and is beginning to recognize the operational efficiencies from this initiative. The Company is actively engaged and has made meaningful progress with potential buyers for Oakville. Once fully executed, this operational efficiency is expected to improve profitability and cash flow by $7 million to $8 million on an annualized basis. The Company currently expects one-time cash charges of approximately $2.7 million and non-cash charges of $4.4 million in conjunction with this action.
- **Business Development:** The Company continues to be active on the business development front, completing the acquisition of four limited-competition ANDAs from Oakrum Pharma in July.

Third Quarter 2022 Financial Results

(in thousands)	Three Months Ended September 30, 2022	2021	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 53,136	$ 35,140	$ 17,996	51.2%
Established brand pharmaceutical products	9,816	14,313	(4,497)	(31.4)%
Contract manufacturing	4,779	2,382	2,397	100.6%
Royalty and other	3,488	226	3,262	NM(1)
Generics, established brands, and other segment total net revenues	$ 71,219	$ 52,061	$ 19,158	36.8%
Rare Disease Segment				
Rare disease pharmaceutical products	$ 12,602	$ —	$ 12,602	NM(1)
Total net revenues	$ 83,821	$ 52,061	$ 31,760	61.0%

(1) Not meaningful.

Net revenues for generic pharmaceutical products were $53.1 million during the three months ended September 30, 2022, an increase of 51% compared to $35.1 million for the same period in 2021. The net increase was primarily driven by revenues from commercial generic products acquired in our acquisition of Novitium Pharma LLC (Novitium), including launch of several limited competition products, partially tempered by a decrease in revenues from sales of several legacy ANI generic products.

Net revenues for established brand pharmaceutical products were $9.8 million during the three months ended September 30, 2022, a decrease of 31% compared to $14.3 million for the same period in 2021 driven by lower volumes of many of the Company's brand products.

Contract manufacturing revenues were $4.8 million during the three months ended September 30, 2022, an increase of 101% compared to $2.4 million for the same period in 2021, due to an increase in the volume of orders, primarily related to the addition of Novitium contract manufacturing revenues.

Royalty and other revenues were $3.5 million during the three months ended September 30, 2022, an increase of $3.3 million from $0.2 million for the same period in 2021, primarily due to a $1.2 million licensing payment and royalty and $0.5 million of royalty revenues related to Novitium arrangements and an additional $1.5 million of product development service revenues, partially offset by decreases in product development revenues earned by ANI Canada.

Net revenues of rare disease pharmaceutical products, which consist entirely of sales of Cortrophin, were $12.6 million during the three months ended September 30, 2022, as the product was launched in late January 2022. There were no sales of rare disease pharmaceutical products during the comparable prior year period.

Operating expenses increased by 60% to $88.8 million for the three months ended September 30, 2022, from $55.6 million in the prior year period.

Cost of sales, excluding depreciation and amortization, increased by $8.5 million to $32.9 million in the third quarter of 2022 compared to $24.4 million in the prior year period, driven primarily by $6.5 million in costs related to Novitium and $1.7 million related to an increase in the sales of products subject to profit sharing arrangements.

Research and development expenses were $7.7 million in the third quarter of 2022, an increase of $5.2 million from the prior year period primarily due to expenses related to Novitium generic and 505(b)(2) research and development activities and in-process research and development charges of $1.2 million recognized in the current year period.

Selling, general and administrative expenses increased to $30.1 million in the third quarter of 2022, or 75%, compared to $17.2 million in the prior year quarter, reflecting a $10.3 million increase in sales and marketing expenses related to our launch of Cortrophin and increased expenses related to the addition of Novitium headcount and activities, partially offset by a $0.4 million decrease in transaction expenses related to the Novitium acquisition.

Depreciation and amortization increased by 25% in the third quarter of 2022 to $14.2 million from $11.3 million in the comparable quarter in 2021, primarily due to amortization of intangible assets acquired in the Novitium acquisition.

Net loss available to common shareholders for the third quarter of 2022 was $(9.0) million as compared to net loss of $(4.4) million in the prior year period. Diluted loss per share for the three months ended September 30, 2022 was $(0.55) compared to diluted loss per share of $(0.37) in the prior year period.

