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

FORM 10-Q

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

For the quarterly period ended September 30, 2021

☐ **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: 001-35006

SPECTRUM PHARMACEUTICALS INC

(Exact name of registrant as specified in its charter)

Delaware				**93-0979187**
(State or other jurisdiction of incorporation or organization)				**(I.R.S. Employer Identification No.)**
11500 South Eastern Avenue	**Suite 220**	**Henderson**	**Nevada**	**89052**
(Address of principal executive offices)				**(Zip Code)**

(702) 835-6300

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	SPPI	The NASDAQ Global Select Market

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, a 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of November 8, 2021, 163,956,341 shares of the registrant's common stock were outstanding.

Spectrum Pharmaceuticals, Inc.
Quarterly Report on Form 10-Q
For the Three and Nine Months Ended September 30, 2021

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Part I: Financial Information

Item 1: Financial Statements

SPECTRUM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and par value amounts)
(Unaudited)

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 107,435	$ 46,009
Marketable securities	26,160	134,016
Accounts receivable, net	—	67
Other receivables	3,863	2,394
Prepaid expenses and other current assets	2,540	4,161
Total current assets	139,998	186,647
Property and equipment, net	507	3,577
Facility and equipment under lease	2,881	2,247
Other assets	4,415	4,327
Total assets	$ 147,801	$ 196,798
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 48,982	$ 43,771
Accrued payroll and benefits	8,290	9,375
Total current liabilities	57,272	53,146
Other long-term liabilities	11,065	9,409
Total liabilities	68,337	62,555
Commitments and contingencies (*Note 6*)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized; 163,957,900 and 146,083,110 issued and outstanding at September 30, 2021 and December 31, 2020, respectively	164	146
Additional paid-in capital	1,086,989	1,021,221
Accumulated other comprehensive loss	(3,481)	(1,829)
Accumulated deficit	(1,004,208)	(885,295)
Total stockholders' equity	79,464	134,243
Total liabilities and stockholders' equity	$ 147,801	$ 196,798

See accompanying notes to these unaudited condensed consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating costs and expenses:				
Selling, general and administrative	$ 12,243	$ 15,116	$ 41,515	$ 44,654
Research and development	20,850	24,453	69,335	62,192
Total operating costs and expenses	33,093	39,569	110,850	106,846
Loss from continuing operations before other income (expense) and income taxes	(33,093)	(39,569)	(110,850)	(106,846)
Other income (expense):				
Interest income, net	11	188	121	1,217
Other income (expense), net	9	(9,131)	(7,948)	(15,720)
Total other income (expense)	20	(8,943)	(7,827)	(14,503)
Loss from continuing operations before income taxes	(33,073)	(48,512)	(118,677)	(121,349)
Provision for income taxes from continuing operations	—	(6)	(9)	(15)
Loss from continuing operations	(33,073)	(48,518)	(118,686)	(121,364)
Income (loss) from discontinued operations, net of income taxes	(11)	66	(227)	255
Net loss	$ (33,084)	$ (48,452)	$ (118,913)	$ (121,109)
Basic and diluted loss per share:				
Loss from continuing operations	$ (0.21)	$ (0.37)	$ (0.77)	$ (1.02)
Income (loss) from discontinued operations	$ (0.00)	$ 0.00	$ (0.00)	$ 0.00
Net loss per share, basic and diluted	$ (0.21)	$ (0.37)	$ (0.78)	$ (1.02)
Weighted average shares outstanding, basic and diluted	159,261,818	131,455,727	153,341,854	118,664,914

See accompanying notes to these unaudited condensed consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (33,084)	$ (48,452)	$ (118,913)	$ (121,109)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net of tax	(1)	73	(1,130)	(61)
Foreign currency translation adjustments	(153)	457	(522)	835
Other comprehensive income (loss)	(154)	530	(1,652)	774
Total comprehensive loss	$ (33,238)	$ (47,922)	$ (120,565)	$ (120,335)

See accompanying notes to these unaudited condensed consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2020	146,083,110	$ 146	$ 1,021,221	$ (1,829)	$ (885,295)	$ 134,243
Net loss	—	—	—	—	(35,697)	(35,697)
Other comprehensive loss, net	—	—	—	(1,678)	—	(1,678)
Recognition of stock-based compensation expense	—	—	4,212	—	—	4,212
Issuance of common shares under an at-the-market sales agreement	5,678,893	6	21,351	—	—	21,357
Restricted stock award grants, net of forfeitures	1,966,333	2	—	—	—	2
Balance as of March 31, 2021	153,728,336	$ 154	$ 1,046,784	$ (3,507)	$ (920,992)	$ 122,439
Net loss	—	—	—	—	(50,132)	(50,132)
Other comprehensive income, net	—	—	—	180	—	180
Recognition of stock-based compensation expense	—	—	4,360	—	—	4,360
Issuance of common shares under an at-the-market sales agreement	10,172,498	10	31,255	—	—	31,265
Issuance of common stock upon exercise of stock options	1,250	—	2	—	—	2
Issuance of common stock for employee stock purchase plan	163,463	—	474	—	—	474
Restricted stock award grants, net of forfeitures	39,127	—	—	—	—	—
Issuance of common stock upon vesting of restricted stock units	1,386	—	—	—	—	—
Balance as of June 30, 2021	164,106,060	$ 164	$ 1,082,875	$ (3,327)	$ (971,124)	$ 108,588
Net loss	—	—	—	—	(33,084)	(33,084)
Other comprehensive income, net	—	—	—	(154)	—	(154)
Recognition of stock-based compensation expense	—	—	4,114	—	—	4,114
Restricted stock award grants, net of forfeitures	(148,160)	—	—	—	—	—
Balance as of September 30, 2021	163,957,900	$ 164	$ 1,086,989	$ (3,481)	$ (1,004,208)	$ 79,464

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2019	113,299,612	$ 113	$ 918,205	$ (3,498)	$ (724,427)	$ 190,393
Net loss	—	—	—	—	(40,572)	(40,572)
Other comprehensive loss, net	—	—	—	(1,329)	—	(1,329)
Recognition of stock-based compensation expense	—	—	5,010	—	—	5,010
Issuance of common stock to 401(k) plan for employees	96,959	—	265	—	—	265
Restricted stock award grants, net of forfeitures	1,377,508	1	—	—	—	1
Balance as of March 31, 2020	114,774,079	$ 114	$ 923,480	$ (4,827)	$ (764,999)	$ 153,768
Net loss	—	—	—	—	(32,085)	(32,085)
Other comprehensive income, net	—	—	—	1,573	—	1,573
Recognition of stock-based compensation expense	—	—	3,988	—	—	3,988
Issuance of common shares under an at-the-market sales agreement	1,024,286	1	3,070	—	—	3,071
Issuance of common stock for employee stock purchase plan	98,362	—	282	—	—	282
Restricted stock award grants, net of forfeitures	1,926,385	3	(3)	—	—	—
Issuance of common stock upon vesting of restricted stock units	861	—	—	—	—	—
Balance as of June 30, 2020	117,823,973	$ 118	$ 930,817	$ (3,254)	$ (797,084)	$ 130,597
Net loss	—	—	—	—	(48,452)	(48,452)
Other comprehensive income, net	—	—	—	530	—	530
Recognition of stock-based compensation expense	—	—	4,108	—	—	4,108
Issuance of common stock from public offering, net	24,916,667	25	69,708	—	—	69,733
Issuance of common shares pursuant to at-the-market offering, net	2,926,112	3	11,828	—	—	11,831
Issuance of common stock upon exercise of stock options	3,542	—	13	—	—	13
Restricted stock award grants, net of forfeitures	260,878	—	—	—	—	—
Balance as of September 30, 2020	145,931,172	$ 146	$ 1,016,474	$ (2,724)	$ (845,536)	$ 168,360

See accompanying notes to these unaudited condensed consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2021	**2020**
Cash Flows From Operating Activities:		
Loss from continuing operations	$ (118,686)	$ (121,364)
Income (loss) from discontinued operations, net of income taxes	(227)	255
Net loss	(118,913)	(121,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	212	(105)
Stock-based compensation	12,686	13,371
Loss on disposal of manufacturing equipment	3,057	—
Non-cash lease expense	1,151	1,148
Other non-cash items	281	585
Realized gain on sale of equity holdings	(4,580)	(678)
Unrealized loss on equity holdings	12,816	16,029
Changes in operating assets and liabilities:		
Accounts receivable, net	66	1
Other receivables	(1,391)	6,370
Prepaid expenses and other current assets	1,620	(2,663)
Other assets	(89)	6
Accounts payable and other accrued liabilities	4,376	426
Accrued payroll and benefits	(1,085)	427
Other long-term liabilities	654	(2,134)
Net cash used in operating activities	(89,139)	(88,326)
Cash Flows From Investing Activities:		
Proceeds from maturities of investments	109,771	94,929
Proceeds from sale of equity holdings	4,406	1,843
Purchases of investments	(16,568)	(73,581)
Purchases of property and equipment, net	(140)	(6,991)
Net cash provided by investing activities	97,469	16,200
Cash Flows From Financing Activities:		
Proceeds from sale of common stock, net of offering expenses	—	69,733
Proceeds from sale of common stock under an at-the-market sales agreement, net	52,622	14,902
Proceeds from sale of stock under our employee stock purchase plan	474	283
Proceeds from employees for exercises of stock options	4	13
Net cash provided by financing activities	53,100	84,931
Effect of exchange rates on cash and cash equivalents	(4)	(91)
Net increase in cash and cash equivalents	61,426	12,714
Cash and cash equivalents—beginning of period	46,009	64,418
Cash and cash equivalents—end of period	$ 107,435	$ 77,132
Supplemental disclosure of cash flow information:		
Cash paid for facility and equipment under operating leases	$ 1,626	$ 1,805
Cash paid for income taxes	$ 12	$ 14
Noncash investing activities:		
Additions of property and equipment that remain in accounts payable and other accrued liabilities	$ —	$ 6,017

See accompanying notes to these unaudited condensed consolidated financial statements.

Spectrum Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, interest rate, and number of years)
(Unaudited)

Note 1. Description of Business, Basis of Presentation, And Operating Segment

(a) Description of Business

Spectrum Pharmaceuticals, Inc. ("Spectrum", the "Company", "we", "our", or "us") is a biopharmaceutical company, with a primary strategy comprised of acquiring, developing, and commercializing novel and targeted oncology therapies. Our in-house development organization includes clinical development, regulatory, quality and data management.

We have three drugs in development:

- ROLONTIS, a novel long-acting granulocyte colony-stimulating factor ("G-CSF") for chemotherapy-induced neutropenia. We submitted a Biologics License Application ("BLA") for ROLONTIS in December 2019, and in August 2021, we received a Complete Response Letter from the U.S. Food and Drug Administration (the "FDA") regarding our Biologics License Application ("BLA"), citing deficiencies related to manufacturing and indicating that a reinspection will be necessary. We are currently working on remediating the manufacturing deficiencies and expect that this work will be complete in the fourth quarter of 2021 and plan to resubmit thereafter;

- Poziotinib, a novel irreversible tyrosine kinase inhibitor under investigation for non-small cell lung cancer ("NSCLC") tumors with various mutations. A New Drug Application ("NDA") based on data from Cohort 2 of ZENITH20, which evaluated previously treated patients with NSCLC with HER2 exon 20 insertion mutation, is expected to be filed with the FDA in 2021; and

- Anti-CD20-IFNα, an antibody-interferon fusion molecule directed against CD20 that is in Phase 1 development for treating relapsed or refractory non-Hodgkin's lymphoma patients.

Our business strategy is the development of our late-stage assets through commercialization and the sourcing of additional assets that are synergistic with our existing portfolio (through purchase acquisitions, in-licensing transactions, or co-development and marketing arrangements).

