

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

FORM 10-Q

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

For the quarterly period ended September 30, 2020



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

(State or other jurisdiction of incorporation or organization)

93-0979187

(I.R.S. Employer Identification No.)

11500 South Eastern Avenue
(Address of principal executive offices)

Suite 240 Henderson Nevada

89052
(Zip Code)

(702) 835-6300

(Registrant's telephone number, including area code)

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

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

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

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

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

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

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

As of October 31, 2020, 145,922,206 shares of the registrant's common stock were outstanding.

SPECTRUM PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2020

TABLE OF CONTENTS

<u>Item</u>		<u>Page</u>
	PART I. FINANCIAL INFORMATION	
Item 1.	Financial Statements (unaudited):	
	Condensed Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019	3
	Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2020 and 2019	4
	Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2020 and 2019	5
	Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2020 and 2019	6
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2020 and 2019	8
	Notes to Condensed Consolidated Financial Statements	10
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	29
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	35
Item 4.	Controls and Procedures	35
	PART II. OTHER INFORMATION	
Item 1.	Legal Proceedings	36
Item 1A.	Risk Factors	36
Item 6.	Exhibits	45
	Signatures	46

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

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PART I: FINANCIAL INFORMATION**ITEM 1: FINANCIAL STATEMENTS****SPECTRUM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and par value amounts)
(Unaudited)**

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 77,132	\$ 64,418
Marketable securities	121,179	159,455
Accounts receivable, net of allowance for credit losses of \$43 and \$43, respectively	453	441
Other receivables	3,186	9,558
Prepaid expenses and other current assets	10,876	10,148
Total current assets	212,826	244,020
Property and equipment, net	18,456	11,607
Facility and equipment under lease	2,662	3,806
Other assets	3,994	4,000
Total assets	\$ 237,938	\$ 263,433
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 52,985	\$ 54,284
Accrued payroll and benefits	8,113	7,686
Total current liabilities	61,098	61,970
Other long-term liabilities	8,480	11,070
Total liabilities	69,578	73,040
Commitments and contingencies (Note 8)		
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; 145,931,172 and 113,299,612 issued and outstanding at September 30, 2020 and December 31, 2019, respectively	146	113
Additional paid-in capital	1,016,474	918,205
Accumulated other comprehensive loss	(2,724)	(3,498)
Accumulated deficit	(845,536)	(724,427)
Total stockholders' equity	168,360	190,393
Total liabilities and stockholders' equity	\$ 237,938	\$ 263,433

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	\$ —	\$ —	\$ —	\$ —
Operating costs and expenses:				
Selling, general and administrative	15,116	13,126	44,654	46,308
Research and development	24,453	17,167	62,192	56,035
Total operating costs and expenses	39,569	30,293	106,846	102,343
Loss from continuing operations before other income (expense) and income taxes	(39,569)	(30,293)	(106,846)	(102,343)
Other income (expense):				
Interest income, net	188	1,521	1,217	4,076
Other income (expense), net	(9,131)	2,015	(15,720)	(5,547)
Total other income (expense)	(8,943)	3,536	(14,503)	(1,471)
Loss from continuing operations before income taxes	(48,512)	(26,757)	(121,349)	(103,814)
(Provision) benefit for income taxes from continuing operations	(6)	200	(15)	8,628
Loss from continuing operations	\$ (48,518)	\$ (26,557)	\$ (121,364)	\$ (95,186)
Income from discontinued operations, net of income taxes	66	572	255	21,547
Net loss	\$ (48,452)	\$ (25,985)	\$ (121,109)	\$ (73,639)
Basic and diluted loss per share:				
Loss from continuing operations	\$ (0.37)	\$ (0.24)	\$ (1.02)	\$ (0.86)
Income from discontinued operations	\$ 0.00	\$ 0.01	\$ 0.00	\$ 0.20
Net loss per share, basic and diluted	\$ (0.37)	\$ (0.23)	\$ (1.02)	\$ (0.67)
Weighted average shares outstanding, basic and diluted	131,455,727	111,178,880	118,664,914	110,291,090

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		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Net loss	\$ (48,452)	\$ (25,985)	\$ (121,109)	\$ (73,639)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net of tax	73	(7)	(61)	93
Foreign currency translation adjustments	457	(760)	835	(922)
Other comprehensive income (loss)	530	(767)	774	(829)
Total comprehensive loss	<u>\$ (47,922)</u>	<u>\$ (26,752)</u>	<u>\$ (120,335)</u>	<u>\$ (74,468)</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, 2019	113,299,612	\$ 113	\$ 918,205	\$ (3,498)	\$ (724,427)	\$ 190,393
Net loss	—	—	—	—	(40,572)	(40,572)
Other comprehensive loss, net	—	—	—	(1,329)	—	(1,329)
Recognition of stock-based compensation expense	—	—	5,010	—	—	5,010
Issuance of common stock to 401(k) plan for employees	96,959	—	265	—	—	265
Restricted stock award grants, net of forfeitures	1,377,508	1	—	—	—	1
Balance as of March 31, 2020	114,774,079	\$ 114	\$ 923,480	\$ (4,827)	\$ (764,999)	\$ 153,768
Net loss	—	—	—	—	(32,085)	(32,085)
Other comprehensive income, net	—	—	—	1,573	—	1,573
Recognition of stock-based compensation expense	—	—	3,988	—	—	3,988
Issuance of common shares pursuant to at-the-market offering	1,024,286	1	3,070	—	—	3,071
Issuance of common stock for employee stock purchase plan	98,362	—	282	—	—	282
Restricted stock award grants, net of forfeitures	1,926,385	3	(3)	—	—	—
Issuance of common stock upon vesting of restricted stock units	861	—	—	—	—	—
Balance as of June 30, 2020	117,823,973	\$ 118	\$ 930,817	\$ (3,254)	\$ (797,084)	\$ 130,597
Net loss	—	—	—	—	(48,452)	(48,452)
Other comprehensive income, net	—	—	—	530	—	530
Recognition of stock-based compensation expense	—	—	4,108	—	—	4,108
Issuance of common stock from public offering, net	24,916,667	25	69,708	—	—	69,733
Issuance of common shares pursuant to at-the-market offering, net	2,926,112	3	11,828	—	—	11,831
Issuance of common stock upon exercise of stock options	3,542	—	13	—	—	13
Restricted stock award grants, net of forfeitures	260,878	—	—	—	—	—
Issuance of common stock upon vesting of restricted stock units	—	—	—	—	—	—
Balance as of September 30, 2020	145,931,172	\$ 146	\$ 1,016,474	\$ (2,724)	\$ (845,536)	\$ 168,360

SPECTRUM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
CONTINUED
(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, 2018	110,525,141	\$ 110	\$ 886,740	\$ (3,702)	\$ (611,738)	\$ 271,410
Net loss	—	—	—	—	(19,259)	(19,259)
Other comprehensive loss, net	—	—	—	(390)	—	(390)
Recognition of stock-based compensation expense	—	—	7,481	—	—	7,481
Issuance of common stock to 401(k) plan for employees	47,347	—	519	—	—	519
Issuance of common stock upon exercise of stock options	146,785	—	831	—	—	831
Restricted stock award grants, net of forfeitures	259,539	1	—	—	—	1
Issuance of common stock upon vesting of restricted stock units	233,760	—	—	—	—	—
Balance as of March 31, 2019	111,212,572	\$ 111	\$ 895,571	\$ (4,092)	\$ (630,997)	\$ 260,593
Net loss	—	—	—	—	(28,395)	(28,395)
Other comprehensive income, net	—	—	—	328	—	328
Recognition of stock-based compensation expense	—	—	4,814	—	—	4,814
Issuance of common stock to 401(k) plan for employees	24,382	—	205	—	—	205
Issuance of common stock for employee stock purchase plan	60,606	—	444	—	—	444
Issuance of common stock upon exercise of stock options	504,226	—	3,023	—	—	3,023
Restricted stock award grants, net of forfeitures	651,072	1	—	—	—	1
Issuance of common stock upon vesting of restricted stock units	10,000	—	—	—	—	—
Issuance of common shares under an at-the-market sales agreement	221,529	—	1,814	—	—	1,814
Balance as of June 30, 2019	112,684,387	\$ 112	\$ 905,871	\$ (3,764)	\$ (659,392)	\$ 242,827
Net loss	—	—	—	—	(25,985)	(25,985)
Other comprehensive loss, net	—	—	—	(767)	—	(767)
Recognition of stock-based compensation expense	—	—	4,021	—	—	4,021
Issuance of common stock to 401(k) plan for employees	21,454	—	165	—	—	165
Issuance of common stock upon exercise of stock options	364,358	1	2,498	—	—	2,499
Restricted stock award grants, net of forfeitures	(81,493)	—	—	—	—	—
Refund of SEC fees in connection with an at-the-market sales agreement for our common shares	—	—	3	—	—	3
Balance as of September 30, 2019	112,988,706	\$ 113	\$ 912,558	\$ (4,531)	\$ (685,377)	\$ 222,763

