

**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 March 31, 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 <small>(State or other jurisdiction of incorporation or organization)</small>			93-0979187 <small>(I.R.S. Employer Identification No.)</small>
11500 South Eastern Avenue <small>(Address of principal executive offices)</small>	Suite 240	Henderson Nevada	89052 <small>(Zip Code)</small>

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

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

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

As of May 10, 2021, 161,520,572 shares of the registrant's common stock were outstanding.

Spectrum Pharmaceuticals, Inc.
Quarterly Report on Form 10-Q
For the Three Months Ended March 31, 2021

TABLE OF CONTENTS

<u>Item</u>		<u>Page</u>
PART I. FINANCIAL INFORMATION		
Item 1.	Financial Statements (unaudited):	
	Condensed Consolidated Balance Sheets	3
	Condensed Consolidated Statements of Operations	4
	Condensed Consolidated Statements of Comprehensive Loss	5
	Condensed Consolidated Statements of Stockholders' Equity	6
	Condensed Consolidated Statements of Cash Flows	7
	Notes to Condensed Consolidated Financial Statements	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	25
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	30
Item 4.	Controls and Procedures	30
PART II. OTHER INFORMATION		
Item 1.	Legal Proceedings	30
Item 1A.	Risk Factors	31
Item 6.	Exhibits	32
	Signatures	33

Items 2 through 5 of Part II have been omitted because they are not applicable with respect to the current reporting period.

SPECTRUM PHARMACEUTICALS, INC. ®, and *ROLONTIS*® are registered trademarks of Spectrum Pharmaceuticals, Inc. and its affiliates. *REDEFINING CANCER CARE*™ and the Spectrum Pharmaceuticals' logos are trademarks owned by Spectrum Pharmaceuticals, Inc. Any other trademarks are the property of their respective owners.

Part I: Financial Information**Item 1: Financial Statements**

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

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 69,521	\$ 46,009
Marketable securities	93,336	134,016
Accounts receivable, net	64	67
Other receivables	2,795	2,394
Prepaid expenses and other current assets	3,491	4,161
Total current assets	169,207	186,647
Property and equipment, net	3,613	3,577
Facility and equipment under lease	1,824	2,247
Other assets	4,363	4,327
Total assets	\$ 179,007	\$ 196,798
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 42,412	\$ 43,771
Accrued payroll and benefits	4,967	9,375
Total current liabilities	47,379	53,146
Other long-term liabilities	9,189	9,409
Total liabilities	56,568	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; 153,728,336 and 146,083,110 issued and outstanding at March 31, 2021 and December 31, 2020, respectively	154	146
Additional paid-in capital	1,046,784	1,021,221
Accumulated other comprehensive loss	(3,507)	(1,829)
Accumulated deficit	(920,992)	(885,295)
Total stockholders' equity	122,439	134,243
Total liabilities and stockholders' equity	\$ 179,007	\$ 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	
	March 31,	
	2021	2020
Revenues	\$ —	\$ —
Operating costs and expenses:		
Selling, general and administrative	14,315	14,794
Research and development	19,371	15,993
Total operating costs and expenses	33,686	30,787
Loss from continuing operations before other income (expense) and income taxes	(33,686)	(30,787)
Other income (expense):		
Interest income, net	84	704
Other expense, net	(2,081)	(10,534)
Total other expense	(1,997)	(9,830)
Loss from continuing operations before income taxes	(35,683)	(40,617)
Benefit for income taxes from continuing operations	7	—
Loss from continuing operations	\$ (35,676)	\$ (40,617)
(Loss) income from discontinued operations, net of income taxes	(21)	45
Net loss	\$ (35,697)	\$ (40,572)
Basic and diluted loss per share:		
Loss from continuing operations	\$ (0.25)	\$ (0.36)
(Loss) income from discontinued operations	\$ 0.00	\$ 0.00
Net loss per share, basic and diluted	\$ (0.25)	\$ (0.36)
Weighted average shares outstanding, basic and diluted	145,371,657	111,780,571