(b) Basis of Presentation

Interim Financial Statements

The interim financial data for the three and nine months ended September 30, 2021 and 2020 is unaudited and is not necessarily indicative of our operating results for a full year. In the opinion of our management, the interim data includes normal and recurring adjustments necessary for a fair presentation of our financial results for the three and nine months ended September 30, 2021 and 2020. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP") have been condensed or omitted pursuant to the Securities and Exchange Commission ("SEC") rules and regulations relating to interim financial statements. Certain prior period amounts have been reclassified for consistency with the current year presentation. The accompanying Condensed Consolidated Financial Statements should be read in conjunction with our audited Consolidated Financial Statements and Notes thereto included within our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (filed with the SEC on March 31, 2021).

Discontinued Operations - Sale of our Commercial Product Portfolio

In March 2019, we completed the sale of our seven then-commercialized drugs, including FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA (the "Commercial Product Portfolio") to Acrotech Biopharma LLC ("Acrotech") (the "Commercial Product Portfolio Transaction"). Upon closing, we received $158.8 million in

an upfront cash payment. We are also entitled to receive up to an aggregate of $140 million upon Acrotech's future achievement of certain regulatory milestones (totaling $40 million) and sales-based milestones (totaling $100 million) relating to the Commercial Product Portfolio.

Principles of Consolidation

The accompanying Condensed Consolidated Financial Statements have been prepared in accordance with GAAP and with the rules and regulations of the SEC. These financial statements include the financial position, results of operations, and cash flows of Spectrum and its subsidiaries, all of which are wholly-owned. All inter-company accounts and transactions among these legal entities have been eliminated in consolidation. Substantially all of the accumulated other comprehensive loss is comprised of foreign currency translation adjustments at September 30, 2021.

Liquidity and Capital Resources

We believe that our $133.6 million in aggregate cash, cash equivalents and marketable securities as of September 30, 2021, are sufficient to fund our current and planned operations for at least the next twelve months. We may however, require additional liquidity as we continue to execute our business strategy, and in connection with opportunistic acquisitions or licensing arrangements. We anticipate that to the extent that we require additional liquidity, it will be funded through additional equity or debt financings, or out-licensing arrangements. However, we cannot provide assurance that we will be able to obtain this additional liquidity on terms favorable to us or our current stockholders, if at all. Additionally, our liquidity and our ability to fund our capital requirements are also dependent on our future financial performance which is subject to various market and economic factors that are beyond our control.

(c) Operating Segment

We operate one reportable operating segment that is focused exclusively on developing (and eventually marketing) oncology and hematology drug products. For the three and nine months ended September 30, 2021 and 2020, all of our revenues and operating costs and expenses were solely attributable to these activities (and as applicable, classified as “discontinued” within the accompanying Condensed Consolidated Statements of Operations).

Note 2. Summary of Significant Accounting Policies And Use of Estimates

The preparation of financial statements in conformity with GAAP requires our management to make informed estimates and assumptions that affect our reported amounts of assets, liabilities, revenues, and expenses. These amounts may materially differ from the amounts ultimately realized and reported due to the inherent uncertainty of any estimate or assumption. On an on-going basis, our management evaluates (as applicable) its most critical estimates and assumptions, including those related to: (i) the realization of our tax assets and estimates of our tax liabilities; (ii) the fair value of our investments; (iii) the valuation of our stock options and the periodic expense recognition of stock-based compensation; and (iv) the potential outcome of our ongoing or threatened litigation.

Our accounting policies and estimates that most significantly impact the presented amounts within these Condensed Consolidated Financial Statements are further described below:

(i) Revenue Recognition

In March 2019, we completed the Commercial Product Portfolio Transaction. In accordance with applicable GAAP (*ASC 205-20, Presentation of Financial Statements*), the revenue-deriving activities of our sold commercial operation are separately classified as “discontinued” for all periods presented within the accompanying Condensed Consolidated Statements of Operations.

***Required Elements of Our Revenue Recognition*:** Revenue from our (a) product sales, (b) out-license arrangements, and (c) service arrangements is recognized under Accounting Standards Update (“*ASU*”) *No. 2014-09, Revenue from Contracts with Customers* (“*Topic 606*”) in a manner that reasonably reflects the delivery of our goods and/or services to customers in return for expected consideration and includes the following elements:

(1) we ensure that we have an executed contract(s) with our customer that we believe is legally enforceable;

(2) we identify the "performance obligations" in the respective contract;

(3) we determine the "transaction price" for each performance obligation in the respective contract;

(4) we allocate the transaction price to each performance obligation; and

(5) we recognize revenue only when we satisfy each performance obligation.

These five elements, as applied to each of our revenue categories, are summarized below:

(a) Product Sales: We sell our products to pharmaceutical wholesalers/distributors or to our product licensees (i.e., our customers). Our wholesalers/distributors in turn sell our products directly to clinics, hospitals, and private oncology-based practices. Revenue from our product sales is recognized as physical delivery of product occurs (when our customer obtains control of the product), in return for agreed-upon consideration.

Our gross product sales (i.e., delivered units *multiplied by* the contractual price per unit) are reduced by our corresponding gross-to-net ("GTN") estimates using the "expected value" method, resulting in reported "product sales, net" that reflects the amount we ultimately expect to realize in net cash proceeds, taking into account our current period gross sales and related cash receipts, and the subsequent cash disbursements on these sales that we estimate for the various GTN categories discussed below. These estimates are based upon information received from external sources (such as written or oral information obtained from our customers with respect to their period-end inventory levels and sales to end-users during the period), in combination with management's informed judgments. Due to the inherent uncertainty of these estimates, the actual amount incurred (of some, or all) of product returns, government chargebacks, prompt pay discounts, commercial rebates, Medicaid rebates, and distribution, data, and group purchasing organization ("GPO") administrative fees may be materially above or below the amount estimated, then requiring prospective adjustments to our reported net product sales.

These GTN estimate categories (that comprise our GTN liabilities) are each discussed below:

Product Returns Allowances: Our customers are contractually permitted to return certain purchased products within the contractual allowable time before/after the applicable expiration date. Returns outside of this aforementioned criteria are not customarily allowed. We estimate expected product returns using our historical return rates. Returned product is typically destroyed since substantially all are due to imminent expiry and cannot be resold.

Government Chargebacks: Our products are subject to pricing limits under certain federal government programs (e.g., Medicare and 340B Drug Pricing Program). Qualifying entities (i.e., end-users) purchase products from our customers at their qualifying discounted price. The chargeback amount we incur represents the difference between our contractual sales price to our customer, and the end-user's applicable discounted purchase price under the government program. There may be significant lag time between our reported net product sales and our receipt of the corresponding government chargeback claims from our customers.

***Prompt Pay Discounts*:** Discounts for prompt payment are estimated at the time of sale, based on our eligible customers' prompt payment history and the contractual discount percentage.

***Commercial Rebates*:** Commercial rebates are based on (i) our estimates of end-user purchases through a GPO, (ii) the corresponding contractual rebate percentage tier we expect each GPO to achieve, and (iii) our estimates of the impact of any prospective rebate program changes made by us.

***Medicaid Rebates*:** Our products are subject to state government-managed Medicaid programs, whereby rebates are issued to participating state governments. These rebates arise when a patient treated with our product is covered under Medicaid, resulting in a discounted price for our product under the applicable Medicaid program. Our Medicaid rebate accrual calculations require us to project the magnitude of our sales, by state, that will be subject to these rebates. There is a significant time lag in our receiving rebate notices from each state (generally several months or longer after our sale is recognized). Our estimates are based on our historical claim levels by state, as supplemented by management's judgment.

***Distribution, Data, and GPO Administrative Fees*:** Distribution, data, and GPO administrative fees are paid to authorized wholesalers/distributors of our products for various commercial services including: contract administration, inventory management, delivery of end-user sales data, and product returns processing. These fees are based on a contractually-determined percentage of our applicable sales.

***(b) License Fees*:** Our out-license arrangements allow licensees to market our product(s) in certain territories for a specific term (representing the out-license of "functional intellectual property"). These arrangements may include one or more of the following forms of consideration: (i) upfront license fees, (ii) sales royalties, (iii) sales milestone-achievement fees, and (iv) regulatory milestone-achievement fees. We recognize revenue for each based on the contractual terms that establish our right to collect payment once the performance obligation is achieved, as follows:

(1) Upfront License Fees: We determine whether upfront license fees are earned at the time of contract execution (i.e., when rights transfer to the customer) or over the actual (or implied) contractual period of the out-license. As part of this determination, we evaluate whether we have any other requirements to provide substantive services that are inseparable from the performance obligation of the license transfer. Our customers' "distinct" rights to licensed "functional intellectual property" at the time of contract execution results in concurrent revenue recognition of all upfront license fees (assuming that there are no other performance obligations at contract execution that are inseparable from this license transfer).

(2) Royalties: Under the "sales-or-usage-based royalty exception" we recognize revenue in the same period that our licensees complete product sales in their territory for which we are contractually entitled to a percentage-based royalty receipt.

(3) Sales Milestones: Under the "sales-or-usage-based royalty exception" we recognize revenue in full within the period that our licensees achieve annual or aggregate product sales levels in their territories for which we are contractually entitled to a specified lump-sum receipt.

(4) Regulatory Milestones: Under the terms of the respective out-license, regulatory achievements may either be our responsibility, or that of our licensee.

- When our licensee is responsible for the achievement of the regulatory milestone, we recognize revenue in full (for the contractual amount due from our licensee) in the period that the approval occurs (i.e., when the "performance obligation" is satisfied by our customer) under the "most likely amount" method. This revenue recognition remains "constrained" (i.e., not recognized) until regulatory approval occurs, given its inherent uncertainty and the requirement of a significant revenue reversal not being probable if achievement does not occur. At each reporting period, we re-evaluate the probability of milestone achievement and the associated revenue constraint; any resulting adjustments would be recorded on a cumulative catch-up basis, thus reflected in our financial statements in the period of adjustment.
- When we are responsible for the achievement of a regulatory milestone, the "relative selling price method" is applied for purposes of allocating the transaction price to our performance obligations. In such case, we consider (i) the extent of our effort to achieve the milestone and/or the enhancement of the value of the delivered item(s) as a result of milestone achievement and (ii) if the milestone payment is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. We have historically assessed the contractual value of these milestones upon their achievement to be identical to the allocation of value of our performance obligations and thus representing the "transaction price" for each milestone at contract inception. We recognize this revenue in the period that the regulatory approval occurs (i.e., when we complete the "performance obligation") under the "most likely amount" method, and revenue recognition is otherwise "constrained" until regulatory approval occurs, given its inherent uncertainty and the requirement of a significant revenue reversal not being probable if achievement does not occur. At each reporting period, we re-evaluate the probability of milestone achievement and the associated revenue constraint; any resulting adjustments would be recorded on a cumulative catch-up basis, thus reflected in our financial statements in the period of adjustment.

(c) Service Revenue: We receive fees under certain arrangements for (i) sales and marketing services, (ii) supply chain services, (iii) research and development services, and (iv) clinical trial management services.

Our rights to receive payment for these services may be established by (1) a fixed-fee schedule that covers the term of the arrangement, so long as we meet ongoing performance obligations, (2) our completion of product delivery in our capacity as a procurement agent, (3) the successful completion of a phase of drug development, (4) favorable results from a clinical trial, and/or (5) regulatory approval events.

We consider whether revenue associated with these service arrangements is reportable each period, based on our completed services or deliverables (i.e., satisfied "performance obligations") during the reporting period, and the terms of the arrangement that contractually result in fixed payments due to us. The promised service(s) within these arrangements are distinct and explicitly stated within each contract, and our customer benefits from the separable service(s) delivery/completion. Further, the nature of the promise to our customer as stated within the respective contract is to deliver each named service individually (not a transfer of combined items to which the promised goods or services are inputs), and thus are separable for revenue recognition.

(ii) Cash and Cash Equivalents

Cash and cash equivalents consist of bank deposits and highly liquid investments with maturities of three months or less from the purchase date.

