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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 10-Q**

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**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended **September 30, 2021**

**OR**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: **001-36421**

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**Aurinia Pharmaceuticals Inc.**

(Exact Name of Registrant as Specified in its Charter)

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**Alberta, Canada**

(State or other jurisdiction of  
incorporation or organization)

**#1203-4464 Markham Street  
Victoria, British Columbia V8Z 7X8**

(Address of principal executive offices)

**46-4129078**

(I.R.S. Employer  
Identification Number)

**(250) 708-4272**

Registrant's telephone number, including area code

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate the number of shares outstanding of each of the registrant's classes of common shares, as of the latest predictable date. As of November 2, 2021, the registrant had 129,670,345 of common shares outstanding.

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

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of exchange on which registered</u>
Common shares, no par value	AUPH	The Nasdaq Global Market LLC

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2021 (unaudited)	December 31, 2020
<b>ASSETS</b>		
<i>Current assets</i>		
Cash and cash equivalents	\$ 57,587	\$ 272,350
Short-term investments	228,813	125,979
Accounts receivable, net	9,814	—
Inventories, net	19,293	13,927
Prepaid expenses and other current assets	13,712	7,171
Total current assets	<u>329,219</u>	<u>419,427</u>
<i>Non-current assets</i>		
Long-term investments	—	24,380
Other non-current assets	11,838	247
Property and equipment, net	4,551	4,786
Acquired intellectual property and other intangible assets, net	8,926	9,332
Right-of-use assets	5,532	5,489
Total assets	<u>360,066</u>	<u>463,661</u>
<b>LIABILITIES</b>		
<i>Current liabilities</i>		
Accounts payable and accrued liabilities	29,970	24,797
Other current liabilities (of which \$2,000 and \$6,000, due to related party in 2021 and 2020, respectively)	6,456	6,412
Operating lease liabilities	1,111	788
Total current liabilities	<u>37,537</u>	<u>31,997</u>
<i>Non-current liabilities</i>		
Other non-current liabilities	16,562	16,295
Operating lease liabilities	7,795	7,619
Total liabilities	<u>61,894</u>	<u>55,911</u>
Commitments and contingencies (Note 18)		
<b>SHAREHOLDER'S EQUITY</b>		
Common shares - no par value, unlimited shares authorized, 129,570 and 126,725 shares issued and outstanding as at September 30, 2021 and December 31, 2020, respectively	967,159	944,328
Additional paid-in capital	54,607	39,383
Accumulated other comprehensive loss	(794)	(805)
Accumulated deficit	(722,800)	(575,156)
Total shareholder's equity	<u>298,172</u>	<u>407,750</u>
Total liabilities and shareholders' equity	<u>\$ 360,066</u>	<u>\$ 463,661</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Revenue				
Product revenue, net	\$ 14,638	\$ —	\$ 22,113	\$ —
License revenue	29	29	88	88
Total revenue	<u>14,667</u>	<u>29</u>	<u>22,201</u>	<u>88</u>
Operating expenses:				
Cost of sales	254	—	610	—
Selling, general and administrative	44,128	30,702	127,196	57,204
Research and development	20,066	12,243	39,990	37,154
Amortization of intangible assets	517	316	1,576	902
Other (income) expense, net	55	(917)	859	1,066
Total cost of sales and operating expenses	<u>65,020</u>	<u>42,344</u>	<u>170,231</u>	<u>96,326</u>
Loss from operations	<u>(50,353)</u>	<u>(42,315)</u>	<u>(148,030)</u>	<u>(96,238)</u>
Interest income	106	170	420	1,381
Net loss before income taxes	<u>(50,247)</u>	<u>(42,145)</u>	<u>(147,610)</u>	<u>(94,857)</u>
Income tax expense (benefit)	8	(15)	34	(251)
Net loss	<u>(50,255)</u>	<u>(42,130)</u>	<u>(147,644)</u>	<u>(94,606)</u>
Other comprehensive loss:				
Unrealized (loss) gain on available-for-sale securities, net of tax of nil	(2)	—	11	—
Comprehensive loss	<u>\$ (50,257)</u>	<u>\$ (42,130)</u>	<u>\$ (147,633)</u>	<u>\$ (94,606)</u>
Basic and diluted loss per share	<u>\$ (0.39)</u>	<u>\$ (0.34)</u>	<u>\$ (1.15)</u>	<u>\$ (0.82)</u>
Weighted-average common shares outstanding used in computation of basic and diluted loss per share	<u>128,443</u>	<u>122,357</u>	<u>128,084</u>	<u>115,738</u>

*The accompanying notes are an integral part of these condensed consolidated financial statements.*

**AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
(in thousands)  
(unaudited)

	Common Shares		Additional paid in capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
<b>Three Months Ended September 30, 2021</b>						
<b>Balance at June 30, 2021</b>	128,396	\$ 954,572	\$ 51,022	\$ (792)	\$ (672,545)	\$ 332,257
Shares issued on exercise of stock options	1,172	12,579	(3,505)	—	—	9,074
Exercise of warrants	2	8	(2)	—	—	6
Share-based compensation	—	—	7,092	—	—	7,092
Other comprehensive income	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	(50,255)	(50,255)
<b>Balance at September 30, 2021</b>	<b>129,570</b>	<b>\$ 967,159</b>	<b>\$ 54,607</b>	<b>\$ (794)</b>	<b>\$ (722,800)</b>	<b>\$ 298,172</b>

	Common Shares		Additional paid in capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
<b>Three Months Ended September 30, 2020</b>						
<b>Balance at June 30, 2020</b>	112,705	\$ 752,357	\$ 31,098	\$ (805)	\$ (524,952)	\$ 257,698
Issue of common shares	13,333	200,000	—	—	—	200,000
Shares issued on exercise of stock options	412	2,386	(861)	—	—	1,525
Share issue costs	—	(12,268)	—	—	—	(12,268)
Share-based compensation	—	—	4,611	—	—	4,611
Net loss	—	—	—	—	(42,130)	(42,130)
<b>Balance at September 30, 2020</b>	<b>126,450</b>	<b>\$ 942,475</b>	<b>\$ 34,848</b>	<b>\$ (805)</b>	<b>\$ (567,082)</b>	<b>\$ 409,436</b>

	Common Shares		Additional paid in capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
<b>Nine Months Ended September 30, 2021</b>						
<b>Balance at December 31, 2020</b>	126,725	\$ 944,328	\$ 39,383	\$ (805)	\$ (575,156)	\$ 407,750
Shares issued on exercise of stock options	2,324	22,097	(6,745)	—	—	15,352
Exercise of warrants	521	734	(697)	—	—	37
Share-based compensation	—	—	22,666	—	—	22,666
Other comprehensive income	—	—	—	11	—	11
Net loss	—	—	—	—	(147,644)	(147,644)
<b>Balance at September 30, 2021</b>	<b>129,570</b>	<b>\$ 967,159</b>	<b>\$ 54,607</b>	<b>\$ (794)</b>	<b>\$ (722,800)</b>	<b>\$ 298,172</b>

	Common Shares		Additional paid in capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
<b>Nine Months Ended September 30, 2020</b>						
<b>Balance at December 31, 2019</b>	111,798	\$ 746,487	\$ 25,394	\$ (805)	\$ (472,476)	\$ 298,600
Shares issued on exercise of stock options	1,318	8,254	(2,854)	—	—	5,400
Issue of common shares	13,333	200,000	—	—	—	200,000
Share issue costs	—	(12,268)	—	—	—	(12,268)
Exercise of warrants	1	2	(1)	—	—	1
Share-based compensation	—	—	12,309	—	—	12,309
Net loss	—	—	—	—	(94,606)	(94,606)
<b>Balance at September 30, 2020</b>	<b>126,450</b>	<b>\$ 942,475</b>	<b>\$ 34,848</b>	<b>\$ (805)</b>	<b>\$ (567,082)</b>	<b>\$ 409,436</b>

*The accompanying notes are an integral part of these condensed consolidated financial statements.*

**AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Nine Months Ended September 30,	
	2021	2020
	(unaudited)	
<b>Cash flows used in operating activities:</b>		
Net loss	\$ (147,644)	\$ (94,606)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation of property and equipment	497	59
Amortization of intangible assets	1,576	902
Upfront license and milestone expense	10,000	—
Share-based compensation expense	22,666	12,309
Other, net	1,005	736
Net changes in operating assets and liabilities		
Accounts receivable	(9,815)	—
Inventories	(5,366)	(471)
Prepaid expenses and other current assets	(6,541)	(3,725)
Non-current assets	247	—
Right of use assets	(43)	(5,576)
Accounts payable, accrued and other liabilities	1,149	9,012
Lease liabilities	499	8,298
Net cash used in operating activities	<u>(131,770)</u>	<u>(73,062)</u>
<b>Cash flows used in investing activities:</b>		
Purchase of investments	(342,831)	(202,951)
Proceeds from investments	263,752	30,779
Upfront lease payment	(11,838)	—
Upfront license payment	(6,000)	—
Purchase of long-lived assets	(262)	(4,095)
Additions to internal use-software implementation costs	(1,198)	(982)
Capitalized patent costs	(6)	(83)
Net cash used in investing activities	<u>(98,383)</u>	<u>(177,332)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options	15,353	5,400
Proceeds from exercise of warrants	37	1
Net proceeds from issuance of common shares	—	187,732
Cash provided by financing activities	<u>15,390</u>	<u>193,133</u>
Net decrease in cash and cash equivalents	<u>(214,763)</u>	<u>(57,261)</u>
Cash and cash equivalents, beginning of period	272,350	306,019
Cash and cash equivalents, end of period	<u>\$ 57,587</u>	<u>\$ 248,758</u>
<b>Supplemental cash flow information</b>		
Cash received for interest	\$ 671	\$ 891
Cash paid for taxes	\$ (236)	\$ (62)
Cash paid for amounts included in the measurement of lease liabilities	\$ (195)	\$ (68)
<b>Supplemental disclosure of noncash transactions</b>		
Initial recognition of operating lease right-of-use asset	\$ 419	\$ 5,804

*The accompanying notes are an integral part of these condensed consolidated financial statements.*

**AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**1. Organization and Description of Business**

Aurinia Pharmaceuticals Inc. is a commercial-stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are suffering from serious diseases with a high unmet medical need. The Company has developed LUPKYNIS™, for the treatment of adult patients with active lupus nephritis (LN) and continues to conduct pre-clinical, clinical, and regulatory advancement to support the voclosporin development program.

On January 22, 2021, the U.S. Food and Drug Administration (FDA) approved LUPKYNIS in combination with a background immunosuppressive therapy regimen to treat adult patients with active LN.

On August 17, 2021, the Company announced the addition of two novel assets AUR200 and AUR300. AUR200 is currently undergoing pre-clinical development with projected submission of an Investigational New Drug Application (IND) to the FDA by the end of 2022. It is anticipated that an IND for AUR300 is expected during the first half of 2023.

Aurinia's head office is located at #1203-4464 Markham Street, Victoria, British Columbia, Canada and its registered office is located at #201, 17873-106 A Avenue, Edmonton, Alberta. Aurinia also has a U.S. commercial office located at 77 Upper Rock Circle, Rockville, Maryland, United States.

Aurinia is incorporated pursuant to the Business Corporations Act (Alberta). The Company's common shares traded on both the Nasdaq Global Market (Nasdaq) under the symbol AUPH and on the Toronto Stock Exchange (TSX) under the symbol AUP until July 30, 2021. As of July 30, 2021, the Company's common shares no longer trade on the TSX following the voluntary delisting by the Company and are solely traded on the Nasdaq.

**2. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments considered necessary for fair presentation in accordance with U.S. GAAP. The condensed consolidated balance sheet as of December 31, 2020 was derived from audited annual financial statements but does not include all annual disclosures required by U.S. GAAP. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020. The results of operations for the nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for the full year or any other future periods.

These unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Aurinia Pharma U.S., Inc. (Delaware incorporated) and Aurinia Pharma Limited (UK incorporated). All intercompany balances and transactions have been eliminated in consolidation.

The Company operates as one operating segment in accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 280, *Segment Reporting*. The Company operates in one operating segment engaged in the research, development and commercialization of therapeutic drugs in which revenues are derived from license, contract and product revenues. The Company's chief executive officer makes decisions for the Company and its subsidiaries as a whole. Accordingly, the Company operates and makes decisions as one reporting unit.

These unaudited condensed consolidated financial statements are presented in U.S. dollars which is the Company's functional currency therefore there is no currency translation adjustment upon consolidation as the remeasurement of gains or losses are recorded in the condensed consolidated statement of operations. All assets and liabilities denominated in a foreign currency are remeasured into U.S. dollars at the exchange rate on the balance sheet date. Revenues and expenses are remeasured at the average exchange rate during the period. Foreign exchange gains and losses arising on translation or settlement of a foreign currency denominated monetary item are included in the condensed consolidated statements of operations.

We are devoting the majority of our operational efforts and financial resources towards the commercialization and post approval commitments of our approved drug, LUPKYNIS. We are also expending efforts towards our newly acquired assets AUR200 and AUR300. Taking into consideration the Company's cash and cash equivalents and investments of \$286.4 million as of September 30, 2021, the Company believes that it has sufficient resources to fund its operations at least one year beyond the date that the unaudited condensed consolidated financial statements are issued.

### 3. Summary of Significant Accounting Policies

Other than as described below, the Company's significant accounting policies have not changed from those previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

**Critical Accounting Estimates:** The preparation of our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP, requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We believe the most complex judgments result primarily from the need to make estimates about the effects of matters that are inherently uncertain and are significant to our condensed consolidated financial statements. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. We evaluate our estimates, judgments and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions and such differences may be material.

The most significant areas involving estimates, judgments and assumptions used in the preparation of our condensed consolidated financial statements are as follows:

- Revenue recognition;
- Cost of sales;
- Inventory;
- Royalty obligation;
- Contingent accruals;
- Clinical trial expenditures;
- Share-based compensation;
- Intangible assets;
- Leases; and
- Income taxes.

**Concentration of Credit Risk:** Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash and cash equivalents, investments and accounts receivable. The Company attempts to minimize the risks related to cash and cash equivalents and investments by investing in a broad and diverse range of financial instruments. The Company established guidelines related to credit ratings and maturities intended to safeguard principal balances, earn a return on investments and to maintain liquidity. The Company's investment portfolio is maintained in accordance with its investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. The Company does not enter into any investment transaction for trading or speculative purposes.

The Company's investment policy limits investments to certain types of instruments such as certificates of deposit, money market instruments, obligations issued by the U.S. government and U.S. government agencies as well as corporate debt securities, and places restrictions on maturities and concentration by type and issuer. The Company may at times maintain cash balances in excess of amounts insured by the Federal Deposit Insurance Corporation and Canada Deposit Insurance Corporation and concentrated within a limited number of financial institutions. The accounts are monitored by management to mitigate the risk. The Company is exposed to financial risk related to the fluctuation of foreign currency exchange rates which could have a material effect on its future operating results or cash flows. Foreign currency risk is the risk that variations in exchange rates between the United States dollar and foreign currencies, primarily with the Canadian dollar, will affect the Company's operating and financial results. The Company holds the majority of its cash and cash equivalents in U.S. dollars and the majority of its expenses are also denominated in U.S. dollars, which limits the risk of material foreign exchange fluctuations.

The Company currently has three main customers for U.S. commercial sales of LUPKYNIS and one customer for sales of voclosporin in the European Union, Japan, as well as the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein and Ukraine. Revenues from two customers accounted for approximately 59% and 40% of the Company's total revenues for the three and nine months ended September 30, 2021. The Company monitors economic conditions, the



creditworthiness of customers and government regulations and funding, both domestically and abroad. The Company regularly communicates with its customers regarding the status of receivable balances, including their payment plans and obtains positive confirmation of the validity of the receivables. An allowance against accounts receivable is established, if needed, using an expected credit loss model. Global economic conditions and customer specific factors may require the Company to periodically re-evaluate the collectability of its receivables and the Company could potentially incur credit losses.

**Investments:** The Company classifies its debt securities at acquisition as either held to maturity or available-for-sale in accordance with the FASB ASC Topic 320 *Investments — Debt Securities*. Investments classified as held to maturity are carried at amortized cost when management has the positive intent and ability to hold them to maturity. Investments classified as available-for-sale are carried at fair value with unrealized gains and losses reported in other comprehensive income/loss within shareholders' equity. Realized gains and losses on held to maturity and available-for-sale securities are recorded in other income (expense), net. Interest income is recorded separately on the consolidated statements of operations. The cost of securities sold is based on the specific-identification method.

**Revenue Recognition:** Pursuant to ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606), the Company recognizes revenue when a customer obtains control of promised goods or services. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. Revenue is recognized through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract and determines those that are performance obligations. Revenue is recognized for the applicable performance element when each distinct performance obligation is satisfied.

#### **Product Revenues**

In the United States (and territories), the Company sells LUPKYNIS primarily to two specialty pharmacies and a specialty distributor. These customers subsequently resell the Company's products to health care providers and patients. Revenues from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer.

