Good Times Restaurants Inc.
Form 10-Q
February 10, 2017

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 December 27, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission File Number: 0-18590

(Exact Name of Registrant as Specified in Its Charter)	
NEVADA (State or Other Jurisdiction of Incorporation or Organization)	84-1133368 (I.R.S. Employer Identification Number)

141 UNION BLVD, SUITE 400, LAKEWOOD, CO 80228
(Address of Principal Executive Offices, Including Zip Code)
(303) 384-1400
(Registrant's Telephone Number, Including Area Code)

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 is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company, as defined in Rule 12b-2 of the Exchange Act

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

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 February 10, 2017, there were 12,297,550 shares of the Registrant's common stock, par value $0.001 per share, issued and outstanding.

Form 10-Q
Quarter Ended December 27, 2016

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PART I. - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Good Times Restaurants Inc. and Subsidiaries
Consolidated Balance Sheets (Unaudited)
(In thousands, except share and per share data)

	Dec. 27, 2016	Sep. 27, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$3,517	$6,330
Receivables, net of allowance for doubtful accounts of $0	566	425
Prepaid expenses and other	395	349
Inventories	647	631
Notes receivable	58	58
Total current assets	5,183	7,793
PROPERTY AND EQUIPMENT:		
Land and building	5,068	5,069
Leasehold improvements	16,343	14,726
Fixtures and equipment	16,655	15,316
Total property and equipment	38,066	35,111
Less accumulated depreciation and amortization	(16,163)	(15,512)
Total net property and equipment	21,903	19,599
Assets held for sale	1,407	93
OTHER ASSETS:		
Notes receivable, net of current portion	56	59
Deposits and other assets	253	268
Trademarks	3,900	3,900
Other intangibles, net	82	89
Goodwill	15,076	15,076
Total other assets	19,367	19,392
TOTAL ASSETS:	$47,860	$46,877
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt and capital lease obligations	$23	$19
Accounts payable	3,364	1,918
Deferred income	26	23
Other accrued liabilities	2,672	3,162
Total current liabilities	6,085	5,122
LONG-TERM LIABILITIES:		
Maturities of long-term debt and capital lease obligations due after one year	$52	$19
Deferred and other liabilities	4,251	3,938
Total long-term liabilities	4,303	3,957
STOCKHOLDERS' EQUITY:		
Good Times Restaurants Inc. stockholders' equity:		
	0	0

Preferred stock, $.01 par value; 5,000,000 shares authorized, no shares issued and outstanding as of 12/27/16 and 09/27/2016		
Common stock, $.001 par value; 50,000,000 shares authorized, 12,297,550 and 12,282,625 shares issued and outstanding as of 12/27/16 and 09/27/16, respectively	12	12
Capital contributed in excess of par value	58,390	58,191
Accumulated deficit	(22,758)	(22,125)
Total Good Times Restaurants Inc. stockholders' equity	35,644	36,078
Non-controlling interests	1,828	1,720
Total stockholders’ equity	37,472	37,798
TOTAL LIABILITIES AND STOCKHOLDERS’ EQUITY	$47,860	$46,877

See accompanying notes to condensed consolidated financial statements

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Good Times Restaurants Inc. and Subsidiaries
Consolidated Statements of Operations
(Unaudited)
(In thousands except share and per share data)

	Quarter Ended	
	Dec 27, 2016	Dec 31, 2015
NET REVENUES:		
Restaurant sales	$16,386	$13,656
Franchise royalties	169	182
Total net revenues	16,555	13,838
RESTAURANT OPERATING COSTS:		
Food and packaging costs	5,155	4,505
Payroll and other employee benefit costs	5,995	4,772
Restaurant occupancy costs	1,294	1,062
Other restaurant operating costs	1,528	1,251
Preopening costs	351	725
Depreciation and amortization	630	459
Total restaurant operating costs	14,953	12,774
General and administrative costs	1,645	1,606
Advertising costs	412	366
Franchise costs	24	27
Loss on restaurant asset sale	(6)	(5)
LOSS FROM OPERATIONS	(473)	(930

30,000

Other liabilities

4,335

4,347

Total liabilities		
	197,535	
	228,299	
Commitments and contingencies (Note 7)		
Stockholders’ equity:		

Preferred stock, $0.01 par value per share, 5,000,000 shares authorized and no shares issued and outstanding at September 30, 2018 and December 31, 2017

—

—

Common stock, $0.01 par value per share, 125,000,000 shares authorized; 100,968,096 shares issued and outstanding at September 30, 2018; 99,666,549 shares issued and outstanding at December 31, 2017

1,009

997

Additional paid-in capital

4,140,033

3,947,552

Accumulated other comprehensive loss

(33,392

)

(34,433

)

Accumulated deficit

(2,629,531

)

(2,147,685

)

Total stockholders’ equity

1,478,119

1,766,431

Total liabilities and stockholders’ equity

$

1,675,654

$

1,994,730

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

ALNYLAM PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product revenues, net	$460	$—	$460	$—
Net revenues from collaborators	1,609	17,096	53,415	51,988
Total revenues	2,069	17,096	53,875	51,988
Costs and expenses:				
Cost of goods sold	137	—	137	—
Research and development (1)	139,945	95,252	374,384	272,863
Selling, general and administrative (1)	116,545	47,644	273,671	131,910
Total costs and expenses	256,627	142,896	648,192	404,773
Loss from operations	(254,558)	(125,800)	(594,317)	(352,785)
Other income (expense):				
Interest income	6,796	3,296	18,691	8,001
Other income (expense)	2,925	(433)	5,468	(3,863)
Gain on litigation settlement	—	—	20,564	—
Total other income	9,721	2,863	44,723	4,138
Loss before income taxes	(244,837)	(122,937)	(549,594)	(348,647)
Provision for income taxes	(445)	—	(462)	—
Net loss	$(245,282)	$(122,937)	$(550,056)	$(348,647)
Net loss per common share - basic and diluted	$(2.43)	$(1.34)	$(5.48)	$(3.93)
Weighted-average common shares used to compute basic and diluted net loss per common share	100,783	91,828	100,430	88,672
Comprehensive loss:				
Net loss	$(245,282)	$(122,937)	$(550,056)	$(348,647)
Unrealized gain (loss) on marketable securities, net of tax	415	218	1,041	(2,194)
Reclassification adjustment for realized loss on marketable securities included in net loss	—	—	—	1,894
Comprehensive loss	$(244,867)	$(122,719)	$(549,015)	$(348,947)

(1) Stock-based compensation expenses included in operating costs and expenses are as follows:

Research and development	$45,784	$15,090	$67,537	$37,035
Selling, general and administrative	42,170	10,865	62,242	28,667

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

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ALNYLAM PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(550,056)	$(348,647)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and accretion, net	8,663	9,653
Stock-based compensation	129,779	65,702
Non-cash gain on litigation settlement	(10,000)	—
Charge for 401(k) company stock match	3,612	1,735
Unrealized gain on marketable equity securities	(5,004)	—
Realized loss on sale of marketable equity securities	—	1,894
Other	—	608
Changes in operating assets and liabilities:		
Proceeds from landlord lease incentive for tenant improvements	11,597	—
Accounts receivable, net	30,640	8,690
Inventory	(10,354)	—
Prepaid expenses and other assets	(34,125)	(2,052)
Accounts payable	(650)	(17,271)
Accrued expenses and other	25,242	5,990
Deferred revenue	(11,503)	(6,044)
Net cash used in operating activities	(412,159)	(279,742)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(89,374)	(83,481)
Purchases of restricted investments	(14,825)	—
Purchases of marketable debt securities	(992,385)	(512,026)
Sales and maturities of marketable securities	1,120,565	465,734
Net cash provided by (used in) investing activities	23,981	(129,773)
Cash flows from financing activities:		
Proceeds from exercise of stock options and other types of equity	61,268	41,600
Proceeds from issuance of common stock, net of offering costs	—	355,150
Proceeds from issuance of common stock to Sanofi Genzyme	—	21,381
Payments for repurchase of common stock for employee tax withholding	(1,176)	(188)
Net cash provided by financing activities	60,092	417,943
Net (decrease) increase in cash, cash equivalents and restricted cash	(328,086)	8,428
Cash, cash equivalents and restricted cash, beginning of period	646,832	195,088
Cash, cash equivalents and restricted cash, end of period	$318,746	$203,516

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within our condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed

consolidated statements of cash flows:

	At September 30,	
	2018	2017
Cash and cash equivalents	$316,608	$202,045
Restricted cash included in long-term other assets	2,138	1,471
Total cash, cash equivalents, and restricted cash shown in the condensed consolidated statements of cash flows	$318,746	$203,516

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

ALNYLAM PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. NATURE OF BUSINESS

We commenced operations on June 14, 2002 as a biopharmaceutical company seeking to develop and commercialize novel therapeutics based on RNA interference, or RNAi. We are focused on discovering, developing and commercializing RNAi therapeutics by establishing and maintaining a strong intellectual property position in the RNAi field, establishing strategic alliances with leading pharmaceutical and life sciences companies, generating revenues through licensing agreements, and ultimately developing and commercializing RNAi therapeutics globally, either independently or with our strategic partners. We have devoted substantially all of our efforts to business planning, research, development and early commercial efforts, acquiring, filing and expanding intellectual property rights, recruiting management and technical staff, and raising capital. In late 2017, we filed a new drug application, or NDA, and a marketing authorisation application, or MAA, seeking regulatory approval of ONPATTRO™ (patisiran), our first product, in the United States and Europe, respectively. We received approval of ONPATTRO from the United States Food and Drug Administration, or FDA, on August 10, 2018 and began commercializing and generating product revenues in the United States in August 2018. On August 30, 2018, we received approval of ONPATTRO from the European Commission, or EC, and began commercializing and generating product revenues outside of the United States in October 2018 following the launch of ONPATTRO in Germany.

We are subject to risks common to companies in our industry including, but not limited to, uncertainties relating to conducting clinical research and development, the manufacture and supply of products for clinical and commercial use, obtaining and maintaining regulatory approvals and pricing and reimbursement for our products, market acceptance, managing global growth and operating expenses, availability of additional capital, competition, obtaining and enforcing patents, stock price volatility, dependence on collaborative relationships and third-party service providers, dependence on key personnel, potential litigation, product liability claims and government investigations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying condensed consolidated financial statements of Alnylam Pharmaceuticals, Inc. are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, applicable to interim periods and, in the opinion of management, include all normal and recurring adjustments that are necessary to state fairly the results of operations for the reported periods. Our condensed consolidated financial statements have also been prepared on a basis substantially consistent with, and should be read in conjunction with, our audited consolidated financial statements for the year ended December 31, 2017, which were included in our Annual Report on Form 10-K that was filed with the Securities and Exchange Commission, or SEC, on February 15, 2018. The year-end condensed consolidated balance sheet data was derived from our audited financial statements, but does not include all disclosures required by GAAP. The results of our operations for any interim period are not necessarily indicative of the results of our operations for any other interim period or for a full fiscal year.

The accompanying condensed consolidated financial statements reflect the operations of Alnylam and our wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. In our condensed consolidated financial statements, there are significant estimates and assumptions related to our inventory valuation and related reserves, income taxes, revenue recognition, research and development expenses, and stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable. Actual results could differ from those estimates.

Liquidity

Based on our current operating plan, we believe that our cash, cash equivalents and marketable debt securities at September 30, 2018, together with the cash we expect to generate from product sales and under our current alliances, will be sufficient to enable us to advance our Alnylam 2020 strategy for at least the next 12 months from the filing of this Quarterly Report on Form 10-Q.

Net Loss Per Common Share

We compute basic net loss per common share by dividing net loss by the weighted-average number of common shares outstanding. We compute diluted net loss per common share by dividing net loss by the weighted-average number of common shares and dilutive potential common share equivalents then outstanding. Potential common shares consist of shares issuable upon the exercise of stock options (the proceeds of which are then assumed to have been used to repurchase outstanding shares using the treasury stock method). Because the inclusion of potential common shares would be anti-dilutive for all periods presented, diluted net loss per common share is the same as basic net loss per common share.

The following table sets forth for the periods presented the potential common shares (prior to consideration of the treasury stock method) excluded from the calculation of net loss per common share because their inclusion would be anti-dilutive, in thousands:

	At September 30,	
	2018	2017
Options to purchase common stock	12,676	11,905
Unvested restricted common stock	16	159
	12,692	12,064

Public Offerings

In November 2017, we sold an aggregate of 6,440,000 shares of our common stock through an underwritten public offering at a price to the public of $125.00 per share. As a result of the offering, which included the full exercise of the underwriters' option to purchase additional shares, we received aggregate net proceeds of $784.5 million, after deducting underwriting discounts and commissions and other offering expenses of $20.5 million.

In May 2017, we sold an aggregate of 5,000,000 shares of our common stock through an underwritten public offering at a price to the public of $71.87 per share. As a result of the offering, we received aggregate net proceeds of $355.2 million after deducting underwriting discounts and commissions and other offering expenses of $4.2 million.

Equity

Total stockholders' equity at September 30, 2018 decreased by $288.3 million compared to December 31, 2017. This decrease was related primarily to our net loss, partially offset during the nine months ended September 30, 2018 by an adjustment to the opening balance of our accumulated deficit related to the adoption of the new revenue standard on January 1, 2018, described below under the heading "Recent Accounting Pronouncements," as well as increases to additional paid-in capital due to proceeds from the exercise of stock options and stock-based compensation.

Fair Value Measurements

The fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable, such as quoted prices (adjusted), interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability. The fair value hierarchy level is determined by the lowest level of significant input.

Investments in Marketable Securities and Cash Equivalents

We invest our excess cash balances in short-term and long-term marketable debt securities. We classify our investments in marketable debt securities as either held-to-maturity or available-for-sale based on facts and circumstances present at the time we purchased the securities. At each balance sheet date presented, we classified all of our investments in debt securities as available-for-sale. We report available-for-sale debt securities at fair value at each balance sheet date and include any unrealized holding gains and losses (the adjustment to fair value) in accumulated other comprehensive income (loss), a component of stockholders' equity. At September 30, 2018, the balance in our accumulated other comprehensive loss was composed solely of activity related to our marketable debt securities and our investment in equity securities of Regulus Therapeutics Inc., or Regulus. Realized gains and losses are determined using the specific identification method and are included in other income (expense). We did not recognize any realized gains or losses from sales of our available-for-sale debt securities during the nine months ended September 30, 2018 or 2017, and as a result, did not reclassify any amount out of accumulated other comprehensive loss for the respective period related to our available-for-sale debt securities. If any adjustment to fair value reflects a decline in the value of the marketable debt securities, we consider all available evidence to evaluate the extent to which the decline is "other than temporary," including our intention to sell and, if so, mark

the investment to market through a charge to our condensed consolidated statements of comprehensive loss. We did not record any impairment charges related to our marketable debt securities during the nine months ended September 30, 2018 or 2017. Our marketable debt securities are classified as cash equivalents if the original maturity, from the date of purchase, is 90 days or less, and as marketable debt securities if the original maturity, from the date of purchase, is in excess of 90 days. Our cash equivalents are composed of commercial paper, corporate notes, U.S. government-sponsored enterprise securities, U.S. treasury securities and money market funds.

