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

SCHEDULE 14A
Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934

Filed by the Registrant ☒
Filed by a Party other than the Registrant ☐

Check the appropriate box:
☐ Preliminary proxy statement.
☐ Confidential, for use of the Commission only (as permitted by Rule 14a-6(e)(2)).
☐ Definitive proxy statement.
☒ Definitive additional materials.
☐ Soliciting material pursuant to §240.14a-12.

ANI Pharmaceuticals, Inc.

(Name of Registrant as Specified in its Charter)

(Name of Person(s) Filing Proxy Statement, if Other Than the Registrant)

Payment of filing fee (check the appropriate box):

☒ No fee required.
☐ Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

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(1) Amount Previously Paid:

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(2) Form, Schedule or Registration Statement No.:

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(4) Date Filed:

FOR IMMEDIATE RELEASE

ANI Pharmaceuticals Reports First Quarter 2021 Results

-- First quarter 2021 net revenues of $54.5 million; net income of $0.1 million and diluted earnings per share of $0.01 --

-- First quarter adjusted non-GAAP EBITDA of $18.9 million and adjusted non-GAAP diluted earnings per share of $1.04 --

-- Cortrophin® Gel sNDA re-filing on track for Q2 2021 submission --

-- Strengthened R&D engine and enhanced generics and CDMO business through pending acquisition of Novitium Pharma--

-- Expanded branded products portfolio through April 1 acquisition of Sandoz Inc. NDAs ---- Strengthened leadership team through key appointments –

Baudette, Minnesota (May 7, 2021) – ANI Pharmaceuticals, Inc. ("ANI" or the "Company") (NASDAQ: ANIP) today announced business highlights and financial results for the three months ended March 31, 2021.

First Quarter and Recent Business Highlights:

- Continued efforts to assemble a robust re-filing package for Cortrophin® Gel in preparation for second-quarter 2021 submission to the U.S. Food and Drug Administration ("FDA").
- Signed a definitive agreement to acquire Novitium Pharma LLC ("Novitium"), a privately held, New Jersey-based high-growth pharmaceutical company. The transaction is expected to close in the second half of this year, pending Federal Trade Commission ("FTC") clearance and shareholder approval of the equity issuances for the transaction. Upon close, Novitium will diversify ANI's commercial portfolio, add a proven best-in-class R&D engine, enhance our North American manufacturing footprint, and yield compelling financial benefits.
- Acquired the new drug applications ("NDAs") for OXISTAT® Lotion, VEREGEN® Ointment, and Pandel® Cream and the abbreviated new drug application ("ANDA") for ApexiCon® E Cream from Sandoz Inc. Collectively, these dermatology products generated net revenues of $13.2 million in 2020. Strengthened leadership team with the addition of key pharmaceutical executives: Christopher K. Mutz as Chief Commercial Officer and Head of Rare Diseases and Ori Gutwerg as Senior Vice President of Generics.
- Received inaugural ratings from the two major rating agencies, Moody's and S&P. Moody's assigned a B2 rating with a stable outlook, and S&P Global Ratings assigned a B+ rating with a positive outlook.

First Quarter 2021 Financial Highlights:

- Net revenues were $54.5 million compared to $49.8 million in Q1 2020.
- GAAP net income was $0.1 million, and diluted GAAP earnings per share was $0.01.
- Adjusted non-GAAP EBITDA was $18.9 million.
- Adjusted non-GAAP diluted earnings per share was $1.04.

Cash and cash equivalents were $25.1 million, net accounts receivable was $91.9 million, and face value of debt was $184.6 million as of March 31, 2021.

“During the first quarter, we made excellent progress on our stated goal of building a sustainable biopharma company well positioned for growth and serving patients in need. Our dedicated Cortrophin technical team is finalizing our sNDA file for resubmission, and Chris has made strong additions to the commercial team to ensure that we are prepared for a successful launch. The pending Novitium acquisition and product acquisitions from Sandoz represent significant steps toward our goals and are aligned with our four pillars for accelerating growth. Since we signed the Novitium deal in March, Novitium has launched several products, including limited competition opportunities such as Gx Famotidine solution, and continues to build momentum in advance of officially joining the ANI family. At the same time, our operational and commercial teams have seamlessly transitioned the Sandoz product assets into the ANI portfolio,” stated Nikhil Lalwani, President and CEO.

