

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 6, 2021

Aurinia Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Canada
(State or Other Jurisdiction of Incorporation)

001-36421
(Commission File No.)

46-4129078
(IRS Employer Identification No.)

#1203-4464 Markham Street
Victoria, British Columbia
V8Z 7X8
(250) 708-4272
(Address and telephone number of registrant's principal executive offices)

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))

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 Shares, without par value	AUPH	The Nasdaq Stock Market LLC
Common Shares, without par value	AUP	Toronto Stock Exchange

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 6, 2021, Aurinia Pharmaceuticals Inc. ("Aurinia") issued a press release announcing its financial results for the quarter ended March 31, 2021. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in this Current Report on Form 8-K and the exhibit hereto are being furnished pursuant to this Item 2.02 and 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 liability of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. In addition, the information included in this Current Report on Form 8-K and the exhibit hereto, that is furnished pursuant to this Item 2.02 shall not be incorporated by reference in any of Aurinia's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated May 6, 2021
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document)

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 hereunto duly authorized.

Date: May 6, 2021

AURINIA PHARMACEUTICALS INC.

By: /s/ Joseph Miller

Name: Joseph Miller

Title: Chief Financial Officer



AURINIA REPORTS FIRST QUARTER 2021 FINANCIAL RESULTS AND RECENT OPERATIONAL HIGHLIGHTS

- Quarter highlights include FDA approval, launch and early market penetration of LUPKYNIS™ as the first approved oral therapy for lupus nephritis (LN) –

-Over 250 patient start forms received by the end of the first quarter -

- Cash and cash equivalents, and investments of \$360.9 million at March 31, 2021 –

- Conference call to be hosted today at 5:00 p.m. ET -

VICTORIA, British Columbia – May 6, 2021 - Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH / TSX: AUP) (“Aurinia” or the “Company”) today issued its financial results for the first quarter ended March 31, 2021. Amounts, unless specified otherwise, are expressed in U.S. dollars.

“2021 started with the FDA approval of LUPKYNIS, the first FDA-approved oral treatment for active lupus nephritis – a devastating complication of lupus,” commented Peter Greenleaf, President and Chief Executive Officer of Aurinia. “Our pivotal decision and work to build a world-class commercial infrastructure prior to approval ultimately led to Aurinia being able to make LUPKYNIS immediately available to patients and physicians following approval. Since that time, the Aurinia team has been encouraged by the feedback we are receiving from physicians and patients and our confidence has only grown as we continue to understand the tremendous need and value of LUPKYNIS, and work to accelerate broader adoption across the underserved LN population.”

Recent Highlights

FDA Approval and Commercial Launch of LUPKYNIS

On January 22, 2021, the FDA approved LUPKYNIS in combination with a background immunosuppressive therapy regimen to treat adult patients with active LN.

Commercial Activities

- Engaged with over 6,000 rheumatologists and nephrologists;
- Received over 250 patient start forms during the first quarter (covering 48 business days post-FDA approval);
- Converted nearly 40% of patient start forms to patients on therapy by the end of the first quarter; and
- Launched LUPKYNIS Patient Marketing Campaign, Focus on the Fight, in April 2021.

“Since launch, the commercial team has focused on educating their customers on the urgency needed in reducing proteinuria for patients with active LN. With more than 250 patient start forms and 40% of those patients on therapy after the first two months on the market, more than 6,000 clinical interactions, continued gradual expansion of payor coverage, and our Aurinia Alliance patient support program fully operational, the LUPKYNIS trajectory is on track against our internal projections. Furthermore, we anticipate that our market access will continue to improve as the rate of COVID vaccinations in the United States continues to climb and healthcare centers re-open their doors to patients,” commented Max Colao, Chief Commercial Officer at Aurinia.