(iii) Marketable Securities

Marketable securities consist of our holdings in equity securities (including mutual funds), bank CDs, government-related debt securities, and corporate debt securities. For equity securities and mutual funds, any realized gains (losses) or unrealized gains (losses) are recognized in "other income (expense), net" within the Condensed Consolidated Statements of Operations. Debt securities and bank CDs are classified as "available-for-sale" investments and (1) realized gains (losses) are recognized in "other income (expense), net" within the Condensed Consolidated Statements of Operations and (2) unrealized gains (losses) are recognized as a component of "accumulated other comprehensive loss" within the Condensed Consolidated Statements of Stockholders' Equity.

(iv) Accounts Receivable, Net

Our accounts receivable, net of allowance for credit losses, are derived from our product sales and license fees, and do not bear interest. The allowance for credit losses is management's best estimate of the amount of expected credit losses in our existing accounts receivable and any anticipated discounts. The allowance for credit losses is adjusted each period through earnings to reflect expected credit losses over the remaining life of the asset. Account balances are written off against the allowance after appropriate collection efforts are exhausted.

(v) Inventories

We value our inventory at the *lower of* (i) the actual cost of its purchase or manufacture, or (ii) its net realizable value. Inventory cost is determined on the first-in, first-out method. We regularly review our inventory quantities in process of manufacture and on hand. When appropriate, we record a provision for obsolete and excess inventory to derive its net realizable value, which takes into account our sales forecast by product and corresponding expiry dates of each product lot.

Manufacturing costs of drug products that are pending FDA approval during clinical development and trials, and at-risk inventory build in anticipation of commercialization, are exclusively recognized through "research and development" expense on the accompanying Condensed Consolidated Statements of Operations.

(vi) Property and Equipment, Net

Our property and equipment, net is stated at historical cost, and is depreciated on a straight-line basis over an estimated useful life that corresponds with its designated asset category. We evaluate the recoverability of "long-lived assets" (which includes property and equipment) whenever events or changes in circumstances in our business indicate that the asset's carrying amount may not be recoverable. Recoverability is measured by a comparison of the carrying amount to the net undiscounted cash flows expected to be generated by the asset group. An impairment loss would be recorded for the excess of net carrying value over the fair value of the asset impaired. The fair value is estimated based on expected discounted future cash flows or other methods such as orderly liquidation value based on assumptions of asset class and observed market data. An orderly liquidation value is the amount that could be realized upon liquidation, given a sufficient amount of time to find a purchaser for a sale of assets in their existing condition and location, as of a specific date, and assuming the sale is to market participants who can utilize such assets in their highest and best use. The orderly liquidation values are applied against the carrying values of the assets and the impairment loss is measured as the difference between the liquidation value and the carrying value of the assets.

See Note 4(d) for further discussion related to an impairment that occurred during the year ended December 31, 2020.

(vii) Stock-Based Compensation

Stock-based compensation expense for equity awards granted to our employees and members of our Board of Directors is recognized on a straight-line basis over each award's vesting period. Recognized compensation expense is net of an estimated forfeiture rate, representing the percentage of awards that are expected to be forfeited prior to vesting, though is ultimately adjusted for actual forfeitures. We use the Black-Scholes option pricing model to determine the fair value of stock options and stock appreciation rights (as of the date of grant) that have service conditions for vesting. We use the Monte Carlo valuation model to value equity awards (as of the date of grant) that have combined market conditions and service conditions for vesting.

The recognition of stock-based compensation expense and the initial calculation of stock option fair value requires uncertain assumptions, including (a) the pre-vesting forfeiture rate of the award, (b) the expected term that the stock option will remain outstanding, (c) our stock price volatility over the expected term (and that of our designated peer group with respect to certain market-based awards), and (d) the prevailing risk-free interest rate for the period matching the expected term.

With regard to (a)-(d) above: we estimate forfeiture rates based on our employees' overall forfeiture history, which we believe will be representative of future results. We estimate the expected term of stock options granted based on our employees' historical exercise patterns, which we believe will be representative of their future behavior. We estimate the volatility of our common stock on the date of grant based on the historical volatility of our common stock for a look-back period that corresponds with the expected term. We estimate the risk-free interest rate based upon the U.S. Department of the Treasury yields in effect at award grant, for a period equaling the expected term of the stock option.

(viii) Basic and Diluted Net Loss per Share

We calculate basic and diluted net loss per share using the weighted average number of common shares outstanding during the periods presented. In periods of a net loss, basic and diluted loss per share are the same. For the diluted earnings per share calculation, we adjust the weighted average number of common shares outstanding to include only stock options, warrants, and other common stock equivalents outstanding during the period to the extent that they are dilutive.

There were 12,708,185 shares and 9,648,862 shares of outstanding securities (including stock options, restricted stock units, stock appreciation rights, and performance awards) as of September 30, 2021 and 2020, respectively, that were excluded from the calculation of diluted net loss per share because their inclusion would have been anti-dilutive.

(ix) Income Taxes

Deferred tax assets and liabilities are recorded based on the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the financial statements, as well as operating losses and tax credit carry forwards using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain.

We apply an estimated annual effective tax rate ("ETR") approach for calculating a tax provision for interim periods. Our ETR differs from the U.S. federal statutory tax rate primarily as a result of nondeductible expenses and the impact of a valuation allowance on our deferred tax assets, which we record because we believe that, based upon a weighting of positive and negative factors, it is more likely than not that these deferred tax assets will not be realized. If/when we were to determine that our deferred tax assets are realizable, an adjustment to the corresponding valuation allowance would increase our net income in the period that such determination was made.

In the event that we are assessed interest and/or penalties from taxing authorities that have not been previously accrued, such amounts would be included in "benefit for income taxes from continuing operations" within the accompanying Condensed Consolidated Statements of Operations for the period in which we received the notice.

In March 2020, we elected to early adopt *ASU 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes,"* which is intended to simplify various aspects related to accounting for income taxes. *ASU 2019-12* removes certain exceptions to the general principles in *Topic 740* and also clarifies and amends existing guidance to improve consistent application.

(x) Research and Development Expenses

(all tabular amounts presented in thousands, except share, per share, interest rate, and number of years)

Our research and development costs are expensed as incurred. Research and development costs consist primarily of salaries, benefits, and other staff-related costs including associated stock-based compensation, laboratory supplies, clinical trial and related clinical manufacturing costs, costs related to manufacturing preparations, fees paid to other entities that conduct certain research and development activities on our behalf and payments made pursuant to license agreements. Clinical trial and other development costs incurred by third parties are expensed as the contracted work is performed. We accrue for costs incurred as the services are being provided by monitoring the status of activities and the invoices received from our external service providers. We adjust our accruals as actual costs become known. Where contingent milestone payments are due to third parties under research and development or license agreements, the milestone payment obligations are expensed when the clinical or regulatory milestone results are achieved.

(xi) Fair Value Measurements

We determine measurement-date fair value based on the proceeds that would be received through the sale of the asset, or that we would pay to settle or transfer the liability, in an orderly transaction between market participants. We utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. These tiers include the following:

Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that are publicly accessible at the measurement date.

Level 2: Observable prices that are based on inputs not quoted on active markets, but that are corroborated by market data. These inputs may include quoted prices for similar assets or liabilities or quoted market prices in markets that are not active to the general public.

Level 3: Unobservable inputs are used when little or no market data is available.

Note 3. Fair Value Measurements

The table below summarizes certain asset and liability fair values that are included within our accompanying Condensed Consolidated Balance Sheets, and their designations among the three fair value measurement categories:

	September 30, 2021 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 92,172	$ —	$ —	$ 92,172
Equity securities	10,237	—	—	10,237
Government-related debt securities	10,023	—	—	10,023
Mutual funds	5,900	9	—	5,909
Key employee life insurance, cash surrender value[1]	—	4,287	—	4,287
	$ 118,332	$ 4,296	$ —	$ 122,628
Liabilities:				
Deferred executive compensation liability[2]	$ —	$ 10,489	$ —	$ 10,489
	$ —	$ 10,489	$ —	$ 10,489

[1] Included within other assets on our Condensed Consolidated Balance Sheets, and the amount is based on the stated cash surrender value of life insurance policies of named current and former employees at each period-end.

[2] Included $1.1 million within accounts payable and other accrued liabilities and $9.4 million within other long-term liabilities on our Condensed Consolidated Balance Sheets. The amounts are based on the period-end market value of mutual fund investments selected by employee participants of the deferred compensation plan.

Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, interest rate, and number of years)
(Unaudited)

	December 31, 2020 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Assets:				
Government-related debt securities	$ 92,928	$ —	$ —	$ 92,928
Corporate debt securities	—	8,848	—	8,848
Money market funds	40,560	—	—	40,560
Equity securities	24,946	—	—	24,946
Bank CDs	—	1,721	—	1,721
Mutual funds	5,573	9	—	5,582
Key employee life insurance, cash surrender value[1]	—	3,963	—	3,963
	$ 164,007	$ 14,541	$ —	$ 178,548
Liabilities:				
Deferred executive compensation liability[2]	$ —	$ 9,783	$ —	$ 9,783
	$ —	$ 9,783	$ —	$ 9,783

[1] Included within other assets on our Condensed Consolidated Balance Sheets, and the amount is based on the stated cash surrender value of life insurance policies of named current and former employees at each period-end.

[2] Included $1.3 million within accounts payable and other accrued liabilities and $8.5 million within other long-term liabilities on our Condensed Consolidated Balance Sheets. The amounts are based on the period-end market value of mutual fund investments selected by employee participants of the deferred compensation plan.

We did not have any transfers between *"Level 1"* and *"Level 2"* measurement categories for any periods presented.

Our carrying amounts of financial instruments such as cash equivalents, accounts receivable, prepaid expenses, accounts payable, and other accrued liabilities approximate their fair values due to their short-term nature of settlement.

Note 4. Balance Sheet Account Detail

The composition of selected financial statement captions that comprise the accompanying Condensed Consolidated Balance Sheets are summarized below:

(a) Cash and Cash Equivalents and Marketable Securities

We maintain cash balances with select major financial institutions. The Federal Deposit Insurance Corporation (FDIC) and other third parties insure a fraction of these deposits. Accordingly, these cash deposits are not insured against the possibility of a substantial or complete loss of principal and are inherently subject to the credit risk of the corresponding financial institution. There were no material unrealized losses on our investment securities at September 30, 2021 or December 31, 2020.

Our investment policy requires that purchased investments may only be in highly-rated and liquid financial instruments and limits our holdings of any single issuer (excluding any debt or equity securities that may be received from our strategic partners in connection with an out-license arrangement).

The carrying amount of our equity securities, money market funds, and bank CDs approximates their fair value (utilizing "Level 1" or "Level 2" inputs) because of our ability to immediately convert these instruments into cash with minimal expected change in value. As of September 30, 2021, our held securities that remain in an unrealized loss position for less than one year were insignificant and are presented in the table below.

The following is a summary of our presented composition of "cash and cash equivalents" and "marketable securities":

Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, interest rate, and number of years)
(Unaudited)

	Historical or Amortized Cost	Fair Value	Cash and Cash Equivalents	Marketable Securities
September 30, 2021				
Money market funds	$ 92,172	$ 92,172	$ 92,172	$ —
Equity securities[(1)]	3,528	10,237	—	10,237
Government-related debt securities	10,023	10,023	—	10,023
Mutual funds	4,753	5,900	—	5,900
Bank deposits	15,263	15,263	15,263	—
Total cash and cash equivalents and marketable securities	$ 125,739	$ 133,595	$ 107,435	$ 26,160
December 31, 2020				
Money market funds	$ 40,560	$ 40,560	$ 40,560	$ —
Equity securities	3,764	24,946	—	24,946
Government-related debt securities	92,881	92,928	—	92,928
Corporate debt securities	8,846	8,848	—	8,848
Mutual funds	4,497	5,573	—	5,573
Bank CDs	1,715	1,721	—	1,721
Bank deposits	5,449	5,449	5,449	—
Total cash and cash equivalents and marketable securities	$ 157,712	$ 180,025	$ 46,009	$ 134,016

[(1)]Our aggregate equity holdings consist of 6.7 million common shares of CASI Pharmaceuticals, Inc., a NASDAQ-listed biopharmaceutical company, with a fair market value of $7.9 million as of September 30, 2021. We completed the sale of 1.8 million shares of common stock and recognized a $4.2 million gain within “other expense, net” within the accompanying Condensed Consolidated Statements of Operations for the nine months ended September 30, 2021. Additionally, we hold 0.8 million common shares of Unicycive Therapeutics, Inc., a NASDAQ-listed biopharmaceutical company, with a fair market value of $2.3 million as of September 30, 2021.