Upon the adoption of the new accounting standard, discussed below under the heading “Recent Accounting Pronouncements,” effective January 1, 2018, we measure marketable equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of an investee), which have readily available prices, at fair value with changes in fair value recognized in other income (expense) on our condensed consolidated statements of comprehensive loss. Prior to January 1, 2018, we recognized unrealized gains and losses on our marketable equity securities through accumulated other comprehensive income (loss) on our condensed consolidated balance sheets. At September 30, 2018, our marketable equity securities were comprised solely of 983,208 shares of Dicerna Pharmaceuticals, Inc., or Dicerna, common stock that we received under a Settlement Agreement and General Release entered into in April 2018, referred to as the Settlement Agreement, described more fully below at Note 7. During the three and nine months ended September 30, 2018, we recorded an unrealized gain of $3.0 million and $5.0 million, respectively, for the change in the fair value of the Dicerna common stock as other income on our condensed consolidated statements of comprehensive loss. At December 31, 2017, there were no marketable equity securities on our condensed consolidated balance sheet.

During the second quarter of 2017, we sold all our remaining holdings in Regulus. We accounted for our investment in Regulus as an available-for-sale marketable equity security. We recognized $1.9 million of realized losses from sales of our Regulus available-for-sale securities as other expense in our condensed consolidated statement of comprehensive loss during the nine months ended September 30, 2017. Intraperiod tax allocation rules require us to allocate our provision for income taxes between continuing operations and other categories of earnings, such as other comprehensive income. In periods in which we have a year-to-date pre-tax loss from continuing operations and pre-tax income in other categories of earnings, such as other comprehensive income, we must allocate the tax provision to the other categories of earnings. We then record a related tax benefit in continuing operations. Upon sales of our marketable equity securities, we apply the aggregate portfolio approach to recognize the related tax provision or benefit into income (loss) from continuing operations. As a result, the disproportionate tax effect remains in accumulated other comprehensive income (loss) as long as we maintain an investment portfolio. At September 30, 2018 and December 31, 2017, there was $32.8 million of accumulated other comprehensive loss, net of tax, recorded on our condensed consolidated balance sheets related to our investment in Regulus.

Accounts Receivable

We record accounts receivable net of customer allowances for distribution services, prompt payment discounts and chargebacks based on contractual terms. As of September 30, 2018, we determined an allowance for doubtful accounts was not required based upon our review of contractual payment terms and individual customer circumstances. We have standard payment terms that generally require payment within approximately 30 to 40 days. Accounts receivable, net on our condensed consolidated balance sheets also includes billed and unbilled collaboration receivables.

Inventory

Prior to initial regulatory approval, we expense costs relating to the production of inventory as research and development expenses on our condensed consolidated statements of comprehensive loss in the period incurred, unless we believe regulatory approval and subsequent commercialization of the product candidate is probable and we expect the future economic benefit from sales of the product to be realized, at which point we capitalize the costs as inventory.

Inventory is measured at the lower of cost or estimated net realizable value. We use a standard cost basis, which approximates average cost determined on a first-in, first-out basis. Inventory costs include all raw materials, direct conversion costs and overhead. Raw and intermediate materials that may be used for either research and development or commercial purposes are classified as inventory until the material is consumed or otherwise allocated for research and development. If the material is used for research and development, it is expensed as research and development once that determination is made.

We capitalize inventory costs that are expected to be sold commercially once we determine there is a high probability that the inventory costs will be recovered through commercial sale based on the review of several factors, including (i) the likelihood that all required regulatory approvals will be obtained, (ii) the expected timing of validation (if not yet completed) of manufacturing processes in the associated facility, (iii) the expected expiration of the inventory, (iv) logistical or commercial constraints that may impede the timely distribution and sale of the product, including transport requirements and reimbursement status, (v) history of approvals of similar products or formulations and (vi) potential legal challenges.

We reduce our inventory to net realizable value for potentially excess, dated or obsolete inventory based on our quarterly assessment of the recoverability of our capitalized inventory. Through September 30, 2018, we have not identified any impairment of our capitalized inventory.

Revenue Recognition

We began to record revenues from product sales in the third quarter of 2018 subsequent to the approval of ONPATTRO by the FDA in August 2018. Prior to the third quarter of 2018, all of our revenues were derived from collaboration agreements that we have entered into with leading pharmaceutical and life sciences companies, including Sanofi Genzyme, the specialty care global business unit of Sanofi, and The Medicines Company, or MDCO. The terms of our collaboration agreements may include consideration such as non-refundable license fees, funding of research and development services, payments due upon the achievement of clinical and pre-clinical performance-based development milestones, regulatory milestones, manufacturing services, sales-based milestones and royalties on product sales.

On January 1, 2018, we adopted the new revenue standard, discussed below under the heading “Recent Accounting Pronouncements,” which amended revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. Our adoption of the new revenue standard had a material impact on our condensed consolidated financial statements, as discussed below under the heading “Recent Accounting Pronouncements.” This new revenue standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. The new revenue standard provides a five-step framework whereby revenue is recognized when control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of the new revenue standard, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when collectability of the consideration to which we are entitled in exchange for the goods or services we transfer to the customer is determined to be probable. At contract inception, once the contract is determined to be within the scope of the new revenue standard, we assess whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct bundle is identified. We then allocate the transaction price (the amount of consideration we expect to be entitled to from a customer in exchange for the promised goods or services) to each performance obligation and recognize the associated revenue when (or as) each performance obligation is satisfied. Our estimate of the transaction price for each contract includes all variable consideration to which we expect to be entitled.

Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less or the amount is immaterial. At September 30, 2018, we have not capitalized any costs to obtain any of our contracts.

During the nine months ended September 30, 2018 and 2017, all of our revenues were attributed to the United States.

Product revenues, net

In the third quarter of 2018, subsequent to FDA approval in August 2018, we began to ship ONPATTRO in the United States to specialty pharmacies, or SPs, and a specialty distributor, or SD, collectively referred to as our

customers. Our customers subsequently resell ONPATTRO to health care providers. We recognize product revenues, net of variable consideration related to certain allowances and accruals, in our condensed consolidated financial statements at the time of sale. In the event the variable consideration is constrained, we include an amount to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur in a future reporting period. We use the expected value method to estimate variable consideration related to ONPATTRO sales. We do not have any material constraints on our variable consideration included within the transaction price of our ONPATTRO revenue arrangements. Each unit of ONPATTRO that is ordered by our customers represents a separate performance obligation that is completed when control of the product is transferred to our customer, which occurs upon delivery of the product to the customer. We record revenues, net of variable consideration and any applicable constraint, at that point in time. We record shipping and handling costs within cost of goods sold on our condensed consolidated statements of comprehensive loss. We classify payments to distributors and other customers in the distribution channel for services that have a separate benefit and fair value as selling, general and administrative expenses on our condensed consolidated statements of comprehensive loss. We have elected to exclude taxes collected from our customers and remitted to governmental authorities from the measurement of the transaction price. We periodically evaluate the creditworthiness of our customers.

The following are the components of variable consideration related to product revenues:

Chargebacks: We estimate obligations resulting from contractual commitments with the government and other entities to sell products to qualified healthcare providers at prices lower than the list prices charged to the SD who purchases ONPATTRO from us. The SD charges us for the difference between what the SD pays to us for the product and the selling price to the qualified healthcare providers. We record reserves, based on contractual terms, for these chargebacks related to product sold to SDs during the reporting period, as well as our estimate of product that remains in the SD distribution channel inventory at the end of the reporting period that we expect will be sold to qualified healthcare providers.

Government rebates: We are subject to discount obligations under government programs, including Medicaid in the United States. We record reserves for government rebates in the same period the related product revenue is recognized, resulting in a reduction of ONPATTRO product revenues and a current liability that is included in accrued expenses on our condensed consolidated balance sheet. Our estimate for government rebates is based on statutory discount rates and expected utilization. On a quarterly basis, we will update our estimates and record any needed adjustments in the period the we identify the adjustments.

Trade discounts and allowances: We provide customary invoice discounts on ONPATTRO sales to our customers for prompt payment and we pay fees for distribution services that are not for a distinct good or service and for which we can reasonably estimate the fair value, such as fees for certain data that customers provide to us. We estimate our customers will earn these discounts and fees, and deduct these discounts and fees in full from gross ONPATTRO revenues and accounts receivable at the time we recognize the related revenues.

Product Returns: ONPATTRO may be returned if it is damaged, defective or expired, with “expired” defined as having three months or less to expiry or within three months past expiry. We estimate the amount of product that will be returned using a probability-weighted estimate, initially calculated based on a portfolio of data from similar products and industry experience for specialty pharmacy products. Based on the distribution model for ONPATTRO, contractual inventory limits with our customers, the price of ONPATTRO and limited contractual return rights, we believe there will be minimal ONPATTRO returns. We have recorded an initial refund liability for our estimate of ONPATTRO returns related to sales during the three months ended September 30, 2018. We will update our estimated refund liability, on at least a quarterly basis, based on actual shipments of ONPATTRO subject to contractual return rights, changes in expectations about the amount of estimated refunds or actual returns as data is known.

Other incentives: Other incentives include co-payment assistance we provide to patients with commercial insurance that have coverage and reside in states that allow co-payment assistance. We estimate the average co-payment assistance amounts for ONPATTRO based on experience with similar products and programs at other pharmaceutical companies and record any such amounts within accrued expenses on our condensed consolidated balance sheet.

During the three and nine months ended September 30, 2018, we recorded product revenues, net, of $0.5 million, which consist of commercial sales of ONPATTRO in the United States.

Revenues from Collaborators

We recognize the transaction price allocated to upfront license payments as revenue upon delivery of the license to the customer and resulting ability of the customer to use and benefit from the license, if the license is determined to be distinct from the other performance obligations identified in the contract. If the license is considered to not be distinct from other performance obligations, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied (i) at a point in time, but only for licenses determined to be distinct from other performance obligations in the contract, or (ii) over time; and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from license payments. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related

revenue recognition.

Many of our collaboration agreements entitle us to additional payments upon the achievement of performance-based milestones. These milestones are generally categorized into three types: development milestones, generally based on the advancement of our pipeline and initiation of clinical trials; regulatory milestones, generally based on the submission, filing or approval of regulatory applications such as a NDA in the United States; and sales-based milestones, generally based on meeting specific thresholds of sales in certain geographic areas. For each collaboration that includes development milestone payments, we evaluate whether it is probable that the consideration associated with each milestone will not be subject to a significant reversal in the cumulative amount of revenue recognized. Amounts that meet this threshold are included in the transaction price using the most likely amount method, whereas amounts that do not meet this threshold are considered constrained and excluded from the transaction price until they meet this threshold. Milestones tied to regulatory approval, and therefore not within our control, are considered constrained until such approval is received. Upfront and ongoing development milestones per our collaboration agreements are not subject to refund if the development activities are not successful. At the end of each subsequent reporting period, we re-evaluate the probability of a

significant reversal of the cumulative revenue recognized for our milestones, 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 revenues from collaborators and loss in the period of adjustment. We exclude sales-based royalties and milestone payments from the transaction price until the sale occurs (or, if later, the underlying performance obligation to which some or all of the royalty has been allocated has been satisfied, or partially satisfied), because the license to our intellectual property is deemed to be the predominant item to which the royalties relate as it is the primary driver of value. Currently, we have not recognized any royalty revenue resulting from any of our agreements.

The new revenue standard requires us to allocate the arrangement consideration on a relative standalone selling price basis for each performance obligation after determining the transaction price of the contract and identifying the performance obligations to which that amount should be allocated. The relative standalone selling price is defined in the new revenue standard as the price at which an entity would sell a promised good or service separately to a customer. If other observable transactions in which we have sold the same performance obligation separately are not available, we are required to estimate the standalone selling price of each performance obligation. Key assumptions to determine the standalone selling price may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Whenever we determine that a contract should be accounted for as a combined performance obligation over time, we determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue is recognized using the proportional performance method. Direct labor hours or full-time equivalents are typically used as the measure of performance. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement.

We evaluate our collaborative agreements for proper classification in our consolidated statements of comprehensive loss based on the nature of the underlying activity. Transactions between collaborators recorded in our consolidated statements of comprehensive loss are recorded on either a gross or net basis, depending on the characteristics of the collaborative relationship. We generally reflect amounts due under our collaborative agreements related to cost-sharing of development activities as revenue if we have a vendor-customer relationship with our collaborator. Costs incurred or shared with our collaboration partners that are deemed to be joint-risk sharing activities are recorded as an adjustment to the related operating expense captions.

For revenue generating arrangements where we, as a vendor, provide consideration to a licensor or collaborator, as a customer, we apply the accounting standard that governs such transactions. This standard addresses the accounting for revenue arrangements where both the vendor and the customer make cash payments to each other for services and/or products. A payment to a customer is presumed to be a reduction of the transaction price unless we receive an identifiable benefit for the payment and we can reasonably estimate the fair value of the benefit received. Payments to a customer that are deemed a reduction of the transaction price are recorded first as a reduction of revenue, to the extent of both cumulative revenue recorded to date and probable future revenues, which include any unamortized deferred revenue balances, under all arrangements with such customer, and then as an expense. Payments that are not deemed to be a reduction of the transaction price are recorded as an expense.

Consideration that does not meet the requirements to satisfy the above revenue recognition criteria is recorded as deferred revenue in the accompanying condensed consolidated balance sheets. Although we follow detailed guidelines in measuring revenue, certain judgments affect the application of our revenue policy. For example, in connection with our existing collaboration agreements, we have recorded on our condensed consolidated balance sheets short-term and long-term deferred revenue based on our best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. Amounts that we expect will not be recognized within the next 12 months are classified as long-term deferred revenue. However, this estimate is based on our current operating plan and, if our operating plan should change in the future, we may recognize a different amount of deferred revenue over the next 12-month period.