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2020	2019
Cash Flows From Operating Activities:		
Loss from continuing operations	\$ (121,364)	\$ (95,186)
Income from discontinued operations, net of income taxes	255	21,547
Net loss	(121,109)	(73,639)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	(105)	1,487
Stock-based compensation	13,371	17,205
Recognized gain on Commercial Product Portfolio Transaction	—	(33,451)
Non-cash lease expense	1,148	1,313
Amortization of discount on investments in debt securities	84	(348)
Realized gain on mutual funds	(136)	—
Income tax recognition on unrealized gain on available-for-sale securities	—	(31)
Realized gain on sale of equity holdings	(542)	(2,674)
Unrealized loss on equity holdings	16,029	9,745
Unrealized loss (gain) from transactions denominated in foreign currency	501	(5)
Change in deferred tax liabilities	—	(1,469)
Change in fair value of contingent consideration	—	1,478
Changes in operating assets and liabilities:		
Accounts receivable, net	1	29,359
Other receivables	6,370	(4,068)
Inventories	—	(2,037)
Prepaid expenses and other current assets	(2,663)	(5,005)
Other assets	6	(1,428)
Accounts payable and other accrued liabilities	426	(35,233)
Accrued payroll and benefits	427	(3,378)
FOLOTYN development liability	—	(4)
Contract liabilities	—	(3,490)
Other long-term liabilities	(2,134)	2,234
Net cash used in operating activities	(88,326)	(103,439)
Cash Flows From Investing Activities:		
Proceeds from Commercial Product Portfolio Transaction	—	158,765
Proceeds from maturities of marketable securities	92,433	38,540
Proceeds from sale of equity holdings	1,843	5,074
Proceeds from sale of mutual funds	2,496	—
Purchases of marketable securities	(71,671)	(127,584)
Purchases of mutual funds	(1,910)	—
Purchases of property and equipment, net	(6,991)	(8,670)
Net cash provided by investing activities	16,200	66,125
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock, net of offering expenses	69,733	—
Proceeds from issuance of common stock pursuant to at-the-market offering	14,902	1,817
Proceeds from sale of stock under our employee stock purchase plan	283	444
Proceeds from employees for exercises of stock options	13	6,355
Net cash provided by financing activities	84,931	8,616
Effect of exchange rates on cash, cash equivalents and restricted cash	(91)	(144)
Net increase (decrease) in cash, cash equivalents and restricted cash	12,714	(28,842)
Cash, cash equivalents and restricted cash—beginning of period	64,418	157,480
Cash, cash equivalents and restricted cash—end of period	\$ 77,132	\$ 128,638
Supplemental disclosure of cash flow information:		
Cash paid for facility and equipment under operating leases	\$ 1,805	\$ 1,266
Cash paid for income taxes	\$ 14	\$ 38
Noncash investing activities:		
Additions of property and equipment that remain in accounts payable and other accrued liabilities	\$ 6,017	\$ 300

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)

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 biopharma 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 in the second half of 2020 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 BLA for ROLONTIS due to the inability to conduct an inspection of our third-party manufacturing facility in South Korea as a result of COVID-19 related travel restrictions;
- Poziotinib, a novel irreversible tyrosine kinase inhibitor under investigation for non-small cell lung cancer (“NSCLC”) tumors with various mutations; 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 (including diffuse large B-cell lymphoma).

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

(b) Basis of Presentation

Interim Financial Statements

The interim financial data for the three and nine months ended September 30, 2020 and 2019 is unaudited and is not necessarily indicative of our operating results for a full year. In the opinion of our management, the interim data includes normal and recurring adjustments necessary for a fair presentation of our financial results for the three and nine months ended September 30, 2020 and 2019. 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. 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, 2019 (filed with the SEC on March 2, 2020).

Discontinued Operations - Sale of our Commercial Product Portfolio

On March 1, 2019, we completed the sale of our seven then-commercialized drugs, including FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA (the “Commercial Product Portfolio”) to Acrotech Biopharma LLC (“Acrotech”) (the “Commercial Product Portfolio Transaction”). Upon closing, we received \$158.8 million in an upfront cash payment (of which \$4 million was held in escrow until November 2019). 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.

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

These Condensed Consolidated Financial Statements reflect the corresponding revenue-deriving activities and allocable expenses of this commercial business within “discontinued operations” (see *Note 10*). We have presented our face financial statements in general conformity with our historical format, even where presented values are \$-0- within continuing operations due to required discontinued operations classification for all periods presented. We believe this format provides increased clarity and comparability with our previously filed financial statements, as well as our expectation that these financial statement captions and associated footnote disclosures will remain relevant to our future business activities.

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. In May 2019, we dissolved Spectrum Pharma Canada Inc., previously consolidated as a “variable interest entity” (as defined under applicable GAAP).

(c) Operating Segment

We operate one reportable operating segment that is focused exclusively on developing (and eventually marketing) oncology and hematology drug products. For the three and nine months ended September 30, 2020 and 2019, all of our revenue 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).

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

On March 1, 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.

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

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

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

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

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

Product Returns Allowances: Our customers are contractually permitted to return certain purchased products within the contractual allowable time before/after its 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 its 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:

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

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

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

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

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

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

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

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

We consider whether revenue associated with these service arrangements is reportable each period, based on our completed services or deliverables (i.e., satisfied "performance obligations") during the reporting period, and the terms of the arrangement that contractually result in fixed payments due to us. The promised service(s) within these arrangements are distinct and explicitly stated within each contract, and our customer benefits from the separable service(s) delivery/completion. Further, the nature of the promise to our customer as stated within the respective contract is to deliver each named service

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

individually (not a transfer of combined items to which the promised goods or services are inputs), and thus are separable for revenue recognition.

(ii) Cash and Cash Equivalents

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

(iii) Marketable Securities

Marketable securities consist of our holdings in equity securities, mutual funds, bank CDs, government-related debt securities, and corporate debt securities. Since we classify these investments as “available-for-sale” any (1) realized gains (losses) or (2) unrealized gains (losses) on these securities are respectively recognized in (1) “other expense, net” on the accompanying Condensed Consolidated Statements of Operations, or (2) depending on the nature of the marketable securities recognized in “accumulated other comprehensive loss” as a separate component of stockholder’s equity on the accompanying Condensed Consolidated Statements of Stockholders’ Equity, or in “other income (expense), net” on the accompanying Condensed Consolidated Statements of Operations.

(iv) Accounts Receivable, Net of Allowance for Credit Losses

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 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 had no material effect on our accompanying Condensed Consolidated Financial Statements.

(v) 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 through our on-going operations.

In August 2018, the FASB issued Accounting Standards Update 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. The Company adopted this standard on a prospective basis for applicable implementation costs, which did not have a material impact on the Company’s consolidated financial statements.

(vi) 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)

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.

(vii) 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.

(viii) 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 have recorded a valuation allowance to reduce our deferred tax assets, 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.

(ix) Research and Development Costs

Our research and development costs are expensed as incurred or as certain milestone payments become contractually due to our licensors, as triggered by the achievement of clinical or regulatory events.

(x) 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.

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

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.

3. FAIR VALUE MEASUREMENTS

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

	September 30, 2020 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
<i>Assets:</i>				
Money market funds	\$ 59,923	\$ —	\$ —	\$ 59,923
Equity securities	14,129	—	—	14,129
Government-related debt securities	90,337	—	—	90,337
Corporate debt securities	—	16,485	—	16,485
Bank CDs	—	3,174	—	3,174
Mutual funds	4,553	9	—	4,562
Key employee life insurance, cash surrender value ⁽¹⁾	—	3,651	—	3,651
	<u>\$ 168,942</u>	<u>\$ 23,319</u>	<u>\$ —</u>	<u>\$ 192,261</u>
<i>Liabilities:</i>				
Deferred executive compensation liability ⁽²⁾	\$ —	\$ 8,376	\$ —	\$ 8,376
	<u>\$ —</u>	<u>\$ 8,376</u>	<u>\$ —</u>	<u>\$ 8,376</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 within other liabilities on our Condensed Consolidated Balance Sheets, and the amount is based on the period-end market value of mutual fund investments selected by employee participants of the deferred compensation plan.