(b) Other Receivables

“Other receivables” consists of the following:

	September 30, 2021	December 31, 2020
Other miscellaneous receivables	$ 2,443	$ 901
Income tax receivable - current portion	1,297	1,297
Interest receivable from marketable securities	123	196
Other receivables	$ 3,863	$ 2,394

(c) Prepaid Expenses and Other Current Assets

“Prepaid expenses and other current assets” consists of the following:

	September 30, 2021	December 31, 2020
Prepaid expenses and deferred costs	$ 2,370	$ 1,996
Prepaid insurance	170	2,165
Prepaid expenses and other current assets	$ 2,540	$ 4,161

(d) Property and Equipment, net

“Property and equipment, net” consists of the following:

(all tabular amounts presented in thousands, except share, per share, interest rate, and number of years)

	September 30, 2021	December 31, 2020
Manufacturing equipment	$ —	$ 3,245
Computer hardware and software	1,802	1,680
Laboratory equipment	5	5
Leasehold improvements	1,267	1,267
Office furniture	307	248
Property and equipment, at cost	3,381	6,445
(Less): Accumulated depreciation	(2,874)	(2,868)
Property and equipment, net	$ 507	$ 3,577

Depreciation expense was immaterial for the three and nine months ended September 30, 2021 and 2020, respectively.

Manufacturing equipment was comprised of our owned ROLONTIS production equipment on location at our contract manufacturer. As of December 31, 2020, we determined that we would no longer proceed with the technology transfer and validation of a second manufacturing source for ROLONTIS and communicated this decision to the second source manufacturer. We had invested significant capital to prepare this facility for production. Due to the decision to halt this work, we determined that the value of certain ROLONTIS production equipment had a carrying amount in excess of the anticipated recoverable value as there would be no future cash flows from these assets other than through the sale of this equipment. We determined the fair value of these assets under an orderly liquidation value method, and based on the valuation performed we recorded an impairment of $19.7 million to our carrying value for this equipment, which was recorded as research and development expense for the year ended December 31, 2020 within the Consolidated Statements of Operations. During the three months ended September 30, 2021, this equipment was surrendered in connection with the termination of our agreement with our second source manufacturer and we recorded incremental research and development expense of $2.9 million. Fair value was based on observable market data (“Level 2”). Due to the specialized nature of this production equipment, adjustments to observable market data were applied (“Level 3”).

(e) Accounts Payable and Other Accrued Liabilities

“Accounts payable and other accrued liabilities” consists of the following:

	September 30, 2021	December 31, 2020
Trade accounts payable and other	$ 40,914	$ 34,385
Lease liability - current portion	1,451	1,544
Commercial Product Portfolio accruals (Note 7)	6,617	7,842
Accounts payable and other accrued liabilities	$ 48,982	$ 43,771

Amounts presented within “accounts payable and other accrued liabilities” in the accompanying Condensed Consolidated Balance Sheets for our categories of GTN estimates related to the Commercial Product Portfolio accruals were as follows:

	Commercial/Medicaid Rebates and Government Chargebacks	Distribution, Data, Inventory and GPO Administrative Fees	Product Return Allowances	Total
Balance as of December 31, 2019	$ 14,671	$ 1,138	$ 4,714	$ 20,523
(Less): Payments and credits against GTN accruals	(12,070)	(196)	(415)	(12,681)
Balance as of December 31, 2020	$ 2,601	$ 942	$ 4,299	$ 7,842
(Less): Payments and credits against GTN accruals	(1,160)	—	(65)	(1,225)
Balance as of September 30, 2021	$ 1,441	$ 942	$ 4,234	$ 6,617

(all tabular amounts presented in thousands, except share, per share, interest rate, and number of years)

Note 5. Stock-Based Compensation

In June 2018, we adopted the 2018 Long-Term Incentive Plan, which provided for the issuance of restricted stock awards and units, incentive and nonqualified stock options, performance unit awards, stock appreciation rights, and other stock-based awards to employees, consultants and members of our Board of Directors.

We report our stock-based compensation expense (inclusive of our incentive stock plan and employee stock purchase plan) in the accompanying Condensed Consolidated Statements of Operations within "total operating costs and expenses" for the three and nine months ended September 30, 2021 and 2020, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Selling, general and administrative	$ 2,927	$ 3,018	$ 8,730	$ 9,773
Research and development	1,187	1,090	3,956	3,598
Total stock-based compensation	$ 4,114	$ 4,108	$ 12,686	$ 13,371

We granted 3.5 million stock options with a weighted average exercise price of $3.65 during the nine months ended September 30, 2021. At September 30, 2021 we had 12.4 million options outstanding with a weighted average exercise price of $5.87. Additionally, we granted 2.4 million restricted stock awards with a weighted average grant date fair value of $3.62 during the nine months ended September 30, 2021. At September 30, 2021 we had 4.9 million restricted stock awards outstanding with a weighted average grant date fair value of $4.70.

Note 6. Financial Commitments and Contingencies and Key License Agreements

(a) Facility and Equipment Leases

Overview

In the ordinary course of our business, we enter into leases with unaffiliated parties for the use of (i) office and research facilities and (ii) office equipment. Our current leases have remaining terms ranging from less than one to five years and none include any residual value guarantees, restrictive covenants, term extensions, or early-termination options.

We lease our principal executive office in Henderson, Nevada under a non-cancelable operating lease expiring October 31, 2021 which has been extended through October 31, 2022. We also lease our research and development facility in Irvine, California under a non-cancelable operating lease expiring July 31, 2022, in addition to other administrative office leases. We entered into a new office facility lease in Boston under a non-cancelable operating lease expiring in December 31, 2024. We recognize lease expense on a straight-line basis over the expected term of these operating leases, as reported within "selling, general and administrative" expense on the accompanying Condensed Consolidated Statements of Operations.

Our facility leases have minimum annual rents, payable monthly, and some carry fixed annual rent increases. Under some of these arrangements, real estate taxes, insurance, certain operating expenses, and common area maintenance are reimbursable to the lessor. These amounts are expensed as incurred, as they are variable in nature and therefore excluded from the measurement of our reported lease asset and liability discussed below. As of September 30, 2021 and 2020, we had no sublease arrangements with us as lessor, and no finance leases, as defined in ASU 2016-02, *Leases* ("Topic 842").

The reported asset and liability, respectively, represents (i) the economic benefit of our use of leased facilities and equipment and (ii) the present-value of our contractual minimum lease payments, applying our estimated incremental borrowing rate as of the lease commencement date (since an implicit interest rate is not readily determinable in any of our leases). The recorded asset and liability associated with each lease is amortized over the respective lease term using the effective interest rate method. During the three and nine months ended September 30, 2021, we recognized $1.8 million of additional right-of-use assets in exchange for $1.8 million lease liabilities.

We elected to not separate "lease components" from "non-lease components" in our measurement of minimum payments for our facility leases and office equipment leases. Additionally, we elected to not recognize a lease asset and liability for a term of 12 months or less.

Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, interest rate, and number of years)
(Unaudited)

Financial Reporting Captions

The below table summarizes the lease asset and liability accounts presented on our accompanying Condensed Consolidated Balance Sheets:

Operating Leases	Condensed Consolidated Balance Sheet Caption	September 30, 2021	December 31, 2020
Operating lease right-of-use assets - non-current	Facility and equipment under lease	$ 2,881	$ 2,247
Operating lease liabilities - current	Accounts payable and other accrued liabilities	1,451	1,544
Operating lease liabilities - non-current	Other long-term liabilities	1,593	883
Total operating lease liabilities		$ 3,044	$ 2,427

As of September 30, 2021 and December 31, 2020, our “facility and equipment under lease” consisted of office and research facilities of $2.5 million and $1.9 million, respectively, and office equipment of $0.4 million and $0.3 million, respectively.

Components of Lease Expense

We recognize lease expense on a straight-line basis over the term of our operating leases, as reported within “selling, general and administrative” expense on the accompanying Condensed Consolidated Statements of Operations. The components of our aggregate lease expense is summarized below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease cost	$ 381	$ 466	$ 1,274	$ 1,398
Variable lease cost	79	86	280	314
Short-term lease cost	13	17	46	46
Total lease cost	$ 473	$ 569	$ 1,600	$ 1,758

Weighted Average Remaining Lease Term and Applied Discount Rate

	Weighted Average Remaining Lease Term	Weighted Average Discount Rate
Operating leases as of September 30, 2021	2.7 years	4.2%
Operating leases as of December 31, 2020	1.6 years	7.8%

Future Contractual Lease Payments

The below table summarizes our (i) minimum lease payments over the next five years, (ii) lease arrangement implied interest, and (iii) present value of future lease payments:

(all tabular amounts presented in thousands, except share, per share, interest rate, and number of years)

Operating Leases - future payments	September 30, 2021
2021 (remaining)	$ 382
2022	1,301
2023	657
2024	669
2025	98
2026	73
Total future lease payments, undiscounted	$ 3,180
(Less): Implied interest	(136)
Present value of operating lease payments	$ 3,044

(b) In/Out Licensing Agreements and Co-Development Arrangements

Overview

The in-license agreements for our development-stage drug products provide us with territory-specific rights to their manufacture and distribution (including further sub-licensing/out-licensing rights). We are generally responsible for all related clinical development costs, patent filings and maintenance costs, marketing costs, and liability insurance costs. We also may enter into out-license agreements for territory-specific rights to these drug products which include one or more of: upfront license fees, royalties from our licensees' sales, and/or milestone payments from our licensees' sales or regulatory achievements. For certain drug products, we may enter into cost-sharing arrangements with licensees and licensors.

We are also obligated to make specified milestone payments to our licensors upon the achievement of certain regulatory and sales milestones, and to pay royalties based on our net sales of all in-licensed products. Depending on the milestone achievement type and whether the product has been approved, we will either (a) capitalize the value to "intangible assets" in the Consolidated Balance Sheets or (b) recognize the payment value within "research and development" or "cost of sales" on the Consolidated Statements of Operations. The liability relating to the payment due to the licensor will be recognized in the earliest period that we determine the respective milestone achievement is probable or occurs.

Impact of Commercial Product Portfolio Transaction

In March 2019, we completed the Commercial Product Portfolio Transaction and substantially all of the contractual rights and obligations associated with the Commercial Product Portfolio were transferred to Acrotech at the closing of the Commercial Product Portfolio Transaction. However, under the terms of this transaction we retained our trade "accounts receivable, net" and GTN liabilities included within "accounts payable and other accrued liabilities" associated with our product sales made on and prior to February 28, 2019.

Accordingly, these Condensed Consolidated Financial Statements reflect the corresponding revenue-deriving activities and allocable expenses of this commercial business within "discontinued operations". The most significant remaining agreements associated with our continuing operations are listed below, along with the key financial terms and our corresponding accounting and reporting conventions for each:

(i) ROLONTIS: Co-Development and Commercialization Agreement with Hanmi

In October 2014, we exercised our option under a License Option and Research Collaboration Agreement dated January 2012 (as amended) with Hanmi Pharmaceutical Co. Ltd. ("Hanmi") for ROLONTIS, a drug based on Hanmi's proprietary LAPSCOVERY™ technology for the treatment of chemotherapy induced neutropenia. Under the terms of this agreement, as amended, we have primary financial responsibility for the ROLONTIS development plan and hold its worldwide rights (except for Korea, China, and Japan). We are contractually obligated to pay Hanmi tiered royalties that range from the low double-digits to mid-teens on our annual net sales of ROLONTIS.

We are responsible for regulatory milestone payments to Hanmi of $10 million upon approval of ROLONTIS, and sales milestone payments of up to $120 million per calendar year based on our annual net sales of ROLONTIS.