The estimate of deferred revenue also reflects management's estimate of the periods of our involvement in certain of our collaborations. Our performance obligations under these collaborations consist of participation on steering committees and the performance of other research and development services. In certain instances, the timing of satisfying these obligations can be difficult to estimate. Accordingly, our estimates may change in the future. Such changes to estimates would result in a change in revenue recognition amounts. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that we recognize and record in future periods. At September 30, 2018, we had short-term and long-term deferred revenue of $3.4 million and $1.6 million, respectively, all related to our collaboration with Vir Biotechnology, Inc.

Cost of Goods Sold

Cost of goods sold includes the cost of producing and distributing inventories that are related to product revenues during the respective period (including salary-related and stock-based compensation expenses for employees involved with production and distribution, freight and indirect overhead costs), third-party royalties payable on our net product revenues and amortization of intangible assets associated with ONPATTRO. Cost of goods sold may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Other Income

As described more fully below at Note 7, in April 2018, we and Dicerna entered into the Settlement Agreement resolving all ongoing litigation between the companies. As a result, during the second quarter of 2018, we recorded $20.6 million as a gain on litigation settlement that is classified as other income on our condensed consolidated statements of comprehensive loss that includes the $10.0 million valuation of Dicerna common stock received at the settlement date, the $2.0 million upfront cash payment received in the second quarter of 2018, and $8.6 million, which represented the discounted present value of the $13.0 million cash payment due from Dicerna by April 18, 2022 under the terms of the Settlement Agreement. Total other income on our condensed consolidated statements of comprehensive loss also includes interest income related to our interest-bearing cash equivalents and marketable debt securities.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued a new revenue recognition standard, which we refer to as the new revenue standard, which amends revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The new revenue standard provides a five-step framework whereby revenue is recognized when control of promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new revenue standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. In August 2015, the FASB deferred the effective date of the new revenue standard from January 1, 2017 to January 1, 2018. In March 2016, the FASB issued amendments to clarify the implementation standard on principal versus agent considerations. In April 2016, the FASB issued amendments to clarify the standard on accounting for licenses of intellectual property and identifying performance obligations. In May 2016, the FASB issued amendments related to collectibility, non-cash consideration, the presentation of sales and other similar taxes collected from customers and transition. The new revenue standard allows for adoption using a full retrospective method or a modified retrospective method. On January 1, 2018, we adopted the new revenue standard by applying the modified retrospective method to all contracts that were not completed as of January 1, 2018. As a result, while reporting periods beginning on our adoption of the new revenue standard are presented under the new revenue standard, prior period amounts have not been adjusted and continue to be presented under the revenue standard in effect prior to January 1, 2018. For contracts that were modified prior to our adoption of the new revenue standard, we reflected the aggregate effect of all modifications that occurred before the beginning of the earliest period presented when identifying performance obligations and allocating the transaction price in accordance with an available practical expedient. Our implementation approach included performing a detailed review of our collaboration agreements not completed as of the transition date. In addition, we designed internal controls to enable the preparation of financial information and have reached conclusions on key accounting assessments related to the new revenue standard, including our assessment that the impact of accounting for costs incurred to obtain a contract is immaterial. There was no impact to cash from or used in operating, financing or investing activities on our condensed consolidated statement of cash flows as a result of the adoption of the new revenue standard.

The following table summarizes the cumulative effect to our condensed consolidated balance sheet upon the adoption of the new revenue standard on January 1, 2018, in thousands:

Condensed Consolidated Balance Sheet	Balance at December 31, 2017	Adjustments	Balance at January 1, 2018

Deferred revenue, current portion	$41,705	$ (34,463)	$7,242
Deferred revenue, net of current portion	$43,075	$ (33,747)	$9,328
Accumulated deficit	$(2,147,685)	$ 68,210	$(2,079,475)

The adoption of the new revenue standard resulted in a cumulative reduction of $68.2 million of deferred revenue with a corresponding adjustment to the opening balance of accumulated deficit recorded in the first quarter of 2018. This adjustment is due primarily to the application of the new revenue standard to our collaboration agreements with Sanofi Genzyme, MDCO and Kyowa Hakko Kirin Co., Ltd., or Kyowa Hakko Kirin. In addition, as a result of the cumulative reduction in deferred revenue, our corresponding deferred tax asset was reduced by $13.6 million, which was offset by a corresponding decrease to our valuation allowance. These offsetting adjustments were recorded to our accumulated deficit in the first quarter of 2018.

A substantial portion of the incremental $68.2 million adjustment is the result of the application of the new revenue standard regarding how entities should measure progress in satisfying performance obligations and the contract's transaction price. In particular, for Sanofi Genzyme and MDCO, the adoption of the new revenue standard resulted in the recognition of previously deferred revenue of $45.7 million and $4.5 million, respectively, due to the change in the way we measure our performance under each agreement, from a straight-line method to a proportional performance model. As a result, at January 1, 2018, the balance of remaining deferred revenues was $3.5 million and $1.2 million, respectively, related to Sanofi Genzyme and MDCO. In addition, the adoption of the new revenue standard resulted in the recognition of $15.5 million of previously deferred revenue related to our Kyowa Hakko Kirin agreement. Under the revenue standard in effect at the time this agreement was executed, we had been unable to reasonably estimate our period of performance under the Kyowa Hakko Kirin agreement as we were unable to estimate the timeline of

our deliverables related to the fixed-price option granted to Kyowa Hakko Kirin for any additional compounds, an obligation that was bundled with all other deliverables into a single unit of accounting. Under the new revenue standard, two distinct performance obligations were identified. The first distinct performance obligation included a license to our program targeting respiratory syncytial virus, or RSV, infection, related know-how and updates, manufacturing supply services and joint steering committee services. The second distinct performance obligation included the fixed-price option to a future follow-on compound. We allocated all consideration to the first performance obligation because the second performance obligation was deemed to have a de minimis relative selling price due to its low likelihood of occurring, in part due to our discontinuation of our RSV program. Given this fact pattern, because we do not expect to incur any future costs related to our RSV program, we concluded our performance obligations were complete in the period prior to our adoption of the new revenue standard and therefore, there would not be a future significant reversal of revenue. As a result, we recorded the $15.5 million of deferred revenue as of December 31, 2017 as an adjustment to the opening balance of our accumulated deficit on January 1, 2018.

In accordance with the new revenue standard requirements, the following tables summarize the impact of adoption on our condensed consolidated balance sheet and condensed consolidated statement of comprehensive loss, in thousands:

	At September 30, 2018		
Condensed Consolidated Balance Sheet	As Reported	Balances Without Adoption of New Revenue Standard	Effect of Change Higher/(Lower)
Deferred revenue, current portion	$3,444	$3,444	$ —
Deferred revenue, net of current portion	$1,623	$19,615	$ (17,992)
Accumulated deficit	$(2,629,531)	$(2,647,608)	$ (18,077)

	Three Months Ended September 30, 2018		
Condensed Consolidated Statement of Comprehensive Loss	As Reported	Balances Without Adoption of New Revenue Standard	Effect of Change Higher/(Lower)
Net revenues from collaborators	$1,609	$2,307	$ (698)

Net loss	$(245,282)	$(244,584)	$ 698
Net loss per common share - basic and diluted	$(2.43)	$(2.43)	$ —

	Nine Months Ended September 30, 2018		
Condensed Consolidated Statement of Comprehensive Loss	As Reported	Balances Without Adoption of New Revenue Standard	Effect of Change Higher/(Lower)
Net revenues from collaborators	$53,415	$103,548	$ (50,133)
Net loss	$(550,056)	$(499,923)	$ 50,133
Net loss per common share - basic and diluted	$(5.48)	$(4.98)	$ 0.50

The impact of our adoption of the new revenue standard did not have a material impact on the amount of net product revenues recognized during the three and nine months ended September 30, 2018.

In addition to the reduction to deferred revenues recorded and corresponding offset to the accumulated deficit described above, on January 6, 2018, we and Sanofi Genzyme entered into an amendment to our 2014 Sanofi Genzyme collaboration. In connection and simultaneously with entering into the amendment to the 2014 Sanofi Genzyme collaboration, we and Sanofi Genzyme also entered into an Exclusive License Agreement with respect to all transthyretin, or TTR, products, including ONPATTRO, ALN-TTRsc02 and any back-up products, referred to as the Exclusive TTR License, and the ALN-AT3 Global License Terms with respect to fitusiran and any back-up products, referred to as the AT3 License Terms. Please read Note 3 for a discussion of our accounting related to the 2014 Sanofi Genzyme collaboration, as amended in January 2018, together with the Exclusive TTR License and the AT3 License Terms.

In January 2016, the FASB issued a new standard on recognition and measurement of financial assets and financial liabilities. The new standard impacts the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. All equity investments in unconsolidated entities (other than those accounted for under the equity method of accounting) will generally be measured at fair value with changes in fair value recognized through earnings. There is no longer an available-for-sale classification (changes in fair value reported in other comprehensive income (loss)) for equity securities with readily determinable fair values. For equity investments that do not have readily determinable fair values, such as privately issued corporate equity securities, we have elected the measurement alternative. As a result, we will record these investments at cost, less any impairment, and adjust for observable price changes in orderly transactions for identical or similar investments of the same issuer. At September 30, 2018 and December 31, 2017, we did not have material equity investments without readily determinable fair values. In addition, the FASB clarified the need for a valuation allowance on deferred tax assets resulting from unrealized losses on available-for-sale debt securities. In general, the new standard requires modified retrospective application to all outstanding instruments, with a cumulative effect adjustment recorded to opening retained earnings. This standard became effective for us on January 1, 2018. This standard had an impact on our condensed consolidated financial statements and related disclosures beginning in the second quarter of 2018 as a result of the 983,208 shares of common stock of Dicerna, a publicly traded company, that we received in April 2018, described more fully above. During the three and nine months ended September 30, 2018, we recorded an unrealized gain of $3.0 million and $5.0 million, respectively, for the change in the fair value of such shares of Dicerna common stock as other income on our condensed consolidated statements of comprehensive loss as a result of the application of this new standard.

In February 2016, the FASB issued a new leasing standard that requires that all lessees recognize the assets and liabilities that arise from leases on the condensed consolidated balance sheet and disclose qualitative and quantitative information about its leasing arrangements. We will adopt this standard using a modified retrospective transition approach to be applied to leases existing as of, or entered into after, January 1, 2019. We expect that our adoption of this standard will result in the recognition of material right-of-use assets and lease liabilities on our condensed consolidated balance sheets. While we are continuing to assess all potential impacts of this standard on our condensed consolidated financial statements and related disclosures, upon adoption we expect that the most significant impact of this standard on our condensed consolidated balance sheets will relate to the accounting for our lease agreement for laboratory and office space located at 675 West Kendall Street, Cambridge, Massachusetts, and our lease agreement, as amended, for laboratory and office space located at 300 Third Street, Cambridge, Massachusetts.

In November 2016, the FASB issued a new standard that requires restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the total beginning and ending amounts for the periods shown on the condensed consolidated statements of cash flows. The new standard became effective for us on January 1, 2018 using a retrospective transition method for each period presented. For the years ended December 31, 2017 and 2016, our restricted cash and restricted cash equivalents were not significant. This standard did not have a significant impact on our condensed consolidated financial statements and related disclosures.

In March 2017, the FASB issued a new standard that amends the amortization period for certain purchased callable debt securities held at a premium by shortening the amortization period for the premium to the earliest call date. The new standard will be effective for us on January 1, 2019. Early adoption is permitted. We are currently evaluating the timing of our adoption and the expected impact that this standard could have on our condensed consolidated financial statements and related disclosures.

In March 2018, the FASB issued a new standard to incorporate SEC Staff Accounting Bulletin No. 118, or SAB 118, which addresses the accounting implications of the Tax Cuts and Jobs Act, or TCJA, enacted on December 22, 2017. SAB 118 allows a company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date and was effective upon issuance. We continue to assess the TCJA, and in certain areas, have made reasonable estimates of the effects on our condensed consolidated financial statements and tax disclosures, described more fully below at Note 8.

In June 2018, the FASB issued amendments to simplify the accounting for share-based payment awards to nonemployees by aligning the measurement and classification guidance, with certain exceptions, to that for share-based payment awards to employees. The amendments expand the scope of the accounting standard for share-based payment awards to include share-based payment awards granted to nonemployees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance related to equity-based payments to non-employees. We elected to early adopt these amendments on July 1, 2018. The adoption of these amendments did not have a significant impact on our condensed consolidated financial statements and related disclosures.

In August 2018, the FASB issued amendments that eliminate, add and modify certain disclosure requirements on fair value measurements. The amendments become effective for our fiscal year, including interim periods, beginning January 1, 2020. Early adoption, of the amendments in full or only the provisions that eliminate or modify the disclosure requirements for fair value measurements, is permitted. We are currently evaluating the timing of our adoption and the expected impact that these amendments could have on our disclosures.

In August 2018, the SEC issued a final rule amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the condensed consolidated balance sheet must be provided in a note or separate statement. This analysis should present a reconciliation of the beginning balance to the ending balance of each caption in stockholders' equity for each period for which a condensed consolidated statement of comprehensive loss is required to be filed. This final rule became effective on November 5, 2018. However, the SEC has issued guidance that the SEC will not object if a company initially presents the changes in stockholders' equity in its first quarterly report for the quarter that begins after the effective date of the final rule. We are currently evaluating the impact of the final rule on our condensed consolidated financial statements and related disclosures.

In November 2018, the FASB issued guidance to clarify the interaction between the accounting guidance for collaborative arrangements and revenue from contracts with customers. The amendments become effective for our fiscal year, including interim periods, beginning January 1, 2020. Early adoption, including adoption in any interim period, is permitted. This guidance is required to be applied retrospectively as of the date of our adoption of the new revenue standard on January 1, 2018. We are currently evaluating the timing of our adoption and the expected impact this guidance could have on our condensed consolidated financial statements and related disclosures.

3. COLLABORATION AGREEMENTS

The following table summarizes our total consolidated net revenues from collaborators, for the periods indicated, in thousands:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Description	2018	2017	2018	2017
Sanofi Genzyme	$(1,560)	$14,603	$40,370	$41,255
Vir Biotechnology	2,957	—	10,313	—
MDCO	—	2,255	1,957	10,141
Other	212	238	775	592
Total net revenues from collaborators	$1,609	$17,096	$53,415	$51,988

The following table summarizes our total consolidated net revenues from collaborators, using the prior revenue standard, for the periods indicated, in thousands:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Description	2018	2017	2018	2017
Sanofi Genzyme	$(862)	$14,603	$86,107	$41,255
Vir Biotechnology	2,957	—	10,313	—
MDCO	—	2,255	6,353	10,141

Other	212	238	775	592
Total net revenues from collaborators	$2,307	$17,096	$103,548	$51,988

The following table presents the balance of our contract liabilities related to our collaboration agreements at September 30, 2018 and January 1, 2018, in thousands:

	At September 30, 2018	At January 1, 2018
Contract liabilities:		
Deferred revenues	$ 5,067	$16,570

During the nine months ended September 30, 2018, we recognized the following revenues as a result of the change in the contract liability balances related to our collaboration agreements, in thousands:

Revenue recognized in the period from:	Nine Months Ended September 30, 2018
Amounts included in contract liability at the beginning of the period	$ 14,953

In order to determine revenue recognized in the period from contract liabilities, we first allocate revenue to the individual contract liability balance outstanding at the beginning of the period until the revenue exceeds that balance. If additional consideration is received on those contracts in subsequent periods, we assume all revenue recognized in the reporting period first applies to the beginning contract liability as opposed to a portion applying to the new consideration for the period.