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	
	March 31,	
	2021	2020
Net loss	\$ (35,697)	\$ (40,572)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities, net of tax	(1,118)	(914)
Foreign currency translation adjustments	(560)	(415)
Other comprehensive loss	(1,678)	(1,329)
Total comprehensive loss	<u>\$ (37,375)</u>	<u>\$ (41,901)</u>

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	<u>153,728,336</u>	<u>\$ 154</u>	<u>\$ 1,046,784</u>	<u>\$ (3,507)</u>	<u>\$ (920,992)</u>	<u>\$ 122,439</u>

	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	<u>114,774,079</u>	<u>\$ 114</u>	<u>\$ 923,480</u>	<u>\$ (4,827)</u>	<u>\$ (764,999)</u>	<u>\$ 153,768</u>

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2021	2020
Cash Flows From Operating Activities:		
Loss from continuing operations	\$ (35,676)	\$ (40,617)
(Loss) income from discontinued operations, net of income taxes	(21)	45
Net loss	(35,697)	(40,572)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	65	140
Stock-based compensation	4,212	5,275
Non-cash lease expense	401	381
Other non-cash items	68	(51)
Realized gain on sale of equity holdings	(2,856)	(189)
Unrealized loss on equity holdings	4,999	10,238
Changes in operating assets and liabilities:		
Other receivables	(324)	762
Prepaid expenses and other current assets	670	(960)
Other assets	(36)	823
Accounts payable and other accrued liabilities	(1,681)	(3,919)
Accrued payroll and benefits	(4,408)	(3,118)
Other long-term liabilities	96	(2,153)
Net cash used in operating activities	(34,491)	(33,343)
Cash Flows From Investing Activities:		
Proceeds from maturities of investments	49,823	50,966
Proceeds from sale of equity holdings	2,858	—
Purchases of investments	(15,964)	(10,208)
Purchases of property and equipment, net	(73)	(1,395)
Net cash provided by investing activities	36,644	39,363
Cash Flows From Financing Activities:		
Proceeds from sale of common stock under an at-the-market sales agreement, net	21,357	—
Net cash provided by financing activities	21,357	—
Effect of exchange rates on cash and cash equivalents	2	(86)
Net increase in cash and cash equivalents	23,512	5,934
Cash and cash equivalents—beginning of period	46,009	64,418
Cash and cash equivalents—end of period	\$ 69,521	\$ 70,352
Supplemental disclosure of cash flow information:		
Cash paid for facility and equipment under operating leases	\$ 620	\$ 593
Cash paid for income taxes	\$ 4	\$ —
Noncash investing activities:		
Additions of property and equipment that remain in accounts payable and other accrued liabilities	\$ 27	\$ 2,772

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 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, which is under review by the U.S. Food and Drug Administration (the “FDA”). On October 26, 2020, the Company announced that the FDA had deferred action on the 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 March 2021, the FDA scheduled the pre-approval inspection of the Hanmi manufacturing facility for May 2021;
- Pozotinib, 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-IFN α , 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 months ended March 31, 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 months ended March 31, 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

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

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.

(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 months ended March 31, 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) gross-to-net revenue adjustments; (ii) the timing of revenue recognition; (iii) the collectability of customer accounts; (iv) whether the cost of our inventories can be recovered; (v) the realization of our tax assets and estimates of our tax liabilities; (vi) the fair value of our investments; (vii) the valuation of our stock options and the periodic expense recognition of stock-based compensation; and (viii) 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

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

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

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

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

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

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.

In June 2016, the Financial Accounting Standards Board (“FASB”) issued *ASU No. 2016-13 (“ASU 2016-13”) “Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments”*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. This new ASU replaces the existing incurred loss impairment model with a current expected credit loss model (“CECL”), which requires the use of forward-looking information to calculate credit loss estimates. The new CECL model requires recognition of credit losses for loans and other receivables at the time the financial asset is originated or acquired, in which the expected credit losses are adjusted each period for changes in expected lifetime credit losses. The new standard also applies to receivables arising from revenue transactions such as contract assets and accounts receivables and requires credit losses related to certain available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. We adopted *ASU 2016-13* as of January 1, 2020, which did not have a material effect on our accompanying Condensed Consolidated Financial Statements.