(ii) Poziotinib: In-License Agreement with Hanmi and Exclusive Patent and Technology License Agreement with MD Anderson

In February 2015, we executed an in-license agreement with Hanmi for poziotinib, a pan-HER inhibitor in Phase 2 clinical trials, (which has also shown single agent activity in the treatment of various cancer types during Phase 1 studies, including breast, gastric, colorectal, and lung cancers) and made an upfront payment to Hanmi for these distribution rights.

Under the terms of this agreement, we received the exclusive global rights to commercialize poziotinib, except for Korea and China. Hanmi and its development partners are fully responsible for the completion of on-going Phase 2 trials in Korea. We are financially responsible for all other clinical studies. We are obligated to make contractual payments to Hanmi upon our achievement of various regulatory milestones that aggregate to $33 million. We are also obligated to pay Hanmi net sales milestones of up to $325 million annually and pay royalties in the low to mid-teen digits on our net sales of poziotinib, potentially reduced by royalties due to other third parties.

In April 2018, we executed an exclusive patent and technology agreement for the use of poziotinib in treating patients with EGFR and HER2 exon 20 mutations in cancer and HER2 exon 19 mutations in cancer with The University of Texas M.D. Anderson Cancer Center (“MD Anderson”). MD Anderson discovered poziotinib’s use in treating these patient-types. We made an upfront payment to MD Anderson of $0.5 million upon the execution of this agreement.

We are contractually obligated to pay nominal fixed annual license maintenance fees to MD Anderson and pay additional fees upon our achievement of various regulatory and sales milestones. These regulatory milestones aggregate $6 million and the sales milestones aggregate $24 million. We are also contractually obligated to pay MD Anderson royalties in the low single-digits on our net sales of poziotinib.

(iii) In-License Agreement with ImmunGene for FIT Drug Delivery Platform

In April 2019, we executed an asset transfer, license, and sublicense agreement with ImmunGene, Inc. (“ImmunGene”) for an exclusive license for the intellectual property related to (a) Anti-CD20-IFNα, an antibody-interferon fusion molecule directed against CD20 that is in Phase 1 development for treating relapsed or refractory non-Hodgkin’s lymphoma, including diffuse large B-cell lymphoma patients, representing a considerable unmet medical need, and (b) an antibody-interferon fusion molecule directed against GRP94, a target for which currently there are no existing approved therapies that have the potential for treating both solid and hematologic malignancies. Both molecules are based on the Focused Interferon Therapeutics (“FIT”) drug delivery platform.

We made upfront payments aggregating $2.8 million to ImmunGene and to several other third parties. We will make further payments to ImmunGene upon our achievement of various regulatory milestones that aggregate to $26.1 million, plus an additional $5 million milestone payment for each new indication (beyond those described above) approved for either drug in the U.S., Europe, or Japan.

Our contractual royalties to ImmunGene are in the high-single digits on our net sales of each drug, potentially reduced by our royalties due to other third parties. We are also contractually obligated to pay nominal fixed annual license maintenance fees to two licensors.

(iv) In-License Agreement with Therapyx

In December 2020, we executed an asset transfer and license agreement with Therapyx, Inc. (“Therapyx”) for an exclusive worldwide license for the intellectual property related to any pharmaceutical or biological product for use in human oncology containing, whether as its sole active or in combination with other active ingredients, an encapsulated IL-12, in any injectable dosage form or formulation.

We made an upfront payment of $0.8 million to Therapyx upon contract execution, which was recorded to “research and development” expense within our Consolidated Statements of Operations for the year ended December 31, 2020. We will make an additional payment of $2.2 million upon our acceptance of certain transferred materials from Therapyx. We will make further payments to Therapyx upon our achievement of various (i) regulatory milestones aggregating up to $30 million for the first approved IL-12 product, plus an additional $2.5 million milestone payment for each new indication approved for each product in the U.S., Europe, or Japan; and (ii) sales milestones aggregating up to $167.5 million based on worldwide annual net sales. We are contractually obligated to pay royalties in the mid-single digits on our net sales of all IL-12 products, potentially

reduced by royalties due to third parties, the loss of IP protection within one or more countries, or the introduction of a competing product within one or more countries.

Depending on the nature of the milestone achievement type we will either (a) capitalize the payment value to “intangible assets” in the Consolidated Balance Sheets or (b) recognize the payment value within “research and development” or “cost of sales” within the Consolidated Statements of Operations. The corresponding liability for the payment due to this licensor will be recognized in the Consolidated Balance Sheets within “accounts payable and other accrued liabilities” in the earliest period that we determine the respective milestone achievement is probable or occurs.

(c) Service Agreements for Research and Development Activities

We have entered into various contracts with numerous third-party service providers for the execution of our research and development initiatives. These vendors include raw material suppliers, clinical trial sites, clinical research organizations, and data monitoring centers, among others. The financial terms of these agreements are varied and generally obligate us to pay in stages, depending on the achievement of certain events specified in the agreements - such as contract execution, progress of service completion, delivery of drug supply, and the dosing of patients in clinical studies.

We recognize these “research and development” expenses and corresponding “accounts payable and other accrued liabilities” in the accompanying financial statements based on estimates of our vendors’ progress of performed services, patient enrollments and dosing, completion of clinical studies, and other events. Should we decide to discontinue and/or slow-down the work on any project, the associated costs for those projects would typically be limited to the extent of the work completed, as we are generally able to terminate these contracts with adequate notice.

(d) Supply and Service Agreements Associated with Product Production

We have various product supply agreements and/or have issued vendor purchase orders that obligate us to agreed-upon raw material purchases from certain vendors. We also have certain drug production service agreements with select contract manufacturers that obligate us to service fees during the contractual period. These collective commitments do not exceed our planned commercial requirements; the corresponding contracted prices do not exceed their current fair market values.

(e) Employment Agreements

We entered into revised employment agreements with each of our named executive officers (chief executive officer, chief operating officer, chief financial officer, chief legal officer, and chief medical officer) in April/June 2018 and June 2019, which supersede any prior change in control severance agreements with such individuals. These agreements provide for the payment of certain benefits to each executive upon his separation of employment under specified circumstances. These arrangements are designed to encourage each to act in the best interests of our stockholders at all times during the course of a change in control event or other significant transaction.

(f) Deferred Compensation Plan

The Spectrum Pharmaceuticals, Inc. Deferred Compensation Plan (the “DC Plan”) is administered by the Compensation Committee of our Board of Directors and is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended.

The DC Plan is maintained to provide special deferred benefits for a select group of our employees (the “DC Participants”). DC Participants make annual elections to defer a portion of their eligible cash compensation which is then placed into their DC Plan accounts. We match a fixed percentage of these deferrals, and may make additional discretionary contributions. At September 30, 2021 and December 31, 2020, the aggregate value of this DC Plan liability was $10.5 million and $9.8 million, respectively, and is included within “accounts payable and other accrued liabilities” and “other long-term liabilities” in the accompanying Condensed Consolidated Balance Sheets.

(g) Litigation

We are involved from time-to-time with various legal matters arising in the ordinary course of business. These claims and legal proceedings are of a nature we believe are normal and incidental to a pharmaceutical business, and may include product

liability, intellectual property, employment matters, and other general claims. We may also be subject to derivative lawsuits from time to time.

We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are assessed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. Although the ultimate resolution of these various matters cannot be determined at this time, we do not believe that such matters, individually or in the aggregate, will have a material adverse effect on our consolidated results of operations, cash flows, or financial condition.

Bioverativ Patent Litigation

On May 28, 2021, Bioverativ Therapeutics Inc. (“Bioverativ”) filed a complaint against us in the U.S. District Court for the District of Delaware, which alleges that our proposed manufacture, use and sale of ROLONTIS would, if approved, infringe claims of three patents owned by Bioverativ (the “Subject Patents”). Bioverativ is seeking an unspecified amount of damages and injunctive relief.

We believe that our manufacture, use and sale of ROLONTIS would not infringe the Subject Patents and intend to vigorously defend our right to develop and commercialize ROLONTIS in accordance with the terms of our agreements with Hanmi.

Pursuant to our agreements with Hanmi, we hold worldwide rights (except for Korea, China, and Japan) to develop and commercialize ROLONTIS. The agreements with Hanmi contain typical license terms including, without limitation, indemnification rights in favor of the Company with respect to any claims of infringement from a third party with respect to our use of a licensed technology, product or compound pursuant to such agreements.

Shareholder Litigation

On August 31, 2021, a shareholder lawsuit was filed against us in the U.S. District Court for the District of Nevada, which alleges that we and certain of our executive officers made false or misleading statements and failed to disclose material facts about our business and the prospects of approval for our BLA to the FDA for ROLONTIS in violation of Section 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Securities Exchange Act of 1934, as amended. On November 1, 2021, four individuals and one entity filed competing motions to be appointed lead plaintiff and for approval of counsel in this putative securities class action. The plaintiffs seek damages, interest, costs, attorneys’ fees, and other unspecified equitable relief. We believe that these claims are without merit, and intend to vigorously defend against these claims.

Note 7. Discontinued Operations

Overview

In March 2019, we completed the Commercial Product Portfolio Transaction. In accordance with applicable GAAP (*ASC 205-20, Presentation of Financial Statements*), the revenue-deriving activities and allocable expenses of our sold commercial operation, connected to the Commercial Product Portfolio, are separately classified as “discontinued” for all periods presented within the accompanying Condensed Consolidated Statements of Operations.

Condensed Consolidated Statements of Operations

The following table presents the various elements of “income (loss) from discontinued operations, net of income taxes” as reported in the accompanying Condensed Consolidated Statements of Operations:

Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, interest rate, and number of years)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	$ —	$ (1)	$ —	$ (101)
Total revenues	—	(1)	—	(101)
Operating costs and expenses:				
Cost of sales (excluding amortization of intangible assets)	6	—	133	(229)
Selling, general and administrative	—	—	—	(1)
Research and development	5	(67)	94	(126)
Total operating costs and expenses	11	(67)	227	(356)
Income (loss) from discontinued operations before income taxes	(11)	66	(227)	255
Provision for income taxes from discontinued operations	—	—	—	—
Income (loss) from discontinued operations, net of income taxes	$ (11)	$ 66	$ (227)	$ 255

Condensed Consolidated Balance Sheets

Accounts receivable derived from our product sales on and prior to February 28, 2019 were not transferred to Acrotech as part of Commercial Product Portfolio Transaction, nor were our GTN liabilities and trade accounts payable assumed by Acrotech that were associated with our commercial activities on and prior to February 28, 2019. Accordingly, these specific assets and liabilities remain presented within “accounts receivable, net and “accounts payable and other accrued liabilities” on the accompanying Condensed Consolidated Balance Sheets.

Note 8. Stockholders’ Equity

Sale of Common Stock Under ATM Agreement

On April 5, 2019, we entered into a collective at-the-market-issuance (“ATM”) sales agreement with Cantor Fitzgerald & Co., H.C. Wainwright & Co., LLC and B. Riley FBR, Inc. (the “April 2019 ATM Agreement”), pursuant to which we may offer and sell shares of our common stock by any method deemed to be an “at the market” offering (the “ATM Offering”). From April 5, 2019 to March 2, 2020, the ATM Offering was conducted pursuant to a sales agreement prospectus filed with our automatic shelf registration statement on Form S-3ASR, filed with the SEC on April 5, 2019, which registered an aggregate offering price of $150 million under the April 2019 ATM Agreement. From May 8, 2020 to June 30, 2020, the ATM Offering was conducted pursuant to a sales agreement prospectus (the “Initial Sales Agreement Prospectus”) filed with our shelf registration statement on Form S-3, filed with the SEC on March 20, 2020, as amended by Pre-Effective Amendment No. 1 thereto, and declared effective by the SEC on May 8, 2020 (the “Registration Statement”), which registered an aggregate offering price of up to $75 million under the April 2019 ATM Agreement. On July 29, 2020, we terminated the Initial Sales Agreement Prospectus, but left the April 2019 ATM Agreement in full force and effect. On November 6, 2020, we filed a new sales agreement prospectus to the Registration Statement, which registered an aggregate offering price of up to $60 million under the April 2019 ATM Agreement.

