CYTOKINETICS INC
Form 10-Q
November 09, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 000-50633

CYTOKINETICS, INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	94-3291317
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
280 East Grand Avenue South San Francisco, California	94080
(Address of principal executive offices)	(Zip Code)

Registrant’s telephone number, including area code: (650) 624-3000

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

Number of shares of common stock, $0.001 par value, outstanding as of November 5, 2018: 54,710,900

CYTOKINETICS, INCORPORATED

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FOR THE three and six months ENDED September 30, 2018

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
CYTOKINETICS, INCORPORATED

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data) (Unaudited)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,624	$ 125,206
Short-term investments	182,686	143,685
Accounts receivable	9,156	1,112
Contract assets	5,876	—
Prepaid and other current assets	1,927	4,292
Total current assets	227,269	274,295
Long-term investments	—	16,518
Property and equipment, net	2,687	3,568
Other assets	323	429
Total assets	$ 230,279	$ 294,810
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,024	$ 5,253
Accrued liabilities	15,652	17,392
Deferred revenue, current	—	9,572
Current portion of long-term debt	3,778	—
Other current liabilities	38	227
Total current liabilities	21,492	32,444
Long-term debt, net	38,127	31,777
Liability related to the sale of future royalties, net	117,718	104,650
Deferred revenue, non-current	—	15,000
Other long-term liabilities	873	1,097
Total liabilities	178,210	184,968
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value	—	—
Common stock, $0.001 par value	55	54
Additional paid-in capital	765,970	755,526
Accumulated other comprehensive income	447	343
Accumulated deficit	(714,403)	(646,081)
Total stockholders' equity	52,069	109,842
Total liabilities and stockholders' equity	$ 230,279	$ 294,810

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

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CYTOKINETICS, INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands, except per share data) (Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Revenues:				
Research and development, milestone, grant and other revenues, net	$8,726	$ 5,862	$16,991	$ 6,680
License revenues	1,915	318	5,133	6,706
Total revenues	10,641	6,180	22,124	13,386
Operating expenses:				
Research and development	21,391	24,947	65,858	64,045
General and administrative	7,164	9,657	23,724	26,210
Total operating expenses	28,555	34,604	89,582	90,255
Operating loss	(17,914)	(28,424)	(67,458)	(76,869)
Interest expense	(867)	(806)	(2,628)	(2,346)
Non-cash interest expense on liability related to sale of future royalties	(4,559)	(3,906)	(13,026)	(9,918)
Interest and other income, net	1,323	779	3,291	1,828
Net loss	$(22,017)	$ (32,357)	$(79,821)	$ (87,305)
Net loss per share — basic and diluted	$(0.40)	$ (0.60)	$(1.47)	$ (1.82)
Weighted-average shares in net loss per share — basic and diluted	54,626	53,719	54,329	47,879
Other comprehensive income:				
Unrealized gain on available-for-sale securities, net	3	512	104	289
Comprehensive loss	$(22,014)	$ (31,845)	$(79,717)	$ (87,016)

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

CYTOKINETICS, INCORPORATED

condensed CONSOLIDATED STATEMENTS OF STOCKHOLDERS' Equity

(In thousands, except share data) (Unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive		Total Stockholders'
	Shares	Amount	Capital	Income	Accumulated Deficit	Equity
Balance, December 31, 2017	53,960,832	$ 54	$ 755,526	$ 343	$ (646,081)	$ 109,842
Stock-based compensation	—	—	7,480	—	—	7,480
Exercise of stock options	415,263	1	3,112	—	—	3,113
Issuance of common stock under Employee Stock Purchase Plan	75,992	—	536	—	—	536
Vesting of restricted stock units, net of taxes withheld	189,433	—	(866)	—	—	(866)
Issuance of warrants	—	—	182	—	—	182
Other comprehensive income	—	—	—	104	—	104
Adoption of ASC 606	—	—	—	—	11,499	11,499
Net loss	—	—	—	—	(79,821)	(79,821)
Balance, September 30, 2018	54,641,520	$ 55	$ 765,970	$ 447	$ (714,403)	$ 52,069

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

CYTOKINETICS, INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands) (Unaudited)

