**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): May 4, 2020**

# 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) | (IRS Employer Identification No.) |

| **210 Main Street West**<br>**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)

☐ 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 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 May 7, 2020, ANI Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial and operating results for the three months ended March 31, 2020. A copy of the press release is furnished herewith as Exhibit 99.1.

**Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On May 4, 2020, the Board appointed Patrick D. Walsh, a member of the Board of Directors of the Company (the "Board"), as interim President and Chief Executive Officer, effective May 11, 2020.

Mr. Walsh has been a member of the Board since 2018. He is President & Managing Member of Diligence Team and Diligence Group LLC, consulting practices he founded and are based in Durham, North Carolina, and brings over 35 years of experience in the pharmaceutical industry.

From May 2019 to April 2020, he was co-founder and CEO of TriPharm Services, an injectable manufacturing business which was acquired by Alcami. From 2015 to February 2019, Mr. Walsh was the chief executive officer of Avista Pharma, a private equity backed global provider of contract manufacturing, development and analytical testing services to pharmaceutical and biotechnology clients that was acquired by Cambrex. Prior to Avista, from 2010 to 2014, Mr. Walsh was the chief executive officer of AAIPharma Services Corporation in Wilmington, North Carolina, a private equity backed global provider of contract manufacturing services. Mr. Walsh's earlier career includes serving as chief executive officer of Kadmus Pharmaceuticals, Inc., in Irvine, California, and serving as president and chief operating officer of publicly-traded Gensia-Sicor Pharmaceuticals, Inc., which was acquired by Teva for $3.2 billion. Mr. Walsh currently serves as an independent director of the Board of Directors of Avid Bioservices, a publicly-traded company based in Tustin, California and serves on its corporate governance committee and is chair of the compensation committee. He is also an independent director of the Board of Directors of Institute Chemica Emiliano (I.C.E.), a privately held specialty chemical company based in Milan, Italy. He is also an Operating Partner (part-time) to healthcare private-equity firm Ampersand Capital, based in Wellesley, Massachusetts.

In connection with Mr. Walsh's appointment as interim President and Chief Executive Officer, the Company agreed to pay Mr. Walsh an annual base salary of $630,000. Additionally, Mr. Walsh will receive 7,050 shares of restricted stock which will vest over a one-year period; provided, however, that such restricted stock shall immediately vest in full on the date Mr. Walsh's service as interim President and Chief Executive Officer terminates.

As previously announced, the Board of Directors has retained an executive search firm to lead the search for a new President and Chief Executive Officer which search is ongoing.

**Forward-Looking Statements**

To the extent any statements made in this report 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 Mr. Walsh's appointment as interim President and Chief Executive Officer 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 ability of the Company to identify and attract qualified candidates for the position of President and Chief Executive Officer, the length of time before a successor is appointed and potential disruption in the management team during the transition period.

The Company's business generally is subject to a number of risks which are described more fully 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 report speak only as of the date of this report 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.

In accordance with General Instruction B.2. of Form 8-K, the information in Item 2.02 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**

| Exhibit | Description |
|---|---|
| 99.1 | Press release dated May 7, 2020, announcing financial and operating results for the three months ended March 31, 2020 and Patrick D. Walsh's pending appointment as interim President and Chief Executive Officer. |

**SIGNATURES**

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 thereunto duly authorized.

**ANI PHARMACEUTICALS, INC.**

By: /s/ Stephen P. Carey
Stephen P. Carey
*Vice President Finance, and Chief Financial Officer*

Dated: May 7, 2020

**Exhibit 99.1**

# ANI Pharmaceuticals Reports First Quarter 2020 Results and Appoints Interim CEO

**For the first quarter 2020, ANI reports:**

- **Net revenues of $49.8 million versus $52.9 million in 2019**
- **GAAP net loss of $7.0 million and diluted GAAP loss per share of $0.59**
- **Adjusted non-GAAP EBITDA of $17.6 million**
- **Adjusted non-GAAP diluted earnings per share of $1.04**

**Integrates Amerigen Pharmaceuticals, Ltd. portfolio**

**Launches five generic products increasing total commercialized product line to 60 product families**

**Appoints Patrick D. Walsh interim President and CEO**

**Suspends guidance for 2020**

**Baudette, Minnesota (May 7, 2020) – ANI Pharmaceuticals, Inc. ("ANI")** (NASDAQ: ANIP) today reported its financial results for the three months ended March 31, 2020. The Company will host its earnings conference call this morning, May 7, 2020, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 5243607.