On July 13, 2021, we filed a shelf registration statement with the SEC on Form S-3, which was declared effective by the SEC on July 21, 2021 (the “Registration Statement”). The Registration Statement registered an aggregate offering price of up to $300 million of securities that may be issued and sold by us from time to time, including up to an aggregate offering price of $150 million of common stock (which amount is included in the $300 million aggregate offering price set forth in the base prospectus) that may be issued and sold pursuant to the April 2019 ATM Agreement.

We sold and issued common shares under the April 2019 ATM Agreement as follows:

Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, interest rate, and number of years)
(Unaudited)

Period in Which Issued	No. of Common Shares Issued	Proceeds Received (Net of Broker Commissions and Fees)
Year ended December 31, 2019	221,529	$ 1,814
Year ended December 31, 2020	3,950,398	$ 14,902
Quarter ended March 31, 2021	5,678,893	$ 21,357
Quarter ended June 30, 2021	10,172,498	$ 31,265
Quarter ended September 30, 2021	—	$ —

Item 2.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, statements regarding our future product development and commercialization activities and costs, the revenue potential (licensing, royalty and sales) of our products and product candidates, the impact of the novel coronavirus ("COVID-19") global pandemic on our business, the success, safety and efficacy of our drug products, revenues and revenue assumptions, clinical studies, including designs and implementation, development and commercialization timelines, product acquisitions, accounting principles, litigation expenses, liquidity and capital resources and trends, and other statements containing forward-looking words, such as, "believes," "may," "could," "would," "will," "expects," "intends," "estimates," "anticipates," "plans," "seeks," "continues," or the negative thereof or variation thereon or similar terminology (although not all forward-looking statements contain these words). Such forward-looking statements are based on the reasonable beliefs of our management as well as assumptions made by and information currently available to our management. All forward-looking statements included in this Form 10-Q speak only as of the date of this Form 10-Q and readers should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in our periodic reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as well as those discussed elsewhere in this Quarterly Report on Form 10-Q, and the following factors, among others:

- our ability to successfully develop, obtain regulatory approval of, and market our products;
- the approval, or timing of approval, of our products or new indications for our products by the U.S. Food and Drug Administration (the "FDA") and other international regulatory agencies;
- the overall impact of COVID-19 on our business, including, without limitation, delays caused by COVID-19 related travel restrictions;
- actions by the FDA and other regulatory agencies, including international agencies;
- the timing and/or results of pending or future clinical trials, and our reliance on contract research organizations;
- our ability to maintain sufficient cash resources to fund our business operations;
- our history of net losses;
- our ability to enter into strategic alliances with partners for manufacturing, development and commercialization;
- our competitors' progress with their drug development programs, which could adversely impact the perceived or actual value of our in-development drugs;
- our dependence on the production capabilities of contract manufacturing organizations ("CMOs") and other third-parties for active pharmaceutical ingredients ("APIs"), drug products, related supplies and logistical services;
- the ability of our manufacturing partners to satisfy regulatory requirements and to meet our product demands and timelines;
- our ability to identify and acquire new product candidates and to successfully integrate those product candidates into our operations;
- our ability to protect our intellectual property rights;
- the impact of legislative or regulatory reform on the pricing for pharmaceutical products;
- the impact of any litigation to which we are, or may become a party, including, without limitation, the patent infringement claims made against us by Bioverativ Therapeutics, Inc.;

- our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries; and
- our ability to maintain the services of our key executives and other personnel.

All subsequent written and oral forward-looking statements attributable to us or by persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. We expressly disclaim any intent or obligation to update information contained in any forward-looking statement after the date thereof to conform such information to actual results or to changes in our opinions or expectations.

Impact of COVID-19 Pandemic

On March 11, 2020, COVID-19 was declared a pandemic by the World Health Organization. Concerns related to the spread of COVID-19 have created global business disruptions as well as disruptions in our operations. The ongoing COVID-19 pandemic has adversely impacted economic activity and conditions worldwide, including workforces, liquidity, capital markets, consumer behavior, supply chains, and macroeconomic conditions. Notably, a new Delta variant of COVID-19, which appears to be the most transmissible variant to date, has begun to spread globally. The impact of the Delta variant cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines against the Delta variant and the response by governmental bodies and regulators.

On October 26, 2020, we announced that the FDA had deferred action on our Biologics License Application (“BLA”) for ROLONTIS due to the inability to conduct an inspection of the Hanmi Pharmaceutical Co. Ltd. (“Hanmi”) third-party manufacturing facility in South Korea as a result of COVID-19 related travel restrictions. In early June 2021, the FDA conducted the pre-approval inspection of the Hanmi manufacturing facility. In August 2021, we received a Complete Response Letter from the FDA regarding our BLA, citing deficiencies related to manufacturing and indicating that a reinspection will be necessary. We are seeking further clarification from the FDA and plan to meet with the agency as soon as possible.

The extent to which the COVID-19 pandemic may continue to impact our results of operations, including the long-term nature of the impacts, depends on numerous evolving factors, which are highly uncertain and difficult to predict, including the adoption rate of the COVID-19 vaccines, the emergence and spread of variants (including the Delta variant, a rapidly spreading strain of coronavirus), the scope and the timing to further contain the virus or treat its impact, and to what extent normal economic and operating conditions can resume, among others. For more information related to the impact of COVID-19 on our business, refer to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 31, 2021, and in our Quarterly Report on Form 10-Q for the period ended June 30, 2021, as filed with the SEC on August 12, 2021.

Company Overview

Spectrum Pharmaceuticals, Inc. (“Spectrum”, the “Company”, “we”, “our”, or “us”) is a biopharmaceutical company, with a primary strategy comprised of acquiring, developing, and commercializing novel and targeted oncology therapies. Our in-house development organization includes clinical development, regulatory, quality and data management. We continue to build out our commercial and marketing capabilities to prepare for the launch of ROLONTIS.

We have three drugs in development:

- ROLONTIS, a novel long-acting granulocyte colony-stimulating factor (“G-CSF”) for chemotherapy-induced neutropenia. We submitted a BLA for ROLONTIS in December 2019, and in August 2021 we received a Complete Response Letter from the FDA regarding our BLA, citing deficiencies related to manufacturing and indicating that a reinspection will be necessary. We are currently working on remediating the manufacturing deficiencies and expect that this work will be complete in the fourth quarter of 2021 and plan to resubmit thereafter;
- Poziotinib, a novel irreversible tyrosine kinase inhibitor under investigation for non-small cell lung cancer (“NSCLC”) tumors with various mutations. A New Drug Application (“NDA”) based on data from Cohort 2 of ZENITH20, which evaluated previously treated patients with NSCLC with HER2 exon 20 insertion mutation is expected to be filed with the FDA in 2021; and
- Anti-CD20-IFNα, an antibody-interferon fusion molecule directed against CD20 that is in Phase 1 development for treating relapsed or refractory non-Hodgkin’s lymphoma patients.

Our business strategy is the development of our late-stage assets through commercialization and the sourcing of additional assets that are synergistic with our existing portfolio (through purchase acquisitions, in-licensing transactions, or co-development and marketing arrangements).

Recent Highlights of Our Business, Product Development Initiatives, and Regulatory Approvals

Our product pipeline is summarized below:

ROLONTIS, a novel long-acting G-CSF:

We submitted our updated BLA for ROLONTIS to the FDA on October 24, 2019, which was accepted for review by the FDA on December 20, 2019. Our BLA is supported by data from two similarly designed Phase 3 clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of ROLONTIS in 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive chemotherapy. On October 26, 2020, we announced that the FDA PDUFA target action date set for October 24, 2020 was deferred pending inspection of the Hanmi manufacturing facility in Korea due to COVID-19 related travel restrictions. In early June 2021, the FDA conducted the pre-approval inspection of the Hanmi manufacturing facility. In August 2021, we received a Complete Response Letter from the FDA regarding our BLA, citing deficiencies related to manufacturing and indicating that a reinspection will be necessary. We are currently working on remediating the manufacturing deficiencies and expect that this work will be complete in the fourth quarter of 2021 and plan to resubmit thereafter.

A company sponsored clinical trial has been initiated to evaluate the administration of ROLONTIS on the same day as chemotherapy. This Phase 1 clinical trial is a randomized, open label, actively controlled study to evaluate the same-day dosing of eflapegrastim on duration of neutropenia when administered at varying intervals following docetaxel and cyclophosphamide (TC) chemotherapy in patients with early-stage breast cancer. On March 4, 2021, at the virtual 38th Annual Miami Breast Cancer Conference®, the company presented positive early data showing rapid absolute neutrophil count (ANC) recovery in the first three patients dosed in the 30-minute arm of the same-day dosing. This arm met the prespecified interim safety evaluation criteria and therefore supports the expansion of this arm to 15 patients. The study design included an interim safety evaluation that was conducted once the first three patients in each arm (30 minutes, 3 hours, or 5 hours) completed Cycle 1. Based on this review, the 30-minute arm will expand to a total of 15 patients, while the 3- and 5-hour dosing arms have been discontinued. In the 30-minute dosing arm, ANC recovery was more rapid compared to the 3- and 5-hour arms. The overall safety profile for the 30-minute arm was similar to what has been seen previously in large randomized studies with GCSF given 24 hours after chemotherapy.

Poziotinib, an irreversible tyrosine kinase inhibitor targeting EGFR and HER2 mutations:

In October 2017, we announced the start of our pivotal ZENITH20 Phase 2 global clinical trial with active sites in the U.S., Canada and Europe. The ZENITH20 trial consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) include previously treated NSCLC patients with exon 20 mutations. Cohort 3 (EGFR) and 4 (HER2) include first-line NSCLC patients with exon 20 mutations. Cohorts 1- 4 are each independently powered for a pre-specified statistical hypothesis and the primary endpoint is overall response rate (“ORR”). Cohort 5 includes previously treated or treatment-naïve NSCLC patients with EGFR or HER2 exon 20 insertion mutations. Cohort 6 includes NSCLC patients with classical EGFR mutations who progressed while on treatment with first-line osimertinib and developed an additional EGFR mutation. Cohort 7 includes NSCLC patients with a variety of less common mutations in EGFR or HER2 exons 18-21 or the extracellular or transmembrane domains. Cohorts 1-3 have completed enrollment while Cohorts 4-7 continue to enroll patients.

On December 26, 2019, we announced that the pre-specified primary endpoint was not met in Cohort 1 of the ZENITH20 trial evaluating poziotinib in previously treated NSCLC patients with EGFR exon 20 insertion mutations. Cohort 1 enrolled a total of 115 patients who received 16 mg/day of poziotinib. The intent-to-treat analysis showed that 17 patients had a response (by RECIST) and 62 patients had stable disease for a 68.7% disease control rate (“DCR”). The confirmed ORR was 14.8% (95% CI 8.9%-22.6%). The median duration of response was 7.4 months and the progression free survival was 4.2 months. The safety profile was in-line with other second-generation EGFR tyrosine kinase inhibitors.

On July 27, 2020, we announced that we met the pre-specified primary endpoint for Cohort 2 in the ZENITH20 trial evaluating previously treated NSCLC patients with HER2 exon 20 insertion mutations. Cohort 2 enrolled a total of 90 patients who received an oral, once daily dose of 16 mg of poziotinib. All the patients had failed at least one line of prior systemic therapy with 60 patients (67%) having failed two or more prior therapies, including chemotherapy and immunotherapy. All responses were read independently and confirmed by a central imaging laboratory using RECIST criteria. The intent-to-treat analysis demonstrated a confirmed ORR of 27.8% (95% CI of 18.9%-38.2%). Based on the pre-specified statistical hypothesis

for the primary endpoint, the observed lower bound of 18.9% exceeded the pre-specified lower bound of 17% in this heavily pre-treated population. The safety profile was in-line with the type of adverse events seen with other second-generation EGFR tyrosine kinase inhibitors. These results were presented at the European Society for Medical Oncology ("ESMO") Virtual Congress 2020 Science Weekend held in September 2020.