	December 31, 2019 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
<i>Assets:</i>				
Government-related debt securities	\$ 47,636	\$ 14,990	\$ —	\$ 62,626
Corporate debt securities	—	58,248	—	58,248
Money market funds	54,199	—	—	54,199
Equity securities	31,047	—	—	31,047
Bank CDs	—	7,376	—	7,376
Mutual funds	5,158	11	—	5,169
Key employee life insurance, cash surrender value ⁽¹⁾	—	3,547	—	3,547
	<u>\$ 138,040</u>	<u>\$ 84,172</u>	<u>\$ —</u>	<u>\$ 222,212</u>
<i>Liabilities:</i>				
Deferred executive compensation liability ⁽²⁾	\$ —	\$ 8,746	\$ —	\$ 8,746
	<u>\$ —</u>	<u>\$ 8,746</u>	<u>\$ —</u>	<u>\$ 8,746</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.

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

⁽²⁾Included within other liabilities on our Condensed Consolidated Balance Sheets, and the amount is 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.

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 September 30, 2020, 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”:

	Historical or Amortized Cost	Foreign Currency Translation	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Marketable Securities
September 30, 2020							
Money market funds	\$ 59,923	\$ —	\$ —	\$ —	\$ 59,923	\$ 59,923	\$ —
Equity securities	5,008	(2,065)	11,186	—	14,129	—	14,129
Government-related debt securities	90,232	—	105	—	90,337	7,499	82,838
Corporate debt securities	16,470	—	15	—	16,485	—	16,485
Mutual funds	3,925	—	628	—	4,553	—	4,553
Bank CDs	3,156	—	18	—	3,174	—	3,174
Bank deposits	9,710	—	—	—	9,710	9,710	—
Total cash and cash equivalents and marketable securities	<u>\$ 188,424</u>	<u>\$ (2,065)</u>	<u>\$ 11,952</u>	<u>\$ —</u>	<u>\$ 198,311</u>	<u>\$ 77,132</u>	<u>\$ 121,179</u>
December 31, 2019							
Money market funds	\$ 54,199	\$ —	\$ —	\$ —	\$ 54,199	\$ 54,199	\$ —
Equity securities	6,310	(2,477)	27,214	—	31,047	—	31,047
Government-related debt securities	62,617	—	19	(10)	62,626	—	62,626
Corporate debt securities	58,235	—	38	(25)	58,248	5,000	53,248
Mutual funds	4,375	—	783	—	5,158	—	5,158
Bank CDs	7,354	—	22	—	7,376	—	7,376
Bank deposits	5,219	—	—	—	5,219	5,219	—
Total cash and cash equivalents and marketable securities	<u>\$ 198,309</u>	<u>\$ (2,477)</u>	<u>\$ 28,076</u>	<u>\$ (35)</u>	<u>\$ 223,873</u>	<u>\$ 64,418</u>	<u>\$ 159,455</u>

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

(b) Other Receivables

“Other receivables” consists of the following:

	September 30, 2020	December 31, 2019
Insurance receivable	\$ 74	\$ 4,015
CASI other receivables	—	2,393
Other miscellaneous receivables	1,393	1,490
Income tax receivable - current portion	1,297	973
Interest receivable from marketable securities	293	561
Reimbursements for incurred research and development expenses	129	126
Other receivables	<u>\$ 3,186</u>	<u>\$ 9,558</u>

(c) Prepaid Expenses and Other Current Assets

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

	September 30, 2020	December 31, 2019
Vendor deposits	\$ 10,804	\$ 8,740
Prepaid insurance	72	1,408
Prepaid expenses and other current assets	<u>\$ 10,876</u>	<u>\$ 10,148</u>

(d) Property and Equipment, net

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

	September 30, 2020	December 31, 2019
Manufacturing equipment	\$ 18,199	\$ 10,355
Computer hardware and software	2,781	3,606
Laboratory equipment	36	36
Leasehold improvements	3,374	3,374
Office furniture	248	248
Property and equipment, at cost	24,638	17,619
(Less): Accumulated depreciation	(6,182)	(6,012)
Property and equipment, net	<u>\$ 18,456</u>	<u>\$ 11,607</u>

Manufacturing equipment is comprised of our owned ROLONTIS production equipment on location at our contract manufacturer. This equipment has alternative future use for the general production of various biologic agents. Accordingly, we have capitalized these purchases, rather than recording it as “research and development” expense in full, despite its current designation for the manufacture of pre-FDA approved product. The majority of this manufacturing equipment was not in use and therefore not being depreciated as of September 30, 2020. Depreciation for installed and ready-for-use equipment is recorded to “research and development” expense prior to FDA approval and will be prospectively recorded to “cost of sales” upon FDA approval of ROLONTIS.

(e) Accounts Payable and Other Accrued Liabilities

“Accounts payable and other accrued liabilities” 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)

	September 30, 2020	December 31, 2019
Trade accounts payable and other	\$ 32,047	\$ 32,012
Lease liability - current portion	1,655	1,683
Accrued commercial/Medicaid rebates	2,122	2,925
Accrued product royalty due to licensors	—	66
Allowance for product returns	4,473	4,714
Accrued data and distribution fees	768	768
Accrued GPO administrative fees	6	6
Accrued inventory management fees	168	364
Allowance for government chargebacks	11,746	11,746
Accounts payable and other accrued liabilities	<u>\$ 52,985</u>	<u>\$ 54,284</u>

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

	Commercial/Medicaid Rebates and Government Chargebacks	Distribution, Data, Inventory and GPO Administrative Fees	Product Return Allowances
Balance as of December 31, 2018	\$ 22,952	\$ 3,932	\$ 5,171
Add: GTN accruals recorded for product sales	7,702	1,209	167
(Less): Payments made and credits against GTN accruals	(15,983)	(4,003)	(624)
Balance as of December 31, 2019	<u>\$ 14,671</u>	<u>\$ 1,138</u>	<u>\$ 4,714</u>
Add: GTN accruals recorded for product sales	—	—	—
(Less): Payments made and credits against GTN accruals	(803)	(196)	(241)
Balance as of September 30, 2020	<u>\$ 13,868</u>	<u>\$ 942</u>	<u>\$ 4,473</u>

5. STOCK-BASED COMPENSATION

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

We report our stock-based compensation expense (inclusive of our incentive stock plan, employee stock purchase plan, and 401(k) contribution matching program) in the accompanying Condensed Consolidated Statements of Operations within “total operating costs and expenses” for the three and nine months ended September 30, 2020 and 2019, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Selling, general and administrative	\$ 3,018	\$ 3,156	\$ 9,773	\$ 10,550
Research and development	1,090	1,030	3,598	3,251
Total stock-based compensation	<u>\$ 4,108</u>	<u>\$ 4,186</u>	<u>\$ 13,371</u>	<u>\$ 13,801</u>

6. NET LOSS PER SHARE

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

Net loss per share was computed by dividing net loss by the weighted average number of common shares outstanding for the three and nine months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Weighted average shares outstanding - basic and diluted	131,455,727	111,178,880	118,664,914	110,291,090
Net loss	\$ (48,452)	\$ (25,985)	\$ (121,109)	\$ (73,639)
Net loss per share – basic and diluted	\$ (0.37)	\$ (0.23)	\$ (1.02)	\$ (0.67)

7. CASI HOLDINGS AND EVOMELA SUPPLY CONTRACT

In 2014, we executed three perpetual out-license agreements for our former products ZEVALIN, MARQIBO, and EVOMELA (“CASI Out-Licensed Products”) with CASI, a publicly-traded biopharmaceutical company (NASDAQ: CASI) with a primary focus on the China market (collectively, the “CASI Out-License”). Under the CASI Out-License, we received CASI common stock and a secured promissory note and CASI gained the exclusive rights to distribute the CASI Out-Licensed Products in greater China (which includes Taiwan, Hong Kong, and Macau).

In March 2019, we completed the Commercial Product Portfolio Transaction and substantially all of the contractual rights and obligations associated with these products, including the CASI Out-License, were transferred to Acrotech at closing. However, on an interim basis we retained our original supply agreement with CASI for EVOMELA. Corresponding revenue for shipped product has been recognized within discontinued operations “product sales, net”. Given our fulfillment of this order in October 2019, this arrangement was complete as of December 31, 2019.