	Nine Months Ended September 30, 2018	September 30, 2017
Cash flows from operating activities:		
Net loss	$(79,821)	$ (87,305)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense on liability related to sale of future royalties	13,026	9,954
Non-cash equity-related expense	7,480	6,588
Depreciation of property and equipment	1,559	1,310
Interest receivable and amortization on investments	(1,237)	—
(Gain) loss on disposal of equipment	—	(82)
Non-cash interest expense related to debt	412	418
Changes in operating assets and liabilities:		
Accounts receivable	(8,044)	(9,976)
Contract assets	13,537	—
Prepaid and other assets	2,026	(2,308)
Accounts payable	(3,230)	1,462
Accrued and other liabilities	(2,109)	(132)
Contract liabilities	(18,750)	—
Deferred revenue	(13,737)	2,383
Net cash used in operating activities	(88,888)	(77,688)
Cash flows from investing activities:		
Purchases of investments	(188,428)	(214,457)
Sales and maturities of investments	167,732	119,963
Purchases of property and equipment	(679)	(2,097)
Net cash used in investing activities	(21,375)	(96,591)
Cash flows from financing activities:		
Public offerings of common stock, net of issuance costs	—	112,224
Sale of future royalties, net of issuance costs	—	90,621
Issuance of common stock related to sale of future royalties, net of issuance costs	—	7,560
Issuance of long term debt, net of debt discount and issuance costs	9,898	—
Issuance of equity for stock-based awards and warrants, net	2,783	13,320
Net cash provided by financing activities	12,681	223,725
Net increase (decrease) in cash and cash equivalents	(97,582)	49,446
Cash and cash equivalents, beginning of period	125,206	66,874
Cash and cash equivalents, end of period	$27,624	$ 116,320

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

CYTOKINETICS, INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization and Significant Accounting Policies

Cytokinetics, Incorporated (the "Company", "we" or "our") was incorporated under the laws of the state of Delaware on August 5, 1997. The Company is a late stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions.

Our financial statements contemplate the conduct of our operations in the normal course of business. We have incurred an accumulated deficit of $714.4 million since inception and there can be no assurance that we will attain profitability. The Company anticipates that it will have operating losses and net cash outflows in future periods.

We are subject to risks common to late stage biopharmaceutical companies including, but not limited to, development of new drug candidates, dependence on key personnel, and the ability to obtain additional capital as needed to fund our future plans. Our liquidity will be impaired if sufficient additional capital is not available on terms acceptable to us. To date, we have funded operations primarily through sales of our common stock, contract payments under our collaboration agreements, sale of future royalties, debt financing arrangements, sales of our convertible preferred stock, government grants and interest income. Until we achieve profitable operations, we intend to continue to fund operations through payments from strategic collaborations, additional sales of equity securities, grants and debt financings. We have never generated revenues from commercial sales of our drugs and may not have drugs to market for at least several years, if ever. Our success is dependent on our ability to enter into new strategic collaborations and/or raise additional capital and to successfully develop and market one or more of our drug candidates. As a result, we may choose to raise additional capital through equity or debt financings to continue to fund operations in the future. We cannot be certain that sufficient funds will be available from such a financing or through a collaborator when required or on satisfactory terms. Additionally, there can be no assurance that our drug candidates will be accepted in the marketplace or that any future products can be developed or manufactured at an acceptable cost. These factors could have a material adverse effect on our future financial results, financial position and cash flows.

Based on the current status of our research and development activities, we believe that our existing cash, cash equivalents and investments will be sufficient to fund cash requirements for at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q. If, at any time, our prospects for financing research and development programs decline, we may decide to reduce research and development expenses by delaying, discontinuing or reducing funding of one or more of our research or development programs. Alternatively, we might raise funds through strategic collaborations, public or private financings or other arrangements. Such funding, if needed, may not be available on favorable terms, or at all. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis of Presentation

Our condensed consolidated financial statements include the accounts of Cytokinetics and our wholly-owned subsidiary. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") for interim financial information and the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The financial statements include all adjustments (consisting only of normal recurring adjustments) that management believes are necessary for the fair statement of our financial information. These interim results are not necessarily indicative of results to be expected for the full fiscal year or any future interim period. The balance sheet at December 31, 2017 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements. The financial statements and related disclosures have been prepared with the

presumption that users of the interim financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and notes thereto contained in the Company's Form 10-K for the year ended December 31, 2017, as filed with the SEC.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the condensed consolidated financial statements and reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, investments, accrued research and development expenses, other long-lived assets, stock-based compensation and the valuation of deferred tax assets. We base our estimates on our historical experience and also on assumptions that we believe are reasonable; however, actual results could significantly differ from those estimates.