The following table provides the research and development expenses incurred by type that are directly attributable to each agreement for the periods indicated, in thousands:

	Three Months Ended September 30,						Nine Months Ended September 30,					
	2018			2017			2018			2017		
	Sanofi Genzyme	Vir	MDCO	Sanofi Genzyme	Vir	MDCO	Sanofi Genzyme	Vir	MDCO	Sanofi Genzyme	Vir	MDCO
Research and development												
Clinical trial and manufacturing	$4,308	$800	$937	$42,772	$—	$307	$32,403	$6,851	$1,578	$127,127	$—	$5,402
External services	588	1,023	1	1,502	—	67	5,095	7,374	1	2,998	—	67
Other	395	—	2	1,394	—	—	1,145	980	2	4,384	—	24
Total research and development expenses	$5,291	$1,823	$940	$45,668	$—	$374	$38,643	$15,205	$1,581	$134,509	$—	$5,493

The research and development expenses incurred for each agreement listed in the table above consist of costs incurred for external development and manufacturing services for which we are reimbursed, licensing payments made to the counterparty to such agreement and costs directly attributable to Sanofi Genzyme transition services. In addition, these expenses include a reasonable estimate of compensation and related costs as billed to our counterparties. As part of our revenue recognition policy, the costs in the above table are considered as an input in our determination of transaction price when they relate to consideration received for the delivery of goods or services. For the three and nine months ended September 30, 2018 and 2017, we did not incur material selling, general and administrative expenses related to our significant agreements.

Product Alliances

Sanofi Genzyme Collaboration

In January 2014, we entered into a global, strategic collaboration with Sanofi Genzyme to discover, develop and commercialize RNAi therapeutics as Genetic Medicines to treat orphan diseases, referred to as the 2014 Sanofi Genzyme collaboration. The 2014 Sanofi Genzyme collaboration superseded and replaced the previous collaboration between us and Sanofi Genzyme entered into in October 2012 to develop and commercialize RNAi therapeutics targeting TTR for the treatment of hereditary ATTR amyloidosis, including patisiran and revusiran, in Japan and the Asia-Pacific region.

On January 6, 2018, we and Sanofi Genzyme entered into an amendment to our 2014 Sanofi Genzyme collaboration. In connection and simultaneously with entering into the amendment to the 2014 Sanofi Genzyme collaboration, we and Sanofi Genzyme also entered into the Exclusive TTR License and the AT3 License Terms. As a result, we have

the exclusive right to pursue the further global development and commercialization of all TTR products, including ONPATTRO, ALN-TTRsc02 and any back-up products, and Sanofi Genzyme has the exclusive right to pursue the further global development and commercialization of fitusiran and any back-up products. The January 2018 transaction was subject to customary closing conditions and clearances, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, and closed during the first quarter of 2018.

2012 Sanofi Genzyme Agreement

Under the 2012 Sanofi Genzyme agreement, Sanofi Genzyme paid us an upfront cash payment of $22.5 million. We were also entitled to receive certain milestone payments under the 2012 Sanofi Genzyme agreement. In the fourth quarter of 2013, we earned $11.0 million in patisiran development milestones under the 2012 Sanofi Genzyme agreement.

We determined that the deliverables under the 2012 Sanofi Genzyme agreement included the license, a joint steering committee and any additional TTR-specific RNAi therapeutic compounds that comprised the ALN-TTR program. We also determined that, pursuant to the accounting guidance governing revenue recognition on multiple element arrangements, the license and undelivered joint steering committee and any additional TTR-specific RNAi therapeutic compounds did not have standalone value due to the specialized nature of the services to be provided by us. In addition, while Sanofi Genzyme had the ability to grant sublicenses, it could not sublicense all or substantially all of its rights under the 2012 Sanofi Genzyme agreement. The uniqueness of our services and the limited sublicense right were indicators that standalone value was not present in the arrangement. Therefore, the deliverables were not separable and, accordingly, the license and undelivered services were treated as a single unit of accounting. We were unable to reasonably estimate the period of performance under the 2012 Sanofi Genzyme agreement, as we were unable to estimate the timeline of our deliverables related to the deliverable for any additional TTR-specific RNAi therapeutic compounds.

Through December 31, 2013, under the prior revenue standard, we had deferred all revenue, or $33.5 million, under the 2012 Sanofi Genzyme agreement.

2014 Sanofi Genzyme Collaboration, as amended in January 2018

In January 2014, we entered into the 2014 Sanofi Genzyme collaboration. As noted above, the 2014 Sanofi Genzyme collaboration superseded and replaced the 2012 Sanofi Genzyme agreement and was amended in January 2018, at which time we also entered into the Exclusive TTR License and the AT3 License Terms.

The 2014 Sanofi Genzyme collaboration is structured as an exclusive relationship for the worldwide development and commercialization of RNAi therapeutics in the field of Genetic Medicines, which includes our current and future Genetic Medicine programs that reach Human Proof-of-Principle Study Completion (as defined in the Sanofi Genzyme master agreement), or Human POP, by the end of 2019, subject to extension to the end of 2021 in various circumstances. We will retain product rights in the United States, Canada and Western Europe, referred to as the Alnylam Territory, while Sanofi Genzyme will obtain exclusive rights to develop and commercialize collaboration products in the rest of the world, referred to as the Sanofi Genzyme Territory, together with worldwide rights for one product. Sanofi Genzyme's rights under the 2014 Sanofi Genzyme collaboration, described in detail below, are structured as an opt-in that is triggered upon achievement of Human POP. We maintain development control for all programs prior to Sanofi Genzyme's opt-in and maintain development and commercialization control after Sanofi Genzyme's opt-in for all programs in the Alnylam Territory. We will retain global rights to any RNAi therapeutic Genetic Medicine program that does not reach Human POP by the end of 2019, subject to certain limited exceptions. We retain full rights to all current and future RNAi therapeutic programs outside of the field of Genetic Medicines, including the right to form new collaborations.

Under the 2014 Sanofi Genzyme collaboration, Sanofi Genzyme's specific license rights and the programs which Sanofi Genzyme opted into prior to the 2018 amendment include the following:

- Regional license terms and programs — Upon opt-in, we will retain product rights in the Alnylam Territory, while Sanofi Genzyme will obtain exclusive rights to develop and commercialize the product in the Sanofi Genzyme Territory. Sanofi Genzyme can elect this license for any of our current and future Genetic Medicine programs that complete Human POP by the end of 2019, subject to limited extension. Development costs for products once Sanofi Genzyme exercises an option will be shared between Sanofi Genzyme and us, with Sanofi Genzyme responsible for twenty percent of the global development costs. Sanofi Genzyme will be required to make payments totaling up to $75.0 million per regional product, consisting of up to $55.0 million in development milestones and $20.0 million in commercial milestones. Sanofi Genzyme will also be required to pay tiered double-digit royalties up to twenty percent for each regional product based on annual net sales, if any, of such regional product by Sanofi Genzyme, its affiliates and sublicensees. Upon the effective date of the 2014 Sanofi Genzyme collaboration, Sanofi Genzyme expanded the scope of its regional license and collaboration for patisiran, which was originally established under the 2012 Sanofi Genzyme agreement. In September 2015, Sanofi Genzyme elected to opt into our fitusiran clinical development program for the treatment of hemophilia and other rare bleeding disorders under the regional license terms. Cost-sharing for the fitusiran program began in January 2016 under the regional license terms. Sanofi Genzyme also had the right to elect to co-develop and co-commercialize fitusiran in the Alnylam Territory pursuant to the co-development/co-commercialize license terms described below. In November 2016, Sanofi Genzyme exercised this right and elected to co-develop and co-commercialize fitusiran in the Alnylam Territory. In addition, during 2016, Sanofi Genzyme elected not to opt into the development and commercialization of givosiran or cemdisiran in the Sanofi Genzyme Territory.

Sanofi Genzyme's rights with respect to patisiran and fitusiran were modified in connection with the 2018 amendment, the Exclusive TTR License and the AT3 License Terms, as described below. Sanofi Genzyme continues to have the right to opt into our future rare genetic disease programs for development and commercialization in the Sanofi

Genzyme Territory under the regional license terms.

- Co-development/co-commercialize license terms and programs — Upon opt-in, we retained product rights in the Alnylam Territory, while Sanofi Genzyme obtained exclusive rights to develop and commercialize the product in the Sanofi Genzyme Territory, and to co-commercialize the product in the Alnylam Territory. Upon the effective date of the 2014 Sanofi Genzyme collaboration, Sanofi Genzyme expanded its regional rights for revusiran, which were originally granted under the 2012 Sanofi Genzyme agreement, to include a co-development/co-commercialize license and collaboration. In October 2016, we decided to discontinue development of revusiran. In our TTR program, we are also developing ALN-TTRsc02. Sanofi Genzyme had a right to elect a co-development/co-commercialize license for ALN-TTRsc02. As noted above, in November 2016, Sanofi Genzyme exercised its right to elect a co-development/co-commercialize license for fitusiran. Development costs for co-development/co-commercialize products, once Sanofi Genzyme exercised an option, were shared between Sanofi Genzyme and us, with Sanofi Genzyme responsible for fifty percent of the global development costs. In connection with the exercise of its co-development/co-commercialize rights for fitusiran, Sanofi Genzyme paid us approximately $6.0 million in January 2017 for its incremental share of co-development costs incurred

from January 2016 through September 2016. Sanofi Genzyme was required to make certain milestone payments for fitusiran, and, prior to the discontinuation of the revusiran program, was required to make certain milestone payments for revusiran. In December 2014, we earned a development milestone payment of $25.0 million based upon the initiation of the first global Phase 3 clinical trial for revusiran. Sanofi Genzyme was also obligated to pay us a milestone of $25.0 million upon the dosing of the first patient in our ATLAS Phase 3 program for fitusiran. In addition, Sanofi Genzyme was required to pay tiered double-digit royalties up to twenty percent for each co-development/co-commercialize product based on annual net sales, if any, in the Sanofi Genzyme Territory for such co-development/co-commercialize product by Sanofi Genzyme, its affiliates and sublicensees. The parties were to share profits equally and we expected to book product sales in the Alnylam Territory.

In connection with the 2018 amendment, the Exclusive TTR License and the AT3 License Terms, as described below, we and Sanofi Genzyme agreed to terminate the co-development and co-commercialization rights related to revusiran, ALN-TTRsc02 and fitusiran under the 2014 Sanofi Genzyme collaboration. No future rights will be granted to Sanofi Genzyme for co-development and co-commercialization under the 2014 Sanofi Genzyme collaboration, as amended by the 2018 amendment.

- Global license terms and programs — Sanofi Genzyme continues to have one right to a global license through 2019, subject to limited extension, for a future Genetic Medicine program that was not one of our defined Genetic Medicine programs as of the effective date of the 2014 Sanofi Genzyme collaboration. Upon opt-in, Sanofi Genzyme will obtain a worldwide license to develop and commercialize the product. Sanofi Genzyme shall be responsible for one hundred percent of global development costs for a global license product. Sanofi Genzyme will be required to make payments totaling up to $200.0 million for such global product, including up to $100.0 million in development milestones and $100.0 million in commercial milestones. Sanofi Genzyme will also be required to pay tiered double-digit royalties up to twenty percent for such global product based on annual net sales, if any, of each global product by Sanofi Genzyme, its affiliates and sublicensees. During the first quarter of 2018, Sanofi Genzyme elected not to exercise its global option for our lumasiran program.

Exclusive TTR License and AT3 License Terms

As noted above, the 2018 amendment, together with the Exclusive TTR License and the AT3 License Terms, revise the terms and conditions of the 2014 Sanofi Genzyme collaboration to (i) provide us the exclusive right to pursue the further global development and commercialization of all TTR products, including ONPATTRO, ALN-TTRsc02 and any back-up products, (ii) provide Sanofi Genzyme the exclusive right to pursue the further global development and commercialization of fitusiran and any back-up products and (iii) terminate the previous co-development and co-commercialization rights related to revusiran, ALN-TTRsc02 and fitusiran under the 2014 Sanofi Genzyme collaboration. Going forward, we are funding all development and commercialization costs for ONPATTRO and ALN-TTRsc02. We are also funding development and commercialization costs for fitusiran through the transition period, up to a cap of $50.0 million, after which Sanofi Genzyme will fund all development and commercialization costs for fitusiran. We substantially completed the transition of the fitusiran program to Sanofi Genzyme in the third quarter of 2018. Each party is responsible for its costs associated with the transfer of the respective program to the other party.

Under the 2018 amendment and the Exclusive TTR License, Sanofi Genzyme will be eligible to receive (i) royalties up to twenty-five percent, increasing over time, based on annual net sales of ONPATTRO in territories excluding the United States, Canada and Western Europe, provided royalties on annual net sales of ONPATTRO in Japan will be twenty-five percent beginning as of the effective date of the Exclusive TTR License, (ii) tiered royalties of fifteen to thirty percent based on global annual net sales of ALN-TTRsc02 (consistent with the royalties due to us from Sanofi Genzyme on fitusiran), and (iii) tiered royalties of up to fifteen percent based on global annual net sales of any back-up products, in each case by us, our affiliates and our sublicensees. Except as described below, there will be no additional milestones due to either party with respect to ONPATTRO, ALN-TTRsc02 or fitusiran.

In consideration for the rights granted to Sanofi Genzyme under the 2018 amendment and the AT3 License Terms, Sanofi Genzyme was required to make one milestone payment of $50.0 million following the dosing of the first

patient in the ATLAS Phase 3 program for fitusiran. This milestone was achieved in the first quarter of 2018. In addition, we will be eligible to receive tiered royalties of fifteen to thirty percent based on global annual net sales of fitusiran and up to fifteen percent based on global annual net sales of any back-up products, in each case by Sanofi Genzyme, its affiliates and its sublicensees. We intend to continue to work with Sanofi Genzyme to ensure continuity for the supply of fitusiran for ongoing clinical studies, and, at Sanofi Genzyme's request, commercial sales. Sanofi Genzyme also has the right to manufacture fitusiran.