Our aggregate equity holdings of 9.2 million common shares as of September 30, 2020 represented less than 10.0% ownership with a fair market value of \$14.1 million. During the second quarter of 2020, we completed the sale of 0.8 million common shares and recognized a \$0.5 million gain within “other income (expense), net” within the accompanying Condensed Consolidated Statements of Operations for the nine months ended September 30, 2020.

8. FINANCIAL COMMITMENTS & 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 four 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 September 30, 2020 and 2019, we had no sublease arrangements with us as lessor, and no finance leases, as defined in *Topic 842*. For the three and nine months ended September 30, 2020 and 2019, our facility and equipment lease expense aggregated \$0.6 million, \$0.5 million, \$1.8 million, and \$1.6 million, respectively.

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

This 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). Upon adoption, we recorded \$4.2 million to our January 1, 2019 balance sheet for both (i) our right-of-use (“ROU”) asset within “facility and equipment under lease” and (ii) our lease liability within “accounts payable and other accrued liabilities” and “other long-term liabilities.” The recorded asset and liability associated with each lease is amortized over the respective lease term using the effective interest rate method. During the nine months ended September 30, 2020, we recognized no additional ROU assets in exchange for lease liabilities. During the nine months ended September 30, 2019, we recognized \$4.6 million of ROU assets in exchange for \$4.6 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:

Operating Leases	Condensed Consolidated Balance Sheet Caption	September 30, 2020	December 31, 2019
Operating lease right-of-use assets - non-current	Facility and equipment under lease	\$ 2,662	\$ 3,806
Operating lease liabilities - current	Accounts payable and other accrued liabilities	1,655	1,683
Operating lease liabilities - non-current	Other long-term liabilities	1,210	2,372
Total operating lease liabilities		\$ 2,865	\$ 4,055

As of September 30, 2020 and December 31, 2019, our “facility and equipment under lease” consisted of office and research facilities of \$2.3 million and \$3.4 million, respectively, and office equipment of \$0.3 million and \$0.4 million, respectively.

Components of Lease Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease cost	\$ 466	\$ 351	\$ 1,398	\$ 1,202
Variable lease cost	86	108	314	323
Short-term lease cost	17	20	46	59
Total lease cost	\$ 569	\$ 479	\$ 1,758	\$ 1,584

Weighted Average Remaining Lease Term and Applied Discount Rate

	Weighted Average Remaining Lease Term	Weighted Average Discount Rate
Operating leases as of September 30, 2020	1.8 years	7.8%
Operating leases as of December 31, 2019	2.5 years	7.8%

Future Contractual Lease Payments

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

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	September 30, 2020
2020 (remaining)	\$ 489
2021	1,671
2022	827
2023	87
2024	—
Total future lease payments, undiscounted	\$ 3,074
(Less): Implied interest	(209)
Present value of operating lease payments	\$ 2,865

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

Overview

The in-license agreements for our development-stage drug products provide us with territory-specific rights to their manufacture and distribution (including further sub-licensing/out-licensing rights). We are generally responsible for all related clinical development costs, patent filings and maintenance costs, marketing costs, and liability insurance costs. We 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. 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.

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 Pharmaceutical Co. Ltd

In October 2014, we exercised our option under a License Option and Research Collaboration Agreement dated January 2012 (as amended) with Hanmi Pharmaceutical Co. Ltd., or 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-teen on our 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 and sales milestone payments of up to \$120 million per calendar year based on our net sales of ROLONTIS.

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

Depending on the milestone achievement type 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 corresponding liability for the payment due to the 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.

(ii) Pozitotinib: 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 pozitotinib, 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 pozitotinib, 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 pozitotinib, potentially reduced by royalties due to other third parties.

In April 2018, we executed an exclusive patent and technology agreement for the use of pozitotinib in treating patients with EGFR and HER2 exon 20 mutations in cancer and HER2 exon 19 mutations in cancer with The University of Texas M.D. Anderson Cancer Center (“MD Anderson”). MD Anderson discovered pozitotinib’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 that we recognized within “research and development” expense in the Consolidated Statements of Operations for the year ended December 31, 2018.

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 pozitotinib.

Depending on 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” on 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.

(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, all of which were recorded within “research and development” expense within our Consolidated Statements of Operations for the year ended December 31, 2019. 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.

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

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

(c) Service Agreements for Research and Development Activities

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

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

(d) Supply and Service Agreements Associated with Product Production

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

(e) Employment Agreements

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

(f) Deferred Compensation Plan

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

The DC Plan is maintained to provide special deferred benefits for a select group of our employees (the “DC Participants”). DC Participants make annual elections to defer a portion of their eligible cash compensation which is then placed into their DC Plan accounts. We match a fixed percentage of these deferrals, and may make additional discretionary contributions. At September 30, 2020 and December 31, 2019, the aggregate value of this DC Plan liability was \$8.4 million and \$8.7 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.

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

Stockholder 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 Hartssock 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 “Hartssock Action”). On November 15, 2016, the Ayeni Action was transferred to the United States District Court for the District of Nevada. The parties stipulated to a consolidation of the Ayeni Action with the Hartssock 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.

9. INCOME TAXES

Early Adoption of ASU 2019-12 — Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes

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 are not required to calculate an income tax benefit for the three and nine months ended September 30, 2020.

We apply an estimated annual effective tax rate (“ETR”) approach for calculating a tax provision for interim periods, as required under GAAP. We recorded a benefit for income taxes from continuing operations of \$8.6 million for the nine months ended September 30, 2019, in the Condensed Consolidated Statements of Operations. Our ETR differs from the U.S. federal statutory tax rate of 21% primarily as a result of nondeductible expenses and the impact of the valuation allowance on our deferred tax assets.

Prior to the early adoption of ASU 2019-12, and for the nine months ended September 30, 2019, the intraperiod tax allocation guidance required that we allocate income taxes between continuing operations and other categories of earnings. When we have a year-to-date pre-tax loss from continuing operations and year-to-date pre-tax income in discontinued operations, ASC 740-20-45-7 required that we allocate the income tax provision to other categories of earnings (including discontinued operations), and then record a related tax benefit in continuing operations. For the three and nine months ended September 30, 2019, we recognized net income from discontinued operations while sustaining losses from continuing operations. Because of the required allocation, we recorded an income tax benefit of \$0.2 million and \$8.6 million for the three and nine months ended September 30, 2019, within “benefit for income taxes from continuing operations” and income tax expense of \$0.2 million and \$7.1 million within “income from discontinued operations, net of income taxes” on the accompanying Condensed Consolidated Statements of Operations.

Our net tax benefit for the three and nine months ended September 30, 2019, prior to the application of intraperiod tax allocation guidance was \$11 thousand and \$1.5 million, respectively. This tax benefit arose from the reversal of deferred tax

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

liabilities recorded on our Consolidated Balance Sheet as of December 31, 2018 that were associated with indefinite-lived intangible assets that were sold as part of our Commercial Product Portfolio Transaction.

10. DISCONTINUED OPERATIONS

Overview

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

Condensed Consolidated Statements of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Product sales, net	\$ (1)	\$ 5,968	\$ (101)	\$ 18,802
License fees and service revenue	—	—	—	290
Total revenues	(1)	5,968	(101)	19,092
Operating costs and expenses:				
Cost of sales (excluding amortization of intangible assets)	—	5,115	(229)	8,716
Selling, general and administrative	—	69	(1)	5,959
Research and development	(67)	(194)	(126)	2,597
Amortization of intangible assets	—	—	—	1,248
Restructuring charges - employee severance	—	—	—	3,858
Total operating costs and expenses	(67)	4,990	(356)	22,378
Income (loss) from discontinued operations	66	978	255	(3,286)
Other (expense) income:				
Change in fair value of contingent consideration	—	—	—	(1,478)
Gain on sale of Commercial Product Portfolio	—	(193)	—	33,451
Total other (expense) income	—	(193)	—	31,973
Income from discontinued operations before income taxes	66	785	255	28,687
Provision for income taxes from discontinued operations	—	(213)	—	(7,140)
Income from discontinued operations, net of income taxes	\$ 66	\$ 572	\$ 255	\$ 21,547

Product sales, net for the three and nine months ended September 30, 2019 includes sales from our Commercial Product Portfolio in January and February 2019 (prior to the completion of the Commercial Product Portfolio Transaction) and EVOMELA sales related to a retained manufacturing contract (see *Note 7*).