(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.

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

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

In August 2018, the FASB issued ASU No. 2018-15, “Intangibles – Goodwill and other – Internal-Use Software (Subtopic 350-40)”, which amended its guidance for costs of implementing a cloud computing service arrangement and aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software, and to expense such capitalized implementation costs over the term of the hosting arrangement. The guidance is effective for fiscal years beginning after December 15, 2019, with early adoption permitted. On January 1, 2020, we adopted this standard on a prospective basis for applicable implementation costs, which did not have a material impact on our accompanying Condensed Consolidated Financial Statements.

(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 dilutive stock options, warrants, and other common stock equivalents outstanding during the period.

(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.

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

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. Based upon this early adoption, we were not required to calculate an income tax benefit (provision) for the three months ended March 31, 2021 and 2020, respectively.

(x) Research and Development Expenses

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:

	March 31, 2021 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	\$ 60,216	\$ —	\$ —	\$ 60,216
Equity securities	18,136	—	—	18,136
Government-related debt securities	60,248	—	—	60,248
Corporate debt securities	—	8,836	—	8,836
Bank CDs	—	737	—	737
Mutual funds	5,379	9	—	5,388
Key employee life insurance, cash surrender value ⁽¹⁾	—	4,039	—	4,039
	<u>\$ 143,979</u>	<u>\$ 13,621</u>	<u>\$ —</u>	<u>\$ 157,600</u>
Liabilities:				
Deferred executive compensation liability ⁽²⁾	\$ —	\$ 9,709	\$ —	\$ 9,709
	<u>\$ —</u>	<u>\$ 9,709</u>	<u>\$ —</u>	<u>\$ 9,709</u>

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

⁽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 \$1.2 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.

	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
	<u>\$ 164,007</u>	<u>\$ 14,541</u>	<u>\$ —</u>	<u>\$ 178,548</u>
Liabilities:				
Deferred executive compensation liability ⁽²⁾	\$ —	\$ 9,783	\$ —	\$ 9,783
	<u>\$ —</u>	<u>\$ 9,783</u>	<u>\$ —</u>	<u>\$ 9,783</u>

⁽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.

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 March 31, 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	Foreign Currency Translation	Unrealized Gains	Fair Value	Cash and Cash Equivalents	Marketable Securities
March 31, 2021						
Money market funds	\$ 60,216	\$ —	\$ —	\$ 60,216	\$ 60,216	\$ —
Equity securities ⁽¹⁾	3,537	(2,097)	16,696	18,136	—	18,136
Government-related debt securities	60,236	—	12	60,248	—	60,248
Corporate debt securities	8,836	—	—	8,836	—	8,836
Mutual funds	4,346	—	1,033	5,379	—	5,379
Bank CDs	735	—	2	737	—	737
Bank deposits	9,305	—	—	9,305	9,305	—
Total cash and cash equivalents and marketable securities	<u>\$ 147,211</u>	<u>\$ (2,097)</u>	<u>\$ 17,743</u>	<u>\$ 162,857</u>	<u>\$ 69,521</u>	<u>\$ 93,336</u>
December 31, 2020						
Money market funds	\$ 40,560	\$ —	\$ —	\$ 40,560	\$ 40,560	\$ —
Equity securities	3,764	(1,546)	22,728	24,946	—	24,946
Government-related debt securities	92,881	—	47	92,928	—	92,928
Corporate debt securities	8,846	—	2	8,848	—	8,848
Mutual funds	4,497	—	1,076	5,573	—	5,573
Bank CDs	1,715	—	6	1,721	—	1,721
Bank deposits	5,449	—	—	5,449	5,449	—
Total cash and cash equivalents and marketable securities	<u>\$ 157,712</u>	<u>\$ (1,546)</u>	<u>\$ 23,859</u>	<u>\$ 180,025</u>	<u>\$ 46,009</u>	<u>\$ 134,016</u>

⁽¹⁾Our aggregate equity holdings consist of 7.6 million common shares of CASI Pharmaceuticals, Inc., a NASDAQ-listed biopharmaceutical company, as of March 31, 2021 which represented less than 10.0% ownership with a fair market value of \$18.1 million. We completed the sale of 0.9 million shares of common stock and recognized a \$2.6 million gain within “other expense, net” within the accompanying Condensed Consolidated Statements of Operations for the three months ended March 31, 2021.