Adjusted non-GAAP diluted earnings per share was $0.64 in the third quarter of 2022 compared to $1.01 in the third quarter of 2021.

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, 2022, the Company had $56.3 million in unrestricted cash and cash equivalents plus $140.4 million in net accounts receivable. The Company had $297.8 million (face value) in outstanding debt as of September 30, 2022.

2022 Guidance

The Company reiterates its 2022 guidance:

- Net Revenue between $295.0 million and $315.0 million, representing approximately 36% to 46% growth as compared to $216.1 million recognized in 2021

- Cortrophin Net Revenue between $40.0 million and $45.0 million

- Adjusted non-GAAP EBITDA between $54.0 million and $60.0 million

- Adjusted non-GAAP Diluted Earnings per Share between $1.34 and $1.62

Conference Call

As previously announced, ANI management will host its third quarter 2022 conference call as follows:

Date	November 9, 2022
Time	8:00 a.m. ET
Toll free (U.S.)	800-245-3047
Global	203-518-9765

Webcast (live and replay) www.anipharmaceuticals.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 800-753-6120 and entering access code 1159760.

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 (loss)/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, Novitium transaction expenses, Cortrophin pre-launch charges, contingent consideration fair value adjustment, 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.

ANI is not providing a reconciliation for the forward-looking full year 2022 adjusted EBITDA guidance because it does not currently have sufficient information to accurately estimate all of the variables and individual adjustments for such reconciliation, including "with" and "without" tax provision information. As such, ANI's management cannot estimate on a forward-looking basis without unreasonable effort the impact these variables and individual adjustments will have on its reported results.

Adjusted non-GAAP Net (Loss)/Income

ANI's management considers adjusted non-GAAP net (loss)/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, non-cash interest expense, depreciation and amortization, Cortrophin pre-launch charges, Novitium transaction expenses, contingent consideration fair value adjustment, and certain other items that vary in frequency and impact on ANI's results of operations. Management uses adjusted non-GAAP net (loss)/income when analyzing Company performance.

Adjusted non-GAAP net (loss)/income is defined as net (loss)/income, plus the excess of fair value over cost of acquired inventory sold, non-cash stock-based compensation expense, Novitium transaction expenses, non-cash interest expense, depreciation and amortization expense, Cortrophin pre-launch charges, contingent consideration fair value adjustment, 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. 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 (loss)/income should be considered in addition to, but not in lieu of, net (loss)/income reported under GAAP. A reconciliation of adjusted non-GAAP net (loss)/income to the most directly comparable GAAP financial measure is provided below.

Adjusted non-GAAP Diluted (Loss)/Earnings per Share

ANI's management considers adjusted non-GAAP diluted (loss)/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, non-cash interest expense, depreciation and amortization, Cortrophin pre-launch charges, Novitium transaction expenses, contingent consideration fair value adjustment, and certain other items that vary in frequency and impact on ANI's results of operations. Management uses adjusted non-GAAP diluted (loss)/earnings per share when analyzing Company performance.

Adjusted non-GAAP diluted (loss)/earnings per share is defined as adjusted non-GAAP net (loss)/income, as defined above, divided by the diluted weighted average shares outstanding during the period. 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 (loss)/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 (loss)/earnings per share to the most directly comparable GAAP financial measure is provided below.

About ANI Pharmaceuticals, Inc.