Revenue Recognition – Adoption of Revenue from Contracts with Customers ASC 606

On January 1, 2018, we adopted Revenue from Contracts with Customers (ASC 606), using the modified retrospective method. On January 1, 2018, for contracts within the scope of ASC 606, we recognized a contract asset or liability and reduced our accumulated deficit by $11.5 million for the effect of adopting ASC 606 and did not revise our prior period financial statements. Pursuant to ASC 606, to recognize revenue from a contract with a customer, we:

(i) identify our contracts with our customers;

(ii) identify our distinct performance obligations in each contract;

(iii) determine the transaction price of each contract;

(iv) allocate the transaction price to the performance obligations; and

(v) recognize revenue as we satisfy our performance obligations.

At contract inception, we assess the goods or services promised within each contract and assess whether each promised good or service is distinct and determine those that are performance obligations. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Collaborative Arrangements

We enter into collaborative arrangements with partners that typically include payment to us for one of more of the following: (i) license fees; (ii) milestone payments related to the achievement of developmental, regulatory, or commercial goals; and (iii) royalties on net sales of licensed products. Each of these payments results in collaboration or other revenues. Where a portion of non-refundable up-front fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as revenue when (or as) the underlying performance obligation is satisfied.

As part of the accounting for these arrangements, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligation. The stand-alone selling price may include such items as, forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success, to determine the transaction price to allocate to each performance obligation.

For our collaboration agreements that include more than one performance obligation, such as a license combined with a commitment to perform research and development services, we make judgments to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate our progress each reporting period and, if necessary, adjust the measure of a performance obligation and related revenue recognition.

License Fees: If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable,

up-front license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments: We use judgement to determine whether a milestone is considered probable of being reached. Using the most likely amount method, we include the value of a milestone payment in the consideration for a contract at inception if we then conclude achieving the milestone is more likely than not. Otherwise, we exclude the value of a milestone payment from contract consideration at inception and recognize revenue for a milestone at a later date, when we judge that it is more likely than not that the milestone will be achieved. If we conclude it is probable that a significant revenue reversal would not occur, the associated milestone is included in the transaction price. We then allocate the transaction price to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

Royalties: For contracts that include sales-based royalties, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied. To date, we have not recognized any royalty revenues resulting from contracts.

Income Taxes

We account for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. We establish valuation allowances when necessary to reduce deferred tax assets to the amounts expected to be realized. We recognize uncertain tax positions taken or expected to be taken on a tax return. Tax positions are initially recognized when it is more likely than not that the position will be sustained upon examination by the tax authorities. We measure our tax positions as the largest amount of tax benefit that is more likely than not of being realized upon ultimate settlement with the tax authority assuming full knowledge of the position and relevant facts. We recognize interest accrued related to unrecognized tax benefits and penalties as income tax expense.

In December 2017, the Tax Cuts and Jobs Act of 2017 (the “Tax Act”) was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a corporate tax rate decrease from 34% to 21% effective for tax years beginning after December 31, 2017. Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of US GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. We continue to analyze certain provisions of the Act including the application of new executive compensation limitation provisions under Internal Revenue Section 162(m). These items are subject to revisions from further analysis of the Tax Act and interpretation of any additional guidance issued by the U.S. Treasury Department, IRS, FASB, and other standard-setting and regulatory bodies.

We did not record a provision for income tax for three and nine months ended September 30, 2018 because we expect to report a net tax loss for the year ending December 31, 2018.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, ‘Financial Instruments — Credit Losses — Measurement of Credit Losses on Financial Instruments. ASU 2016-13 changes the impairment model for most financial assets and certain other instruments and is effective for annual and interim reporting periods beginning after December 15, 2019. We do not expect the adoption of ASU 2016-13 to have a material impact on our financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). ASU 2016-02 requires us to record right-of-use asset and lease liability on the statement of financial position for operating leases with lease terms of more than 12 months and is effective for annual and interim reporting periods beginning on or after December 15, 2018. We expect to adopt this standard beginning in 2019 using the modified retrospective approach. We do not expect that this standard will have a material impact on our results of operations, but we do expect that upon adoption, it will have a material impact on our assets and liabilities. The primary effect of adoption will be the requirement to record right-of-use assets and corresponding lease obligations for current operating leases with lease terms of more than 12 months.