**Financial Summary**

| *(in thousands, except per share data)* | **Q1 2020** | **Q1 2019** |
|---|---|---|
| **Net revenues** | $ 49,774 | $ 52,887 |
| **Net (loss)/income** | $ (7,011) | $ 449 |
| **GAAP (loss)/earnings per diluted share** | $ (0.59) | $ 0.04 |
| **Adjusted non-GAAP EBITDA[(a)]** | $ 17,554 | $ 22,299 |
| **Adjusted non-GAAP diluted earnings per share[(b)]** | $ 1.04 | $ 1.30 |

(a) See Table 3 for US GAAP reconciliation.
(b) See Table 4 for US GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

> "ANI generated net revenues and non-GAAP earnings that met management's expectations during a period that was marked by significant uncertainties due to the COVID-19 pandemic. Our performance during this period is a testament to the commitment of our employees and to the strength of the business that we have built. I am proud of the accomplishments that were made during my eleven-year tenure as CEO of ANI. During this time, we have built ANI from a small private company to a thriving public specialty pharmaceutical business with an increasing diverse commercial product offering and an incredibly valuable pipeline opportunity in Cortrophin® Gel. As I depart ANI, I am confident that I leave the business in good health, in the hands of a very strong management team, and with its best days ahead of it. I welcome Patrick Walsh from the Board of Directors to the role of interim CEO and trust in his ability to lead the Company until such time as my replacement is identified."

**Appoints Interim CEO**

As previously announced, Mr. Przybyl will depart as President and CEO on May 10, 2020. The Board of Directors of ANI (BOD) has appointed Patrick D. Walsh interim President and CEO, effective May 11, 2020, until such time that Mr. Przybyl's permanent replacement is hired. Mr. Walsh has served on the ANI BOD since 2018 and has extensive pharmaceutical industry experience. For Mr. Walsh's complete bio, please refer to ANI's proxy statement filed on April 23, 2020. The BOD has retained nationally recognized executive search firm Heidrick & Struggles and is currently conducting the search for a President and CEO.

**Continues Expansion of Commercialized Product Portfolio**

During the first quarter of 2020, we successfully integrated the Amerigen Pharmaceuticals, Ltd. U.S. product portfolio, which was purchased in January for $52.5 million. This transaction increased our commercialized generic product portfolio by nine products from 35 to 44 and increased our pipeline portfolio by an additional thirteen opportunities. In addition, we launched five generic products during the quarter, further expanding our generic offerings to 49, and our total commercialized offerings including brands to 60.

**First Quarter Results**

| **Net Revenues** (in thousands) | **Three Months Ended March 31,** | | | |
|---|---|---|---|---|
| | **2020** | **2019** | **Change** | **% Change** |
| Generic pharmaceutical products | $ 37,495 | $ 31,599 | $ 5,896 | 19% |
| Branded pharmaceutical products | 9,157 | 17,543 | (8,386) | (48)% |
| Contract manufacturing | 1,974 | 2,437 | (463) | (19)% |
| Royalty and other income | 1,148 | 1,308 | (160) | (12)% |
| Total net revenues | $ 49,774 | $ 52,887 | $ (3,113) | (6)% |

***Generic Pharmaceutical Products***

Net revenues for generic pharmaceutical products were $37.5 million during the three months ended March 31, 2020, an increase of 19% compared to $31.6 million for the same period in 2019. The primary drivers of the increase are the September 2019 launch of Vancomycin Oral Solution and the January 2020 launch of Miglustat, Mixed Amphetamine Salts, Penicillamine and Paliperidone, all products acquired in January from Amerigen Pharmaceuticals, Ltd. ("Amerigen"). These increases were tempered by decreases in sales of Vancomycin capsules, Esterified Estrogen with Methyltestosterone ("EEMT"), Erythromycin Ethylsuccinate ("EES"), and Ezetimibe Simvastatin.

***Branded Pharmaceutical Products***

Net revenues for branded pharmaceutical products were $9.2 million during the three months ended March 31, 2020, a decrease of 48% compared to $17.5 million for the same period in 2019. The primary reasons for the decrease were lower unit sales of Inderal XL, Inderal LA and Atacand as well as decreased sales of Arimidex.