*Reserves for discounts and allowances:* Product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). The Company's estimates of reserves established for variable consideration are generally calculated based upon utilizing the expected value method. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment.

More specifically, these adjustments include the following:

*Prompt pay discounts:* The Company generally provides invoice discounts on product sales to its customers for prompt payment. The Company estimates that its customers will earn these discounts and fees, and deducts the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized.

*Customer fees:* The Company pays certain customer fees, such as fees for certain data that customers provide to the Company. The Company records fees paid to its customers as a reduction of revenue, unless the payment is for a distinct good or service from the customer and the Company can reasonably estimate the fair value of the goods or services received. If both conditions are met, the Company records the consideration paid to the customer as a selling, general and administrative (SG&A) expense.

*Government rebates:* The Company estimates its government rebates, primarily Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses on the consolidated balance sheet.

Medicaid rebates relate to the Company's estimated obligations to states under established reimbursement arrangements. Rebate accruals are recorded in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability, which is included in other current liabilities. The Company's liability for Medicaid rebates consists of estimates for claims that a state will make for the current quarter, claims for prior quarters that have been estimated for which an invoice has not been received, invoices received for claims from the prior quarters that have not been paid and an estimate of potential future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated potential future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

*Co-payment assistance:* Co-payment assistance represents financial assistance to qualified patients, assisting them with prescription drug co-payments required by insurance. The program is administered by the specialty pharmacies. The calculation of the accrual adjustment for co-payment assistance is based on the co-payments made on the Company's behalf by the specialty pharmacies; and estimated potential future claims that will be made for product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period.

#### *License, Collaboration and Other Revenues*

The Company enters into out-licensing agreements that are within the scope of ASC 606, under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees, development, regulatory and commercial milestone payments, payments for manufacturing supply services and pass-through costs that the Company provides through its contract manufacturers, and royalties on net sales of licensed products. Each of these payments results in license, collaboration and other revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

*Licenses of intellectual property:* If the license to the Company's intellectual property (IP) is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

*Manufacturing supply services:* Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

*Milestone payments:* At the inception of each arrangement that includes development or commercial sales milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-

evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment. Any consideration related to sales-based royalties (and sales-based milestones) will be recognized when the related sales occur.

**Research, Development and/or Manufacturing Services.** The Company's agreements may include research and development (R&D) or manufacturing services to be performed by the Company on behalf of the counterparty. If these services are determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to these services as revenue over time based on an appropriate measure of progress when the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. If these services are determined not to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the combined performance obligation as the related performance obligations are satisfied.

**Cost of sales:** Cost of sales consist primarily of cost of inventories for LUPKYNIS, which mainly includes third party manufacturing costs, transportation, storage, insurance and allocated internal labor and depreciation.

**Research and development expenses:** R&D expenses are accounted for in accordance with ASC Topic 730, *Research and Development*, and are expensed as incurred. R&D costs consist primarily of the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, acquired licenses, subcontractors (such as contract research organizations) and materials used for R&D activities, including nonclinical studies, clinical trials, clinical manufacturing costs and professional services. The costs of services performed by others in connection with the R&D activities of the Company, including R&D conducted by others on behalf of the Company, shall be included in R&D costs and expensed as the contracted work is performed. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial or project and the invoices received from its external service providers.

**Selling, general and administrative expenses:** The Company's SG&A expenses include commercial and allocated administrative personnel, corporate facility and external costs required to support the marketing and sales of LUPKYNIS. These SG&A costs include corporate facility operating expenses and allocated depreciation; commercial, marketing, pharmacovigilance, publications, tradeshow, advisory boards, samples and operations in support of LUPKYNIS; patient assistance program costs; human resources; finance, legal, information technology and support personnel expenses; and other corporate costs such as telecommunications, insurance, audit and government affairs. We expense SG&A expenses as they are incurred.

The Company uses a third-party logistics provider to perform a full order to cash service, which includes warehousing and shipping directly to two specialty pharmacies and receiving orders from a specialty distributor for shipping to hospitals, on our behalf. As such, since these costs are not integral to bringing the inventories to a salable condition, we elected not to treat shipping and handling costs as a fulfillment activity. Shipping and handling costs related to order fulfillment are recorded in SG&A expenses.

**Accounts receivable, net:** Accounts receivable are stated at their net realizable value. As of September 30, 2021, accounts receivable, net are \$9.8 million. Estimates of the Company's allowance for doubtful accounts are determined based on existing contractual payment terms, historical payment patterns of our customers and individual customer circumstances. The allowance for doubtful accounts was \$nil as of September 30, 2021 and as of December 31, 2020.

**Share-Based Compensation:** The Company follows ASC Topic 718, Compensation - Stock Compensation (ASC 718), which requires the measurement and recognition of compensation expense, based on estimated fair values, for all share-based awards made to employees and directors. The Company records compensation expense based on the fair value on the grant date for all share-based payments related to stock options, performance awards, restricted stock units and purchases under the Company's Employee Stock Purchase Plan.

#### ***Recently adopted accounting pronouncements***

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, these standards now require allowances to be recorded instead of reducing the amortized cost of the investment. These standards limit the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit

losses if fair value increases. The Company adopted the standard as of January 1, 2020 and did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirement for Fair Value Measurement*. Topic 820 requires to disclose transfers into and out of Level 3 of the fair value hierarchy and purchases and issues of Level 3 assets and liabilities. For investments in certain entities that calculate net asset value, an entity is required to disclose the timing of liquidation of an investee's assets and the date when the restrictions from redemptions might lapse only if the investee has communicated the timing to the entity or announced the timing publicly. The new standard also amends that the measurement uncertainty disclosure is to communicate information about the uncertainty in measurement as of the reporting date. The new standard is effective for fiscal years beginning after December 15, 2019. The standard should be applied retrospectively to the date of initial application of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The Company elected to adopt the amendment as of January 1, 2020, which did not have a material impact on the consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40)-Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the accounting for implementation costs incurred in a hosting arrangement that is a service contract with the accounting for implementation costs incurred to develop or obtain internal-use software under ASC 350-40, in order to determine which costs to capitalize and recognize as an asset and which costs to expense. ASU 2018-15 is effective for annual reporting periods, and interim periods within those years, beginning after December 15, 2019, and can be applied either prospectively to implementation costs incurred after the date of adoption or retrospectively to all arrangements. The Company adopted ASU 2018-15 effective January 1, 2020 and applied the standard prospectively to implementation costs incurred in its cloud computing arrangements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangement (Topic 808): Clarifying the Integration between Topic 808 and Topic 606*. The new standard clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. Further, the new standard adds unit-of-account guidance to Topic 808 to align with the guidance in Topic 606 when an entity is assessing whether the collaborative arrangement or part of the arrangement is within the scope of Topic 606. The new standard requires that in transactions with a collaborative arrangement participant that is not directly related to sales to third parties, presenting under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The new standard is effective for fiscal years beginning after December 15, 2019. The standard should be applied retrospectively to the date of initial application of ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The Company elected to adopt the amendment as of January 1, 2020, which did not have a material impact on the consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which clarifies and simplifies certain aspects of the accounting for income taxes. The standard is effective for years beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2020. The Company elected to adopt the amendment as of January 1, 2021, which did not have a material impact on the consolidated financial statements.

#### 4. Investments

As of September 30, 2021 and December 31, 2020, the Company had \$228.8 million and \$nil and \$126.0 million and \$24.4 million of short and long-term investments, respectively, mainly consisting of commercial paper and bonds as summarized below. As of September 30, 2021, the Company classifies its investments as debt securities of which \$21.5 million are held to maturity debt securities which are carried at amortized cost and are approximately equal to fair market value. As of September 30, 2021, \$07.3 million are available-for-sale debt securities which are carried at fair market value and are approximately equal to amortized cost. As of December 31, 2020, \$150.4 million were classified as held to maturity and \$nil were available-for-sale.

<b>(in thousands)</b>	<b>September 30, 2021</b>	<b>December 31, 2020</b>
Cashable Guaranteed Investment Certificate	\$ 5,644	\$ 2,000
Corporate Bond	25,435	40,372
Commercial Paper	197,734	67,747
Treasury Bill	—	7,999
Treasury Bond	—	5,045
Yankee Bond	—	2,816
Total short-term investments	228,813	125,979
Corporate Bonds - total long-term investments	—	24,380
Total investments	\$ 228,813	\$ 150,359

Currently, the Company does not intend to sell investments that are classified as held-to-maturity and has the ability and intent to hold these investments until maturity in order to collect interest payments over the life of the investments. As of September 30, 2021 and December 31, 2020, accrued interest receivable from the investments were \$0.1 million and \$0.5 million, respectively. During the three and nine months ended September 30, 2021, the Company had \$2 thousand and \$11 thousand unrealized losses and gains on available-for-sale securities, net of tax, respectively, which are included as a component of comprehensive loss on the consolidated statements of operations. The Company's investments as of September 30, 2021 mature at various dates through September 2022.