ANI Pharmaceuticals, Inc. is a diversified biopharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceutical products, including for diseases with high unmet medical need. Our team is focused on delivering sustainable growth by building a successful Purified Cortrophin® Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. For more information, please visit our website www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release 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, those relating to the commercialization and potential sales of the product and any additional product launches from the Company's generic pipeline, 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 costs involved in commercializing Cortrophin, the ability to maintain regulatory approval of the product and maintain sufficiency of the product, the ability to obtain reimbursement from third-party payors for this product, evolving government legislation, the opinions and views of key opinion leaders and physicians who treat patients with chronic diseases and who may prescribe Cortrophin, ANI's ability to generate projected net product revenue and gain market share on the timeline expected, actions taken by competitors in response to a new market entrant; the ability of the Company to successfully maintain manufacturing capabilities and adequate commercial quantities of Cortrophin at acceptable costs and quality levels; broad acceptance of Cortrophin by physicians, patients and the healthcare community; the acceptance of pricing and placement of Cortrophin on payers' formularies; risks the Company may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of our products from both domestic and overseas sources due to supply chain disruptions or for any other reason; the use of single source suppliers and the time it may take to validate and qualify another supplier, if necessary; manufacturing difficulties or delays, ANI's reliance on third parties over which it may not always have full control, increased competition and strategies employed by competitors; the ability to realize benefits anticipated from acquisitions, including but not limited to, the Oakrum product acquisition and post-close integration activities related to the Novitium acquisition; disruptions to our operations resulting from the ongoing shutdown and sale process relating to our Oakville, Ontario, manufacturing plant, including the transition of certain products manufactured there to our other facilities, or difficulties finding a buyer for the plant; 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 and uncertainties regarding the COVID-19 pandemic and inflationary pressures; market trends for our products; regulatory environment and changes; and regulatory and other approvals relating to product development and manufacturing, and other risks and uncertainties that are described in ANI's Annual Report on Form 10-K, quarterly reports on Form 10-Q, and other periodic reports filed with the Securities and Exchange Commission.

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 (SEC), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. 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. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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SOURCE: ANI Pharmaceuticals, Inc.

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,	
	2022	**2021**	**2022**	**2021**
Net Revenues	$ 83,821	$ 52,061	$ 222,153	$ 155,207
Operating Expenses:				
Cost of sales (excl. depreciation and amortization)	32,894	24,413	102,459	66,712
Research and development	7,657	2,456	17,096	8,229
Selling, general, and administrative	30,081	17,181	90,856	53,588
Depreciation and amortization	14,167	11,346	42,488	33,568
Contingent consideration fair value adjustment	2,476	-	2,134	-
Legal settlement expense	-	-	-	8,400
Purified Cortrophin Gel pre-launch charges	-	227	-	780
Restructuring activities	1,541	-	4,111	-
Intangible asset impairment charge	-	-	112	-
Total Operating Expenses	88,816	55,623	259,256	171,277
Operating Loss	(4,995)	(3,562)	(37,103)	(16,070)
Other Expense, net				
Interest expense, net	(7,264)	(2,497)	(20,546)	(7,482)
Other income/(expense), net	37	(1,071)	712	(1,653)
Loss Before Benefit for Income Taxes	(12,222)	(7,130)	(56,937)	(25,205)
Benefit for income taxes	3,622	2,683	13,284	6,738
Net Loss	$ (8,600)	$ (4,447)	$ (43,653)	$ (18,467)
Dividends on Series A Convertible Preferred Stock	(406)	-	(1,218)	-
Net Loss Available to Common Shareholders	$ (9,006)	$ (4,447)	$ (44,871)	$ (18,467)
Basic and Diluted Loss Per Share:				
Basic Loss Per Share	$ (0.55)	$ (0.37)	$ (2.76)	$ (1.53)
Diluted Loss Per Share	$ (0.55)	$ (0.37)	$ (2.76)	$ (1.53)
Basic Weighted-Average Shares Outstanding	16,303	12,107	16,238	12,066
Diluted Weighted-Average Shares Outstanding	16,303	12,107	16,238	12,066