Due to the uncertainty of pharmaceutical development and the high historical failure rates generally associated with drug development, we may not receive any additional milestone payments or any royalty payments from Sanofi Genzyme under the 2014 Sanofi Genzyme collaboration, as amended, or any royalty payments under the AT3 License Terms.

The 2014 Sanofi Genzyme collaboration, as amended, will continue to be governed by an alliance joint steering committee that is comprised of an equal number of representatives from each party. Additional committees manage various aspects of each regional and global program and oversee certain matters, including transition planning, that may arise under the Exclusive TTR License and the AT3 License Terms.

As noted above, the Sanofi Genzyme collaboration originally entered into in 2012 was materially modified during its term when the agreement was amended in 2014, prior to our adoption of the new revenue standard on January 1, 2018. In accordance with the new revenue standard, we evaluated the Sanofi Genzyme collaboration with the aggregate effect of all modifications when identifying performance obligations, determining the transaction price and allocating the transaction price. We determined that certain promises included in these agreements are within the scope of the new revenue standard since Sanofi Genzyme is a customer with respect to the license of the rights to its territories. We also determined, however, that certain aspects of these agreements are within the scope of the collaboration accounting guidance with respect to co-commercialization activities as these activities are joint risk-sharing and are not reflective of a vendor-customer relationship. We apply the new revenue standard to all promises associated with the transfer of goods and services to a customer.

We concluded that Sanofi Genzyme meets the definition of a customer as we are delivering intellectual property and know-how rights as well as research and development activities for the TTR programs and fitusiran programs in support of territories in which we are not jointly sharing the risks and rewards. We concluded that the accounting for the original 2014 Sanofi Genzyme collaboration, and the collaboration, as amended, should be assessed as separate contracts for (i) the patisiran and revusiran (TTR) programs, upon the initiation of the 2014 Sanofi Genzyme collaboration, and (ii) the subsequent opt-in by Sanofi Genzyme for the fitusiran program. In addition, we determined that the Sanofi Genzyme collaboration met the requirements to be accounted for as a contract, including that it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services that will be delivered to Sanofi Genzyme. We identified contract promises or deliverables for licenses to our intellectual property and know-how rights, associated development activities, joint steering committee participation and information exchange. We determined that, pursuant to the new revenue standard (and consistent with our accounting prior to the adoption of the new revenue standard), the performance obligations were not separately identifiable and were not distinct (and did not have standalone value) due to the specialized nature of the services to be provided by us and the dependent relationship between the performance obligations. Given this fact pattern, we have concluded each of the TTR and fitusiran contracts have a single identified or combined performance obligation.

When applying the previous revenue standard, we determined that the co-commercialization activities prior to the 2018 amendment were within the scope of the collaboration accounting standard since both parties would actively participate in the co-commercialization and be subject to significant risks and rewards. As a result of this determination, we recorded any payments or cash receipts for these joint risk-sharing activities as an adjustment to the related operations expense captions. The amounts recorded as a reduction of our selling, general and administrative activities were not material.

The transaction price as of January 1, 2018 of $127.6 million for the 2014 Sanofi Genzyme collaboration related to the license to the TTR programs included the $22.5 million upfront payment and $11.0 million of development milestone payments earned under the now superseded 2012 Sanofi Genzyme agreement, a $25.0 million development milestone payment for revusiran achieved in 2014, the estimated patisiran and revusiran cost-share reimbursements of $63.6 million and $57.0 million, net of payments to Sanofi Genzyme, respectively, and the $51.5 million equity discount related to the stock purchase agreement, described below. Since the fair value of the stock at the time of closing was more than the consideration received by us by $51.5 million, we reduced the transaction price of the license and collaboration contract, treating the equity discount in a manner consistent with a payment to the customer. The transaction price related to our license to the fitusiran program as of January 1, 2018, accounted for as a separate agreement, included estimated fitusiran development cost-share reimbursements of $147.3 million, net of payments to Sanofi Genzyme. There are no refund provisions in the agreement and, therefore, none of the consideration received to date has been excluded from the transaction price calculation. None of the unearned milestones as of January 1, 2018

were included in the transaction price, as all unearned milestone amounts were determined to be fully constrained. We considered several factors, including that achievement of the milestones is outside our control and contingent upon success in clinical trials and regulatory decisions and the licensee's efforts. Any consideration related to sales-based royalties (including milestones) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Sanofi Genzyme and as a result have also been excluded from the transaction price. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

We allocated the transaction price to the combined performance obligation. We have determined that this combined performance obligation is satisfied over time based on our performance that is creating or enhancing an asset that Sanofi Genzyme controls. In this instance, Sanofi Genzyme received control over the asset, or the licensed intellectual property, and know-how, at the time the contract was executed since the licensed intellectual property and know-how meet the definition of functional intellectual property per the new revenue standard, which defines functional intellectual property as intellectual property that derives a substantial portion of its utility from its standalone functionality rather than the entity's ongoing activities (thus, once the asset is fully developed, our ongoing involvement is not required for the licensee to derive value). The other promises included in the performance obligation, however, are enhancing the controlled asset, and thus the combined performance obligation is being satisfied over time.

The new revenue standard requires a single method of measuring performance for each performance obligation satisfied over time. Since we do not have a reliable method of estimating progress based upon its outputs, it was determined that the most reliable method of estimating progress would be using a cost-to-cost input method. We have determined that our completion of certain clinical and regulatory development tasks is relevant and directly related to our progress in completing the combined performance obligation. As such, we measured our progress upon adoption and will continue to measure our progress during each reporting period based upon the amount of development costs incurred divided by the total amount of development costs expected to be incurred over the course of the agreement. We exclude costs that are not related to our completion of this performance obligation, such as the completion of tasks (and incurring of costs) associated with the marketing and commercialization of the drug. We estimated our internal costs during the last three years, excluding non-reimbursable costs that were not deemed to directly relate to the delivery of the development services to Sanofi Genzyme. Historically, we have been unable to reliably measure our performance based upon our lack of historical experience in completing the development of a drug candidate and have, as a result, defaulted to straight-line attribution for many of our licensing agreements. At the time of adoption of the new revenue standard, however, we have completed a substantial portion of our development obligations and determined we have sufficient information to estimate the remaining development costs for the fitusiran program and sufficient experience to reasonably estimate our development costs.

We determined that the 2018 amendment, together with the Exclusive TTR License and the AT3 License Terms, referred to as the 2018 restructured agreement, are included in the scope of the modification provisions of the new revenue standard. We had identified that the agreement for the TTR programs under the 2014 Sanofi Genzyme collaboration should be accounted for separately from any subsequent option exercises, including with respect to fitusiran. Therefore, we concluded it is appropriate to account for the 2018 restructured agreement as two separate modifications to the 2014 Sanofi Genzyme collaboration: one related to the TTR programs and one related to the fitusiran program. Our conclusions related to scoping under the prior revenue standard are consistent with the new revenue standard.

As noted above, the 2018 amendment, together with the Exclusive TTR License, provide us with the exclusive right to pursue the further global development and commercialization of all TTR products, including ONPATTRO. We are responsible for all development and commercialization costs for ONPATTRO and ALN-TTRsc02. As of the 2018 restructured agreement, we are no longer required to complete the delivery of any of the performance obligations under the agreement related to the TTR programs. As a result, the transaction price prior to the 2018 amendment has been reduced as we are no longer entitled to cost-share reimbursements or any of the previously constrained consideration, such as milestones and royalties. Since the 2018 amendment affected the transaction price but did not add any incremental and distinct performance obligations, we concluded this amendment should be accounted for as a change to the existing agreement and recorded the revenue on a cumulative catch-up basis. At the time of the 2018 amendment, we had $2.9 million in revenue deferred as a contract liability on our condensed consolidated balance sheet related to this contract for TTR programs, all of which we recognized in the first quarter of 2018 under the proportional performance model as we no longer expected to incur costs associated with the delivery of goods or services. If we had not adopted the new revenue standard, at the time of the 2018 restructured agreement, we would have had $25.8 million of deferred revenues on our condensed consolidated balance sheet that would have been

recognized in full upon the date of the 2018 restructured agreement as we would have similarly concluded there were no ongoing deliverables under the 2018 restructured agreement related to the TTR programs. We expect to record future royalties payable to Sanofi Genzyme with respect to any sales of ONPATTRO within cost of goods sold on our condensed consolidated statements of comprehensive loss as Sanofi Genzyme is no longer considered our customer after the 2018 restructured agreement for sales of all TTR products, including ONPATTRO, and as such, these royalty payments are outside of the scope of the new revenue standard, including with respect to principal versus agent guidance.

The 2018 amendment, together with the AT3 License Terms, as noted above, provide Sanofi Genzyme the exclusive right to pursue the further global development and commercialization of fitusiran and any back-up products and terminates the previous co-development and co-commercialization rights related to fitusiran under the 2014 Sanofi Genzyme collaboration. The 2018 restructured agreement provides a broader license that permits global development, manufacturing and commercialization, and we are required to facilitate the transfer of all ongoing activities, contracts, intellectual property, know-how and other materials and information related to fitusiran to Sanofi Genzyme.

In connection with the 2018 restructured agreement for fitusiran, we funded development and commercialization costs for fitusiran through the transition period, which was substantially completed in the third quarter of 2018, up to a limit of $50.0 million. The only milestone under the 2018 restructured agreement, which was achieved in the first quarter of 2018 following the dosing of the first patient in the ATLAS Phase 3 program for fitusiran, is considered variable consideration for the license and transition services related to the fitusiran program. We have agreed to reimburse Sanofi Genzyme for certain transition activities that are reflected as a reduction in the transaction price. As a result, the transaction price has been reduced as we are no longer entitled to cost-share reimbursements or any of the previously constrained consideration, such as milestones and royalties.

We concluded that the modification that resulted from the 2018 restructured agreement related to fitusiran would be treated as a termination and replacement of the 2014 Sanofi Genzyme collaboration and accounted for prospectively as the remaining license and transition services are considered distinct from that under the agreement prior to this modification. However, the incremental consideration under the 2018 restructured agreement does not directly reflect the standalone selling price of the incremental performance obligation. Therefore, we concluded the 2018 restructured agreement for fitusiran should be accounted for on a prospective basis. At the time of the 2018 amendment, we had $0.6 million in revenue deferred as a contract liability on our condensed consolidated balance sheet related to the 2014 Sanofi Genzyme collaboration for the fitusiran program. The transaction price of the 2018 restructured agreement for fitusiran is $37.6 million, primarily related to the $50.0 million milestone that was achieved in the first quarter of 2018. Consistent with our accounting prior to this 2018 modification, we are applying the sales-based royalty under the new revenue standard to exclude from the transaction price the royalties earned on Sanofi Genzyme’s sales of fitusiran as we have determined in the context of all the performance obligations, including those delivered prior to the 2018 modification, that the value of the broader license will continue to represent a substantial portion of the value provided to Sanofi Genzyme; and therefore the license to the intellectual property is the predominant item to which the royalty relates.

We have determined that Sanofi Genzyme’s right to purchase additional clinical and commercial material from us reflects optional purchases that are distinct from other performance obligations. Revenues associated with these purchases will be recognized as Sanofi Genzyme obtains control of any purchased material.

We are recognizing the transaction price of the 2018 restructured agreement related to fitusiran under a separate proportional performance model as we perform transition services over the transition period, which was substantially completed in the third quarter of 2018. We measured our performance based on a percentage of our costs expected to be incurred in connection with the transition. During the transition, we incurred a total cost of $38.0 million. In the three and nine months ended September 30, 2018, under the proportional performance model, we recognized an adjustment to decrease revenues of $1.6 million and recognized revenues of $37.6 million, respectively, related to the 2018 restructured agreement for fitusiran. If we had not adopted the new revenue standard, at the time of the 2018 restructured agreement, we would have had $23.4 million of deferred revenues on our condensed consolidated balance sheet, that would have represented an incremental $22.8 million to the transaction price. Similar to under the new revenue standard, we consider the 2018 restructured agreement related to fitusiran to include a combined performance obligation. Under the prior revenue standard and our historical practice to account for contract modifications, we would apply a separate model to the consideration. Historically, we have measured our performance under our models based on the passage of time due to our inability to estimate performance under another method. However, as a result of the 2018 restructured agreement related to fitusiran, we have the ability to measure our performance under the prior revenue standard based on costs expected to be incurred, and therefore measure performance under the prior standard consistent with that of the new revenue standard. Under the prior revenue standard, we would have recorded an adjustment to decrease revenues of $0.9 million and recorded revenues of $60.3 million, respectively, in the three and nine months ended September 30, 2018.

We determined that the opt-in rights that Sanofi Genzyme continues to have for future Genetic Medicine programs represent separate and additional optional purchases that Sanofi Genzyme may receive from us in future periods.

Accounting for Equity Purchases in Connection with our 2014 Sanofi Genzyme Collaboration

Upon the closing of the equity transaction in February 2014, we sold to Sanofi Genzyme 8,766,338 shares of our common stock and Sanofi Genzyme paid $700.0 million in aggregate cash consideration to us. As a condition to the closing of the equity transaction, Sanofi Genzyme entered into an investor agreement with us containing provisions regarding Sanofi Genzyme's holding and "standstill" obligations, additional purchase, voting and registration rights, as well as certain other rights and obligations of the parties.

We recorded the issuance of 8,766,338 shares of our common stock under the stock purchase agreement using the price of our common stock on the date the shares were issued to Sanofi Genzyme. Based on the common stock price of $85.72, the fair value of the shares issued was $751.5 million, which was $51.5 million in excess of the proceeds received from Sanofi Genzyme for the issuance of our common stock. This $51.5 million has been reflected as a reduction of the transaction price for the ALN-TTR programs. In addition, due to intraperiod tax allocation rules, upon closing of the equity transaction we recorded a benefit from income taxes of $15.2 million due to the Sanofi Genzyme equity purchase being recorded in additional paid-in capital, net of tax.

In accordance with the investor agreement, as a result of our issuance of shares in connection with our acquisition of Sirna Therapeutics, Inc. in March 2014, Sanofi Genzyme exercised its right to purchase an additional 344,448 shares of our common stock for $23.0 million. In addition, in connection with our public offerings, Sanofi Genzyme exercised its right to purchase directly from us, in concurrent private placements, 744,566 shares of common stock in January 2015 at the public offering price resulting in $70.7 million in proceeds to us and 297,501 shares of common stock in May 2017 at the public offering price resulting in $21.4 million in proceeds to us. The sales of common stock to Sanofi Genzyme were not registered as part of these public offerings, though they were consummated simultaneously with the public offering.