Upcoming Milestones

- Anticipate filing a marketing authorization application (MAA) with the European Medicines Agency (EMA) during the first half of 2021 with partner, Otsuka;
- Abstracts discussing voclosporin accepted for presentation at the Annual European Congress of Rheumatology (EULAR 2021 Congress), June 2 – 5, 2021, and at the Nephrology Virtual Congress (ERA-EDTA 2021), June 5 – 8, 2021;
- Expect to initiate a study of voclosporin in adolescent patients (VOCAL study) during the second half of 2021; and
- Anticipate reporting top-line results from the ongoing AURORA-2 continuation study during the first quarter of 2022.

Financial Liquidity at March 31, 2021

As of March 31, 2021, Aurinia had cash and cash equivalents and investments of \$360.9 million compared to \$422.7 million at December 31, 2020. The decrease is primarily related to the commercial infrastructure spend to support the launch of LUPKYNIS in addition to an upfront payment made as part of a collaborative agreement with Lonza to build a dedicated manufacturing facility (also referred to as “monoplant”) and one-time payment to a related party upon achievement of specific milestones.

Net cash used in operating activities was \$53.5 million for the quarter ended March 31, 2021 compared to \$22.6 million for the quarter ended March 31, 2020. The increase is primarily due to the commercial infrastructure spend to support the launch of LUPKYNIS in addition to a one-time payment to a related party upon achievement of specific milestones. In the prior year, the Company was still in the development phase of LUPKYNIS and as a result, did not incur any material related selling expenses.

The Company believes that it has sufficient financial resources to fund its current plans, which include funding commercial activities, including our FDA related post approval commitments, manufacturing and packaging of commercial drug supply, conducting our planned research and development (R&D) programs, and operating activities into at least 2023.

Financial Results for the Quarter Ended March 31, 2021

For the quarter ended March 31, 2021, Aurinia recorded a net loss of \$50.4 million or \$0.40 net loss per common share, as compared to a net loss of \$25.9 million or \$0.23 net loss per common share for the quarter ended March 31, 2020.

Revenues were \$0.9 million and \$30 thousand for the quarters ended March 31, 2021 and March 31, 2020, respectively. The increase was the result of the commercial sales of LUPKYNIS, which began in January 2021.

Cost of sales were \$48 thousand and nil for the quarters ended March 31, 2021 and March 31, 2020, respectively. The increase was the result of commercial sales of LUPKYNIS and drug substance. Gross margin for the quarter ended March 31, 2021 was approximately 95%.

Selling, general and administrative (SG&A) expenses were \$39.3 million and \$11.1 million for the quarters ended March 31, 2021 and March 31, 2020, respectively. The increase was primarily due to the expansion of the commercial infrastructure, administrative functions and patient assistance programs to support the launch of LUPKYNIS. SG&A share-based compensation expense for the quarter ended March 31, 2021 was \$6.6 million.

R&D expenses were \$9.8 million and \$13.8 million for the quarters ended March 31, 2021 and March 31, 2020, respectively. The decrease was primarily due to lower Contract Research Organization (CRO) expenses and other third-party clinical trial expenses following the approval of LUPKYNIS, including a reduction in NDA preparation costs, capitalization of supply costs following approval, and termination of the dry eye trial during the fourth quarter of 2020. R&D share-based compensation expense for the quarter ended March 31, 2021 was \$1.1 million.

This press release is intended to be read in conjunction with the Company’s unaudited condensed consolidated financial statements and Management’s Discussion and Analysis for the quarter ended March 31, 2021 in the Company’s Quarterly

Report on Form 10-Q, which is accessible on Aurinia's website at www.auriniapharma.com, on SEDAR at www.sedar.com or on EDGAR at www.sec.gov/edgar.

Conference Call Details

Aurinia will host a conference call and webcast to discuss the quarter ended March 31, 2021 financial results today, Thursday, May 6, 2021 at 5:00 p.m. ET. The audio webcast can be accessed under "News/Events" through the "Investors" section of the Aurinia corporate website at www.auriniapharma.com. In order to participate in the conference call, please dial +1-888-506-0062 (toll-free U.S.) or +1-973-528-0011 (international); entry code: 662377. A replay of the conference call will also be available on Aurinia's website approximately two hours after the live call is completed.