The pre-tax gain on sale represents the \$158.8 million gross proceeds from the Commercial Product Portfolio Transaction less our \$121.2 book value of transferred net assets (inclusive of assumed liabilities) to Acrotech on the March 1, 2019 closing date less legal and banker fees aggregating \$3.9 million. In the third quarter of 2019, we reduced the gain for a \$0.2 million contract cancellation fee associated with our sold commercial operations; this value was deducted from the \$4.0 million escrow account (reported as “restricted cash” on the Condensed Consolidated Balance Sheet until its release in November 2019). In the fourth quarter of 2019, we increased this gain by \$1.1 million to correct for certain inventory that did not contractually transfer to the buyer.

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

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.

Condensed Consolidated Statement of Cash Flows

The following table presents significant non-cash items for our discontinued operations that are included as adjustments in the accompanying Condensed Consolidated Statements of Cash Flows:

	Nine Months Ended September 30,	
	2020	2019
Depreciation and amortization	\$ —	\$ 1,263
Stock-based compensation	\$ —	\$ 3,404
Change in fair value of contingent consideration	\$ —	\$ 1,478

11. RESTRUCTURING COSTS RELATED TO SALE OF COMMERCIAL PRODUCT PORTFOLIO

Employee Severance

In March 2019, we completed the Commercial Product Portfolio Transaction and 87 of our employees were (1) terminated March 1, 2019 or (2) given notice of May 31, 2019 termination and asked to provide transition services for the benefit of Acrotech through that date (as provided by a transition services agreement with Acrotech entered contemporaneously with our sale). For the three and nine months ended September 30, 2019, we recognized \$0 million and \$0.7 million of income for services rendered to Acrotech under this agreement within “other income (expense), net” on our accompanying Condensed Consolidated Statements of Operations.

The employees in (1) above were entitled to cash severance payments and acceleration of their unvested restricted stock awards and stock options. For the nine months ended September 30, 2019, we fully recognized the aggregate value of \$5.1 million for this severance benefit, of which \$3.9 million, \$1.0 million, and \$0.2 million is included on the accompanying Condensed Consolidated Statements of Operations within “income from discontinued operations, net of income taxes”, “selling, general, and administrative” expenses and “research and development” expenses, respectively.

The employees in (2) above were also entitled to cash severance payments and acceleration of their unvested restricted stock awards and stock options, though on May 31, 2019. The aggregate value of these one-time cash payments and stock-based award accelerations was \$0.5 million. Due to then ongoing service requirements of these employees, we amortized this value through expense on a ratable basis beginning March 1, 2019 through May 31, 2019. For the three and nine months ended September 30, 2019, we recognized \$0 million and \$0.5 million for this severance benefit, which is included within “selling, general, and administrative” expenses on the accompanying Condensed Consolidated Statements of Operations, and within “accrued payroll and benefits” and “additional paid-in capital” (for stock-based awards) on the accompanying Condensed Consolidated Balance Sheets as of September 30, 2019.

Unpaid cash severance for our former employees was \$0.1 million and \$0.4 million at September 30, 2020 and 2019, respectively, and is recorded within “accrued payroll and benefits” on the accompanying Condensed Consolidated Balance Sheets.

12. STOCKHOLDERS’ EQUITY

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

Public Offering of Common Stock

On July 30, 2020, we announced the pricing of an underwritten public offering of 21,666,667 shares of our common stock at a public offering price of \$3.00 per share. The net proceeds from the offering were approximately \$61.1 million, after deducting underwriting discounts and commissions. In addition, we granted the underwriters a 30-day option to purchase up to an additional 3,250,000 shares of common stock.

On August 3, 2020, the underwriters fully exercised their option to purchase an additional 3,250,000 shares of our common stock at the public offering price of \$3.00 per share, less underwriting discounts and commissions, for additional net proceeds of approximately \$9.2 million. After giving effect to the exercise in full of the underwriters' option, the total number of shares sold in the public offering was 24,916,667 shares and net proceeds were approximately \$69.7 million, net of underwriting discounts and offering expenses of \$5.0 million.

Sale of Common Stock Under ATM Agreement

On April 5, 2019, we entered into a new collective at-market-issuance ("ATM") sales agreement with Cantor Fitzgerald & Co., H.C. Wainwright & Co., LLC and B. Riley FBR, Inc. (the "April 2019 ATM Agreement"), pursuant to which we may offer and sell shares of our common stock by any method deemed to be an "at the market" offering (the "ATM Offering"). From April 5, 2019 to March 2, 2020, the ATM Offering was conducted pursuant to a sales agreement prospectus filed with our automatic shelf registration statement on Form S-3ASR, filed with the SEC on April 5, 2019 (the "April Registration Statement"), 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 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 "March Registration Statement"), which registered an aggregate offering price of \$75 million under the April 2019 ATM Agreement.

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

Quarter in Which Issued	No. of Common Shares Issued	Proceeds Received (Net of Broker Commissions and Fees)
Quarter ended June 30, 2019	221,529	\$ 1,814
Quarter ended June 30, 2020	1,024,286	\$ 3,071
Quarter ended September 30, 2020	2,926,112	\$ 11,831

ITEM 2.

MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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, 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 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, development 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,” “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. 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, 2019, as well as those discussed elsewhere in this Quarterly Report on Form 10-Q, and the following factors:

- 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.

Company Overview

Spectrum Pharmaceuticals, Inc. (“Spectrum”, the “Company”, “we”, “our”, or “us”) is a biopharma 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 in the second half of 2020 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 BLA for ROLONTIS due to the inability to conduct an inspection of our third-party manufacturing facility in South Korea as a result of COVID-19 related travel restrictions;
- Pozitotinib, a novel irreversible tyrosine kinase inhibitor under investigation for non-small cell lung cancer (“NSCLC”) tumors with various mutations; 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 (including diffuse large B-cell lymphoma).

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 nine months ended September 30, 2020, we continued our strategic shift in our business following the completion of the sale of our legacy commercialized drug 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 with 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 identically 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. The PDUFA date for ROLONTIS was October 24, 2020. Due to the restrictions on travel related to the COVID-19 pandemic, the FDA was unable to conduct an inspection of our third-party manufacturing plant in South Korea during the current review cycle. As a result, the FDA deferred action on the application until an inspection can be completed. We will continue to actively work to obtain an approval for ROLONTIS as soon as possible. We have confirmed with the FDA that the deferral is not a Complete Response Letter.

Spectrum presented preclinical data evaluating the administration of ROLONTIS on the same day as chemotherapy at the American Association for Cancer Research (“AACR”) Virtual Annual Meeting II. The duration of neutropenia in a rat model of chemotherapy induced neutropenia was observed to be significantly shorter with eflapegrastim versus pegfilgrastim, regardless of the timing of administration: concomitantly or on the same day post-chemotherapy at 2, 5 or 24 hours post-chemotherapy.

A company sponsored clinical study has been initiated to evaluate the administration of ROLONTIS on the same day as chemotherapy. The first patient was dosed in April 2020. The trial will evaluate the duration of severe neutropenia when administered at three different time points on the same day following standard chemotherapy in patients with early stage breast cancer.

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

In October 2017, we announced the start of a pivotal Phase 2 global study with active sites in the U.S., Canada and Europe (“ZENITH20”). The ZENITH20 study consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) have completed enrollment of previously treated NSCLC patients with exon 20 mutations. Cohort 3 (EGFR) recently completed enrollment and Cohort 4 (HER2) is currently enrolling 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 objective response rate (“ORR”). Cohort 5 includes previously treated or treatment-naïve NSCLC patients with EGFR or HER2 exon 20 insertion mutations. Cohort 6 includes NSCLC patients with classical EGFR mutations who progressed while on treatment with first-line osimertinib and developed an additional EGFR mutation. Cohort 7 includes NSCLC patients with a variety of less common mutations in EGFR or HER2 exons 18-21 or the extracellular or transmembrane domains.

On December 26, 2019, we announced that the pre-specified primary endpoint in our Phase 2 clinical trial evaluating poziotinib in previously treated NSCLC patients with EGFR exon 20 insertion mutations was not met in Cohort 1 of the ZENITH20 trial. Cohort 1 enrolled a total of 115 patients who received 16 mg/day of poziotinib. The intent-to-treat analysis showed that 17 patients had a response (by RECIST) and 62 patients had stable disease for a 68.7% disease control rate (“DCR”). The confirmed ORR was 14.8% (95% Confidence Interval (“CI”) 8.9%-22.6%). Based on the FDA reviewed protocol, an observed ORR of 30%, with 17% as the lower bound for 95% CI was considered to be the clinically meaningful efficacy in our study. The median duration of response was 7.4 months and progression free survival was 4.2 months. The safety profile was in-line with the type of adverse events seen with other second-generation EGFR tyrosine kinase inhibitors.