Note 2 — Net Loss Per Share

We excluded the following from diluted net loss per share because inclusion would have been antidilutive (in thousands):

	Nine Months Ended September 30,	
	2018	2017
Options to purchase common stock	5,451	6,020
Warrants to purchase common stock	107	100

Restricted Stock and Performance units	562	459
Shares issuable related to the ESPP	28	41
	6,148	6,620

Note 3 — Revenue Recognition

We believe recognizing revenue as research and development services are performed provides a faithful depiction of the transfer of the services because completion of clinical programs results in data useful to determine satisfaction of our promise. We may fund research and development in advance of the performance of the services. When we complete our performance obligation, if we have received more than we incurred, we are obligated to return unused advance funding. We recognize these advance payments as deferred revenue until we perform the related services.

Our revenue for the three and nine months ended September 30, 2018 was affected by adopting ASC 606 as follows (in thousands):

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Research and development revenue using guidance in effect prior to ASC 606	$ (872)	$ (2,206)
Impact of adoption of ASC 606	9,598	19,197
Research and development revenue	$ 8,726	$ 16,991
License revenue using guidance in effect prior to ASC 606	$ 4,954	$ 12,901
Impact of adoption of ASC 606	(3,039)	(7,768)
License revenue	$ 1,915	$ 5,133

The impact of adoption of ASC 606 on our net loss per share was as follows (in thousands):

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Net loss per share using guidance in effect prior to ASC 606	$ (0.52)	$ (1.68)
Impact of adoption of ASC 606	0.12	0.21
Net loss per share	$ (0.40)	$ (1.47)

We have completed our performance obligations for the Co-Invest Option and the 2014 Astellas agreement. We expect to complete our performance obligations for the 2016 Astellas Amendment in 2019. Our contract assets and liabilities changed during the period, as follows (in thousands):

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Contract liability from the Amgen Agreement for the Co-Invest Option		
Balance at beginning of period	$ 6,250	$ 18,750
Payments made for the Co-Invest Option	(6,250)	(18,750)
Balance at end of period	$ —	$ —
Contract asset from the 2016 Astellas Amendment		
Balance at beginning of period	$ 10,375	$ 19,413
Reduction for services performed	(5,562)	(12,865)
Cash received in advance of services performed	1,063	(672)
Balance at end of period	$ 5,876	$ 5,876
Contract liability from the 2014 Astellas Amendment		
Balance at beginning of period	$ 1,882	$ 6,288
Reduction for services performed	(1,882)	(6,288)
Balance at end of period	$ —	$ —

Note 4 — Research and Development Arrangements

Amgen Inc. (“Amgen”)

We and Amgen continue activities related to novel small molecule therapeutics, including omecamtiv mecarbil, that activate cardiac muscle contractility for potential applications in the treatment of heart failure under the collaboration and option agreement between the Company and Amgen, as amended (the “Amgen Agreement”). We recognize research and development revenue for reimbursements from Amgen of both internal costs of certain full-time employee equivalents and other costs related to the Amgen Agreement.

In July 2018, we paid Amgen the final $6.3 million and completed the exercise of our option under the Amgen Agreement to co-invest $40.0 million in the Phase 3 development program of omecamtiv mecarbil in exchange for a total incremental royalty from Amgen of up to 4% on increasing worldwide sales of omecamtiv mecarbil outside Japan (the “Co-Invest Option”). We paid Amgen $18.8 million to fund the Co-Invest Option during the nine months ended September 30, 2018. Payments we made to fund the Co-Invest Option in 2016 and 2017 reduced research and development revenues in 2016 and 2017 by $1.3 million and $20.0 million, respectively.

Adoption of ASC 606

We determined that the Amgen Agreement was within the scope of ASC 606. As of January 1, 2018, all the performance obligations under the Amgen Agreement were complete. On January 1, 2018, we recognized a contract liability for $18.8 million with a corresponding increase in accumulated deficit for the Co-Invest Option. We paid Amgen $6.3 million and $18.8 million for the Co-Invest Option during the three and nine months ended September 30, 2018, respectively.

Revenue recognized related to the Amgen Agreement during the first nine months of 2017 consisted of $10.0 million for a development milestone related to the start of GALACTIC-HF in Japan and $1.3 million for research and development services, offset by our Co-Invest Option payments of $13.8 million.

Under the Amgen Agreement, we are eligible to receive over $300.0 million in additional development milestone payments based on various clinical milestones, including the initiation of certain clinical studies, the submission of an application for marketing authorization for a drug candidate to certain regulatory authorities and the receipt of such approvals. Additionally, we are eligible to receive up to $300.0 million in commercial milestone payments provided certain sales targets are met. Due to the nature of drug development, including the inherent risk of development and approval of drug candidates by regulatory authorities, we cannot estimate if and when these milestone payments could be achieved or become due and, accordingly, we consider the milestone payments to be constrained and exclude the milestone payments from the transaction price.