About Lupus Nephritis

LN is a serious progression of systemic lupus erythematosus (SLE), a chronic and complex autoimmune disease. About 200,000-300,000 people live with SLE in the U.S. and approximately one out of three of these individuals have already developed LN at the time of SLE diagnosis. If poorly controlled, LN can lead to permanent and irreversible tissue damage within the kidney, resulting in kidney failure. Black and Asian individuals with SLE are four times more likely to develop LN and individuals with Hispanic ancestry are approximately twice as likely to develop the disease when compared with Caucasian individuals. Black and Hispanic individuals with SLE also tend to develop LN earlier and have poorer outcomes when compared to Caucasian individuals.

About Aurinia

Aurinia Pharmaceuticals is a fully integrated biopharmaceutical company focused on delivering therapies to treat targeted patient populations that are impacted by serious diseases with a high unmet medical need. The Company has introduced LUPKYNIS (voclosporin), the first FDA-approved oral therapy dedicated for the treatment of adult patients with active LN. The Company's head office is in Victoria, British Columbia, its U.S. commercial hub is in Rockville, Maryland, and the Company focuses its development efforts globally.

Forward-Looking Statements

Certain statements made in this press release may constitute forward-looking information within the meaning of applicable Canadian securities law and forward-looking statements within the meaning of applicable United States securities law. These forward-looking statements or information include but are not limited to statements or information with respect to: Aurinia's estimates as to the number of patients with SLE in the U.S. and the proportion of those persons who will develop LN; Aurinia's belief that it is on track to meet its internal expectations for the prescribing of LUPKYNIS; Aurinia's belief that it has sufficient financial resources to fund its current plans until 2023; Aurinia's belief that it has a world-class commercial infrastructure; Aurinia's belief that commercial activity will accelerate as the rate of COVID vaccinations in the United States continue to climb and healthcare centers re-open their doors to patients; the planned timing to file an MAA with the EMA; the planned presentation of abstracts covering voclosporin; the timing to initiate the VOCAL study; and the planned timing for reporting top-line results from the ongoing AURORA-2 continuation study. It is possible that such results or conclusions may change based on further analyses of these data. Words such as "anticipate", "will", "believe", "estimate", "expect", "intend", "target", "plan", "goals", "objectives", "may" and other similar words and expressions, identify forward-looking statements. We have made numerous assumptions about the forward-looking statements and information contained herein, including among other things, assumptions about: the accuracy of reported data from third party studies and reports; that Aurinia's intellectual property rights are valid and do not infringe the intellectual property rights of third parties; Aurinia's assumptions relating to the capital required to fund operations into 2023; the assumption that Aurinia's current good relationships with its suppliers, service providers and other third parties will be maintained; assumptions relating to the burn rate of Aurinia's cash for operations; the relationship between COVID vaccinations and patient treatment; and that Aurinia's third party service providers will comply with their contractual obligations. Even though the management of Aurinia believes that the assumptions made, and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking information will prove to be accurate.

Forward-looking information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance, or achievements of Aurinia to be materially different from any future results, performance or achievements expressed or implied by such forward-looking information. Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in forward-looking statements or information. Such risks, uncertainties and other factors include, among others, the following: difficulties Aurinia may experience in completing the commercialization of voclosporin; the market for the LN business may not be as estimated; Aurinia may have to pay unanticipated expenses; Aurinia may not be able to obtain sufficient supply to meet commercial demand for voclosporin in a timely fashion; unknown impact and difficulties imposed by the COVID-19 pandemic on Aurinia's business operations including nonclinical, clinical, regulatory and commercial activities; the results from Aurinia's clinical studies and from third party studies and reports may not be accurate; Aurinia's third party service providers may not, or may not be able to, comply with their obligations under their agreements with Aurinia; and Aurinia's assets or business activities may be subject to disputes that may result in litigation or other legal claims. Although Aurinia has attempted to identify factors that would cause actual actions, events, or results to differ materially from those described in forward-looking statements and information, there may be other factors that cause actual results, performances, achievements, or events to not be as anticipated, estimated or intended. Also, many of the factors are beyond Aurinia's control. There can be no assurance that forward-looking statements or information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, you should not place undue reliance on forward-looking statements or information.