#### 5. Inventories

Inventories are valued under a standard costing methodology on a first-in, first-out basis and are stated at the lower of cost or net realizable value. The Company capitalizes inventory costs related to products to be sold in the ordinary course of business. The Company makes a determination of capitalizing inventory costs for a product based on, among other factors, status of regulatory approval, information regarding safety, efficacy and expectations relating to commercial sales and recoverability of costs. For our product LUPKYNIS, the Company commenced capitalization of inventory once FDA approval was deemed to be probable, which occurred during the third quarter of 2020. Capitalized costs of inventories for LUPKYNIS mainly include third party manufacturing costs, transportation, storage, insurance, depreciation and allocated internal labor.

The components of inventory as of September 30, 2021 and December 31, 2020 are as follows:

<b>(in thousands)</b>	<b>September 30, 2021</b>	<b>December 31, 2020</b>
Raw materials	\$ 2,217	\$ —
Work in process	12,074	13,927
Finished goods	5,002	—
Total inventories	\$ 19,293	\$ 13,927

## 6. Prepaid Expenses and Other Current Assets

The following table summarizes prepaid expenses and other current assets.

(in thousands)	September 30, 2021	December 31, 2020
Prepaid assets	\$ 5,871	\$ 3,701
Prepaid insurance	2,524	2,054
Other current assets	728	1,018
Prepaid deposits	4,589	398
Total prepaid expenses and other current assets	<u>\$ 13,712</u>	<u>\$ 7,171</u>

## 7. Intangible Assets

The following table summarizes the carrying amount of intangible assets, net of accumulated amortization.

(in thousands)	September 30, 2021		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Amount
Patents	\$ 1,471	\$ (1,152)	\$ 319
Acquired intellectual property and reacquired rights	15,125	(8,545)	6,580
Internal-use software implementation costs	2,873	(846)	2,027
	<u>\$ 19,469</u>	<u>\$ (10,543)</u>	<u>\$ 8,926</u>

  

(in thousands)	December 31, 2020		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Amount
Patents	\$ 1,651	\$ (1,203)	\$ 448
Acquired intellectual property and reacquired rights	15,126	(7,770)	7,356
Internal-use software implementation costs	1,675	(147)	1,528
	<u>\$ 18,452</u>	<u>\$ (9,120)</u>	<u>\$ 9,332</u>

Amortization expense for the three months ended September 30, 2021 and 2020 was \$0.5 million and \$0.3 million, respectively, and for the nine months ended September 30, 2021 and 2020 was \$1.6 million and \$0.9 million, respectively.

## 8. Property and Equipment, net

Property and equipment as of September 30, 2021 and December 31, 2020 are as follows:

(in thousands)	September 30, 2021	December 31, 2020
Construction in progress	\$ 360	\$ 4,467
Leasehold improvements	2,978	34
Office equipment and furniture	1,621	83
Computer equipment	265	381
	<u>5,224</u>	<u>4,965</u>
Less accumulated depreciation	(673)	(179)
Property and equipment, net	<u>\$ 4,551</u>	<u>\$ 4,786</u>

Depreciation expense for the three month period ended September 30, 2021 and September 30, 2020 was \$0.2 million and \$nil, respectively, and for the nine months ended September 30, 2021 and 2020 was \$0.5 million and \$0.1 million. which is included in SG&A expenses in the condensed consolidated statements of operations.

## 9. Lease Obligations

The Company has the following lease obligations:

### *Victoria, British Columbia*

During the fourth quarter of 2020, the Company entered into facility and furniture leases for its head office located in Victoria, British Columbia for a total space of 3,206 square feet of office space for the facility lease. The lease terms commenced on January 1, 2021 for the facility and furniture leases. As of September 30, 2021, the Company had \$0.2 million right-of-use assets (ROU assets) and \$0.2 million lease liabilities related to the leases. The Company recognized operating lease costs that are included in SG&A expense in the condensed consolidated statement of operations. The incremental borrowing rate applied to the lease liabilities was 4.08% based on financial position, geographical region and terms of leases.

During August 2020, the Company signed a lease for commercial office space in Victoria, British Columbia. The lease term is expected to begin in 2022. The present value of the minimum lease payments for this lease are \$2.7 million. As of September 30, 2021, the lease has not commenced and as a result there has been no accounting recognition associated with the lease.

### *Rockville, Maryland*

During March 2020, the Company entered into a lease for its commercial office in Rockville, Maryland. The lease has a remaining term of approximately 11 years and has an option to extend for two five-year periods after the 11 years has elapsed and has an option to terminate after seven years. As of September 30, 2021, the Company had a right-of-use asset of \$5.3 million and lease liability of \$8.7 million included in the condensed consolidated balance sheets. As of December 31, 2020, the Company had a right of use asset of \$5.5 million and lease liability of \$8.4 million included in the condensed consolidated balance sheets. During 2020, the Company received reimbursements for tenant leasehold improvements by the landlord in the amount of \$2.3 million for the Maryland lease. The Company recorded these leasehold improvement incentives as additions to the lease liability. The lease term commenced on March 12, 2020. When measuring the lease liability, the Company discounted lease payments using its incremental borrowing rate at March 12, 2020. The incremental borrowing rate applied to the lease liability on March 12, 2020 was 5.2% based on the financial position of the Company, geographical region and term of lease.

### *Edmonton, Alberta*

During the fourth quarter of 2020, the Company entered into an agreement to lease premises in Edmonton, Alberta, commencing on October 1, 2020 and ending September 30, 2021. During the third quarter of 2021, the lease was extended until September 30, 2022. The Company recognizes short-term leases on a straight-line basis and did not record a related lease asset or liability for the Edmonton lease. The Company recognized short-term rent expense for this lease, which is included in SG&A expense in the condensed consolidated statement of operations.

The following table provides supplemental balance sheet information related to the operating lease ROU assets and lease liabilities:

(in thousands)	Balance Sheet Classification	September 30, 2021	December 31, 2020
<b>Assets</b>			
Operating lease right of-use assets	Right-of-use assets	\$ 5,532	\$ 5,489
<b>Liabilities</b>			
Current operating lease liabilities	Current operating lease liabilities	1,111	788
Non-current operating lease liabilities	Non-current operating lease liabilities	7,795	7,619
<b>Total lease liabilities</b>		<b>\$ 8,906</b>	<b>\$ 8,407</b>

Beginning January 1, 2021, the Company began to incur variable lease costs under the existing Victoria and Rockville leases. These costs include operation and maintenance costs for the three and nine month periods ended September 30, 2021. The following provides a summary of the components of leasing costs and rent for the three and nine month periods ended September 30, 2021 and September 30, 2020.

(in thousands)	Consolidated Statement of Operations	Three months ended September 30,		Nine Months Ended September 30,	
		2021	2020	2021	2020
Operating lease costs					
Operating lease costs	Selling, general and administrative	\$ 261	\$ 196	\$ 783	\$ 456
Short-term lease costs					
Office Building	Selling, general and administrative	7	74	21	215
Variable lease costs					
Office building	Selling, general and administrative	44	1	124	3
Total rent expense		\$ 312	\$ 271	\$ 928	\$ 674

The following table represents the weighted-average remaining lease term and discount rate as of September 30, 2021:

	As of September 30, 2021	
	Weighted Average Remaining Lease Term (years)	Weighted Average Discount Rate
Operating leases	9.68	5.20%

The following table provides a summary of operating lease liabilities maturities for the next five years and thereafter:



(in thousands)	Operating Lease Payments	
Remainder of 2021	\$	281
2022		1,143
2023		1,061
2024		1,085
2025		1,109
Thereafter		6,773
Total future minimum lease payments		<u>11,452</u>
Less: lease imputed interest		<u>(2,546)</u>
Total future minimum lease payments	\$	<u>8,906</u>

#### Finance Lease

On December 15, 2020, the Company entered into a collaborative agreement with Lonza to build a dedicated manufacturing facility within Lonza's existing small molecule facility in Visp, Switzerland. The dedicated facility (also referred to as "monoplant") will be equipped with state-of-the-art manufacturing equipment to provide cost and production efficiency for the manufacture of voclosporin, while expanding existing capacity and providing supply security to meet future commercial demand.