“Similar to many of our industry peers, we have seen a combination of pandemic-related and seasonal factors that have contributed to softness in prescription levels. Despite these challenges, we are at an inflection point, and I believe that the Novitium transaction and sizable market opportunity for Cortrophin have the potential to be transformational for ANI. We remain focused on the work to be done to unlock value for all of our stakeholders and to continue to serve patients in need,” concluded Lalwani.

“We continue to make good progress on our Term Loan B in support of the Novitium transaction, and receiving our inaugural ratings from Moody’s and S&P represents another milestone in the maturation of the Company,” stated Stephen Carey, CFO.

First Quarter 2021 Financial Results

Net Revenues (in thousands)	**Three Months Ended March 31,**	
	2021	**2020**
Generic pharmaceutical products	$ 32,988	$ 37,495
Branded pharmaceutical products	7,517	9,157
Contract manufacturing	2,573	1,974
Royalty and other income	11,443	1,148
Total net revenues	$ 54,521	$ 49,774

Net revenues for generic pharmaceutical products were $33.0 million during the three months ended March 31, 2021, a decrease of 12.0% compared to $37.5 million for the same period in 2020. Based upon an analysis of IQVIA/IMS data, during the three months ended March 31, 2021, the total market for generic prescriptions in the United States declined approximately 9% when compared to the three months ended March 31, 2020. We believe that this overall decline in prescription activity is principally due to the COVID-19 pandemic, and it negatively impacted the market for many of our generic pharmaceutical products. From a product perspective, the net decrease was driven by declines in sales of Ezetimibe Simvastatin, Methazolamide, Miglustat, and Diphenoxylate, somewhat tempered by increased revenues from sales of Paliperidone ER and Erythromycin Ethylsuccinate ("EES")].

Net revenues for branded pharmaceutical products were $7.5 million during the three months ended March 31, 2021, a decrease of 17.9% compared to $9.2 million for the same period in 2020. The decrease primarily reflects lower unit sales of Inderal XL and InnoPran XL, tempered by increased sales of Casodex and Inderal LA.

Contract manufacturing revenues were $2.6 million during the three months ended March 31, 2021, an increase of 30.3% compared to $2.0 million for the same period in 2020, due to an increased volume of orders from contract manufacturing customers in the period.

Royalty and other revenues were $11.4 million during the three months ended March 31, 2021, an increase of $10.3 million from $1.1 million for the same period in 2020, primarily due to the recognition of royalties due ANI for patent rights related to Kite Pharma, Inc.'s oncology product, YESCARTA®.

Operating expenses decreased to $51.5 million for the three months ended March 31, 2021, from $57.6 million in the prior year period.

Cost of sales, excluding depreciation and amortization, decreased by $1.8 million to $20.0 million in the first quarter of 2021, primarily as a result of the non-recurrence 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 three months ended March 31, 2020.

Research and development expenses decreased to $3.0 million in the first quarter of 2021, a decrease of 53.2% from $6.3 million in the first quarter of 2020, primarily due to the non-recurrence of the $3.8 million in-process research and development expense from the Amerigen acquisition in the first quarter 2020.

Selling, general and administrative expenses rose by $3.9 million in the first quarter of 2021 to $17.6 million compared to $13.7 million in the comparable quarter in 2020.The increase primarily reflects $2.9 million of transaction expenses related to the pending Novitium acquisition incurred during the three months ended March 31, 2021, 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 decreased by $0.3 million in the first quarter of 2021 to $10.9 million compared to $11.2 million in the comparable quarter in 2020.

Net income for the first quarter of 2021 was $0.1 million as compared to net loss of $7.0 million in the prior year period. Diluted earnings per share for the three months ended March 31, 2021 was $0.01, compared to diluted loss per share of $0.59 in the prior year period.

Adjusted non-GAAP diluted earnings per share was $1.04 in the first quarter of 2021 and 2020.

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 March 31, 2021, the Company had $25.1 million in unrestricted cash and cash equivalents plus $91.9 million in net accounts receivable. The Company had $184.6 million (face value) in outstanding debt as of March 31, 2021.

Conference Call

As previously announced, ANI Pharmaceuticals management will host its first quarter 2021 conference call as follows:

Date	Friday, May 7, 2021
Time	8:30 a.m. ET
Toll free (U.S.)	(866) 518-6930
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 800-934-5153 and entering access code 5412658.