All forward-looking information contained in this presentation is qualified by this cautionary statement. Additional information related to Aurinia, including a detailed list of the risks and uncertainties affecting Aurinia and its business, can be found in Aurinia's most recent Annual Report on Form 10-K available by accessing the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at www.sedar.com or the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at www.sec.gov/edgar, or on Aurinia's website at www.auriniapharma.com.

Investor Contact:

Glenn Schulman, PharmD, MPH
Corporate Communications, Aurinia
gschulman@auriniapharma.com
or ir@auriniapharma.com

Corporate Contact:

Dana Lynch
Corporate Communications, Aurinia
dlynch@auriniapharma.com

Media Contact:

Stefan Riley
Ten Bridge Communications
stefan@tenbridgecommunications.com

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	<u>March 31, 2021</u>	<u>December 31, 2020</u>
	<u>(unaudited)</u>	
ASSETS		
<i>Current assets</i>		
Cash and cash equivalents	\$ 156,591	\$ 272,350
Short-term investments	191,668	125,979
Accounts receivable, net	1,187	—
Inventories, net	15,936	13,927
Prepaid expenses and other current assets	6,864	7,171
Total current assets	<u>372,246</u>	<u>419,427</u>
<i>Non-current assets</i>		
Long-term investments	12,603	24,380
Other non-current assets	11,856	247
Property and equipment, net	4,758	4,786
Acquired intellectual property and other intangible assets, net	9,854	9,332
Right-of-use assets	5,761	5,489
Total assets	<u>417,078</u>	<u>463,661</u>
LIABILITIES		
<i>Current liabilities</i>		
Accounts payable and accrued liabilities	17,694	24,797
Other current liabilities (of which \$2,000 and \$6,000, due to related party in 2021 and 2020, respectively)	2,382	6,412
Operating lease liabilities	1,075	788
Total current liabilities	<u>21,151</u>	<u>31,997</u>
<i>Non-current liabilities</i>		
Other non-current liabilities	17,893	16,295
Operating lease liabilities	7,806	7,619
Total liabilities	<u>46,850</u>	<u>55,911</u>
SHAREHOLDER'S EQUITY		
Common shares - no par value, unlimited shares authorized, 128,121 and 126,725 shares issued and outstanding as at March 31, 2021 and December 31, 2020, respectively	952,673	944,328
Additional paid-in capital	43,889	39,383
Accumulated other comprehensive loss	(799)	(805)
Accumulated deficit	(625,535)	(575,156)
Total shareholder's equity	<u>370,228</u>	<u>407,750</u>
Total liabilities and shareholders' equity	<u>\$ 417,078</u>	<u>\$ 463,661</u>

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Three months ended	
	March 31,	
	2021	2020
	<u>unaudited</u>	
Revenue		
Product revenue, net	\$ 884	\$ —
License revenue	30	30
Total revenue	914	30
Operating expenses:		
Cost of sales	48	—
Selling, general and administrative	39,282	11,053
Research and development	9,833	13,835
Amortization of intangible assets	523	286
Other expense, net	1,771	1,916
Total cost and operating expenses	51,457	27,090
Loss from operations	(50,543)	(27,060)
Interest income	172	890
Net loss before income taxes	(50,371)	(26,170)
Income tax expense (benefit)	8	(238)
Net loss	\$ (50,379)	\$ (25,932)
Basic and diluted loss per share	\$ (0.40)	\$ (0.23)
Weighted-average common shares outstanding used in computation of basic and diluted loss per share	127,401	112,209