The first capital expenditure payment was made in February 2021 of \$1.8 million which was treated as an upfront lease payment and recorded under other non-current assets on the condensed consolidated balance sheets. The second payment is not due until the facility fulfills the required operational qualifications which is estimated to be during 2023. Upon completion of the monoplant, the Company will have the right to maintain sole dedicated use of the monoplant by paying a quarterly fixed facility fee.

The Company expects to account for the arrangement as a finance lease under ASC 842. The present value of the minimum lease payments total approximately \$4.0 million, beginning April 2023 and expiring in 2030, and are not included in the above table.

#### 10. Accounts Payable and Accrued Liabilities

The following table summarizes the Company's accounts payable and accrued liabilities.

(in thousands)	September 30, 2021		December 31, 2020	
Trade payables	\$	3,263	\$	2,635
Other accrued liabilities		8,322		6,616
Accrued R&D projects		3,865		4,185
Employee accruals		14,520		11,361
Total accounts payable and accrued liabilities	\$	<u>29,970</u>	\$	<u>24,797</u>

#### 11. Non-current Liabilities

The Company recorded other non-current liabilities of \$16.6 million and \$16.3 million as of September 30, 2021 and December 31, 2020, respectively. The balance as of September 30, 2021 and December 31, 2020 primarily included obligations that are the result of a resolution of the board of directors of the Company dated March 8, 2012 whereby certain executive officers at that time were provided with future potential employee benefit obligations for remaining with the Company, for a certain period of time. These obligations were also contingent on the occurrence of uncertain future events.

## 12. Fair Value Measurements

The Company's financial instruments consist primarily of cash and cash equivalents, investments, accounts receivable, accounts payable and accrued liabilities. The carrying value of accounts receivable, accounts payable and accrued liabilities approximate their fair value because of their short-term nature. Estimated fair values of held to maturity and available-for-sale debt securities are generally based on prices obtained from commercial pricing services.

In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from sources independent from the Company) and to minimize the use of unobservable inputs (the Company's assumptions about how market participants would price assets and liabilities). As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

- Level 1 - Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 - Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3 - Unobservable inputs that reflect the reporting entity's own assumptions.

The Company's Level 1 instruments include deposits held with banks and short-term investments that are valued using quoted market prices. Level 2 instruments include the Company's short and long-term investments that are valued through third-party pricing services that use verifiable observable market data. The Company has no Level 3 instruments as of September 30, 2021 and December 31, 2020.

There were no transfers between Level 1, Level 2 and Level 3 instruments in the periods presented.

The following tables present the financial assets measured at fair value on a recurring basis:

(in thousands)	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents:				
Deposits held with banks	\$ 35,070	\$ —	\$ —	\$ 35,070
Short-term highly liquid investments	19,417	3,100	—	22,517
Investments	197,734	31,079	—	228,813
Total	\$ 252,221	\$ 34,179	\$ —	\$ 286,400

(in thousands)	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents:				
Deposits held with banks	\$ 130,807	\$ —	\$ —	\$ 130,807
Short-term highly liquid investments	141,543	—	—	141,543
Investments	69,746	80,613	—	150,359
Total	\$ 342,096	\$ 80,613	\$ —	\$ 422,709

Refer to Note 4, "Investments," for the carrying amount and related unrealized gains (losses) by type of investment.

## 13. License and Collaboration Agreements

### Riptide License

On August 17, 2021, AUR300 (M2 macrophage modulation via CD206 binding) was secured through a global licensing and research agreement with Riptide Bioscience, Inc. (Riptide), a private company. As part of the agreement, the Company paid Riptide an upfront license fee of \$ 6.0 million which was expensed as research and development on the condensed consolidated

statement of operations. Additional milestone payments are due upon certain development, clinical and regulatory milestones, and royalties will be payable upon commercialization. It is anticipated that clinical development for AUR300 will commence during the first half of 2023.

#### *Otsuka Contract*

On December 17, 2020, the Company entered into a collaboration and license agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka) for the development and commercialization of oral LUPKYNIS for the treatment of patients with active LN in the EU, Japan, as well as the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein and Ukraine.

As part of the agreement, Aurinia received an upfront cash payment of \$50.0 million for the license agreement and has the potential to receive up to \$50.0 million in regulatory milestones. Aurinia will receive tiered royalties on future sales ranging from 10 to 20 percent (dependent on achievement of sale thresholds) on net sales upon commercialization, along with additional milestone payments based on the attainment of certain annual sales by Otsuka. In addition, voclosporin will be provided to Otsuka under a cost-plus supply agreement.

The Company evaluated the Otsuka Agreement under ASC 606. Based on that evaluation, the license transferred was determined to be functional IP that has significant standalone functionality. That is, the treatment of LN and other diseases provides significant benefit to Otsuka at the point of transfer, and it is not expected that the utility of the IP will substantively change as a result of any remaining clinical trials or ongoing activities of Aurinia. The Company determined the upfront fee of \$50.0 million was fixed consideration for the transfer of the license and was recognized upon transfer of the license in December 2020.

The remaining forms of consideration are variable because they are dependent on achieving milestones or are based on aggregate future net sales for the regions. None of the regulatory milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including the magnitude of a potential reversal of revenue, uncertainty about if or when the milestone related performance obligations might be achieved, and that receipt of the milestones are outside the control of the Company since they are dependent on efforts to be undertaken by Otsuka and regulatory approval by various foreign government agencies. Any consideration related to sales-based royalties (and sales-based thresholds) will be recognized when the related sales occur.

As of September 30, 2021, there has been no additional consideration earned or received since the upfront payment of \$50.0 million during the fourth quarter of 2020.

#### **14. Net Loss per Common Share**

Basic and diluted net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding. The numerator and denominator used in the calculation of basic and diluted net loss per common share are as follows:

<b>(in thousands, except per share data)</b>	<b>Three months ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Net loss	\$ (50,255)	\$ (42,130)	\$ (147,644)	\$ (94,606)
Weighted average common shares outstanding	128,443	122,357	128,084	115,738
Net loss per common share (expressed in \$ per share)	\$ (0.39)	\$ (0.34)	\$ (1.15)	\$ (0.82)

The Company did not include the securities in the following table in the computation of the net income per common share because the effect would have been anti-dilutive during each period:

(in thousands)	Nine months ended September 30,	
	2021	2020
Stock options	12,837	11,443
Unvested performance awards	857	—
Unvested restricted units	201	—
Warrants	1,012	1,690
	<b>14,907</b>	<b>13,133</b>

## 15. Share-based Compensation

The Company's Amended and Restated Equity Incentive Plan (the Plan), which was adopted and approved by the Company's shareholders in June 2021, allows for an issuance of up to an aggregate of 23.8 million shares (inclusive of outstanding awards). Also in June 2021, the Company's shareholders adopted and approved the Company's Employee Stock Purchase Plan (2021 ESPP), which allows for the issuance of up to 2.5 million shares. The 2021 ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code (the "Code") but also permits the Company to include the employees, including non-United States employees, in offerings not intended to qualify under Section 423. The purpose of the 2021 ESPP is to provide eligible employees with opportunities to purchase the Company's common shares at a discounted price.

As of September 30, 2021 and December 31, 2020, 129.6 million and 126.7 million, common shares were issued and outstanding.

### *Stock Options*

The Plan requires the exercise price of each option not to be less than the closing market price of the Company's common shares on the day immediately prior to the date of grant. The board of directors approves the vesting criteria and periods at its discretion. The options issued under the plan are accounted for as equity-settled share-based payments.

The Company used the Black-Scholes option pricing model to estimate the fair value of the options granted. The Company considers historical volatility of its common shares in estimating its future stock price volatility. The risk-free interest rate for the expected life of the options was based on the yield available on government benchmark bonds with an approximate equivalent remaining term at the time of the grant. The expected life is based upon the contractual term, taking into account expected employee exercise and expected post-vesting employment termination behavior. The following weighted average assumptions were used to estimate the fair value of the options granted during the nine month periods ended September 30, 2021 and September 30, 2020:

	September 30, 2021	September 30, 2020
Annualized volatility	66 %	43%
Risk-free interest rate	0.38 %	0.70 %
Expected life of options in years	4.0 years	3.0 years
Estimated forfeiture rate	8.9 %	12 %
Dividend rate	0.0 %	0.0%
Fair value per common share option	\$ 6.64	\$ 5.05

The following table summarizes the option award activity during the nine months ended September 30, 2021:

	September 30, 2021	
	Number of shares (in thousands)	Weighted average exercise price \$
Outstanding - Beginning of Period	14,047	11.35
Granted	2,059	13.42
Exercised	(2,324)	6.60
Cancelled/Forfeited	(945)	13.72
Outstanding - End of Period	12,837	12.37
Vested and expected to vest - End of Period	2,635	14.54
Options exercisable - End of Period	5,244	10.81

#### *Performance Awards and Restricted Stock Units*

On October 23, 2020, the Company issued 439,000 performance awards (PAs) to executive management of the Company whose vesting is contingent upon meeting specific performance metrics based on the results for the year ended December 31, 2021. Each PA which vests entitles the participant to receive common shares on the basis of the performance metrics set. On March 18, 2021 performance metrics were set and formally communicated. Therefore, March 18, 2021 was the grant date and the fair value on the grant date was \$13.56.