(b) Other Receivables

“Other receivables” consists of the following:

	March 31, 2021	December 31, 2020
Other miscellaneous receivables	1,239	901
Income tax receivable - current portion	1,297	1,297
Interest receivable from marketable securities	259	196
Other receivables	<u>\$ 2,795</u>	<u>\$ 2,394</u>

(c) Prepaid Expenses and Other Current Assets

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

	March 31, 2021	December 31, 2020
Vendor deposits	\$ 2,022	\$ 1,996
Prepaid insurance	1,469	2,165
Prepaid expenses and other current assets	<u>\$ 3,491</u>	<u>\$ 4,161</u>

(d) Property and Equipment, net

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

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

	March 31, 2021	December 31, 2020
Manufacturing equipment	\$ 3,245	\$ 3,245
Computer hardware and software	1,779	1,680
Laboratory equipment	5	5
Leasehold improvements	1,267	1,267
Office furniture	248	248
Property and equipment, at cost	6,544	6,445
(Less): Accumulated depreciation	(2,931)	(2,868)
Property and equipment, net	<u>\$ 3,613</u>	<u>\$ 3,577</u>

Depreciation expense was immaterial for the three months ended March 31, 2021 and 2020, respectively.

Manufacturing equipment is comprised of our owned ROLONTIS production equipment on location at our contract manufacturer. This manufacturing equipment was not in use and therefore not being depreciated as of March 31, 2021. 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. 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:

	March 31, 2021	December 31, 2020
Trade accounts payable and other	\$ 33,578	\$ 34,385
Lease liability - current portion	1,415	1,544
Commercial Product Portfolio accruals	7,419	7,842
Accounts payable and other accrued liabilities	<u>\$ 42,412</u>	<u>\$ 43,771</u>

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	(361)	—	(62)	(423)
Balance as of March 31, 2021	<u>\$ 2,240</u>	<u>\$ 942</u>	<u>\$ 4,237</u>	<u>\$ 7,419</u>

Note 5. Stock-Based Compensation

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

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 months ended March 31, 2021 and 2020, as follows:

	Three Months Ended March 31,	
	2021	2020
Selling, general and administrative	\$ 2,798	\$ 3,877
Research and development	1,414	1,398
Total stock-based compensation	<u>\$ 4,212</u>	<u>\$ 5,275</u>

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 year to three 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. 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 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 March 31, 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 months ended March 31, 2021, we recognized no additional ROU assets in exchange for lease liabilities. As of March 31, 2020, we recognized \$5.3 million of ROU assets in exchange for \$5.3 million of 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.

Financial Reporting Captions

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

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

Operating Leases	Condensed Consolidated Balance Sheet Caption	March 31, 2021	December 31, 2020
Operating lease right-of-use assets - non-current	Facility and equipment under lease	\$ 1,824	\$ 2,247
Operating lease liabilities - current	Accounts payable and other accrued liabilities	1,415	1,544
Operating lease liabilities - non-current	Other long-term liabilities	567	883
Total operating lease liabilities		\$ 1,982	\$ 2,427

As of March 31, 2021 and December 31, 2020, our “facility and equipment under lease” consisted of office and research facilities of \$1.5 million and \$1.9 million, respectively, and office equipment of \$0.3 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 March 31,	
	2021	2020
Operating lease cost	\$ 466	\$ 466
Variable lease cost	125	114
Short-term lease cost	17	15
Total lease cost	\$ 608	\$ 595

Weighted Average Remaining Lease Term and Applied Discount Rate

	Weighted Average Remaining Lease Term	Weighted Average Discount Rate
Operating leases as of March 31, 2021	1.4 years	7.8%
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:

Operating Leases - future payments	March 31, 2021	
2021 (remaining)	\$	1,182
2022		828
2023		87
2024		—
2025		—
Total future lease payments, undiscounted	\$	2,097
(Less): Implied interest		(115)
Present value of operating lease payments	\$	1,982

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

Overview

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

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" 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 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.