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

	September 30, 2022	December 31, 2021
Current Assets		
Cash and cash equivalents	$ 56,281	$ 100,300
Accounts receivable, net	140,433	128,526
Inventories, net	95,893	81,693
Prepaid income taxes	3,778	3,667
Assets held for sale	8,020	-
Prepaid expenses and other current assets	4,972	7,589
Total Current Assets	309,377	321,775
Non-current Assets		
Property and equipment	72,935	75,627
Accumulated depreciation	(30,105)	(22,956)
Property and equipment, net	42,830	52,671
Restricted cash	5,003	5,001
Deferred tax assets, net of deferred tax liabilities and valuation allowance	77,340	67,936
Intangible assets, net	264,237	294,122
Goodwill	28,221	27,888
Derivatives and other non-current assets	12,102	2,205
Total Assets	$ 739,110	$ 771,598
Current Liabilities		
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	18,992	22,967
Accrued royalties	6,585	6,225
Accrued compensation and related expenses	7,745	8,522
Accrued government rebates	8,745	5,492
Returned goods reserve	33,984	35,831
Accrued expenses and other	4,726	7,650
Total Current Liabilities	81,627	87,537
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	285,882	286,520
Non-current contingent consideration	33,434	31,000
Derivatives and other non-current liabilities	1,492	7,801
Total Liabilities	$ 402,435	$ 412,858
Mezzanine Equity		
Convertible preferred stock, Series A	24,850	24,850
Stockholders' Equity		
Common stock	1	1
Treasury stock	(4,975)	(3,135)
Additional paid-in capital	399,396	387,844
Accumulated deficit	(92,636)	(47,765)
Accumulated other comprehensive income/(loss), net of tax	10,039	(3,055)
Total Stockholders' Equity	311,825	333,890
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 739,110	$ 771,598

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

	Three Months Ended September 30,	
	2022	2021
Net Loss	$ (8,600)	$ (4,447)
Add/(Subtract):		
Interest expense, net	7,264	2,497
Other (income)/expense, net [1]	(37)	2,271
Benefit for income taxes	(3,622)	(2,683)
Depreciation and amortization	14,167	11,346
Contingent consideration fair value adjustment	2,476	-
Restructuring activities	1,541	-
Impact of Canada operations[2]	840	-
Cortrophin pre-launch charges and sales & marketing expenses[3]	-	2,192
Stock-based compensation	3,869	2,807
Excess of fair value over cost of acquired inventory	443	2,225
Novitium transaction expenses	59	431
In-process research and development charge	1,151	-
Adjusted non-GAAP EBITDA	$ 19,551	$ 16,639

	Reconciliation of certain adjusted non-GAAP accounts:							
	Net Revenues		Cost of sales (excl. depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
	Three Months Ended September 30,		Three Months Ended September 30,		Three Months Ended September 30,		Three Months Ended September 30,	
	2022	2021	2022	2021	2022	2021	2022	2021
As reported:	$ 83,821	$ 52,061	$ 32,894	$ 24,413	$ 30,081	$ 17,181	$ 7,657	$ 2,456
Impact of Canada operations[2]	(969)	-	(681)	-	(1,052)	-	(76)	-
Cortrophin pre-launch charges and sales & marketing expenses[3]	-	-	-	-	-	(1,965)	-	-
Stock-based compensation	-	-	(149)	(5)	(3,524)	(2,653)	(196)	(149)
Excess of fair value over cost of acquired inventory	-	-	(443)	(2,225)	-	-	-	-
Novitium transaction expenses	-	-	-	-	(59)	(431)	-	-
In-process research and development charge	-	-	-	-	-	-	(1,151)	-
As adjusted:	$ 82,852	$ 52,061	$ 31,621	$ 22,183	$ 25,446	$ 12,132	$ 6,234	$ 2,307

[1] Adjustment to other (income)/expense, net excludes $1.2 million of income related to the sale of an ANDA during the three months ended September 30, 2021.

[2] Impact of Canada operations includes revenues and operating expenses, exclusive of restructuring activities, stock-based compensation and depreciation and amortization, which are included within their respective line items above.

[3] Beginning in 2022, we no longer adjust for "Cortrophin pre-launch charges and sales and marketing expenses in arriving at Adjusted non-GAAP EBITDA.