***Contract Manufacturing***

Contract manufacturing revenues were $2.0 million during the three months ended March 31, 2020, a decrease of 19% compared to $2.4 million for the same period in 2019, due to the timing and volume of orders from contract manufacturing customers in the period.

***Royalty and Other***

Royalty and other were $1.1 million during the three months ended March 31, 2020, a decrease of $0.2 million from $1.3 million for the same period in 2019, primarily due to a decrease in royalty and laboratory service revenues, tempered by increases in product development revenues earned by ANI Canada during the three months ended March 31, 2020.

***Operating Expenses***

Operating expenses increased to $57.6 million for the three months ended March 31, 2020, from $48.5 million in the prior year period. The increase was primarily due to the following:

- $7.1 million increase in cost of sales, primarily as a result of $2.7 million in cost of sales representing the excess of fair value over cost for inventory acquired in the Amerigen acquisition and subsequently sold during the period, increased volumes related to a shift in product mix towards generic products, current period inventory reserve charges and increased sales of products subject to profit-sharing arrangements,
- $4.6 million in the build of Cortrophin® pre-launch commercial inventories (which are expensed for US GAAP); there were no such comparable activities in the first quarter 2019, and
- $2.0 million increase in research and development expense, primarily due to $3.8 million in-process research and development expense from the Amerigen acquisition, partially offset by a decrease in expense related to the Cortrophin® re-commercialization project as we begin to complete our development efforts.

These increases were tempered by a $4.9 million decrease in depreciation and amortization expense, primarily due to the non-reoccurrence of amortization expense recorded in relation to the January 2019 royalty buy out, partially offset by the amortization of the Abbreviated New Drug Applications and marketing and distribution rights acquired in January 2020 from Amerigen.

Cost of sales exclusive of the $2.7 million net impact related to the excess of fair value over the cost of inventory sold during the period as a percentage of net revenues increased to 38% during the three months ended March 31, 2020, from 28% during same period in 2019, primarily as a result of a shift in product mix to an increased volume of generic products, which have lower average selling prices, inventory reserve charges in the current quarter as well as increased sales of products subject to profit-sharing arrangements during the current quarter.

***Net Loss and Diluted Loss per Share***

Net loss was $7.0 million for the three months ended March 31, 2020, as compared to net income of $0.4 million in the prior year period. The effective consolidated tax benefit rate for the three months ended March 31, 2020 was 29.7%.

Diluted loss per share for the three months ended March 31, 2020 was $0.59, based on 11,902 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.04 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.04, as compared to adjusted non-GAAP diluted earnings per share of $1.30 in the prior year period. For a reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure, please see Table 4.

**Cortrophin® Gel Re-commercialization Update**

| Product | Required Filing | Total Annual Market[(c)] |
|---|---|---|
| Cortrophin® Gel | sNDA | $950 million |

[(c)] Based on data from IQVIA

ANI filed the sNDA for Cortrophin® Gel re-commercialization on March 23, 2020, on track with our long-standing publicly projected Q1 2020 target filing date. The FDA initially set a PDUFA goal date of July 23, 2020, however as announced on April 29, 2020, subsequently issued a Refusal to File (RTF) letter. ANI will request a Type-A meeting with the FDA in order to discuss the deficiencies identified in the RTF letter and our plan to address each of them. In addition, significant accomplishments since the fourth quarter 2020 press release (dated February 27, 2020) include:

- ANI successfully completed manufacturing for a sixth commercial scale batch of Corticotropin API. All six commercial scale batches have been analytically consistent with each other and have met all API release specifications.
- ANI obtained 6 months accelerated and real-time stability on all API registration batches which facilitated sNDA filing by the end of first quarter 2020.
- ANI successfully completed three media fill simulations demonstrating sterility assurance for our Cortrophin® Gel manufacturing process.
- ANI obtained 6 months accelerated and real-time stability on all drug product registration batches which also facilitated sNDA filing by the end of first quarter 2020.
- ANI successfully completed full shipping validation which confirmed that the integrity of Cortrophin® Gel is fully maintained to support our commercial launch and distribution plan.
- In preparation for a future launch, ANI has continued to stockpile porcine pituitaries and corticotropin API to ensure that it can satisfy market demand.

For further details, please see ANI's Cortrophin® Gel Re-commercialization Milestone Update in Table 5.