In January 2016, the first patient was dosed with ROLONTIS in a clinical trial. This triggered our contractual milestone payment to Hanmi, and in April 2016, we issued 318,750 shares of our common stock to Hanmi. 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.

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

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-IFN α , 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.

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

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 March 31, 2021 and December 31, 2020, the aggregate value of this DC Plan liability was \$9.7 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.

Shareholder Litigation

Olutayo Ayeni v. Spectrum Pharmaceuticals, Inc., et al. (Filed September 21, 2016 in the United States District Court, Central District of California; Case No. 2:16-cv-07074) (the “Ayeni Action”) and *Glen Hartsock v. Spectrum Pharmaceuticals, Inc., et al.* (Filed September 28, 2016 in the United States District Court, District Court of Nevada Case; No. 2:16-cv-02279-RFB-GWF) (the “Hartsock Action”). On November 15, 2016, the Ayeni Action was transferred to the United States District Court for the District of Nevada (the “Court”). The parties have stipulated to a consolidation of the Ayeni Action with the

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

Hartscock Action. These class action lawsuits allege 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 New Drug Application to the FDA for QAPZOLA 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 July 23, 2019, we entered into a memorandum of understanding with these plaintiffs for a collective settlement pending court approval. Plaintiffs filed an unopposed motion for preliminary approval of the class action settlement on December 27, 2019, which was granted on February 19, 2020. Following notice of the settlement to the class, the Court granted final approval of the class action settlement on July 28, 2020. The settlement amount has been paid, and the Court dismissed the actions with prejudice on August 12, 2020.

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 “(loss) income from discontinued operations, net of income taxes” as reported in the accompanying Condensed Consolidated Statements of Operations:

	Three Months Ended March 31,	
	2021	2020
Revenues:		
Product sales, net	\$ —	\$ (220)
Total revenues	—	(220)
Operating costs and expenses:		
Cost of sales (excluding amortization of intangible assets)	—	(229)
Selling, general and administrative	—	(1)
Research and development	21	(35)
Total operating costs and expenses	21	(265)
(Loss) income from discontinued operations before income taxes	(21)	45
Provision for income taxes from discontinued operations	—	—
(Loss) income from discontinued operations, net of income taxes	\$ (21)	\$ 45

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 of allowance for credit losses” 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

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

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.

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

<u>Period in Which Issued</u>	<u>No. of Common Shares Issued</u>	<u>Proceeds Received (Net of Broker Commissions and Fees)</u>
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

Note 9. Subsequent Events

During April 2021 and through the date of this filing, we sold and issued 8.0 million shares of our common stock for net proceeds of \$23.9 million under the April 2019 ATM Agreement.

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, 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 on the timing of the completion of the FDA’s review of our Biologics License Application (“BLA”) of ROLONTIS;
- 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;
- the ability of our manufacturing partners 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;
- 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. On October 26, 2020, we announced that the FDA had deferred action on the 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 March 2021, the FDA scheduled the pre-approval inspection of the Hanmi manufacturing facility for May 2021. 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.

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, which is under review by the FDA. On October 26, 2020, the Company announced that the FDA had deferred action on the BLA for ROLONTIS due to the inability to conduct an inspection of the Hanmi third-party manufacturing facility in South Korea as a result of COVID-19 related travel restrictions. In March 2021, the FDA scheduled the pre-approval inspection of the Hanmi manufacturing facility for May 2021;
- 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-IFN α , 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

During the three months ended March 31, 2021, we continued our strategic shift in our business following the completion of the sale of our legacy Commercial Product Portfolio in March 2019. We also continued to make meaningful progress in the advancement of our product pipeline, as 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 March 2021, the FDA scheduled the pre-approval inspection of the Hanmi manufacturing facility for May 2021.

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 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% 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 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.