We presented additional results for Cohort 1 from our Phase 2 clinical trial, ZENITH20, evaluating poziotinib in previously treated NSCLC patients with EGFR exon 20 insertion mutations, at a plenary session of the AACR Annual Meeting on April 27, 2020. The podium presentation included additional safety and efficacy data. We also provided an update on our strategy for the ZENITH20 Phase 2 clinical trial evaluating poziotinib in NSCLC patients with EGFR and HER2 exon 20 insertion mutations. The protocol has been amended to explore additional dosing regimens and the earlier use of corticosteroids in an effort to increase drug compliance.

On July 27, 2020, we announced that we met the pre-specified primary endpoint for Cohort 2 in the ZENITH20 Phase 2 clinical trial evaluating previously treated NSCLC patients with HER2 exon 20 insertion mutations. Cohort 2 of the ZENITH20 clinical trial 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. We have been granted a pre-NDA meeting with the FDA based on the positive results from Cohort 2 to seek a path forward for poziotinib registration for the treatment of patients with previously treated locally advanced or metastatic NSCLC with HER2 exon 20 insertion mutations.

In September 2020, we presented the results from Cohort 2 at the European Society for Medical Oncology (ESMO) Virtual Congress.

We expect to provide a dosing strategy update and topline results from Cohort 3 of the ZENITH20 trial in first-line EGFR NSCLC patients by year end 2020.

CHARACTERISTICS OF OUR REVENUE AND EXPENSES

See *Item 7. Characteristics of Our Revenue and Expenses* of our Annual Report on Form 10-K for the year ended December 31, 2019, 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. Critical Accounting Policies and Estimates* of our Annual Report on Form 10-K for the year ended December 31, 2019, for a discussion of significant estimates and assumptions 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;
- Income taxes;
- Stock-based compensation; and

- Litigation accruals (as required).

RESULTS OF OPERATIONS

Operations Overview – Three and Nine Months Ended September 30, 2020 and 2019

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(\$ in thousands)		(\$ in thousands)	
Revenues	\$ —	\$ —	\$ —	\$ —
Operating costs and expenses:				
Selling, general and administrative	15,116	13,126	44,654	46,308
Research and development	24,453	17,167	62,192	56,035
Total operating costs and expenses	39,569	30,293	106,846	102,343
Loss from continuing operations before other income (expense) and income taxes	(39,569)	(30,293)	(106,846)	(102,343)
Interest income, net	188	1,521	1,217	4,076
Other income (expense), net	(9,131)	2,015	(15,720)	(5,547)
Total other income (expense)	(8,943)	3,536	(14,503)	(1,471)
Loss from continuing operations before income taxes	(48,512)	(26,757)	(121,349)	(103,814)
(Provision) benefit for income taxes from continuing operations	(6)	200	(15)	8,628
Loss from continuing operations	\$ (48,518)	\$ (26,557)	\$ (121,364)	\$ (95,186)
Income from discontinued operations, net of income taxes	66	572	255	21,547
Net loss	\$ (48,452)	\$ (25,985)	\$ (121,109)	\$ (73,639)

THREE MONTHS ENDED SEPTEMBER 30, 2020 AND 2019

Operating Expenses

	Three months ended September 30,		\$ Change	% Change
	2020	2019		
	(\$ in millions)			
Operating costs and expenses:				
Selling, general and administrative	\$ 15.1	\$ 13.1	\$ 2.0	15.3 %
Research and development	24.5	17.2	7.3	42.4 %
Total operating costs and expenses	\$ 39.6	\$ 30.3	\$ 9.3	30.7 %

Selling, General and Administrative. Selling, general and administrative expenses increased by \$2.0 million in the current year period, primarily related to \$1.0 million of increased IT infrastructure and system expenses and \$0.9 million of increased personnel expenses as a result of preparing for the launch of ROLONTIS.

Research and Development. Research and development expenses increased by \$7.3 million in the current period, primarily related to (i) a \$6.3 million increase for ROLONTIS, largely due to a purchase of drug substance in preparation for the upcoming commercial launch, and (ii) a \$1.9 million increase related to staff and other expenses. These amounts were partially offset by a \$0.9 million decrease in poztotinib costs related to the timing of drug substance purchases.

Total Other Income (Expense)

	Three months ended September 30,		\$ Change	% Change
	2020	2019		
	(\$ in millions)			
Total other income (expense)	\$ (8.9)	\$ 3.5	\$ (12.4)	(354.3)%

Total other income decreased by \$12.4 million primarily due to (i) an \$11.4 million of decrease in the market value of our equity holding in the current period versus the prior period, and (ii) \$1.0 million of decreased interest income on our marketable securities.

Income Taxes

	Three months ended September 30,		\$ Change	% Change
	2020	2019		
	(\$ in millions)			
(Provision) benefit for income taxes from continuing operations	\$ 0.0	\$ 0.2	\$ (0.2)	(100.0)%

For the three months ended September 30, 2020 we did not record a benefit for income taxes from continuing operations based on the recent adoption of ASU 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes," during the period. For the three months ended September 30, 2019 we reported pre-tax losses from continuing operations. This requires our application of intraperiod tax allocation guidance, resulting in the presented income tax benefit values (though is not indicative of income tax refunds due to us). Further, these values in each period are substantially offset by the corresponding income tax provision within "discontinued operations".

NINE MONTHS ENDED SEPTEMBER 30, 2020 AND 2019

	Nine months ended September 30,		\$ Change	% Change
	2020	2019		
	(\$ in millions)			
Operating costs and expenses:				
Selling, general and administrative	\$ 44.7	\$ 46.3	\$ (1.6)	(3.5)%
Research and development	62.2	56.0	6.2	11.1 %
Total operating costs and expenses	\$ 106.9	\$ 102.3	\$ 4.6	4.5 %

Selling, General and Administrative. Selling, general and administrative expenses decreased by \$1.6 million in the current period, primarily related to (i) \$1.5 million of decreased expense related to prior period non-recurring employee severance resulting from the sale of our commercial product portfolio in March 2019 and (ii) a decrease in overall travel of \$1.6 million as a result of COVID-19, which has been ongoing since the first quarter of 2020. These amounts were partially offset by a \$1.5 million increase related to IT infrastructure, systems, facilities and other expenses.

Research and Development. Research and development expenses increased by \$6.2 million in the current period, primarily related to (i) a \$4.3 million increase in ROLONTIS costs, primarily related to manufacturing and regulatory in preparation for the upcoming commercial launch, (ii) a \$0.5 million increase in pozotinib related expenses, and (iii) a \$1.4 million increase related to staff and other expenses.

Total Other Expense

	Nine months ended September 30,		\$ Change	% Change
	2020	2019		
	(\$ in millions)			
Total other expense	\$ (14.5)	\$ (1.5)	\$ (13.0)	(866.7)%

Total other expense increased by \$13.0 million primarily due to (i) a decrease of \$6.3 million in the market value of our equity holding in the current period versus the prior period, (ii) \$2.1 million of lower realized gains in the current period compared to the prior period from the sale of our equity holdings, (iii) \$3.5 million of decreased interest income and changes in value on certain investments, (iv) a \$0.7 million decrease in billable services rendered to Acrotech as part of a transition services agreement that expired in May 2019, and (v) a \$0.5 million increase in loss on foreign currency exchange.

Income Taxes

	Nine months ended September 30,		\$ Change	% Change
	2020	2019		
	(\$ in millions)			
(Provision) benefit for income taxes from continuing operations	\$ 0.0	\$ 8.6	\$ (8.6)	(100.0)%

For the nine months ended September 30, 2020, we did not record a benefit for income taxes from continuing operations based on the recent adoption of ASU 2019-12, “Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes,” during the period. For the nine months ended September 30, 2019 we reported pre-tax losses from continuing operations. This requires our application of intraperiod tax allocation guidance, resulting in the presented income tax benefit values (though is not indicative of income tax refunds due to us). Further, these values in each period are substantially offset by the corresponding income tax provision within “discontinued operations”.