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, expense from acquired in-process research and development, Novitium transaction expenses, Cortrophin pre-launch charges, asset impairments, 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, non-cash interest expense, depreciation and amortization, Cortrophin pre-launch charges, acquired in-process research and development ("IPR&D") expense, Novitium transaction expenses, asset impairments, 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, Novitium transaction expenses, non-cash interest expense, depreciation and amortization expense, expense from acquired in-process research and development, Cortrophin pre-launch charges, asset impairments, 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 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, non-cash interest expense, depreciation and amortization, Cortrophin pre-launch charges, acquired IPR&D expense, Novitium transaction expenses, asset impairments, 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. 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 focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities including controlled substances, oncology products (anti-cancer), hormones and steroids, and complex formulations. 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 corporate strategy, the pending acquisition of Novitium and anticipated benefits and results of such acquisition, 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 resubmission 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 not be able to obtain the requisite approvals or satisfy other closing conditions to complete the Novitium acquisition, risks 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.

Additional Information about the Proposed Novitium Transaction and Where to Find It

In connection with the proposed acquisition of Novitium (the "Merger") and the issuances of equity contemplated thereby and in the accompanying PIPE transaction (collectively, the "Proposed Transactions") described in a separate press release issued today and related SEC filing, the Company has filed a proxy statement on Schedule 14A with the SEC to obtain the approval of ANI shareholders for such equity issuances as required by the Nasdaq listing standards. Additionally, the Company plans to file other relevant materials with the SEC in connection with the Proposed Transactions. This release is not a substitute for the proxy statement or any other document relating to the Proposed Transactions which the Company may file with the SEC. The definitive proxy statement has been sent or given to the stockholders of the Company and contains important information about the Proposed Transactions. INVESTORS IN AND SECURITY HOLDERS OF THE COMPANY ARE URGED TO READ THE PROXY STATEMENT AND ANY OTHER RELEVANT DOCUMENTS THAT HAVE BEEN FILED OR FURNISHED OR WILL BE FILED OR WILL BE FURNISHED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY BEFORE MAKING ANY VOTING OR INVESTMENT DECISION WITH RESPECT TO THE PROPOSED TRANSACTIONS BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE MERGER, RELATED MATTERS AND THE PARTIES TO THE MERGER. The materials filed by the Company with the SEC may be obtained free of charge at the SEC's website at www.sec.gov or by contacting the investor relations department of the Company.

Participants in the Solicitation

This press release does not constitute a solicitation of a proxy from any stockholder with respect to the Proposed Transactions. However, the Company and its directors and executive officers may be deemed to be participants in the solicitation of proxies from Company stockholders in connection with the Proposed Transactions. Investors and security holders may obtain more detailed information regarding the names, affiliations and interests of the Company's executive officers and directors in the solicitation by reading the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2020, the Company's definitive proxy statement on Schedule 14A for the 2021 Annual Meeting of Stockholders and the other relevant materials filed with the SEC in connection with the Proposed Transactions. Additional information concerning the interests of the Company's participants in the solicitation, which may, in some cases, be different than those of the Company's stockholders generally, is set forth in the proxy statement relating to the Proposed Transactions. You may obtain free copies of these documents as described in the preceding paragraph filed, with or furnished to the SEC. All such documents, when filed or furnished, are available free of charge at the SEC's website at www.sec.gov or by contacting the investor relations department of the Company.

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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 March 31,	
	2021	**2020**
Net Revenues	$ 54,521	$ 49,774
Operating Expenses:		
Cost of sales (excl. depreciation and amortization)	19,985	21,804
Research and development	2,968	6,344
Selling, general, and administrative	17,587	13,683
Depreciation and amortization	10,898	11,183
Cortrophin pre-launch charges	38	4,602
Total Operating Expenses	51,476	57,616
Operating Income/(Loss)	3,045	(7,842)
Other Expense, Net		
Interest expense, net	(2,454)	(2,032)
Other (expense)/income, net	(515)	10
Income/(Loss) Before Benefit for Income Taxes	76	(9,864)
Benefit for income taxes	10	2,853
Net Income/(Loss)	$ 86	$ (7,011)
Earnings/(Loss) Per Share		
Basic Earnings/(Loss) Per Share	$ 0.01	$ (0.59)
Diluted Earnings/(Loss) Per Share	$ 0.01	$ (0.59)
Basic Weighted-Average Shares Outstanding	12,004	11,902
Diluted Weighted-Average Shares Outstanding	12,017	11,902