Anti-CD20-IFN α :

In April 2019, we executed a license agreement with ImmunGene for an antibody-interferon fusion molecule directed against CD20 (Anti-CD20-IFN α) that is in Phase 1 development for treating relapsed or refractory NHL. This technology is designed to selectively target NHL with therapeutic doses of IFN α , 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 Months Ended March 31, 2021 and 2020

	Three Months Ended March 31,		Change	
	2021	2020	\$	%
	(in thousands)		(in thousands)	
Revenues	\$ —	\$ —	\$ —	— %
Operating costs and expenses:				
Selling, general and administrative	14,315	14,794	(479)	(3.2)%
Research and development	19,371	15,993	3,378	21.1 %
Total operating costs and expenses	33,686	30,787	2,899	9.4 %
Loss from continuing operations before other income (expense) and income taxes	(33,686)	(30,787)	(2,899)	9.4 %
Interest income, net	84	704	(620)	(88.1)%
Other expense, net	(2,081)	(10,534)	8,453	(80.2)%
Total other expense	(1,997)	(9,830)	7,833	(79.7)%
Loss from continuing operations before income taxes	(35,683)	(40,617)	4,934	(12.1)%
Benefit for income taxes from continuing operations	7	—	7	— %
Loss from continuing operations	\$ (35,676)	\$ (40,617)	\$ 4,941	(12.2)%
(Loss) income from discontinued operations, net of income taxes	(21)	45	(66)	(146.7)%
Net loss	\$ (35,697)	\$ (40,572)	\$ 4,875	(12.0)%

Selling, General and Administrative. Selling, general and administrative expenses decreased by \$0.5 million in the current year period. This decrease primarily relates to (i) decreased legal costs of \$1.2 million, (ii) a decrease in stock-based compensation expense of \$0.9 million, and (iii) a decrease in travel expenses of \$0.4 million as a result of COVID-19, which has been ongoing since March 2020. These decreases were partially offset by \$1.6 million of increased deferred compensation expense given increases in the overall market compared to the prior year period, and \$0.5 million of increased information technology and consulting costs which were incurred in preparation for our planned commercial launch of ROLONTIS.

Research and Development. Research and development expenses increased by \$3.4 million in the current period, primarily due to (i) \$1.8 million of increased personnel-related expenses, and (ii) increased program activities of \$0.8 million for ROLONTIS, \$0.6 million for poziotinib, and \$0.3 million related to our early stage compounds.

Total Other Expense. Total other expense decreased by \$7.8 million primarily due to (i) \$5.2 million of increase in the market value of our equity holdings compared to the prior year period, (ii) \$2.7 million of realized gains recorded during the current period for the sale of our equity holdings, and (iii) \$0.5 million of increased value of our deferred compensation plan assets. These increases were partially offset by a \$0.6 million decrease in interest income and changes in value on certain investments.

Liquidity and Capital Resources

We believe that our \$162.9 million in aggregate cash, cash equivalents and marketable securities as of March 31, 2021, together with the net proceeds of subsequent period sales of shares of common stock under our at-the-market sales agreement through the date of this filing (Note 9), 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.

Net Cash Used In Operating Activities

Net cash used in operating activities was \$34.5 million for the three months ended March 31, 2021, as compared to \$33.3 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 \$36.6 million for the three months ended March 31, 2021, as compared to \$39.4 million during the prior year period. The cash provided by investing activities for the first three months of 2021 primarily relates to \$49.8 million of proceeds from maturities of our investments and \$2.9 million of proceeds received from the sale of our equity holdings. This cash received was partially offset by \$16.0 million of purchased investments and \$0.1 million of purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$21.4 million for the three months ended March 31, 2021, as compared to \$0 during the prior year period. Our cash provided by financing activities for the first three months of 2021 relates entirely to proceeds from shares of common stock sold pursuant to an at-the-market sales agreement.

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 March 31, 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 March 31, 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 first 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

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.

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 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).					X

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.

May 13, 2021

/s/ JOSEPH W. TURGEON

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

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.

May 13, 2021

/s/ Kurt A. Gustafson

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

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 March 31, 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: May 13, 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.

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 March 31, 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: May 13, 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.