On August 6, 2021, the Company granted approximately 619,000 PAs and restricted stock units (RSUs). The grant date for the PAs and RSUs was August 6, 2021 and the fair value on the grant date was \$14.42 as this was the date performance measures were set and communicated to employees. The PAs vest on the employee's first anniversary of the grant date and the employee must achieve at least one of the performance metrics to obtain the portion of the award associated with the metric. The RSUs have no performance metrics and will vest on the one year anniversary of the grant.

The Company recorded approximately \$0.7 million and \$1.1 million of share-based compensation expense related to PAs and RSUs during the three and nine month periods ended September 30, 2021.

#### *Compensation Expense*

The Company recognized share-based compensation expense for the three and nine month periods ended September 30, 2021 and September 30, 2020 as follows:

(in thousands)	Three months ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 1,038	\$ 814	\$ 3,201	\$ 3,111
Selling, general and administrative	6,000	3,750	19,189	9,151
Capitalized under inventories	54	47	276	47
Share-based compensation expense	\$ 7,092	\$ 4,611	\$ 22,666	\$ 12,309

As of September 30, 2021, there was \$16.9 million of unrecognized share-based compensation expense related to unvested awards granted which is expected to be recognized over a weighted-average period of approximately 1.1 years.

#### **16. Income Taxes**

The effective tax rates for the three and nine months ended September 30, 2021 and September 30, 2020 differed from the federal statutory rate applied to losses before income taxes primarily as a result of the mix of income, losses and valuation allowances. The Company recognized an income tax expense of \$8 thousand and \$34 thousand for the three and nine months ended September 30, 2021, respectively, and an income tax benefit of \$15 thousand and \$251 thousand for the three and nine months ended September 30, 2020, respectively. The expense recognized for the three and nine months ended September 30,

2021 was a result of income in certain jurisdictions. This tax expense is not offset by a tax benefit as the Company has losses which are fully offset by a valuation allowance in its significant jurisdictions.

The tax benefit recognized for the three and nine months ended September 30, 2020 was a result of a discrete tax benefit recorded in the U.S. pursuant to certain tax provisions provided under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) enacted in the United States on March 27, 2020. The CARES Act permits the Company to carry back net operating losses to offset taxable income generated in the five preceding years, some of which were taxed at a federal income tax rate higher than the current enacted rate.

#### **17. Related Party Transactions**

ILJIN is considered to be a related party due to their equity ownership of over 5%. The outstanding related party amount payable to ILJIN is the result of a settlement completed on September 20, 2013 between ILJIN and the Company. During the first quarter of 2021, Aurinia paid \$4.0 million upon achievement of specific milestones. The amount payable to ILJIN of \$2.0 million and \$6.0 million as of September 30, 2021 and December 31, 2020 was recorded in other current liabilities, respectively. The final \$2.0 million outstanding amount payable has been achieved and will be paid during the fourth quarter 2021.

Stephen P. Robertson was a partner at Borden Ladner Gervais LLP (BLG) and acted as our corporate secretary through October 2020. We incurred legal fees in the normal course of business to BLG of \$0.1 million and \$0.3 million for the three and nine months ended September 30, 2020. We had no ongoing contractual or other commitments as a result of engaging Mr. Robertson to act as our corporate secretary and Mr. Robertson received no additional compensation for acting as the corporate secretary. On November 2, 2020 we announced the appointment of Stephen Robertson as our Executive Vice President, General Counsel, Corporate Secretary and Chief Compliance Officer.

#### **18. Commitments and Contingencies**

The Company may, from time to time, be subject to claims and legal proceedings brought against it in the normal course of business. Such matters are subject to many uncertainties. Management believes the ultimate resolution of such contingencies will not have a material adverse effect on the consolidated financial position of the Company. The Company's commitments and contingencies have not changed from those previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

#### ***Manufacturing Commitments***

The Company has various manufacturing agreements to support our commercial and clinical product supply requirements.

We rely on Lonza, a third party manufacturer, to produce a portion of commercial and clinical quantities of our commercial and clinical drug substance requirements. We have firm orders with Lonza, with remaining total non-cancellable future commitments of approximately \$25.4 million through 2023 of which \$3.5 million was paid during the second quarter of 2021. If we terminate certain firm orders with Lonza without cause, we will be required to pay for drug substance scheduled for manufacture under our arrangement.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report. The information in this discussion contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act, which are subject to the "safe harbor" created by those sections, as well as "forward-looking information" as defined in applicable Canadian securities laws. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans; objectives of management; the key potential benefits of LUPKYNIS; our belief that we have sufficient financial resources to fund our current plans for at least the next 12 months; and our potential to receive certain payments and royalties under our agreement with Otsuka. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "propose," "intend," "continue," "potential," "possible," "foreseeable," "likely," "unforeseen" and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the 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 our IP rights are valid and do not infringe the IP rights of third parties; our assumptions relating to the capital required to fund operations for the next 12 months; the assumption that our current good relationships with our suppliers, service providers and other third parties will be maintained; assumptions relating to the burn rate of our cash for operations; that our third party service providers will comply with their contractual obligations. Even though management 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. We discuss many of these risks, uncertainties and other factors in greater detail under the heading "Risk Factors" in Part I, Item 1A of our 2020 Annual Report on Form 10-K, as filed with the U.S. Securities and Exchange Commission on February 24, 2021 and with applicable Canadian securities regulatory authorities. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this discussion completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we assume no obligation to update our forward-looking statements publicly, or to update the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.*

### Overview

Aurinia is a commercial-stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are suffering from serious diseases with a high unmet medical need. We have commercially launched LUPKYNIS in the United States for the treatment of adult patients with active LN, and continue to conduct pre-clinical, clinical, and regulatory activities to support the voclosporin development program.

LUPKYNIS is a calcineurin inhibitor (CNI) immunosuppressant, that improves near and long-term outcomes in LN when used in combination with mycophenolate mofetil and steroids, the current standard of care for LN (although not currently approved as such). By inhibiting calcineurin, LUPKYNIS reduces cytokine activation and blocks interleukin IL-2 expression and T-cell mediated immune responses. LUPKYNIS also potentially stabilizes podocytes, which can reduce proteinuria. Voclosporin, the active ingredient in LUPKYNIS, is made by a modification of a single amino acid of the cyclosporine molecule. The mechanism of action of LUPKYNIS has been validated with certain earlier generation CNIs for the prevention of rejection in patients undergoing solid organ transplants and in several autoimmune indications, including uveitis, keratoconjunctivitis sicca, psoriasis, rheumatoid arthritis, and for LN in Japan. We believe that LUPKYNIS possesses pharmacologic properties with the potential to demonstrate best-in-class differentiation.

Earlier generation CNIs have demonstrated efficacy for a number of conditions, including transplant and other autoimmune diseases; however, side effects exist which can limit their long-term use and tolerability. Some clinical complications of earlier generation CNIs include hypertension, hyperlipidemia, diabetes, and both acute and chronic nephrotoxicity.

Based on published data, we believe the key potential benefits of LUPKYNIS in the treatment of adult patients with active LN versus marketed CNIs include:

- increased potency compared to cyclosporine A, allowing for lower dosing requirements and potentially fewer off

target effects;

- limited inter and intra patient variability, allowing for easier dosing without the need for monitoring blood levels for therapeutic drug monitoring;
- less cholesterolemia and triglyceridemia than cyclosporine A; and
- limited incidence of glucose intolerance and diabetes at therapeutic doses compared to tacrolimus.