Astellas Pharma Inc. (“Astellas”)

Cytokinetics and Astellas continue activities focused on the research, development, and commercialization of skeletal muscle activators, including reldesemtiv, as novel drug candidates for diseases and medical conditions associated with muscle weakness under the Amended and Restated License and Collaboration Agreement dated December 22, 2014, as amended (the “Astellas Agreement”).

We have recognized research and development revenue from Astellas for reimbursements of internal costs of certain full-time employee equivalents, supporting collaborative research and development programs, and of other costs related to those programs.

In 2014, we and Astellas amended and restated the license and collaboration agreement (the “2014 Astellas Amendment”) and expanded the objective of the collaboration to include spinal muscular atrophy (“SMA”) and

potentially other neuromuscular indications for reldesemtiv and other fast skeletal muscle troponin activators ("FSTAs"); in connection therewith, Astellas paid us a $30.0 million non-refundable upfront license fee and a $15.0 million milestone payment. We determined at that time that the license for the expanded SMA rights did not have stand-alone value and the license and research and development services were a single unit of accounting and recognized revenue for these payments using the proportional performance model. As of September 30, 2018, all our performance obligations under the 2014 Astellas Amendment were complete.

In 2016, we and Astellas amended the Astellas Agreement (the "2016 Astellas Amendment") to expand the collaboration to include the development of reldesemtiv for the potential treatment of amyotrophic lateral sclerosis ("ALS"), as well as the possible development in ALS of other FSTAs previously licensed by us to Astellas, and Astellas paid us a $35.0 million non-refundable upfront amendment fee and an accelerated $15.0 million milestone payment for the initiation of the first Phase 2 clinical trial of reldesemtiv in ALS that was otherwise provided for in the Astellas Agreement, as if such milestone had been achieved upon the execution of the 2016 Astellas Amendment, and committed research and development consideration of $44.2 million, for total consideration of $94.2 million. We allocated the consideration to the license and to the research and development services, and recognized license revenue and research and development revenue using the proportional performance model.

Astellas' Option on Tirasemtiv

In 2016, Astellas paid us a $15.0 million non-refundable option fee for the option for a global collaboration for the development and commercialization of tirasemtiv, our first-generation fast skeletal muscle troponin activator (the "Option on Tirasemtiv").

While Astellas holds the Option on Tirasemtiv, we are responsible for and have final decision-making authority on the development of tirasemtiv at our expense. We concluded in 2016 that (i) we had no obligation to Astellas related to any development services pursuant to the Option on Tirasemtiv, (ii) the Option on Tirasemtiv was a substantive option and not a deliverable under the 2016 Astellas Amendment, and (iii) the $15.0 million payment was deferred revenue until the Option on Tirasemtiv is exercised or expires unexercised. The $15.0 million payment was included as deferred revenue in our non-current liabilities at December 31, 2017 (prior to adopting ASC 606).

Adoption of ASC 606

On January 1, 2018, in adopting ASC 606, we concluded: (i) that the original agreement with Astellas in 2013 was outside the scope of ASC 606, since all performance obligations thereunder were completed prior to entering into the 2014 Astellas Amendment and the 2014 Astellas Amendment was not an amendment of the original agreement, (ii) the 2014 Astellas Amendment is a separate agreement within the scope of ASC 606 with no effect on the ongoing accounting for the related license and research and development service deliverables and (iii) the 2016 Astellas Amendment is a separate agreement within the scope of ASC 606. In adopting ASC 606 we determined:

- Our performance obligations were the delivery of the license and performance of research and development services;
- The transaction price included the $50.0 million in non-refundable fees, $35.6 million in committed research and development fees and the $15.0 million Astellas paid us for the Option on Tirasemtiv;
- The consideration allocated to the license resulted in a contract asset of $19.4 million included in other current assets, with a corresponding decrease to accumulated deficit on January 1, 2018, and to be realized using the proportional performance model; and
- Research services we perform under the Astellas Agreement in 2018 and beyond are a separate contract.

The transaction price above was allocated to the license (approximately $83 million) and to the services (approximately $18 million) based on their respective stand-alone prices.