In March 2021, we announced that the FDA granted Fast Track designation for poziotinib based on data from Cohort 2 of ZENITH20, which evaluated previously treated patients with NSCLC with HER2 exon 20 insertion mutations. In December 2020, we reported that its pre-specified primary endpoint in Cohort 3 evaluating poziotinib in first-line NSCLC patients with EGFR exon 20 insertion mutations was not met. We additionally reported that preliminary data from patients receiving 8 mg of poziotinib twice daily demonstrated meaningful improvement in tolerability as measured by adverse events and dosing interruptions.

Cohort 3 of the ZENITH20 clinical trial enrolled a total of 79 patients who received an oral once daily dose of 16 mg of poziotinib. The median time of follow up of all patients was 9.2 months with 12 ongoing patients still on treatment. The intent-to-treat analysis showed that 22 patients had a partial response (by RECIST) and 68 patients had stable disease for an 86.1% DCR. 91% of patients experienced tumor reduction with a median reduction of 25.5%. The confirmed ORR was 27.8% (95% CI 18.4-39.1%). Based on the pre-specified statistical hypothesis for the primary endpoint, the observed lower bound of 18.4% did not meet the pre-specified lower bound of >20%. The median duration of response was 6.5 months and the median progression free survival was 7.2 months. The safety profile was similar with the type of adverse events observed with other second-generation EGFR tyrosine kinase inhibitors. Grade 3 treatment related rash was 33% and diarrhea was 23%. 94% of patients had drug interruptions with 6 patients (8%) permanently discontinuing due to adverse events.

In April 2021, new data was presented at the American Association for Cancer Research (AACR) Virtual Annual Meeting 2021 from ZENITH20 Cohort 5 which demonstrated improved efficacy and tolerability for twice daily dosing. In the 38 patients, comprised of EGFR or HER2 exon 20 insertion mutations, who received 16 mg per day and randomized either to poziotinib 16 mg once daily or 8 mg twice daily in Cohort 5, improved responses were observed in the twice daily arm with 31.6% of patients reaching a partial response, while Grade 3 or higher adverse events were reduced by approximately 60%. Additionally, the twice daily dosing allowed for an improved rate of dose reductions and interruptions relative to the once daily dose.

In September 2021, new data was presented at the ESMO meeting that took place in Paris. Cohort 4 of the ZENITH20 clinical trial is enrolling treatment-naïve NSCLC patients with HER2 exon 20 insertion mutations. This cohort is investigating the efficacy of poziotinib with a once daily ("QD") and twice daily ("BID") (ongoing) dosing strategy. Poziotinib 16mg was administered orally once daily for the first 48 patients allowing dose reductions/interruptions for toxicity. For these first 48 patients that were dosed at the 16mg once per day dose, the ORR was 44%. The disease control rate was 75%. The median duration of response was 5.4 months and the median progression free survival was 5.6 months. 88% of patients had dose interruptions and 77% had reductions from the 16mg QD starting dose, while 13% had AE related discontinuations. The most common treatment related adverse events were typical of TKIs and what we've seen in prior studies. Grade 3 AEs were rash, stomatitis, diarrhea, and paronychia. Importantly, Grade 3 pneumonitis was only seen in one patient. In general, the safety profile was manageable. Following these first 48 patients, we are now dosing patients at the 8mg BID dosing schedule.

Anti-CD20-IFNα:

In April 2019, we executed a license agreement with ImmunGene for an antibody-interferon fusion molecule directed against CD20 (Anti-CD20-IFNα) that is in Phase 1 development for treating relapsed or refractory non-Hodgkin's lymphoma ("NHL"), This technology is designed to selectively target NHL with therapeutic doses of IFNa, while minimizing systemic toxicity. Under the terms of this agreement, we received the exclusive worldwide rights to commercialize this drug for any indication, and are financially responsible for the clinical and regulatory development programs.

Components of Operating Results

See *Item 7. Components of Operating Results* of our Annual Report on Form 10-K for the year ended December 31, 2020, for a discussion of the nature of our revenue and operating expense line items within our accompanying Condensed Consolidated Statements of Operations.

Critical Accounting Policies and Estimates

See *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates* of our Annual Report on Form 10-K for the year ended December 31, 2020, for a discussion of significant estimates and assumptions made by our management as part of the preparation of our accompanying Condensed Consolidated Financial Statements. These critical accounting policies and estimates arise in conjunction with the following accounts in the preparation of this Form 10-Q:

- Revenue recognition;
- Property and equipment, net;
- Stock-based compensation; and
- Research and development costs.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2021 and 2020

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2021	2020	$	%	2021	2020	$	%
	(in thousands)		(in thousands)		($ in thousands)		(in thousands)	
Operating costs and expenses:								
Selling, general and administrative	$ 12,243	$ 15,116	$ (2,873)	(19.0)%	$ 41,515	$ 44,654	$ (3,139)	(7.0)%
Research and development	20,850	24,453	(3,603)	(14.7)	69,335	62,192	7,143	11.5
Total operating costs and expenses	33,093	39,569	(6,476)	(16.4)	110,850	106,846	4,004	3.7
Loss from continuing operations before other income (expense) and income taxes	(33,093)	(39,569)	6,476	(16.4)	(110,850)	(106,846)	(4,004)	3.7
Interest income, net	11	188	(177)	(94.1)	121	1,217	(1,096)	(90.1)
Other income (expense), net	9	(9,131)	9,140	(100.1)	(7,948)	(15,720)	7,772	(49.4)
Total other income (expense)	20	(8,943)	8,963	(100.2)	(7,827)	(14,503)	6,676	(46.0)
Loss from continuing operations before income taxes	(33,073)	(48,512)	15,439	(31.8)	(118,677)	(121,349)	2,672	(2.2)
Provision for income taxes from continuing operations	—	(6)	6	(100.0)	(9)	(15)	6	(40.0)
Loss from continuing operations	(33,073)	(48,518)	15,445	(31.8)	(118,686)	(121,364)	2,678	(2.2)
Income (loss) from discontinued operations, net of income taxes	(11)	66	(77)	(116.7)	(227)	255	(482)	(189.0)
Net loss	$ (33,084)	$ (48,452)	$ 15,368	(31.7)%	$ (118,913)	$ (121,109)	$ 2,196	(1.8)%

Quarterly Discussion

***Selling, General and Administrative*.** Selling, general and administrative expense decreased by $2.9 million in the current year period, primarily related to $0.8 million of decreased IT infrastructure and system expenses and $1.6 million of decreased professional and outside service expenses as a result of a reduction in audit and consultancy fees.

Research and Development. Research and development expenses decreased by $3.6 million in the current period, primarily due to decreased program activities of $6.3 million for Rolontis, partially offset by $2.2 million of increased Poziotinib process development and testing expenses and $0.6 million of increased personnel-related expenses.

Total Other Income (Expense). Total other income (expense) increased by $9.0 million due to $9.0 million of unrealized gains recorded from our equity holdings compared to the prior year period.

Year to Date Discussion

***Selling, General and Administrative*.** Selling, general and administrative expenses decreased $3.1 million in the current year period, primarily related to $2.8 million of decreased professional and outside service expenses as a result of a reduction in audit and consultancy fees and $0.3 million of decreased personnel related expense compared to the prior period.

Research and Development. Research and development expenses increased by $7.1 million in the current period, primarily due to (i) increased program activities of $9.0 million for poziotinib, and (ii) $3.7 million of increased personnel-related expenses. These increases were partially offset by (i) $4.7 million of decreased program activities for Rolontis, and (ii) $1.6 million of decreased spend related to our early stage compounds.

Total Other Expense. Total other expense decreased by $6.7 million in the current year period primarily due to an increase of (i) $3.2 million in the market value of our equity holdings, (ii) $3.9 million of realized gains from the sale of our equity holdings, (iii) $0.2 million of gains from our life insurance policies, and (iv) $0.5 million of lower currency exchange losses, compared to the prior year period. These gains were partially offset by $1.1 million of lower interest income from our investments.

Liquidity and Capital Resources

We believe that our $133.6 million in aggregate cash, cash equivalents and marketable securities as of September 30, 2021, will be sufficient to fund our current and planned operations for at least the next twelve months. We may however, require additional liquidity as we continue to execute our business strategy, and in connection with opportunistic acquisitions or licensing arrangements. We anticipate that to the extent that we require additional liquidity, it will be funded through additional equity or debt financings, or out-licensing arrangements. However, we cannot provide assurance that we will be able to obtain this additional liquidity on terms favorable to us or our current stockholders, if at all. Additionally, our liquidity and our ability to fund our capital requirements are also dependent on our future financial performance which is subject to various market and economic factors that are beyond our control.

Net Cash Used In Operating Activities

Net cash used in operating activities was $89.1 million for the nine months ended September 30, 2021, as compared to $88.3 million in the prior year period. This increase in net cash used in operating activities was primarily related to increased research and development program spend.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was $97.5 million for the nine months ended September 30, 2021, as compared to $16.2 million during the prior year period. The cash provided by investing activities for the first nine months of 2021 primarily relates to $109.8 million of proceeds from maturities of our investments and $4.4 million of proceeds received from the sale of our equity holdings. This cash received was partially offset by $16.6 million of purchased investments and $0.1 million of purchased property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $53.1 million for the nine months ended September 30, 2021, as compared to $84.9 million during the prior year period. Our cash provided by financing activities for the first nine months of 2021 primarily relates to $52.6 million of proceeds from shares of common stock sold pursuant to an at-the-market sales agreement and $0.5 million of proceeds from employee stock purchases under our employee stock purchase plan.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements during the periods presented, nor do we currently have any, as defined under SEC rules.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. The term "disclosure controls and procedures," as defined in *Rules 13a-15(e) and 15d-15(e)* under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. These include controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our chief executive officer and chief financial officer concluded that, as of that date, our disclosure controls and procedures were effective.

Changes in Internal Controls Over Financial Reporting

There has been no change in our internal controls over financial reporting (as defined in *Rules 13a-15(f) and 15d-15(f)* under the Exchange Act) during the third fiscal quarter of 2021 that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

Limitations on Ensuring the Effectiveness of Internal Controls

An internal control system, no matter how well conceived and operated, cannot provide more than reasonable assurance that its objectives are completely met due to inherent limitations. Accordingly, no evaluation can provide absolute assurance that all internal control issues within a company have been detected. As part of our ongoing activities, we continuously seek to improve the efficiency and effectiveness of our business operations and accompanying internal controls.

Part II. Other Information

Item 1. Legal Proceedings

We are involved from time-to-time with various legal matters arising in the ordinary course of business. These claims and legal proceedings are of a nature we believe are normal and incidental to a pharmaceutical business, and may include product liability, intellectual property, employment matters, and other general claims. We may also be subject to derivative lawsuits from time to time.

We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are assessed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a

particular case. Litigation is inherently unpredictable. Although the ultimate resolution of these various matters cannot be determined at this time, we do not believe that such matters, individually or in the aggregate, will have a material adverse effect on our consolidated results of operations, cash flows, or financial condition.

Certain of the legal proceedings in which we are involved are discussed in *Note 6(g)*, "Financial Commitments and Contingencies and Key License Agreements," to our accompanying Condensed Consolidated Financial Statements, and are hereby incorporated by reference.

Item 1A. Risk Factors

Except as set forth below, as of the date of this filing, there have been no material changes to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 31, 2021, and our Quarterly Report on Form 10-Q for the period ended June 30, 2021, as filed with the SEC on August 12, 2021.

Our supply of APIs and drug products is and will remain dependent upon the production capabilities of CMOs and other third-parties for related supplies and logistical services. Some of these vendors are based overseas. If our CMOs and other suppliers are not able to meet our requirements or FDA scrutiny, we may be unable to obtain approval for our products. Even if we do obtain approval for our products, we may be limited in our ability to meet demand for our products, ensure regulatory compliance, or maximize profit on the future sale of our products. Any manufacturing-related disruptions could create significant demand on our limited capital resources, and there can be no assurance that we would be able to continue as a going concern.