**ANI Guidance for the Full Year 2020**

Due to inherent uncertainties regarding the duration and impact of the coronavirus (COVID-19) pandemic, ANI is suspending its previously announced 2020 financial guidance.

**ANI Product Development Pipeline**

ANI's pipeline consists of 116 products, addressing a total annual market size of $5.8 billion, based on data from IQVIA. Of these, ANI expects that at least 52 can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

**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, depreciation, amortization, the excess of fair value over cost of acquired inventory, stock-based compensation expense, expense from acquired in-process research and development, gains on inventory reserve recoveries, transaction and integration expenses, Cortrophin pre-launch charges, other income / expense 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 in Table 3.

***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, non-cash interest expense, depreciation and amortization, inventory reserve recoveries, 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 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, stock-based compensation expense, 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. 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 in Table 4.

***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, non-cash interest expense, depreciation and amortization, inventory reserve recoveries, 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 in Table 4.

**About ANI**

ANI Pharmaceuticals, Inc. (the “Company” or “ANI”) is an integrated specialty pharmaceutical company developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include controlled substances, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit the Company’s 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, statements about price increases, the Company’s future operations, products, financial position, operating results and prospects, the Company’s pipeline or potential markets therefor, the appointment of an Interim President and CEO and our ongoing CEO search 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; increased competition; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approvals from the U.S. Food and Drug Administration; the ability to identify and attract qualified candidates for the President and Chief Executive Officer position, the length of time before a successor is appointed and potential disruption in the management team during the transition period; general business and economic conditions; market trends; regulatory environment; products development; regulatory and other approvals; and marketing.

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 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.

For more information about ANI, please contact:
Investor Relations
IR@anipharmaceuticals.com

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Net Revenues | $ 49,774 | $ 52,887 |
| | | |
| Operating Expenses | | |
| Cost of sales (excl. depreciation and amortization) | 21,804 | 14,725 |
| Research and development | 6,344 | 4,373 |
| Selling, general, and administrative | 13,683 | 13,284 |
| Depreciation and amortization | 11,183 | 16,103 |
| Cortrophin pre-launch charges | 4,602 | - |
| | | |
| Total Operating Expenses | 57,616 | 48,485 |
| | | |
| Operating (Loss)/Income | (7,842) | 4,402 |
| | | |
| Other Expense, Net | | |
| Interest expense, net | (2,032) | (3,354) |
| Other income/(expense), net | 10 | (130) |
| | | |
| (Loss)/Income Before Benefit/(Provision) for Income Taxes | (9,864) | 918 |
| | | |
| Benefit/(Provision) for Income Taxes | 2,853 | (469) |
| | | |
| Net (Loss)/Income | $ (7,011) | $ 449 |
| | | |
| **(Loss)/Earnings Per Share** | | |
| Basic (Loss)/Earnings Per Share | $ (0.59) | $ 0.04 |
| Diluted (Loss)/Earnings Per Share | $ (0.59) | $ 0.04 |
| | | |
| Basic Weighted-Average Shares Outstanding | 11,902 | 11,747 |
| Diluted Weighted-Average Shares Outstanding | 11,902 | 11,823 |

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

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Current Assets | | |
| Cash and cash equivalents | $ 20,414 | $ 62,332 |
| Accounts receivable, net | 82,379 | 72,129 |
| Inventories, net | 52,902 | 48,163 |
| Prepaid income taxes | - | 1,076 |
| Prepaid expenses and other current assets | 2,967 | 3,995 |
| Total Current Assets | 158,662 | 187,695 |
| Property and equipment, net | 40,353 | 40,551 |
| Restricted cash | 5,002 | 5,029 |
| Deferred tax assets, net of deferred tax liabilities and valuation allowance | 57,906 | 38,326 |
| Intangible assets, net | 215,619 | 180,388 |
| Goodwill | 3,580 | 3,580 |
| Other non-current assets | 1,110 | 1,220 |
| Total Assets | $ 482,232 | $ 456,789 |
| Current Liabilities | | |
| Current debt, net of deferred financing costs | $ 11,872 | $ 9,941 |
| Accounts payable | 12,485 | 14,606 |
| Accrued expenses and other | 4,378 | 2,362 |
| Accrued royalties | 6,285 | 5,084 |
| Accrued compensation and related expenses | 3,151 | 3,736 |
| Current income taxes payable, net | 15,223 | - |
| Accrued government rebates | 8,030 | 8,901 |
| Returned goods reserve | 17,614 | 16,595 |
| Deferred revenue | 318 | 451 |
| Total Current Liabilities | 79,356 | 61,676 |
| Non-current debt, net of deferred financing costs and current borrowing component | 188,094 | 175,808 |
| Other non-current long-term liabilities | 13,611 | 6,514 |
| Total Liabilities | 281,061 | 243,998 |
| Stockholders' Equity | | |
| Common stock | 1 | 1 |
| Treasury stock | (1,211) | (723) |
| Additional paid-in capital | 203,505 | 200,800 |
| Retained earnings | 10,565 | 17,584 |
| Accumulated other comprehensive loss, net of tax | (11,689) | (4,871) |
| Total Stockholders' Equity | 201,171 | 212,791 |
| **Total Liabilities and Stockholders' Equity** | $ 482,232 | $ 456,789 |