Of the revenue we recognized in 2018, $4.4 million was included in the contract liability at the end of 2017. This revenue includes the cumulative effect of changes made during the period in the estimated costs of research and development services to be incurred to satisfy the related deliverable.

Revenue from Astellas included (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Research and development revenues	$8,526	$ 2,112	$16,791	$ 8,810
License revenues	1,915	318	5,133	6,707
Total Revenue from Astellas	$10,441	$ 2,430	$21,924	$ 15,517

As of September 30, 2018, we have completed all our deliverables for the 2014 Astellas Amendment and have recognized as revenue all the consideration under that agreement. As of September 30, 2018, approximately $9.5 million of the transaction price for the 2016 Astellas Amendment allocated to research and development services remains unrecognized. We had accounts receivable from Astellas of $9.2 million at September 30, 2018 and no accounts receivable at December 31, 2017.

Under the Astellas Agreement, additional research and early and late state development milestone payments for research and clinical milestones, including the initiation of certain clinical studies, the submission of an application for marketing authorization for a drug candidate to certain regulatory authorities and the commercial launch of collaboration products could total over $600.0 million and includes up to $95.0 million relating to reldesemtiv in non-neuromuscular indications, and over $100.0 million related to reldesemtiv in each of SMA, ALS and other neuromuscular indications. Additionally, $200.0 million in commercial milestones could be received under the Astellas Agreement provided certain sales targets are met. We are eligible to receive up to $2.0 million in research

milestone payments under the collaboration for each future potential drug candidate. Due to the nature of drug development, including the inherent risk of development and approval of drug candidates by regulatory authorities, it is not possible to estimate if and when these milestone payments could be achieved or become due, and accordingly, are constrained and not included in the transaction price.

Note 5 — Cash Equivalents and Investments

The amortized cost and fair value of cash equivalents and available for sale investments at September 30, 2018 and December 31, 2017 were as follows (in thousands):

	September 30, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$26,353	$ —	$ —	$26,353
U.S. Treasury securities	79,489	-	(97)	79,392
Agency bonds	27,675	—	(9)	27,666
Commercial paper	62,872	-	(16)	62,856
Corporate obligations	13,883	—	(4)	13,879
	$210,272	$ -	$ (126)	$210,146

	December 31, 2017			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents	$111,501	$ —	$ —	$111,501
Short-term investments	$143,895	$ —	$ (210)	$143,685
Long-term investments	$16,538	$ —	$ (20)	$16,518

Investments available for sale at September 30, 2018 excludes an investment in equity with a fair value and unrealized gain of $0.9 million. At September 30, 2018, there were no investments that had been in a continuous unrealized loss position for 12 months or longer.

Interest income was $1.3 million and $3.3 million for the three and nine months ended September 30 2018 and $0.8 million and $1.8 million for the three and nine months ended September 30, 2017, respectively.

Note 6 — Fair Value Measurements

We value our financial assets and liabilities at fair value, defined as the price that would be received for assets when sold or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). We utilize market data or assumptions that we believe market participants would use in pricing the asset or liability, including assumptions about risk and the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market corroborated or generally unobservable.

We primarily apply the market approach for recurring fair value measurements and endeavors to utilize the best information reasonably available. Accordingly, we use valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, and consider the security issuers' and the third-party issuers' credit risk in our assessment of fair value.

We classify fair value based on the observability of those inputs using a hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement):

Level 1 — Observable inputs, such as quoted prices in active markets for identical assets or liabilities;

Level 2 — Inputs, other than the quoted prices in active markets, that are observable either directly or through corroboration with observable market data; and

Level 3 — Unobservable inputs, for which there is little or no market data for the assets or liabilities, such as internally-developed valuation models.

Fair value of financial assets:

Financial assets measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2017 are classified in the table below in one of the three categories described above (in thousands):

	September 30, 2018 Fair Value Measurements Using			Assets
	Level 1	Level 2	Level 3	At Fair Value
Assets:				
Money market funds	$26,353	$—	$ —	$26,353
U.S. Treasury securities	79,392	—	—	79,392
Agency bonds	—	27,666	—	27,666
Commercial paper	—	62,856	—	62,856
Corporate obligations	—	13,879	—	13,879
	$105,745	$104,401	$ —	$210,146

	December 31, 2017 Fair Value Measurements Using			Assets
	Level 1	Level 2	Level 3	At Fair Value
Assets:				
Money market funds	$51,001	$ —	$ —	$51,001
U.S. Treasury securities	165,801	—		