Sanofi Genzyme also has the right at the beginning of each year to purchase a number of shares of our common stock based on the number of shares we issued during the previous year for compensation-related purposes. Sanofi Genzyme exercised this right to purchase directly from us 196,251 shares of our common stock in January 2015 for $18.3 million and 205,030 shares of our common stock in February 2016 for $14.3 million. The sales of these shares to Sanofi Genzyme were consummated as private placements.

Sanofi Genzyme currently holds approximately 11 percent of our outstanding common stock.

We applied the guidance in the equity accounting standard for the stock purchase arrangement since the sale of our equity is not part of our ordinary activities and, therefore, does not qualify as a contract with a customer that is within the scope of the new revenue standard.

4. INVENTORY

The following table presents our inventory of ONPATTRO at September 30, 2018 and December 31, 2017, in thousands:

	At September 30, 2018	At December 31, 2017
Raw materials	$ 4,789	$ —
Work in process	6,213	—
Finished goods	79	—
Total inventory	$ 11,081	$ —

At September 30, 2018, all of our inventory was related to ONPATTRO, which was approved by the FDA and the EC on August 10, 2018 and August 30, 2018, respectively. In the third quarter of 2018, we began to capitalize inventory costs for ONPATTRO as a result of the approval of ONPATTRO by the FDA and commercial sales forecasts for ONPATTRO. Prior to the third quarter of 2018, we recorded the costs associated with ONPATTRO raw materials, work in process and finished goods as research and development expenses on our condensed consolidated statements of comprehensive loss. At September 30, 2018, we had $21.3 million of this zero-cost ONPATTRO inventory. At September 30, 2018, we have determined a reserve related to ONPATTRO inventory is not required based on our evaluation of factors including commercial sales forecasts for ONPATTRO and the shelf life of ONPATTRO

inventory.

5. FAIR VALUE MEASUREMENTS

The following tables present information about our assets that are measured at fair value on a recurring basis at September 30, 2018 and December 31, 2017, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value, in thousands:

Description	At September 30, 2018	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Corporate notes	$ 2,729	$—	$ 2,729	$ —
U.S. government-sponsored enterprise securities	1,985	—	1,985	—
U.S. treasury securities	9,974	—	9,974	—
Money market funds	232,073	232,073	—	—
Marketable debt securities:				
Certificates of deposit	18,800	—	18,800	—
Commercial paper	101,376	—	101,376	—
Corporate notes	324,379	—	324,379	—
U.S. government-sponsored enterprise securities	111,339	—	111,339	—
U.S. treasury securities	349,328	—	349,328	—
Marketable equity securities	15,004	15,004	—	—
Restricted cash (money market funds)	1,476	1,476	—	—
Total	$ 1,168,463	$248,553	$ 919,910	$ —

Description	At December 31, 2017	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Commercial paper	$ 82,262	$—	$82,262	$ —
Corporate notes	18,116	—	18,116	—
U.S. government-sponsored enterprise securities	231,122	—	231,122	—
U.S. treasury securities	62,855	—	62,855	—
Money market funds	122,986	122,986	—	—
Marketable debt securities:				
Certificates of deposit	30,200	—	30,200	—
Commercial paper	56,951	—	56,951	—

Corporate notes	373,252	—	373,252	—
U.S. government-sponsored enterprise securities	398,298	—	398,298	—
U.S. treasury securities	200,475	—	200,475	—
Restricted cash (money market funds)	1,471	1,471	—	—
Total	$ 1,577,988	$124,457	$1,453,531	$ —

During the nine months ended September 30, 2018 and 2017, there were no transfers between Level 1 and Level 2 financial assets. The carrying amounts reflected in our condensed consolidated balance sheets for cash, accounts receivable, net, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities. As of September 30, 2018, we had $9.0 million included in long-term other assets on our condensed consolidated balance sheet that represents the discounted present value, based on a Level 2 fair value measurement, of the $13.0 million cash payment due from Dicerna by April 18, 2022 under the terms of the Settlement Agreement, described more fully above at Note 2. We are accounting for this receivable as a transaction between two parties and imputing the interest through interest income on our condensed consolidated statements of comprehensive loss. To determine the present value of this receivable, we used an interest rate of 11 percent as of the settlement date for a note that would have resulted if an independent borrower and independent lender had negotiated a similar transaction. The fair value of our long-term debt at September 30, 2018, computed pursuant to a discounted cash flow technique using a market interest rate, was $30.1 million and is considered a Level 3 fair value measurement. The effective interest rate reflects the current market rate.

6. MARKETABLE DEBT SECURITIES

We obtain fair value measurement data for our marketable debt securities from independent pricing services. We perform validation procedures to ensure the reasonableness of this data. This includes meeting with the independent pricing services to understand the methods and data sources used. Additionally, we perform our own review of prices received from the independent pricing services by comparing these prices to other sources and confirming those securities are trading in active markets. At September 30, 2018, $29.7 million due to us for marketable securities with a September 30, 2018 settlement date, for which cash was received in October 2018, is reflected in prepaid expenses and other current assets on our condensed consolidated balance sheet.

The following tables summarize our marketable debt securities at September 30, 2018 and December 31, 2017, in thousands:

	At September 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	$18,800	$ —	$ —	$18,800
Commercial paper	101,379	—	(3)	101,376
Corporate notes	324,615	11	(247)	324,379
U.S. government-sponsored enterprise securities	111,427	—	(88)	111,339
U.S. treasury securities	349,601	1	(274)	349,328
Total	$905,822	$ 12	$ (612)	$905,222

	At December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	$30,200	$ —	$ —	$30,200
Commercial paper	56,951	—	—	56,951
Corporate notes	373,736	11	(495)	373,252
U.S. government-sponsored enterprise securities	399,281	—	(983)	398,298
U.S. treasury securities	200,649	1	(175)	200,475
Total	$1,060,817	$ 12	$ (1,653)	$1,059,176

We classify our debt security investments based on their contractual maturity dates. The following table summarizes our available-for-sale debt securities by contractual maturity, at September 30, 2018, in thousands:

	At September 30, 2018	
	Amortized Cost	Fair Value
Less than one year	$905,822	$905,222
Greater than one year but less than two years	—	—
Total	$905,822	$905,222

7. COMMITMENTS AND CONTINGENCIES

300 Third Street

We lease office and laboratory space located at 300 Third Street, Cambridge, Massachusetts for our corporate headquarters under a non-cancelable real property lease agreement by and between us and ARE-MA Region No. 28, LLC, or ARE-MA, dated as of September 26, 2003, as amended by five amendments, referred to collectively as the 300 Third Street Lease. Pursuant to the 300 Third Street Lease, we lease a total of approximately 129,000 square feet of office and laboratory space. The term of the 300 Third Street Lease was set to expire on September 30, 2021.

On August 14, 2018, we and ARE-MA entered into a Sixth Amendment to Lease, pursuant to which the term of the 300 Third Street Lease was extended for an additional twelve years and four months, through January 31, 2034. Under the Sixth Amendment to Lease, we have the option to extend the 300 Third Street Lease, as amended, for two additional five-year terms.

Beginning in October 2021, annual rent under the 300 Third Street Lease, as amended by the Sixth Amendment, exclusive of operating expenses and real property taxes, will be $10.5 million for the first twelve months, with annual increases of 2.5 percent thereafter. Under the terms of the Sixth Amendment, ARE-MA will provide a tenant improvement allowance up to $8.4 million, which may be used to fund appropriate improvements to the premises.

101 Main Street

We lease office space located on the 10th floor at 101 Main Street, Cambridge, Massachusetts under a non-cancelable real property lease agreement by and between us and RREEF America REIT II CORP. PPP, or RREEF, dated as of March 9, 2015, as amended, referred to as the 101 Main Street Lease. Pursuant to the 101 Main Street Lease, we lease a total of approximately 23,350 square feet of office space on the 10th floor. The term of the 101 Main Street Lease was set to expire on March 31, 2019.

On September 27, 2018, we and RREEF entered into a Second Amendment to Lease, pursuant to which the term of the 101 Main Street Lease was extended for an additional five years, through March 31, 2024. Under the 101 Main Street Lease, as amended by the Second Amendment, we have the option to extend the term of the 101 Main Street Lease for an additional five years.

Beginning in April 2019, annual rent under the 101 Main Street Lease, as amended by the Second Amendment, will be $2.1 million for the first twelve months, with annual increases of 2.0 percent thereafter.

Manufacturing Facility

In April 2016, we purchased 12 acres of undeveloped land in Norton, Massachusetts. We are constructing a manufacturing facility at this site for drug substance, including small interfering RNAs, or siRNAs, and siRNA conjugates, for clinical and commercial use. At September 30, 2018 and December 31, 2017, property, plant and equipment, net, on our condensed consolidated balance sheets reflects $199.3 million and $140.5 million, respectively, of land and associated costs related to the construction of our drug substance manufacturing facility.

Credit Agreements

On April 29, 2016, we entered into (i) a Credit Agreement, or the BOA Credit Agreement, with Alnylam U.S., Inc., our wholly-owned subsidiary, as the borrower, us, as a guarantor, and Bank of America N.A., or BOA, as the lender and (ii) a Credit Agreement, or the Wells Credit Agreement, together with the BOA Credit Agreement, the Credit Agreements, by and among Alnylam U.S., Inc., as the borrower, us, as a guarantor, and Wells Fargo Bank, National Association, or Wells, as the lender. The Credit Agreements were entered into in connection with the planned build out of our new drug substance manufacturing facility.

The BOA Credit Agreement provided for a $120.0 million term loan facility and was scheduled to mature on April 29, 2021. In December 2017, we repaid in full the $120.0 million outstanding principal amount under the BOA Credit Agreement and the BOA Credit Agreement terminated in accordance with its terms upon repayment of the outstanding indebtedness. The Wells Credit Agreement provides for a $30.0 million term loan facility and matures on April 29, 2021. The proceeds of the borrowing under the BOA Credit Agreement were, and under the Wells Credit Agreement are, to be used for working capital and general corporate purposes. Interest on borrowings under the BOA Credit Agreement was, and under the Wells Credit Agreement is calculated based on LIBOR plus 0.45 percent, except in the event of default. The borrower may prepay loans under the Wells Credit Agreement at any time, without premium or penalty, subject to certain notice requirements and LIBOR breakage costs.

The obligations of the borrower and us under the BOA Credit Agreement were, and under the Wells Credit Agreement are secured by cash collateral in an amount equal to, at any given time, at least 100 percent of the principal amount of all term loans outstanding under such Credit Agreement at such time. At each of September 30, 2018 and

December 31, 2017, we have recorded $30.0 million of cash collateral in connection with the Wells Credit Agreement as restricted investments on our condensed consolidated balance sheets. The Wells Credit Agreement contains limited representations and warranties and limited affirmative and negative covenants, including quarterly reporting obligations, as well as certain customary events of default.

Litigation

From time to time, we are a party to legal proceedings in the course of our business, including the matters described below. The claims and legal proceedings in which we could be involved include challenges to the scope, validity or enforceability of patents relating to our product candidates, and challenges by us to the scope, validity or enforceability of the patents held by others. These include claims by third parties that we infringe their patents. The outcome of any such legal proceedings, regardless of the merits, is inherently uncertain. In addition, litigation and related matters are costly and may divert the attention of our management and other resources that would otherwise be engaged in other activities. If we were unable to prevail in any such legal proceedings, our business, results of operations, liquidity and financial condition could be adversely affected. Our accounting policy for accrual of legal costs is to recognize such expenses as incurred.

Silence Litigation

In October 2017, Silence Therapeutics plc, or Silence, served its previously announced claim in the High Court of England and Wales, or the High Court, issued in the name of Silence Therapeutics GmbH against Alnylam UK Ltd., Alnylam Pharmaceuticals, Inc., and The Medicines Company UK Ltd, seeking a declaration that Silence was entitled to a Supplementary Protection Certificate, or SPC, for Silence's European Patent No. 2 258 847, referred to as the '847 patent, when each of patisiran, fitusiran, givosiran and inclisiran obtained a marketing authorization in Europe. In June 2018, Silence withdrew this claim against both us and The Medicines Company. Silence also withdrew its previously filed claim alleging infringement of its European Patent No. 1 857 547, referred to as the '547 patent, by fitusiran.

On December 10, 2018, the High Court will hear the claim brought against us by Silence alleging that ONPATTRO (patisiran) infringes the '547 patent, as amended in the United Kingdom, and will also hear our claim seeking a declaration of non-infringement by ONPATTRO and revocation of the '547 patent in its entirety. Silence is seeking monetary damages as well as a permanent injunction.

Silence also served patent infringement proceedings against us in Portugal alleging that patisiran infringes the '547 patent as granted. Silence is seeking a permanent injunction against the commercialization of patisiran in Portugal.

We believe the '847 and '547 patents as originally filed and as amended in the United Kingdom, were and are invalid and not infringed by any of our products and intend to defend against any claim of infringement brought against any of our products, including the present claim of infringement by ONPATTRO of the '547 patent, as amended.

On October 10, 2018, Silence filed for Preliminary Relief with the District Court of The Hague, The Netherlands, related to Silence European Patent No. 3 222 724, referred to as the '724 patent, alleging that ONPATTRO infringes one or more claims of the '724 patent, seeking a cross-border preliminary injunction in those European countries where the patent has been validated. A hearing has been set for January 23, 2019. We believe the '724 patent is invalid and not infringed by ONPATTRO and intend to vigorously defend against this claim.

We have filed an opposition with the European Patent Office, or EPO, seeking revocation of the '847 and '547 patents in their entirety and intend to file an opposition to the '724 patent prior to the deadline. Although we believe these patents are invalid and not infringed by any of our products, a court or patent office could ultimately rule against us or find that Silence's patents are valid.

In March 2018, we filed an action against Silence in the United States District Court for the District of Massachusetts seeking a declaratory judgement of non-infringement by patisiran of Silence U.S. Patent Nos: 7,893,245; 8,324,370; 8,933,215; 9,222,092; and 9,695,423. This action is pending before the court and awaiting a briefing schedule from the judge on jurisdictional matters.

Between April and July 2018, we filed petitions for Post Grant Review, or PGR, of five Silence granted U.S. Patents with the United States Patent and Trademark Office, or USPTO, seeking a cancellation of all claims as being unpatentable under 35 U.S.C. §§ 112 and 102. On October 10, 2018, the USPTO failed to institute the PGR of U.S. Patent No. 9,695,423, ruling that it was not PGR eligible. The USPTO did not rule on the ultimate validity or scope of the claims. We disagree with the ruling and have filed a request for reconsideration.