In addition, our dependence on these ex-U.S. vendors also subjects us to business interruption risks related to COVID-19, and/or similar outbreaks, which could have a material adverse impact on us.

We have no internal manufacturing capacity for APIs or our drug products. We therefore have entered into agreements with CMOs and other suppliers to supply us with APIs and our finished drug products. Success in the development and marketing of our drug products depends, in part, upon our ability to maintain, expand and enhance these existing relationships and establish new sources of supply. The manufacture of APIs and finished drug products, including the acquisition of compounds used in the manufacture of the finished drug products, may require considerable lead times. We have little or no control over the production processes of third-party manufacturers, CMOs or other suppliers. Some of the third-party manufacturing facilities used in the production of APIs and our drug products are located outside of the U.S. and require FDA approval, which they may have limited experience with obtaining. Our CMOs and other suppliers are subject to inspection by the FDA and may receive observations that they may not be able to resolve in a timely or effective manner, which could impact whether our products can be approved on a timely basis, if at all. We recently received a Complete Response Letter from the FDA for our Rolontis BLA that cited various manufacturing deficiencies at our API and our fill-and-finish suppliers. There is no guarantee that the remediation efforts will be found to be acceptable by the FDA.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of manufacturing and testing techniques, process controls, and scaling of production to meet commercial requirements. Manufacturers of pharmaceutical products often encounter difficulties during preparation for production, including technical challenges production costs, yields, quality control and assurance. If manufacturing deficiencies are noted by the FDA at any of the manufacturing facilities utilized in our products, there can be no assurance that we, or our CMOs, can resolve these manufacturing deficiencies on a timely basis, if at all. Any manufacturing-related disruptions could create significant demand on our limited capital resources, and there can be no assurance that we would be able to continue as a going concern.

Our ability to source APIs and drug products is also dependent on providers of logistical services who may be subject to disruptions that we cannot predict or sufficiently plan around. Accordingly, while we do not currently anticipate shortages of supply, circumstances could arise in which we will not have adequate supplies to timely meet our requirements or market demand for a particular drug product could outstrip the ability of our supply source to timely manufacture and deliver the product, thereby causing us to lose sales. In addition, our ability to make a profit on the sale of our drug products depends on our ability to obtain favorable pricing for these arrangements.

If problems arise during the manufacture of a batch of our drug products, that batch of product may have to be discarded. This could, among other things, lead to increased costs, lost revenue, damage to customer relations, time and expense spent investigating the cause of the problem and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred. To the extent that one of our suppliers experiences significant manufacturing problems, this could have a material adverse effect on our revenues and profitability.

Reliance on CMOs entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance and adherence to the FDA's current Good Manufacturing Practice ("cGMP") requirements, the possible breach of the manufacturing agreement by the CMO and the possibility of termination or non-renewal of the agreement by the CMO, based on its own business priorities, at a time that is costly or inconvenient for us. Before we can obtain marketing approval for our drug products, our CMO facilities must be approved by the FDA and typically pass a pre-approval inspection. In order to obtain FDA approval, the FDA must conclude that all of the suppliers' manufacturing methods, equipment and processes comply with cGMP requirements.

The cGMP requirements govern organization and personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling control, holding and distribution, laboratory controls, records and reports, and returned and salvaged drug products. In addition, our CMOs will be subject to on-going periodic inspection by the FDA and corresponding state and foreign agencies for compliance with their cGMP requirements, regulations and other regulatory standards. We do not have control over our CMOs' compliance with these regulations and standards. Any failure of our third party manufacturers or us to comply with applicable regulations, including an FDA pre-approval inspection, periodic on-going inspection by the FDA and cGMP requirements, could result in sanctions being imposed on them or us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operation restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

Finally, our business could be adversely impacted by the effects of the COVID-19 pandemic, or by other public health emergencies. We source some of our APIs and other materials from Asia, including China and South Korea. Due to our current reliance on these vendors for ROLONTIS and poziotinib supply, we risk disruption in our supply chain (including restrictions on export or shipment), depending on the severity of the coronavirus outbreak and the potential government restrictions placed on our vendors or their transports.

If our suppliers fail to deliver materials and services needed for commercial manufacturing in a timely and sufficient manner or fail to comply with applicable regulations, and if we fail to timely identify and qualify alternative suppliers, our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities could decline.

We must rely on all of our suppliers to comply with relevant regulatory and other legal requirements, including the production of API in accordance with the FDA's cGMP for drug products. Although we conduct our own inspections and review and/or approve investigations of each supplier, there can be no assurance that the FDA, upon inspection, would find that the supplier is complying with the cGMP requirements, where applicable. If a supplier fails to comply with these requirements or the comparable requirements in foreign countries, regulatory authorities may subject them or us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products. If we are required to find a new or additional supplier, we will need to evaluate that supplier's ability to provide material that meets regulatory requirements, including cGMP requirements, as well as our specifications and quality requirements, which would require significant time and expense and could delay the production of our drug products. In general, if any of our suppliers is unwilling or unable to meet its supply obligations or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, and we are unable to secure an alternative supply source in a timely manner and on favorable terms, our business, financial condition, and results of operations may be harmed and the market price of our common stock may decline.

The ongoing COVID-19 pandemic and the future outbreak of other highly infectious or contagious diseases, could materially and adversely impact or disrupt our business and our financial condition, results of operations, cash flows and performance.

The global health crisis caused by the COVID-19 pandemic and its resurgences has and may continue to negatively impact global economic activity, which, despite progress in vaccination efforts, remains uncertain and cannot be predicted with confidence. In addition, a new Delta variant of COVID-19, which appears to be the most transmissible variant to date, has begun to spread globally. The impact of the Delta variant cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines against the Delta variant, and the response by governmental bodies and regulators. The ongoing COVID-19 pandemic has impacted our business and will likely continue to impact our business directly and/or indirectly for the foreseeable future.

We have maintained our operations during the COVID-19 pandemic by requiring most of our employees to work remotely. Only those employees performing essential activities that must be completed on-site are allowed in our facilities. These modifications to business activity may negatively impact productivity and cause disruptions and delays to our business. Longer term remote working environments could increase our cyber security risk, create data accessibility concerns, and make

us more susceptible to communication disruptions. When we reopen our facilities, we could encounter delays in connection with implementing precautionary measures to mitigate the risk of exposing our employees to COVID-19.

Although the COVID-19 pandemic has not materially affected our clinical development programs to date, certain of our clinical programs have seen slower enrollment and there have also been delays in initiating new studies as a result of the COVID-19 pandemic. These delays are not seen across all our trials and are specific to certain trials enrolling at certain sites. In the future, the COVID-19 pandemic could further adversely affect our ability to enroll and recruit patients in current and future clinical trials, as well as delay data collection and analysis, any of which could cause a delay or denial of regulatory approval of our product candidates. Our success is dependent on our ability to advance our development programs into later stages of clinical development. Many pharmaceutical and biotechnology companies have indicated that their clinical trials will be delayed and enrollment of current and ongoing trials will suffer as a result of the COVID-19 pandemic. We anticipate the potential for delays in the initiation and enrollment of planned clinical trials until the pandemic resolves.

The COVID-19 pandemic, including the more contagious Delta variant of COVID-19, could also potentially affect the business of the FDA as well as other health regulatory authorities, which may have slower response times or be under-resourced and, as a result, review, inspection, and other timelines may be materially delayed. This could result in delays in our communications with these authorities and ultimately in the ability for us and our partners to have drug products approved. In 2020 and 2021, a number of companies announced receipt of Complete Response Letters due to COVID-19 related issues including the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review or inspections resulting from such disruptions could materially affect the development and study of our drug candidates.

On October 26, 2020, we announced that the FDA had deferred action on the BLA for ROLONTIS due to its inability to conduct an inspection of the Hanmi manufacturing facility in South Korea as a result of travel restrictions associated with the COVID-19 pandemic. In early June 2021, the FDA conducted the pre-approval inspection of the Hanmi manufacturing facility. In August 2021, we received a Complete Response Letter from the FDA regarding our BLA, citing deficiencies related to manufacturing and indicating that a reinspection will be necessary. We are currently working on remediating the manufacturing deficiencies and expect that this work will be complete in the fourth quarter of 2021 and plan to resubmit thereafter. However, we cannot guarantee that we, together with our contract manufacturers, will be able to remediate the cited deficiencies in a timely manner, or at all, and we cannot predict whether the COVID-19 pandemic will again delay or even prevent the FDA from completing any reinspections that may be required in connection with a resubmission of the BLA for ROLONTIS.

The COVID-19 pandemic could also adversely affect our supply chain for other third party vendors for research supplies, development activities including manufacturing of drug product for our clinical studies and testing of drug material. If any of the vendors in our supply chain of products or services are severely affected from the COVID-19 pandemic, it will adversely affect our ability to continue our research and development activities and also continue our clinical trial activities. Disruptions to our business operations or operations of our third-party manufacturers and CROs on which we rely to conduct our clinical trials could be significant and of undetermined length. Significant restrictions or bans on travel could impede, delay, limit or prevent our employees and CROs from continuing research and development activities.

The COVID-19 pandemic, including the recent Delta variant, and mitigation measures have continued to adversely impact global economic conditions which could have an adverse effect on our business and financial condition, including impairment of our ability to raise capital when needed. The trading prices for biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. In addition, the continued spread of COVID-19 could cause a recession, depression, or other sustained adverse market event which could materially and adversely affect our business and the value of our common shares. In particular, it is unclear how our business may be affected by the emergence of new variants of COVID-19, such as the Delta variant, and recent resurgence in number and rates of COVID-19 infections. Furthermore, to the extent the ongoing COVID-19 pandemic adversely affects our operations and business, it may also heighten the other risks described in our Annual Report on Form 10-K for the year ended December 31, 2020, and other filings that we have made with the SEC.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	Form No.	Exhibit	Filing Date	
2.1	Asset Purchase Agreement, dated January 17, 2019, by and among Spectrum Pharmaceuticals, Inc., Acrotech Biopharma LLC and Aurobindo Pharma USA, Inc.	8-K	001-35006	10.1	1/17/2019	
3.1	Restated Certificate of Incorporation.	8-K	001-35006	3.1	6/18/18	
3.2	Third Amended and Restated Bylaws	8-K	001-35006	3.1	3/29/2018	
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) promulgated under the Securities Exchange Act of 1934.					X
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a) promulgated under the Securities Exchange Act of 1934.					X
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b)/15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.					X
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b)/15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.					X
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.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101 filed herewith).					

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.

SPECTRUM PHARMACEUTICALS, INC.

Date: November 10, 2021

By: /s/ Kurt A. Gustafson
Kurt A. Gustafson
Executive Vice President and Chief Financial Officer
(Authorized Signatory and Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Joseph W. Turgeon, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Spectrum Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 10, 2021

/s/ JOSEPH W. TURGEON

Joseph W. Turgeon
President and Chief Executive Officer
(Chief Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Kurt A. Gustafson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Spectrum Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 10, 2021

/s/ Kurt A. Gustafson

Kurt A. Gustafson
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Joseph W. Turgeon, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report of Spectrum Pharmaceuticals, Inc. on Form 10-Q for the quarterly period ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents in all material respects the financial condition and results of operations of Spectrum Pharmaceuticals, Inc.

Date: November 10, 2021

By: /s/ JOSEPH W. TURGEON
Name: Joseph W. Turgeon
Title: Chief Executive Officer and President

This certification accompanies the Report pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities and Exchange Act of 1934, or otherwise subject to the liability of that section. This certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, or, the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporated by reference.

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Kurt A. Gustafson, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report of Spectrum Pharmaceuticals, Inc. on Form 10-Q for the quarterly period ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents in all material respects the financial condition and results of operations of Spectrum Pharmaceuticals, Inc.

Date: November 10, 2021

By: /s/ Kurt A. Gustafson
Name: Kurt A. Gustafson
Title: Executive Vice President and Chief Financial Officer

This certification accompanies the Report pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities and Exchange Act of 1934, or otherwise subject to the liability of that section. This certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, or, the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporated by reference.