LIQUIDITY AND CAPITAL RESOURCES

We believe that our \$198.3 million in aggregate cash and equivalents and marketable securities as of September 30, 2020 are sufficient to fund our current and planned operations for 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 \$88.3 million for the nine months ended September 30, 2020, as compared to \$103.4 million in the prior year period. This decrease in net cash used in operating activities was primarily related to the decrease in expenses incurred after the Commercial Product Portfolio Transaction as a result of no longer being a commercial stage entity during the nine months ended September 30, 2020.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was \$16.2 million for the nine months ended September 30, 2020, as compared to \$66.1 million during the prior year period. The cash provided by investing activities for the nine months of 2020 primarily relates to (i) \$92.4 million of proceeds from maturities of our marketable securities, (ii) \$2.5 million of proceeds from the sale of mutual funds, and (iii) \$1.8 million of proceeds received from the sale of our equity holdings. This cash received was partially offset by (i) \$71.7 million of purchases of marketable securities, (ii) \$1.9 million of purchases for investments in mutual funds, and (iii) \$7.0 million of equipment purchases substantially related to ROLONTIS manufacturing.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$84.9 million for the nine months ended September 30, 2020, as compared to \$8.6 million during the prior year period. Our cash provided by financing activities during the first nine months of 2020 relates to (i) \$69.7 million of proceeds from our public offering, net of offering expenses (ii) \$14.9 million of proceeds received from common shares sold pursuant to an at-the-market-issuance sales agreement, and (iii) \$0.3 million of proceeds from employee stock purchases under our employee stock purchase plan.

Impact of COVID-19 Pandemic

In March 2020, concerns related to the spread of COVID-19 began to create global business disruptions as well as disruptions in our operations and to create potential negative impacts on our future revenues of ROLONTIS and other financial results. COVID-19 was declared a pandemic by the World Health Organization on March 11, 2020. The extent to which COVID-19 will impact our financial condition, results of operations or future cash flows is currently uncertain and depends on factors including the duration and severity of the outbreak (See Item 1A: “Risk Factors” for additional details).

Proceeds From the Commercial Product Portfolio Transaction

In March 2019, we completed the sale of our Commercial Product Portfolio to Acrotech. Upon the closing of the Commercial Product Portfolio Transaction, we received \$158.8 million in an upfront cash payment (of which \$4 million was held in escrow until November 2019). We are also entitled to receive up to an aggregate of \$140 million upon Acrotech's achievement of certain regulatory and sales-based milestones relating to the Commercial Product Portfolio.

We are using the proceeds from the Commercial Product Portfolio Transaction to advance our in-development drug pipeline, as well as provide for our general working capital requirements.

Off-Balance Sheet Arrangements

As of September 30, 2020, we have no off-balance sheet arrangements that provide financing, liquidity, market or credit risk support, or involve derivatives. In addition, we have no arrangements that may expose us to liability that are not expressly reflected in the accompanying Condensed Consolidated Financial Statements and/or notes thereto.

As of September 30, 2020, we did not have any relationships with unconsolidated entities or financial partnerships, often referred to as “structured finance” or “special purpose entities,” established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not subject to any material financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the normal course of business, our operations are exposed to risks associated with fluctuations in foreign currency exchange rates, prices of raw materials for drug production, and changes in the value of our equity holdings. We believe that these risks have been appropriately addressed for our business as further discussed below.

Foreign currency: We have limited exposure to currency exchange rate fluctuations for our cash receipts in foreign currency from license partners, as well as payments we make to employees, vendors, and license partners in foreign currency (typically in Euros, Canadian dollars, or Indian rupees). We further mitigate this limited risk by maintaining a fraction of our cash in these foreign currencies for our current operational needs. A hypothetical 10% change in these foreign exchange rates would not be material to our reported operating results and period-end financial position due to minimal amounts held in foreign currency-denominated bank accounts during 2020.

Equity price: We hold publicly-traded equity securities, received as part of out-license consideration. At September 30, 2020, the market value of these equity holdings was \$14.1 million. Our monetization of this value is subject to changes in market prices at the time of sale, thus a hypothetical 10% change in market value (whether realized or unrealized) would not be material to our reported operating results and period-end financial position in 2020. We have evaluated this share price risk and decided to not enter into derivative contracts for potential risk mitigation.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2020. The term “disclosure controls and procedures,” as defined in *Rules 13a-15(e) and 15d-15(e)* under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. These include controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2020, our chief executive officer and chief financial officer concluded that, as of that date, our disclosure controls and procedures were effective.

Changes in Internal Controls Over Financial Reporting

There has been no change in our internal controls over financial reporting (as defined in *Rules 13a-15(f) and 15d-15(f)* under the Exchange Act) during the third fiscal quarter of 2020 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 8(g)*, “Financial Commitments & 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, 2019, as filed with the SEC on March 2, 2020, except as noted below.

The market price and trading volume of our common stock fluctuate significantly and could result in substantial losses for individual investors.

The stock market from time to time experiences significant price and trading volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price and trading volume of our common stock to decrease. In addition, the market price and trading volume of our common stock is often highly volatile.

Factors that may cause the market price and volume of our common stock to decrease include, among other things:

- the impact of COVID-19 on the U.S. and global economies;
- adverse results or delays in our clinical trials, including as a result of COVID-19;
- fluctuations in our results of operations;
- timing and announcements of our technological innovations or new products or those of our competitors;

- developments concerning any strategic alliances or acquisitions we may enter into;
- announcements of FDA non-approval of our products, or delays in the FDA or other foreign regulatory review processes or actions, including the deferral of action on the BLA for ROLONTIS due to the inability to conduct an inspection of the manufacturing facility citing COVID-19 related travel restrictions;
- changes in recommendations or guidelines of government agencies or other third parties regarding the use of our products;
- adverse actions taken by regulatory agencies with respect to our drug products, clinical trials, manufacturing processes or sales and marketing activities;
- concerns about our in-development products being reimbursed at requisite levels in the future;
- any lawsuit involving us or our products;
- developments with respect to our patents and proprietary rights;
- public concern as to the safety of products developed by us or others;
- regulatory developments in the U.S. and in foreign countries;
- changes in stock market analyst recommendations regarding our common stock or lack of analyst coverage;
- failure of our results of operations to meet the expectations of stock market analysts and investors;
- sales of our common stock by our executive officers, directors and significant stockholders or sales of substantial amounts of our common stock generally; and
- loss of any of our key scientific or management personnel.

Also, certain dilutive securities such as warrants can be used as hedging tools which may increase volatility in our stock and cause a price decline. While a decrease in market price could result in direct economic loss for an individual investor, low trading volume could limit an individual investor's ability to sell our common stock, which could result in substantial economic loss as well. From January 1, 2020 through October 28, 2020, the closing price of our common stock ranged between \$1.83 and \$4.90, and the daily trading volume was as high as 31,122,530 shares and as low as 507,400 shares.

Following periods of volatility in the market price of a company's securities, a securities class action litigation may be instituted against that company. Regardless of their merit, these types of lawsuits generally result in substantial legal fees and management's attention and resources being diverted from the operations of a business.

The COVID-19 outbreak could adversely impact our business.

In December 2019, it was first reported that there had been an outbreak of COVID-19 in China. Since then, COVID-19 has continued to spread outside of China, including throughout the United States and other parts of the world, becoming a global pandemic. The COVID-19 pandemic has impacted our business and will likely continue to impact our business directly and/or indirectly for the foreseeable future. We are unable to accurately predict the full impact that the COVID-19 pandemic will have on our results from operations, financial condition and clinical studies due to numerous factors that are not within our control, including the duration and severity of the outbreak.

Governments in affected regions have implemented and may continue to implement safety precautions, including stay-at-home orders, travel restrictions, business closures, cancellations of public gatherings and other measures. These measures are disrupting normal business operations both in and outside of affected areas. We continue to monitor our operations and government recommendations and have made appropriate modifications to our operations because of COVID-19, including transitioning to a remote work environment and substantial modifications to employee travel. We are also unable to make site visits at this time due to social distancing guidelines. Over time, these factors could reduce our overall productivity and collaboration. In addition, enrollment has been negatively impacted, with great variability by geographic location in our on-going trials, which could result in a delay in completing enrollment in such trials. We anticipate the potential for delays in the initiation and enrollment of planned clinical trials until the pandemic resolves.

On October 26, 2020 we announced that an inspection of the Hanmi Bioplant in South Korea is required before the FDA can approve our BLA for ROLONTIS. The FDA was unable to conduct an inspection during the current review cycle due to restrictions on travel related to the COVID-19 pandemic. Therefore, the FDA has deferred action on the application until an

inspection can be completed. The PDUFA target action date was October 24, 2020. The FDA has not provided us a timeline on when the inspection might occur, but further delays could adversely impact our results of operations and financial projections.