Securities Litigation

On September 26, 2018, Caryl Hull Leavitt individually and on behalf of all others similarly situated, filed a class action complaint for violation of federal securities laws against Alnylam, our Chief Executive Officer and our Chief Financial Officer in the United States District Court for the Southern District of New York. The complaint purports to bring a federal securities class action on behalf of a class of persons who acquired our securities between February 15,

2018 and September 12, 2018 and seeks to recover damages caused by defendants' alleged violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The complaint alleges, among other things, that the defendants made materially false and misleading statements related to the efficacy and safety of our product, ONPATTRO (patisiran) lipid complex injection. The plaintiff seeks, among other things, the designation of this action as a class action, an award of unspecified compensatory damages, interest, costs and expenses, including counsel fees and expert fees, and other relief as the court deems appropriate.

We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. We cannot predict at this point the length of time that this action will be ongoing or the liability, if any, which may arise therefrom.

Dicerna Litigation

On June 10, 2015, we filed a trade secret misappropriation lawsuit against Dicerna in the Superior Court of Middlesex County, Massachusetts seeking to stop misappropriation by Dicerna of our confidential, proprietary and trade secret information related to the RNAi assets we purchased from Merck, including certain N-acetylgalactosamine, or GalNAc, conjugate technology. In addition to permanent injunctive relief, we were also seeking monetary damages from Dicerna. In August 2017, Dicerna successfully added counterclaims against us in the trade secret lawsuit alleging that our lawsuit represented abuse of process and claiming tortious interference with its business. In September 2017, we filed a motion to dismiss Dicerna's counterclaims, which motion was denied. In addition, in August 2017, Dicerna filed a lawsuit against us in the United States District Court of Massachusetts alleging attempted monopolization by us under the Sherman Antitrust Act. In October 2017, we filed a motion to dismiss the antitrust lawsuit.

On April 18, 2018, we and Dicerna entered into a Settlement Agreement resolving all ongoing litigation between the companies. The terms of the Settlement Agreement include mutual releases and dismissal with prejudice of all claims and counterclaims in the following litigation between the parties: (i) Alnylam Pharmaceuticals, Inc. v. Dicerna Pharmaceuticals, Inc., No. 15-4126, pending in the Massachusetts Superior Court for Middlesex County; and (ii) Dicerna Pharmaceuticals, Inc. v. Alnylam Pharmaceuticals, Inc., No. 1:17-cv-11466, pending in the United States District Court for the District of Massachusetts.

Under the terms of the Settlement Agreement, Dicerna will pay us an aggregate of $25.0 million, including an upfront cash payment of $2.0 million and 983,208 shares of Dicerna common stock, valued at $10.0 million, that were received in the second quarter of 2018, and an additional $13.0 million over the next four years, the timing of which will be dependent upon revenue Dicerna receives pursuant to future partnerships and collaborations related to Ga1NAc-conjugated RNAi research and development, provided that such additional amount must be paid by no later than April 18, 2022. In addition, Dicerna will be restricted in its development and other activities relating to oligonucleotide-based therapeutics directed toward a defined set of targets, for periods ranging from 18 months up to four years. The Settlement Agreement does not include any license to our GalNAc conjugate intellectual property or any licenses to any other intellectual property from either party. Nor does the Settlement Agreement include any admission of liability or wrongdoing by either company.

8. INCOME TAXES

For the three months ended September 30, 2018, we recorded a provision for income taxes of $0.4 million due to foreign income taxes recorded during the third quarter of 2018. For the nine months ended September 30, 2018, we recorded a net provision for income taxes of $0.5 million related to $1.3 million due to foreign income taxes recorded during the nine months ended September 30, 2018 partially offset by a $0.8 million benefit for refundable credits related to the TCJA.

Our preliminary estimate of the TCJA and the remeasurement of our deferred tax assets and liabilities is subject to the finalization of management's analysis related to certain matters, such as developing interpretations of the provisions of the TCJA, changes to certain estimates and the filing of our tax returns. U.S. Treasury regulations, administrative interpretations or court decisions interpreting the TCJA may require further adjustments and changes in our estimates. The final determination of the TCJA and the remeasurement of our deferred assets and liabilities will be completed as additional information becomes available, but no later than one year from the enactment of the TCJA. For the nine months ended September 30, 2018, there were no changes to management's analysis originally performed as of December 31, 2017.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. The statements contained in this Quarterly Report on Form 10-Q that are not purely historical are 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. Without limiting the foregoing, the words "may," "will," "should," "could," "expects," "plans," "intends," "anticipates," "believes," "estimates," "predicts," "potential," "continue," "target," "goal" and si expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. All forward-looking statements included in this Quarterly Report on Form 10-Q are based on information available to us up to, and including, the date of this document, and we expressly disclaim any obligation to update any such forward-looking statements to reflect events or circumstances that arise after the date hereof. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain important factors, including those set forth in this Item 2 — "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as under Part II, Item 1A — "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. You should carefully review those factors and also carefully review the risks outlined in other documents that we file from time to time with the Securities and Exchange Commission, or SEC.

Overview

We are a global commercial-stage biopharmaceutical company developing novel therapeutics based on RNA interference, or RNAi. RNAi is a naturally occurring biological pathway within cells for sequence-specific silencing and regulation of gene expression. By harnessing the RNAi pathway, we have developed a new class of innovative medicines, known as RNAi therapeutics. RNAi therapeutics are comprised of small interfering RNA, or siRNA, and function upstream of today's medicines by potently silencing messenger RNA, or mRNA, that encode for disease-causing proteins, thus preventing them from being made. This is a revolutionary approach with the potential to transform the care of patients with genetic and other diseases.

Our research and development strategy is to target genetically validated liver-expressed genes that have been implicated in the cause or pathway of human disease. We utilize a lipid nanoparticle, or LNP, or N-acetylgalactosamine, or GalNAc, conjugate approach to enable hepatic delivery of siRNAs. Our focus is on clinical indications where there is a high unmet need, early biomarkers for the assessment of clinical activity in Phase 1 clinical studies, and a definable path for drug development, regulatory approval, patient access and commercialization.

Specifically, our broad pipeline of investigational RNAi therapeutics is focused in four Strategic Therapeutic Areas, or "STArs:" Genetic Medicines; Cardio-Metabolic Diseases; Hepatic Infectious Diseases; and Central Nervous System, or CNS, Diseases. We are committed to the advancement of our Alnylam 2020 strategy, which is to achieve a company profile with three marketed products and ten RNAi therapeutic clinical programs, including four in late stages of development, across three or more of our STArs by the end of 2020. In August 2018, the United States Food and Drug Administration, or FDA, approved our new drug application, or NDA, for ONPATTRO™ (patisiran), a lipid complex injection for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis, or hATTR amyloidosis, in adults. ONPATTRO was reviewed by the FDA under Priority Review and was granted Breakthrough Therapy and Orphan Drug Designations. Also, in August 2018, the European Commission, or EC, granted marketing authorisation for ONPATTRO for the treatment of hATTR amyloidosis in adults with Stage 1 or Stage 2 polyneuropathy. We began selling ONPATTRO in the United States in August 2018 and in Germany in October 2018.

In September 2018, we submitted a NDA to Japan's Pharmaceuticals and Medical Devices Agency, or PMDA, for approval of patisiran for the treatment of hATTR amyloidosis. Patisiran has orphan drug designation from the Ministry of Health, Labor and Welfare, or MHLW, which makes it eligible for priority review as well as 10 years of market exclusivity, if approved. Based on the priority review timeline, we expect a decision from the MHLW and PMDA in mid-2019. If approved patisiran will be commercialized in Japan under the brand name ONPATTRO. In

Canada, the safety and efficacy of patisiran are under priority review and market authorization has not yet been granted. Regulatory filings in additional markets in Europe and elsewhere are planned throughout 2018 and 2019.

In September 2018, we reported positive topline interim analysis results from our ENVISION Phase 3 study of givosiran, an investigational RNAi therapeutic targeting aminolevulinic acid synthase 1, or ALAS1, for the treatment of acute hepatic porphyria, or AHP. In October 2018, we announced that in consultation with the FDA, we plan to pursue a full approval based on the complete results of the ENVISION Phase 3 study of givosiran, rather than filing based on the interim Phase 3 results. The FDA has also agreed to a rolling submission of a NDA for givosiran, which we intend to initiate in 2018 with full clinical sections submitted in mid-2019, assuming positive study results.

Based on our expertise in RNAi therapeutics and broad intellectual property estate, we have formed alliances with leading pharmaceutical and life sciences companies to support our development and commercialization efforts, including Sanofi Genzyme, the specialty care global business unit of Sanofi, The Medicines Company, or MDCO, and Vir Biotechnology, Inc., or Vir. In addition, in late 2017, we joined a research consortium with the UK Biobank, Regeneron Pharmaceuticals, Inc., or Regeneron, and four major pharmaceutical companies aimed at generating 500,000 human exome sequences linked to medical records by the end of 2019. We and each of the other collaborators agreed to commit $10.0 million to enable an acceleration of sequencing timelines. We believe that the broad and ongoing access to detailed health and full exome sequencing data for the 500,000 UK Biobank participants will greatly enhance our target identification and validation efforts, contributing to the sustainability of our RNAi therapeutics product engine.

In March 2018, we entered into a discovery collaboration with Regeneron to identify RNAi therapeutics for the chronic liver disease nonalcoholic steatohepatitis, or NASH, and potentially other related diseases, and we and Regeneron plan to enter into a separate, fifty-fifty collaboration to further research, co-develop and commercialize any therapeutic product candidates that emerge from these discovery efforts.

In March 2018, we also entered into a manufacturing services agreement with Agilent Technologies, Inc., or Agilent, providing for the commercial supply of ONPATTRO drug substance by Agilent for an initial five-year term.

In April 2018, we and Dicerna Therapeutics, Inc., or Dicerna, entered into a Settlement Agreement and General Release, referred to as the Settlement Agreement, resolving all ongoing litigation between the companies. For a discussion of the terms of the Settlement Agreement, please read Note 2, Summary of Significant Account Policies – Investments in Marketable Securities and Cash Equivalents and Note 7, Commitments and Contingencies – Litigation, to our condensed consolidated financial statements included in Part I, Item 1, “Financial Statements (Unaudited),” of this quarterly report on Form 10-Q.

We have incurred significant losses since we commenced operations in 2002 and expect such losses to continue for the foreseeable future. At September 30, 2018, we had an accumulated deficit of $2.63 billion. Historically, we have generated losses principally from costs associated with research and development activities, acquiring, filing and expanding intellectual property rights and general administrative costs. As a result of planned expenditures for research and development activities relating to our research platform, our drug development programs, including clinical trial and manufacturing costs, the establishment of late stage clinical and commercial capabilities, including global operations, continued management and growth of our patent portfolio, collaborations and general corporate activities, we expect to incur additional operating losses for the foreseeable future. We also anticipate that our operating results will fluctuate for the foreseeable future. Therefore, period-to-period comparisons should not be relied upon as predictive of the results in future periods.

We currently have programs focused on a number of therapeutic areas and, as noted above, in August 2018, received regulatory approval from the FDA and EC for ONPATTRO. As a result of the regulatory approval of ONPATTRO, we began to generate net revenues from product sales during the third quarter of 2018. However, our ongoing development efforts may not be successful and we may not be able to commence sales of any other products and/or successfully market and sell ONPATTRO or any other such products in the future. A substantial portion of our total revenues in recent years has been derived from collaboration revenues from strategic alliances with Sanofi Genzyme and MDCO. In addition to revenues from the commercial sale of ONPATTRO and potentially from sales of future products, we expect our sources of potential funding for the next several years to continue to be derived in part from existing and new strategic alliances, which may include license and other fees, funded research and development, milestone payments and royalties on product sales by our licensors, and proceeds from the sale of equity or debt.

Research and Development

Since our inception, we have focused on drug discovery and development programs. Research and development expenses represent a substantial percentage of our total operating expenses, as reflected by our broad pipeline of clinical development programs, which includes several programs in late-stage development.

The following is a summary of our product development programs as of October 31, 2018. It identifies those programs in which we have achieved human proof-of-concept, or POC, by demonstrating target gene knockdown and/or additional evidence of activity in clinical studies, those programs for which we have received Breakthrough Therapy Designation from the FDA, the development stage of our programs, and our commercial rights to such programs:

During the third quarter of 2018 and recent period, we reported the following updates from ONPATTRO and our late-stage clinical programs:

Commercial

- We launched ONPATTRO in the United States and the EU, initially in Germany, and recognized ONPATTRO net revenues of $0.5 million for the quarter ended September 30, 2018.

Late-Stage Clinical Development

- We achieved the first-ever regulatory approval of an RNAi therapeutic, ONPATTRO, in the United States and the EU, submitted a NDA to Japan’s PMDA and received a Priority Review designation in Canada.

- We continued to advance ALN-TTRsc02, a subcutaneously administered investigational RNAi therapeutic in development for the treatment of ATTR amyloidosis, and aligned the design of HELIOS-A, a pivotal Phase 3 study of ALN-TTRsc02 in patients with hATTR amyloidosis polyneuropathy, with FDA and European Medicines Agency, or EMA, feedback. We are on track to start the Phase 3 study in late 2018 and plan to initiate additional Phase 3 studies of ALN-TTRsc02, including in hereditary and wild-type ATTR amyloidosis cardiomyopathy, in 2019.
- We continued to advance givosiran for the treatment of AHPs, announcing positive topline results from the interim analysis of the ENVISION Phase 3 study of givosiran. We plan to initiate a rolling submission of a NDA and pursue full approval based on complete results from the ENVISION Phase 3 study, which are expected in early 2019. The rolling NDA submission is expected to be initiated in 2018, with full clinical sections submitted in mid-2019, assuming positive results.
- We continued to advance lumasiran, an investigational RNAi therapeutic in development for the treatment of primary hyperoxaluria type 1, or PH1, announcing the initiation of ILLUMINATE-A, a global Phase 3 pivotal trial of lumasiran in children and adults with PH1. We expect to report topline results from ILLUMINATE-A in late 2019 and, if positive, submit filings for global regulatory approvals starting in early 2020. We also reached alignment with the FDA on the trial design for ILLUMINATE-B, a Phase 3 study of lumasiran in PH1 patients less than six years of age with preserved renal function.
- Our partner, MDCO, announced in October 2018 that the Independent Data Monitoring Committee for the ongoing inclisiran Phase 3 clinical trials (ORION 9, 10, and 11) conducted its fourth planned review of safety and efficacy data from the ORION trials and recommended that they continue without modification. MDCO has accumulated approximately 1,900 patient-years of safety for inclisiran.
- Enrollment in the ATLAS Phase 3 program for fitusiran, an investigational RNAi therapeutic in development for the treatment of hemophilia A and B with or without inhibitors, is ongoing. The fitusiran program has been transitioned to our partner, Sanofi Genzyme.