	Nine Months Ended September 30,	
	2022	2021
Net Loss	$ (43,653)	$ (18,467)
Add/(Subtract):		
Interest expense, net	20,546	7,482
Other (income)/expense, net[1]	38	2,853
Benefit for income taxes	(13,284)	(6,738)
Depreciation and amortization	42,488	33,568
Contingent consideration fair value adjustment	2,134	-
Legal settlement expense	-	8,400
Intangible asset impairment charge	112	-
Restructuring activities	4,111	-
Impact of Canada operations[2]	2,661	-
Cortrophin pre-launch charges and sales & marketing expenses[3]	-	5,236
Stock-based compensation	10,862	7,520
Excess of fair value over cost of acquired inventory	5,246	3,717
Novitium transaction expenses	1,276	5,064
In-process research and development charge	1,151	-
Adjusted non-GAAP EBITDA	$ 33,688	$ 48,635

	Reconciliation of certain adjusted non-GAAP accounts:							
	Net Revenues		Cost of sales (excl. depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
	Nine Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021	2022	2021	2022	2021
As reported:	$ 222,153	$ 155,207	$ 102,459	$ 66,712	$ 90,856	$ 53,588	$ 17,096	$ 8,229
Impact of Canada operations[2]	(2,014)	-	(1,930)	-	(2,598)	-	(147)	-
Cortrophin pre-launch charges and sales & marketing expenses[3]	-	-	-	-	-	(4,456)	-	-
Stock-based compensation	-	-	(442)	(15)	(9,858)	(7,082)	(562)	(423)
Excess of fair value over cost of acquired inventory	-	-	(5,246)	(3,717)	-	-	-	-
Novitium transaction expenses	-	-	-	-	(1,276)	(5,064)	-	-
In-process research and development charge	-	-	-	-	-	-	(1,151)	-
As adjusted:	$ 220,139	$ 155,207	$ 94,841	$ 62,980	$ 77,124	$ 36,986	$ 15,236	$ 7,806

[1] Adjustment to other (income)/expense, net excludes $750 thousand and $1.2 million of income related to the sale of an ANDA during the nine months ended September 30, 2022 and 2021, respectively.

[2] Impact of Canada operations includes revenues and operating expenses, exclusive of restructuring activities, stock-based compensation and depreciation and amortization, which are included within their respective line items above.

[3] Beginning in 2022, we no longer adjust for "Cortrophin pre-launch charges and sales and marketing expenses" in arriving at Adjusted non-GAAP EBITDA.

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,	
	2022	2021	2022	2021
Net Loss Available to Common Shareholders	$ (9,006)	$ (4,447)	$ (44,871)	$ (18,467)
Add/(Subtract):				
Non-cash interest expense	963	559	2,883	1,644
Depreciation and amortization expense	14,167	11,346	42,488	33,568
Contingent consideration fair value adjustment	2,476	-	2,134	-
Restructuring activities	1,541	-	4,111	-
Legal settlement expense	-	-	-	8,400
Intangible asset impairment charge	-	-	112	-
Impact of Canada operations(1)	840	-	2,661	-
Cortrophin pre-launch charges and sales& marketing expenses(2)	-	2,192	-	5,236
Stock-based compensation	3,869	2,807	10,862	7,520
Excess of fair value over cost of acquired inventory	443	2,225	5,246	3,717
Credit facility ticking fee expense	-	2,434	-	2,434
Novitium transaction expenses	59	431	1,276	5,064
In-process research and development charge	1,151	-	1,151	-
Less:				
Estimated tax impact of adjustments (calc. at 24%)	(6,122)	(5,279)	(17,502)	(16,220)
Adjusted non-GAAP Net Income Available to Common Shareholders	$ 10,381	$ 12,269	$ 10,551	$ 32,896
Diluted Weighted-Average Shares Outstanding	16,303	12,107	16,238	12,066
Adjusted Diluted Weighted-Average Shares Outstanding	16,317	12,119	16,252	12,080
Adjusted non-GAAP Diluted Earnings per Share	$ 0.64	$ 1.01	$ 0.65	$ 2.72

(1) Impact of Canada operations includes revenues and operating expenses, exclusive of restructuring activities, stock-based compensation and depreciation and amortization, which are included within their respective line items above.
(2) Beginning in 2022, we no longer adjust for "Cortrophin pre-launch charges and sales and marketing expenses" in arriving at Adjusted non-GAAP Net Loss.