## Developments

- On January 22, 2021, the FDA approved LUPKYNIS in combination with a background immunosuppressive therapy regimen to treat adult patients with active LN. As a condition of approval, we are required and are on track to conduct two pediatric studies (with reports due in 2025 and 2031), a milk only lactation study (with a report due in 2026), a drug-drug interaction study (with a report due in 2023) and submit a final study report on our AURORA-2 continuation study (by March 2022).
- On May 10, 2021, *The Lancet*, an international, peer-reviewed medical journal, published the results of the Company's Phase 3 AURORA 1 study evaluating LUPKYNIS (voclosporin) in adults with LN.
- On May 20, 2021, we announced that the interim analysis of the AURORA 2 continuation study showed that subjects in the LUPKYNIS treatment arm sustained meaningful reductions in proteinuria, with no change in mean estimated glomerular filtration rate (eGFR) at 104 weeks of treatment.
- On June 7, 2021, our shareholders adopted and approved the Plan, which allows for the issuance of up to an additional 11.5 million shares. The purpose of the Plan is to advance the interests of the Company by encouraging equity participation in the Company through the acquisition of common shares. Also in June 2021, our shareholders adopted and approved the 2021 ESPP, which allows for the issuance of up to 2.5 million shares. The purpose of the 2021 ESPP is to provide eligible employees with opportunities to purchase the Company's common shares at a discounted price.
- On June 14, 2021, we appointed Dr. Brinda Balakrishnan, M.D., Ph.D., to our Board of Directors effective June 14, 2021. Dr. Balakrishnan is Group Vice President, Corporate and Business Development of BioMarin Pharmaceutical Inc.
- On June 25, 2021, our licensing partner, Otsuka, filed an initial marketing authorization application with the European Medicines Agency seeking approval for the use of voclosporin for the treatment of adult patients with active LN in the European Union, as well as Norway, Iceland and Liechtenstein. Upon approval we would be eligible for up to an additional \$30 million USD in approval related milestones, low double-digit royalties on sales, and additional revenues for the supply of product to Otsuka under a cost-plus arrangement.
- On July 16, 2021, we announced we will voluntarily delist the common shares from the TSX effective as of the close of trading on July 30, 2021. Our common shares will no longer be traded on the TSX but will continue to trade on the Nasdaq under the symbol AUPH.
- On August 17, 2021, we announced the addition of two novel pipeline assets AUR200 and AUR300. AUR200 is a Fc protein targeting BAFF/APRIL (B-cell Activating Factor, known as BAFF, and A Proliferation-Inducing Ligand known as APRIL). AUR200 is currently undergoing pre-clinical development with projected submission of an IND to the FDA by the end of 2022. AUR300 is a novel peptide therapeutic that modulates M2 macrophages (a type of white blood cells) via the macrophage mannose receptor CD206. Dysregulation of M2 macrophages drives fibrosis. AUR300 acts to reduce M2 dysregulation and decrease inflammatory cytokines, and therefore may have significant clinical applications for autoimmune and fibrotic diseases. AUR300 IND filing is expected during the first half of 2023.
- On October 1, 2021, Aurinia's licensing partner, Otsuka Pharmaceutical Co., Ltd., filed an initial marketing authorization application (MAA) with the Swiss Agency for Therapeutic Products (Swissmedic) seeking approval for the use of voclosporin for the treatment of adult patients with active LN. The Swiss filing was based on the June 24, 2021 MAA submission to the European Medicines Agency (EMA).
- Regulatory review of the EMA MAA remains on track with a CHMP opinion expected around mid-2022 followed by an EMA decision expected sometime in the third quarter of 2022. Additionally, Otsuka continues to work to finalize the timeline for the JNDA regulatory filing with PMDA to seek approval of voclosporin for the treatment of LN in Japan.

## Impact of COVID-19 Pandemic

In the event of a prolonged disruption related to the COVID-19 pandemic, there could be detrimental impact to our ongoing and future clinical trials, our ongoing commercial launch and future commercialization activities for LUPKYNIS, and our ability to access capital markets. For further information, refer to Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2020.



### **Critical Accounting Policies and Significant Judgments and Estimates**

The preparation of our unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and the revenues and expenses incurred during the reported periods. We base our estimates on historical experience and on various other factors that we believe are relevant under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity in Note 2 to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020 and any updates in Item 1. Note 3 from our Summary of Significant Accounting Policies.

There have been no material changes to our critical accounting policies and estimates as compared to those disclosed in our Annual Report.

We believe that of our critical accounting policies, the most significant areas involving critical estimates, judgments and assumptions used in the preparation of our consolidated financial statements are as follows:

- Revenue recognition;
- Cost of sales;
- Inventory;
- Royalty obligation;
- Contingent accruals;
- Clinical trial expenditures;
- Share-based compensation;
- Intangible assets;
- Leases; and
- Income taxes.

## Results of Operations

### *Three and Nine Month Periods ended September 30, 2021 compared to Three and Nine Month Periods ended September 30, 2020*

The following table sets forth our results of operations for the three and nine month periods ended September 30, 2021 and September 30, 2020.

	Three months ended September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
	(in thousands)			(in thousands)		
<b>Revenue</b>						
Product revenue, net	\$ 14,638	\$ —	\$ 14,638	\$ 22,113	\$ —	\$ 22,113
License revenue	29	29	—	88	88	—
Total revenue	14,667	29	14,638	22,201	88	22,113
<b>Operating expenses:</b>						
Cost of sales	254	—	254	610	—	610
Selling, general and administrative	44,128	30,702	13,426	127,196	57,204	69,992
Research and development	20,066	12,243	7,823	39,990	37,154	2,836
Amortization of intangible assets	517	316	201	1,576	902	674
Other (income) expense, net	55	(917)	972	859	1,066	(207)
Total cost of sales and operating expenses	65,020	42,344	22,676	170,231	96,326	73,905
Loss from operations	(50,353)	(42,315)	(8,038)	(148,030)	(96,238)	(51,792)
Interest income	106	170	(64)	420	1,381	(961)
Net loss before income taxes	(50,247)	(42,145)	(8,102)	(147,610)	(94,857)	(52,753)
Income tax expense (benefit)	8	(15)	23	34	(251)	285
Net loss	\$ (50,255)	\$ (42,130)	\$ (8,125)	\$ (147,644)	\$ (94,606)	\$ (53,038)

#### *Revenues*

Total revenue was \$14.7 million and \$29 thousand for the three months ended September 30, 2021 and September 30, 2020, respectively. Total revenue was \$22.2 million and \$88 thousand for the nine months ended September 30, 2021 and September 30, 2020, respectively. Our revenues primarily consisted product revenue, net of adjustments, for LUPKYNIS following FDA approval in January 2021.

#### *Cost of Sales*

Cost of sales were \$254 thousand and \$nil for the three months ended September 30, 2021 and September 30, 2020, respectively. Cost of sales were \$610 thousand and \$nil for the nine months ended September 30, 2021 and September 30, 2020, respectively. The increase was primarily the result of commercial sales of LUPKYNIS. Gross margin for the three and nine months ended September 30, 2021 was approximately 98% and 97% respectively.

*Selling, General and Administrative Expenses*

SG&A expenses increased to \$44.1 million for the three months ended September 30, 2021 compared to \$30.7 million for the three months ended September 30, 2020. For the nine months ended September 30, 2021 and September 30, 2020, SG&A expenses were \$127.2 million and \$57.2 million, respectively. SG&A expenses consisted of the following:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Salaries, incentive pay and employee benefits	\$ 19,981	\$ 13,795	\$ 58,723	\$ 22,375
Professional fees and services	13,110	8,668	34,536	18,229
Share-based compensation expense	6,000	3,750	19,189	9,151
Other public company costs, facility costs, insurance, information technology, amortization of property and equipment	3,304	4,030	9,579	6,548
Travel, trade shows and sponsorships	1,733	459	5,169	901
	<u>\$ 44,128</u>	<u>\$ 30,702</u>	<u>\$ 127,196</u>	<u>\$ 57,204</u>

The primary drivers for the increase for the three and nine months ended September 30, 2021 as compared to the same periods ended 2020 were an increase in salaries, incentive pay and employee benefits and share-based compensation expense related to the expansion of the commercial and administrative functions to support the launch of LUPKYNIS which ramped up during the third quarter of 2020. Also contributing was an increase in professional fees for activities such as patient assistance programs, consulting, recruiting, legal, market research and marketing.

*Research and Development Expenses*

R&D expenses were \$20.1 million and \$12.2 million for the three months ended September 30, 2021 and September 30, 2020, respectively. For the nine months ended September 30, 2021 and September 30, 2020, R&D expenses were \$40.0 million and \$37.2 million, respectively. R&D expenses consisted of the following:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Contract research organizations (CRO) and developmental expenses	\$ 15,873	\$ 5,581	\$ 25,579	\$ 18,928
Clinical supply and distribution	872	2,502	3,242	6,882
Salaries, incentive pay and employee benefits	2,070	2,976	7,807	7,351
Share-based compensation expense	1,038	814	3,201	3,111
Travel, insurance, patent annuity fees, legal fees and other	213	370	161	882
	<u>\$ 20,066</u>	<u>\$ 12,243</u>	<u>\$ 39,990</u>	<u>\$ 37,154</u>

The primary driver for the increase for the three months ended September 30, 2021 as compared to the same period of 2020 was due to an upfront license and accrued milestone expense related to our recently acquired developmental programs AUR200 and AUR300. In accordance with U.S. GAAP, these transactions did not meet the definition of a business combination and therefore, were recorded as asset acquisitions. The Company expensed the cost of the assets as R&D expense at the acquisition dates. The increase was partially offset by a decrease in clinical supply and distribution costs due to our new drug application and voclosporin related clinical trial expenditures in 2020 not recurring in 2021. Also contributing was a decrease in salaries, incentive pay and employee benefits due to the allocation of costs related to post approval support of LUPKYNIS to SG&A.