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

	March 31, 2021	December 31, 2020
Current Assets		
Cash and cash equivalents	$ 25,073	$ 7,864
Accounts receivable, net	91,876	95,793
Inventories, net	59,927	60,803
Prepaid expenses and other current assets	5,922	5,861
Total Current Assets	182,798	170,321
Property and equipment	59,541	58,797
Accumulated depreciation	(18,774)	(17,528)
Property and equipment, net	40,767	41,269
Restricted cash	5,000	5,003
Deferred tax assets, net of deferred tax liabilities and valuation allowance	52,006	51,704
Intangible assets, net	178,859	188,511
Goodwill	3,580	3,580
Other non-current assets	833	802
Total Assets	$ 463,843	$ 461,190
Current Liabilities		
Current debt, net of deferred financing costs	$ 14,438	$ 13,243
Accounts payable	13,769	11,261
Accrued expenses and other	2,381	2,456
Accrued royalties	5,310	6,407
Accrued compensation and related expenses	5,533	6,231
Current income taxes payable, net	3,659	3,906
Accrued government rebates	8,672	7,826
Returned goods reserve	28,944	27,155
Deferred revenue	62	80
Total Current Liabilities	82,768	78,565
Non-current debt, net of deferred financing costs and current borrowing component	168,985	172,443
Derivatives and other non-current liabilities	8,378	14,482
Total Liabilities	260,131	265,490
Stockholders' Equity		
Common stock	1	1
Treasury stock	(2,594)	(2,246)
Additional paid-in capital	216,223	214,354
Accumulated deficit	(4,886)	(4,972)
Accumulated other comprehensive loss, net of tax	(5,032)	(11,437)
Total Stockholders' Equity	203,712	195,700
Total Liabilities and Stockholders' Equity	$ 463,843	$ 461,190

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,	
	2021	**2020**
Net Income/(Loss)	$ 86	$ (7,011)
Add/(Subtract):		
Interest expense, net	2,454	2,032
Other expense/(income), net	515	(10)
Benefit for income taxes	(10)	(2,853)
Depreciation and amortization	10,898	11,183
Cortrophin pre-launch charges and sales & marketing expenses	141	4,602
Stock-based compensation	1,869	2,424
Acquired IPR&D expense	-	3,784
Asset impairments[(1)]	-	752
Excess of fair value over cost of acquired inventory	-	2,651
Novitium transaction expenses	2,943	-
Adjusted non-GAAP EBITDA	$ 18,896	$ 17,554

(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.

	Reconciliation of certain adjusted non-GAAP accounts:					
	Cost of sales (excl. depreciation and amortization)		**Selling, general, and administrative expenses**		**Research and development expenses**	
	Three Months Ended March 31,		**Three Months Ended March 31,**		**Three Months Ended March 31,**	
	2021	**2020**	**2021**	**2020**	**2021**	**2020**
As reported:	$ 19,985	$ 21,804	$ 17,587	$ 13,683	$ 2,968	$ 6,344
Cortrophin pre-launch charges and sales & marketing expenses			(103)			
Stock-based compensation	(4)	(30)	(1,746)	(2,199)	(119)	(195)
Acquired IPR&D expense						(3,784)
Asset impairments[(1)]		(700)		(52)		
Excess of fair value over cost of acquired inventory		(2,651)				
Novitium transaction expenses			(2,943)			
As adjusted:	$ 19,981	$ 18,423	$ 12,795	$ 11,432	$ 2,849	$ 2,365

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,	
	2021	**2020**
Net Income/(Loss)	$ 86	$ (7,011)
Add/(Subtract):		
Non-cash interest expense	546	157
Depreciation and amortization expense	10,898	11,183
Cortrophin pre-launch charges and sales & marketing expenses	141	4,602
Acquired IPR&D expense	-	3,784
Stock-based compensation	1,869	2,424
Excess of fair value over cost of acquired inventory	-	2,651
Asset Impairments[(1)]	-	752
Novitium transaction expenses	2,943	-
Less:		
Estimated tax impact of adjustments (calc. at 24%)	(3,935)	(6,133)
Adjusted non-GAAP Net Income	$ 12,548	$ 12,409
Diluted Weighted-Average Shares Outstanding	12,017	11,902
Adjusted Diluted Weighted-Average Shares Outstanding	12,017	11,945
Adjusted non-GAAP Diluted Earnings per Share	$ 1.04	$ 1.04

(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.