**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 March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Net (Loss)/Income | $ (7,011) | $ 449 |
| Add/(Subtract): | | |
| Interest expense, net | 2,032 | 3,354 |
| Other (income)/expense, net, less loss on and expense on repurchase of convertible debt | (10) | 130 |
| (Benefit)/provision for income taxes | (2,853) | 469 |
| Depreciation and amortization | 11,183 | 16,103 |
| Cortrophin pre-launch charges | 4,602 | - |
| Stock-based compensation | 2,424 | 1,710 |
| Acquired IPR&D expense | 3,784 | - |
| Asset impairments[(1)] | 752 | - |
| Excess of fair value over cost of acquired inventory | 2,651 | - |
| Transaction and integration expenses | - | 84 |
| Adjusted non-GAAP EBITDA | $ 17,554 | $ 22,299 |

[(1)] Asset Impairments comprised of finished goods inventory reserve for Bretylium and accounts receivable reserve due to customer bankruptcy, tempered by 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 March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Net (Loss)/Income | $ (7,011) | $ 449 |
| Add/(Subtract): | | |
| Non-cash interest expense | 157 | 1,799 |
| Depreciation and amortization expense | 11,183 | 16,103 |
| Cortrophin pre-launch charges | 4,602 | - |
| Acquired IPR&D expense | 3,784 | - |
| Stock-based compensation | 2,424 | 1,710 |
| Excess of fair value over cost of acquired inventory | 2,651 | - |
| Asset Impairments[(1)] | 752 | - |
| Transaction and integration expenses | - | 84 |
| Less | | |
| Tax impact of adjustments | (6,133) | (4,727) |
| Adjusted non-GAAP Net Income | $ 12,409 | $ 15,418 |
| Diluted Weighted-Average | | |
| Shares Outstanding | 11,902 | 11,823 |
| Adjusted Diluted Weighted-Average | | |
| Shares Outstanding | 11,945 | 11,823 |
| Adjusted non-GAAP | | |
| Diluted Earnings per Share | $ 1.04 | $ 1.30 |

(1) Asset Impairments comprised of finished goods inventory reserve for Bretylium and accounts receivable reserve due to customer bankruptcy, tempered by modest recovery of previously reserved inventory related to market exits.

**ANI Pharmaceuticals, Inc. and Subsidiaries**
**Table 5: Cortrophin® Gel Re-Commercialization Milestone Update**

| Objective | Duration | Steps / Details | Status |
|---|---|---|---|
| **Manufacture Commercial Scale Batches of Corticotropin API** | 2-3 months per batch | • Scale-up manufacturing process 5x to projected commercial scale<br>• Finalize API manufacturing process & initiate PV / registration batches<br>• Method development for API characterization methods<br>• Method validation for API release / stability methods<br>• Perform viral clearance studies and validation | Complete<br>Complete<br>Complete<br>Complete<br>Complete |
| **Manufacture Commercial Scale Batches of Cortrophin® Gel Drug Product** | 1 month per batch | • Finalize drug product manufacturing process<br>• Initiate process validation<br>• Method validation for API release / stability methods<br>• Manufacture three API and three drug product registration batches | Complete<br>Complete<br>Complete<br>Complete |
| **Registration Stability for sNDA** | 6 months | • Initiate registration stability studies<br>• Demonstrate 6 months accelerated and real-time stability prior to sNDA submission | Complete<br>Complete |
| **sNDA Submission** | 4 months | • In process of requesting Type-A meeting with FDA to address comments received in RTF letter | In progress |