The primary drivers for the increase for the nine months ended September 30, 2021 as compared to the same period of 2020 were due to the upfront license and accrued milestone expense related to our recently acquired developmental programs, AUR200 and AUR300 and higher CRO expenses related to our new clinical programs offset by a decrease in clinical supply and distribution costs following the approval of LUPKYNIS, including a reduction in new drug application preparation costs and termination of the dry eye trial during the fourth quarter of 2020.

## Liquidity and Capital Resources

As of September 30, 2021, we had cash and cash equivalents and investments of \$286.4 million compared to cash and cash equivalents and investments of \$422.7 million at December 31, 2020. The decrease is primarily related to the commercial infrastructure spend to support the launch of LUPKYNIS, payments for inventory, an upfront payment made as part of a collaborative agreement with Lonza to build a dedicated manufacturing capability (or monoplant) and an upfront license payment related to our recently acquired developmental program. Cash and cash equivalents and investments are primarily held in U.S. dollars. As of September 30, 2021 and December 31, 2020, we had working capital of \$291.7 million and \$387.4 million, respectively.

We are devoting the majority of our operational efforts and financial resources towards the commercialization and post approval commitments of our approved drug, LUPKYNIS. We are also expending efforts towards our newly acquired assets AUR200 and AUR300. Taking into consideration the cash and cash equivalents and investments as of September 30, 2021, we believe that our cash position is sufficient to fund our current plans which include funding commercial activities, including our FDA related post approval commitments, manufacturing commercial drug supply, funding our supporting commercial infrastructure, conducting our planned R&D programs, investing in our pipeline and funding our supporting corporate and working capital for at least the next 12 months.

## Cash Flow Summary

The following table summarizes our cash flows for the nine months ended September 30, 2021 and September 30, 2020:

(in thousands)	Nine months ended September 30,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	\$ (131,770)	\$ (73,062)
Investing activities	(98,383)	(177,332)
Financing activities	15,390	193,133
Net decrease in cash and cash equivalents	<u>\$ (214,763)</u>	<u>\$ (57,261)</u>

Net cash used in operating activities was \$131.8 million for the nine months ended September 30, 2021 compared to \$73.1 million for the nine months ended September 30, 2020. The increase is primarily due to the commercial infrastructure spend to support the launch of LUPKYNIS, payments for inventory, and a one-time payment to a related party upon achievement of specific milestones partially offset by an increase in cash receipts. In the prior year, the Company was still in the development phase of LUPKYNIS.

Cash used in investing activities during the nine months ended September 30, 2021 was \$98.4 million compared to cash used in investing activities of \$177.3 million during the nine months ended September 30, 2020. Investing activities during the nine months ended September 30, 2021 consisted primarily of \$342.8 million for purchases of investments, \$11.8 million for an upfront lease payment and \$6.0 million for an upfront license payment which was offset by \$263.8 million of proceeds of maturities of investments. Cash used in investing activities of \$177.3 million for the nine months ended September 30, 2020 was primarily attributable to purchases of short-term investments.

Cash provided by financing activities during the nine months ended September 30, 2021 was \$15.4 million compared to cash provided by financing activities of \$193.1 million during the nine months ended September 30, 2020. The decrease was primarily due to the public offering during the third quarter of 2020.

## Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as such term is defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Act.

## Contractual Obligations

There have been no material changes outside the ordinary course of business to our contractual obligations and commitments as described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2020.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risks**

Our activities can expose us to market risks which include interest rate risk, foreign currency risk, inflation risk and credit risk. Risk management is carried out by management under policies approved by our board of directors. Our overall risk management program seeks to minimize adverse effects on our financial performance.

#### ***Interest rate risk***

Financial assets and financial liabilities with variable interest rates expose us to cash flow interest rate risk. We manage our interest rate risk by maximizing the interest income earned on excess funds while maintaining the liquidity necessary to conduct operations on a day-to-day basis. Our investment portfolio includes cash and cash equivalents and investments that earn interest at market rates. Our investments held during the year were comprised of instruments such as certificates of deposit, money market instruments, obligations issued by the U.S. government and U.S. government agencies as well as corporate debt securities, and places restrictions on maturities and concentration by type and issuer. As of September 30, 2021, these instruments have a maturity of one year or less. Accounts receivable, accounts payable and accrued liabilities bear no interest. We do not believe that the results of operations or cash flows would be affected to any significant degree by a sudden change in market interest rates relative to our investment portfolio.

#### ***Foreign currency risk***

We are exposed to financial risk related to the fluctuation of foreign currency exchange rates. Foreign currency risk for the Company is the risk variations in exchange rates between the U.S. dollar and foreign currencies, primarily with the Canadian dollar and Swiss franc, which could affect our operating and financial results. A 10% increase or decrease of the U.S. dollar would have no material effect assuming all other variables remained constant.

#### ***Inflation Risk***

Inflation may generally affect us by increasing our cost of labor, commercial support and clinical trial expenditures. Inflation has not had a material effect on our business, financial condition or results of operations during the three and nine months ended September 30, 2021 and 2020.

#### ***Credit risk***

Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash and cash equivalents, investments and accounts receivable. The Company attempts to minimize the risks related to cash and cash equivalents and investments by investing in a broad and diverse range of financial instruments. The Company established guidelines related to credit ratings and maturities intended to safeguard principal balances, earn a return on investments and to maintain liquidity. The Company's investment portfolio is maintained in accordance with its investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. The Company does not enter into any investment transaction for trading or speculative purposes.

### **Item 4. Controls and Procedures.**

#### ***Evaluation of Disclosure Controls and Procedures***

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of September 30, 2021, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the SEC, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

#### ***Changes in Internal Control over Financial Reporting***

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the quarter ended September 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Our management believes that there are currently no claims or actions pending against us, the ultimate dispositions of which could have a material adverse effect on our results of operations, financial condition or cash flows.

There are no material developments in respect of previously disclosed litigation to report.

### Item 1A. Risk Factors.

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020 we identified important factors that could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Quarterly Report. There has been no material change in our risk factors subsequent to the filing of our prior reports referenced above. However, the risks described in our reports are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

### Item 3. Defaults Upon Senior Securities.

None.

### Item 4. Mine Safety Disclosures.

None.

### Item 5. Other Information.

None.

### Item 6. Exhibits.

The following exhibits are filed as part of this report:

Exhibit Number	Description
3.1	<a href="#">Articles of Amalgamation, as amended, as currently in effect (filed as Exhibit 3.1 to the Company's Annual Report on Form 10-K with the SEC on February 24, 2021 and incorporated herein by reference)</a>
3.2	<a href="#">By Law No. 2, in effect from June 7, 2020 to April 22, 2021 (filed as Exhibit 4.2 to the Company's Form S-8 with the SEC on June 9, 2020 and incorporated herein by reference)</a>
3.3	<a href="#">Amended and Restated By-Law No. 2 amended as of April 23, 2021 (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on April 27, 2021 and incorporated herein by reference)</a>
31.1*	<a href="#">Certification of Principal Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2*	<a href="#">Certification of Principal Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1**	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2**	<a href="#">Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

\* Filed herewith.

\*\* Furnished herewith. Exhibits 32.1 and 32.2 are being furnished and shall not be deemed "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, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise specifically stated in such filing.



**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.

**AURINIA PHARMACEUTICALS INC.**

November 3, 2021

By: \_\_\_\_\_  
**Peter Greenleaf**  
**Chief Executive Officer, Director**  
**(Principal Executive Officer)**

November 3, 2021

By: \_\_\_\_\_  
**Joseph Miller**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**





**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Aurinia Pharmaceuticals Inc. (the "Company") on Form 10-Q for the period ending September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter Greenleaf, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 3, 2021

By: \_\_\_\_\_  
/s/ Peter Greenleaf  
**Peter Greenleaf**  
**Chief Executive Officer**  
**(Principal Executive Officer)**

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Aurinia Pharmaceuticals Inc. (the "Company") on Form 10-Q for the period ending September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph Miller, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 3, 2021

By: \_\_\_\_\_ /s/ Joseph Miller

**Joseph Miller**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**