As the COVID-19 pandemic continues to evolve, we may experience these and other disruptions that could severely impact our business and regulatory filings, including, but not limited to:

- disruption in our ability to manufacture our API and future drug products;
- disruption in our ability to source materials;
- ongoing delays or difficulties in obtaining FDA approval for ROLONTIS and completing other regulatory work;
- fewer individuals undertaking or completing cancer treatments, whether due to contracting COVID-19, self-isolating or quarantining to lower the risk of contracting COVID-19 or being unable to access care as a result of healthcare providers tending to COVID-19 patients;
- impact to the financial markets which could impact our ability to raise capital;
- limitations on our employees' ability to work, due to potential sickness of employees or their families;
- disruption in our ability to sell our future commercialized products including in foreign markets; and
- additional repercussions on our ability to operate our business.

While the long-term economic impact and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, which could reduce our ability to access capital and could negatively affect our liquidity and the liquidity and stability of markets for our common stock. In addition, a recession, further market correction or depression resulting from the spread of COVID-19 could materially affect our business and the value our common stock.

Risks Relating to Our Intellectual Property

From time to time we may need to in-license patents and proprietary technologies from third parties, which may be difficult or expensive to obtain.

We may need to obtain licenses to patents and other proprietary rights held by third parties to successfully develop, manufacture and market our drug products. As an example, it may be necessary to use a third party's proprietary technology to reformulate one of our drug products in order to improve upon the capabilities of the drug product. If we are unable to timely obtain these licenses on reasonable terms, or at all, our ability to commercially exploit our drug products may be inhibited or prevented.

If we are unable to adequately protect our technology or enforce our patent rights, our business could suffer.

Our success with the drug products that we develop will depend, in part, on our ability and the ability of our licensors to obtain and maintain patent protection for these products. We currently have a number of U.S. and foreign patents issued and pending, however, we primarily rely on patent rights licensed from others. Our license agreements generally give us the right and/or obligation to maintain and enforce the subject patents. We may not receive patents for any of our pending patent applications or any patent applications we may file in the future. If our pending and future patent applications are not allowed or, if allowed and issued into patents, if such patents and the patents we have licensed are not upheld in a court of law, our ability to competitively exploit our drug products would be substantially harmed. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by our competitors, in which case our ability to commercially exploit these products may be diminished.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in pharmaceutical and biotechnology patents has emerged to date in the U.S. The laws of many countries may not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Filing, prosecuting and defending patents on all our products or product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions not covered by any of our patent claims or other intellectual property rights.

Changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. We do not know whether any of our patent applications will result in the issuance of any patents,

and we cannot predict the breadth of claims that may be allowed in our patent applications or in the patent applications we license from others.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- in certain jurisdictions, we or our licensors might not have been the first to make the inventions covered by each of our or our licensors' pending patent applications and issued patents, and we may have to participate in expensive and protracted interference proceedings to determine priority of invention;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative product candidates or duplicate any of our or our licensors' product candidates;
- our or our licensors' pending patent applications may not result in issued patents;
- our or our licensors' issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;
- others may design around our or our licensors' patent claims to produce competitive products that fall outside the scope of our or our licensors' patents;
- we may not develop or in-license additional patentable proprietary technologies related to our product candidates; or
- the patents of others may prevent us from marketing one or more of our product candidates for one or more indications that may be valuable to our business strategy.

An issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Patents issued to us and our licensors and those that may be issued in the future to us and our licensors may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing related product candidates or could limit the length of the term of patent protection of our product candidates. Our competitors may independently develop similar technologies. In addition, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are a party to exclusive license agreements with our partners and may need to obtain additional licenses from others to advance our research and development activities or allow the commercialization of our current product candidates and future product candidates we may identify and pursue. Our license agreements may impose, and we expect that future license agreements could impose various requirements on us, such as obligations related to development, diligence and commercialization, among others. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of our current product candidates or other product candidates that we may identify. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and;
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

We also rely on trade secret protection and contractual protections for our unpatented and proprietary drug compounds. Trade secrets are difficult to protect. While we enter into confidentiality agreements with our employees, consultants and others, these agreements may not successfully protect our trade secrets or other confidential and proprietary information. It is possible that these agreements will be breached, or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. Likewise, although we conduct periodic trade secret audits of certain partners, vendors and contract manufacturers, these trade secret audits may not protect our trade secrets or other confidential and proprietary information. It is possible that despite having certain trade secret audit security measures in place, trade secrets or other confidential and proprietary information may still be leaked or disclosed to a third party. It is also possible that our trade secrets will become known or independently developed by our competitors.

We also rely on trademarks to protect the names of our products. These trademarks may be challenged by others. If we enforce our trademarks against third parties, such enforcement proceedings may be expensive. Some of our trademarks are owned by, or assignable to, our licensors and, upon expiration or termination of the applicable license agreements, we may no longer be able to use these trademarks. If we are unable to adequately protect our technology, trade secrets or proprietary know-how, or enforce our patents and trademarks, our business, financial condition and prospects could suffer.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States.

In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies

awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the United States Patent and Trademark Office (“USPTO”) after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor’s patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us when the fees are due, and we employ an outside firm to automatically pay these fees to both US and non-U.S agencies and we rely on our outside counsel to verify and confirm payment of these fees. The USPTO and various non-U.S. governmental patent agencies require compliance

with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Intellectual property rights are complex and uncertain and therefore may subject us to infringement claims.

The patent positions related to our drug products are inherently uncertain and involve complex legal and factual issues. We believe that there is significant litigation in the pharmaceutical and biotechnology industry regarding patent and other intellectual property rights. A patent does not provide the patent holder with freedom to operate in a way that infringes the patent rights of others. We may be accused of patent infringement at any time. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the U.S.

Although we are not aware of any infringement by any of our drug products of any valid patent rights of any third party, there may be third party patents or other intellectual property rights, including trademarks and copyrights, relevant to our drug products of which we are not aware. Third parties may assert patent or other intellectual property infringement claims against us, or our licensors and collaborators, with products. Any claims that might be brought against us relating to infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages and result in the loss of our use of the intellectual property that is critical to our business strategy.

In the event that we or our partners are found to infringe any valid claim of a patent held by a third party, we may, among other things, be required to:

- pay damages, including up to treble damages and the other party's attorneys' fees, which may be substantial;
- cease the development, manufacture, use and sale of our products that infringe the patent rights of others through a court-imposed sanction such as an injunction;
- expend significant resources to redesign our products so they do not infringe others' patent rights, which may not be possible;
- discontinue manufacturing or other processes incorporating infringing technology; or
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, while we require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

We may be involved in additional lawsuits to defend or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe upon our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S. or in Europe.

Furthermore, because of the substantial amount of discovery that could be required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our stock price.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have licensed are generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act, and implementing regulations. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation, and may change in the future. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

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 Aurobino 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	
4.1	Rights Agreement, dated as of December 13, 2010, between the Registrant and Computershare Trust Company, N.A. (formerly U.S. Stock Transfer Corporation), as Rights Agent	8-K	001-35006	4.1	12/13/2010	
4.2	First Amendment to Rights Agreement, dated as of October 13, 2017, between Registrant and Computershare Trust Company, N.A., as Rights Agent	8-K	001-35006	4.1	10/13/2017	
4.3	Second Amendment to Rights Agreement, dated as of March 27, 2018, between Registrant and Computershare Trust Company, N.A., as Rights Agent	8-K	001-35006	4.1	3/29/2018	
10.1	Underwriting Agreement by and between Spectrum Pharmaceuticals, Inc. and Jefferies LLC, dated July 29, 2020	8-K	001-35006	1.1	8/3/2020	
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) promulgated under the Securities Exchange Act of 1934.					X
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a) promulgated under the Securities Exchange Act of 1934.					X
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b)/15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.					X
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b)/15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.					X
101.INS	Inline XBRL Instance Document. The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101 filed herewith).					

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SPECTRUM PHARMACEUTICALS, INC.

Date: November 4, 2020

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

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Joseph W. Turgeon, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Spectrum Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 4, 2020

/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.

November 4, 2020

/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 September 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents in all material respects the financial condition and results of operations of Spectrum Pharmaceuticals, Inc.

Date: November 4, 2020

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.