There is a risk that any drug discovery or development program may not result in revenue for a variety of reasons, including the possibility that we will not be able to adequately demonstrate the safety and effectiveness of the product candidate. For example, in October 2016, we announced the discontinuation of our revusiran clinical development program due to safety concerns and in September 2017, we announced that we had temporarily suspended dosing in all ongoing fitusiran studies. Moreover, there are uncertainties specific to any new field of drug discovery, including RNAi. The success of ONPATTRO or any other product candidate we develop is highly uncertain. In addition, even if we are able to successfully develop and obtain approval for other product candidates in addition to ONPATTRO, the amount of revenues we are able to generate will depend on many factors, including but not limited to the breadth of the indication approved by regulatory authorities, the size of the appropriate patient population, the acceptability of the product profile and competition from competing approved products, as well as products in development. Due to the numerous risks associated with developing drugs, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of any potential product candidate, or the period, if any, in which material net cash inflows will commence from any approved product.

Any failure to complete any stage of the development of any potential products in a timely manner or successfully launch, market and sell any approved product, including ONPATTRO, could have a material adverse effect on our operations, financial position and liquidity. A discussion of some of the risks and uncertainties associated with completing our projects on schedule, or at all, and the potential consequences of failing to do so, are set forth in Part II, Item 1A below under the heading “Risk Factors.”

Strategic Alliances

Our business strategy is to develop and commercialize a broad pipeline of RNAi therapeutic products directed towards our four STArs. As part of this strategy, we have entered into, and expect to enter into additional, collaboration and licensing agreements as a means of obtaining resources, capabilities and funding to advance our investigational RNAi therapeutic programs.

Our collaboration strategy is to form alliances that create significant value for ourselves and our collaborators in the advancement of RNAi therapeutics as a new class of innovative medicines. Specifically, with respect to our Genetic Medicine pipeline, we formed a broad strategic alliance with Sanofi Genzyme in 2014 pursuant to which we retain development and commercial rights for our current and future Genetic Medicine products in the United States, Canada and Western Europe, and Sanofi Genzyme will develop and commercialize our current and future Genetic Medicine products for which it elects to opt-in, in the rest of the world, referred to as the Sanofi Genzyme Territory, subject to certain broader rights. In January 2018, we and Sanofi Genzyme amended our 2014 Sanofi Genzyme collaboration and entered into an Exclusive License Agreement with respect to all TTR products, including ONPATTRO, ALN-TTRsc02 and any back-up products, referred to as the Exclusive TTR License, and the ALN-AT3 Global License Terms with respect to fitusiran and any back-up products, referred to as the AT3 License Terms. The 2018 amendment, together with the Exclusive TTR License and the AT3 License Terms, revise the terms and conditions of the 2014 collaboration to (i) provide us with the exclusive right to pursue the further global development and commercialization of all TTR products, including ONPATTRO,

ALN-TTRsc02 and any back-up products, (ii) provide Sanofi Genzyme the exclusive right to pursue the further global development and commercialization of fitusiran and any back-up products and (iii) terminate the previous co-development and co-commercialization rights related to revusiran, ALN-TTRsc02 and fitusiran under the 2014 Sanofi Genzyme collaboration. Sanofi Genzyme continues to have the right to opt into our other rare genetic disease programs for development and commercialization in territories outside of the Alnylam Territory as contemplated in the 2014 Sanofi Genzyme collaboration, as well as one right to a global license.

With respect to our Cardio-Metabolic pipeline, we intend to seek future strategic alliances for these programs, under which we may retain certain product development and commercialization rights, or we may structure as global alliances, as we did in our collaboration with MDCO to advance inclisiran. In March 2018, we entered into a discovery collaboration with Regeneron to identify RNAi therapeutics for NASH and potentially other related diseases, and we and Regeneron plan to enter into a separate, fifty-fifty collaboration to further research, co-develop and commercialize any therapeutic product candidates that emerge from these discovery efforts.

With respect to our Hepatic Infectious Disease pipeline, in October 2017, we announced an exclusive licensing agreement with Vir for the development and commercialization of RNAi therapeutics for infectious diseases, including chronic hepatitis B virus infection.

We may also seek future strategic alliances for one or more programs in our early stage CNS pipeline.

Intellectual Property

The strength of our intellectual property portfolio relating to the development and commercialization of siRNAs as therapeutics is essential to our business strategy. We own or license issued patents and pending patent applications in the United States and in key markets around the world claiming fundamental features of siRNAs and RNAi therapeutics as well as those claiming crucial chemical modifications and promising delivery technologies. Specifically, we have a portfolio of patents, patent applications and other intellectual property covering: fundamental aspects of the structure and uses of siRNAs, including their use as therapeutics, and RNAi-related mechanisms; chemical modifications to siRNAs that improve their suitability for therapeutic and other uses; siRNAs directed to specific targets as treatments for particular diseases; delivery technologies, such as in the fields of carbohydrate conjugates and cationic liposomes; and all aspects of our specific development candidates.

We believe that no other company possesses a portfolio of such broad and exclusive rights to the patents and patent applications required for the commercialization of RNAi therapeutics. Our intellectual property estate for RNAi therapeutics includes over 3,800 active cases and over 1,700 granted or issued patents, of which over 600 are issued or granted in the United States, the EU, including by the European Patent Office, or EPO, and Japan. We continue to seek to grow our portfolio through the creation of new technology in this field. In addition, we are very active in our evaluation of third-party technologies. Given the importance of our intellectual property portfolio to our business operations, we intend to vigorously enforce our rights and defend against challenges that have arisen or may arise in this area.

Critical Accounting Policies and Estimates

Revenue Recognition

On January 1, 2018, we adopted the new revenue standard by applying the modified retrospective method to all contracts that were not completed as of January 1, 2018. As a result, while reporting periods beginning on our adoption of the new revenue standard are presented under the new revenue standard, prior period amounts have not been adjusted and continue to be presented under the revenue standard in effect prior to January 1, 2018. The new revenue standard had a material impact on our consolidated financial statements. We did not have product revenues prior to our launch of ONPATTRO in the United States in the third quarter of 2018. Please read Note 2 to our

condensed consolidated financial statements included in Part I, Item 1, “Financial Statements (Unaudited),” of this quarterly report on Form 10-Q for a discussion of our revenue recognition policy, including for net product revenues, and the impact of this new revenue standard.

Inventory

We capitalize inventory costs that are expected to be sold commercially once we determine there is a high probability that the inventory costs will be recovered through commercial sale based on the review of several factors, including (i) the likelihood that all required regulatory approvals will be obtained, (ii) the expected timing of validation (if not yet completed) of manufacturing processes in the associated facility, (iii) the expected expiration of the inventory, (iv) logistical or commercial constraints that may impede the timely distribution and sale of the product, including transport requirements and reimbursement status, (v) history of approvals of similar products or formulations and (vi) potential legal challenges. Prior to the capitalization of inventory costs, we record such costs as research and development expenses on our condensed consolidated statements of comprehensive loss.

On a quarterly basis, we evaluate the recoverability of capitalized inventory using significant judgements, estimates and assumptions, primarily those related to commercial sales forecasts and product shelf life. In the event we determine our capitalized inventory to be impaired, we would reduce our inventory to net realizable value. Through September 30, 2018, we have not identified any impairment of our capitalized inventory.

Our critical accounting policies are described in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of our Annual Report on Form 10-K for the year ended December 31, 2017, which we filed with the SEC on February 15, 2018. There have been no significant changes to our critical accounting policies since the beginning of this fiscal year other than with respect to revenue recognition and inventory as described above.

Results of Operations

The following data summarizes the results of our operations for the periods indicated, in thousands:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenues	$2,069	$17,096	$53,875	$51,988
Operating costs and expenses	256,627	142,896	648,192	404,773
Loss from operations	(254,558)	(125,800)	(594,317)	(352,785)
Net loss	$(245,282)	$(122,937)	$(550,056)	$(348,647)

Discussion of Results of Operations

Revenues

The following table summarizes our total consolidated revenues for the periods indicated, in thousands, together with the changes, in thousands:

	Three Months Ended	Nine Months Ended
	September 30,	September 30,

Description	2018	2017	Dollar Change	2018	2017	Dollar Change
Product revenues, net	$460	$—	$460	$460	$—	$460
Net revenues from collaborators	1,609	17,096	(15,487)	53,415	51,988	1,427
Total revenues	$2,069	$17,096	$(15,027)	$53,875	$51,988	$1,887

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We began to record net product revenues in the third quarter of 2018 following the approval of ONPATTRO by the FDA on August 10, 2018 and its subsequent commercial launch in the United States. Prior to the third quarter of 2018, our revenues were generated entirely through research and development collaborations.

Product revenues, net

During the three and nine months ended September 30, 2018, we recognized $0.5 million of net product revenues related to sales of ONPATTRO in the United States that began in August 2018. We expect net product revenues to increase for the fourth quarter of 2018 as compared to the third quarter of 2018 primarily due to ONPATTRO sales in the United States and the commercial launch of ONPATTRO in Europe, beginning with Germany in October 2018.

Net revenues from collaborators

The following table summarizes our total consolidated net revenues from collaborators under our research and development collaborations, for the periods indicated, in thousands, together with the changes, in thousands:

	Three Months Ended September 30,			Nine Months Ended September 30,		
Description	2018	2017	Dollar Change	2018	2017	Dollar Change
Sanofi Genzyme	$(1,560)	$14,603	$(16,163)	$40,370	41,255	$(885)
Vir	2,957	—	2,957	10,313	—	10,313
MDCO	—	2,255	(2,255)	1,957	10,141	(8,184)
Other	212	238	(26)	775	592	183
Total net revenues from collaborators	$1,609	$17,096	$(15,487)	$53,415	$51,988	$1,427

The following table summarizes our total consolidated net revenues from collaborators, under the prior revenue standard, for the periods indicated, in thousands, together with the changes, in thousands:

	Three Months Ended September 30,			Nine Months Ended September 30,		
Description	2018	2017	Dollar Change	2018	2017	Dollar Change
Sanofi Genzyme	$(862)	$14,603	$(15,465)	$86,107	$41,255	$44,852
Vir	2,957	—	2,957	10,313	—	10,313
MDCO	—	2,255	(2,255)	6,353	10,141	(3,788)
Other	212	238	(26)	775	592	183
Total net revenues from collaborators	$2,307	$17,096	$(14,789)	$103,548	$51,988	$51,560

Net revenues from collaborators decreased significantly during the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 due primarily to the substantial completion of our performance obligations under the Sanofi Genzyme agreement in July 2018, that included a true-up of estimated costs that were reimbursed to Sanofi Genzyme as part of the transition and were recorded as a reduction of the transaction price. Net revenues from collaborators increased slightly during the nine months ended September 30, 2018 as a result of work performed under our collaboration with Vir, primarily offset by a decrease in reimbursable activities, as well as the adoption of the new revenue standard, related to our MDCO agreement. Upon our adoption of the new revenue standard on January 1, 2018, we recorded a cumulative reduction of $45.7 million of deferred revenues related to our collaboration with Sanofi Genzyme, resulting in a remaining balance of $3.5 million. As a result, we recorded significantly lower revenues related to our collaboration with Sanofi Genzyme in the nine months ended September 30, 2018 than we would have recorded under the prior revenue standard.

We expect net revenues from collaborators to increase for the fourth quarter of 2018 as compared to the third quarter of 2018 primarily due to increased reimbursable activities.

We had $5.1 million of deferred revenue at September 30, 2018 related to our collaboration with Vir. At December 31, 2017, prior to the adoption of the new revenue standard, we had $84.8 million of deferred revenue, which consisted of payments we have received from collaborators, primarily Sanofi Genzyme, MDCO and Kyowa Hakko Kirin Co., Ltd., but had not yet recognized pursuant to our revenue recognition policies. As a result of our adoption of the new revenue standard on January 1, 2018, we recorded a cumulative reduction of $68.2 million of deferred revenue with a corresponding adjustment to accumulated deficit in the first quarter of 2018. Please read Note 2 to our condensed consolidated financial statements included in Part I, Item 1, “Financial Statements

(Unaudited),” of this quarterly report on Form 10-Q for a discussion of our revenue recognition policy and the impact of this new revenue standard.

Operating costs and expenses

The following tables summarize our operating costs and expenses for the periods indicated, in thousands and as a percentage of total operating costs and expenses, together with the changes, in thousands:

Description	Three Months Ended September 30, 2018	% of Total Operating Costs and Expenses		Three Months Ended September 30, 2017	% of Total Operating Costs and Expenses		Dollar Change
Cost of goods sold	$ 137	0	%	$ —	0	%	$137
Research and development	139,945	55	%	95,252	67	%	44,693
Selling, general and administrative	116,545	45	%	47,644	33	%	68,901
Total operating costs and expenses	$ 256,627	100	%	$ 142,896	100	%	$113,731

Description	Nine Months Ended September 30, 2018	% of Total Operating Costs and Expenses		Nine Months Ended September 30, 2017	% of Total Operating Costs and Expenses		Dollar Change
Cost of goods sold	$ 137	0	%	$ —	0	%	$137
Research and development	374,384	58	%	272,863	67	%	101,521
Selling, general and administrative	273,671	42	%	131,910	33	%	141,761
Total operating costs and expenses	$ 648,192	100	%	$ 404,773	100	%	$243,419

Cost of Goods Sold

Cost of goods sold includes the cost of producing and distributing inventories that are related to ONPATTRO product revenues in the United States during the respective period (including salary-related and stock-based compensation expenses for employees involved with ONPATTRO production and distribution) and third-party royalties payable on our net product revenues for ONPATTRO. We began capitalizing ONPATTRO inventory costs during the third quarter of 2018 in connection with FDA approval and our expectation that these costs are recoverable through commercialization of ONPATTRO. Prior to the capitalization of ONPATTRO inventory costs, such costs were recorded as research and development expenses in our condensed consolidated statements of comprehensive loss. During the three and nine months ended September 30, 2018, we recorded $137,000 of cost of goods sold, including $34,000 related to royalties. The cost of goods sold during the three and nine months ended September 30, 2018 only reflects a portion of the manufacturing cost of ONPATTRO. Utilizing the average cost per unit of ONPATTRO manufactured, cost of goods sold for manufacturing costs for the three and nine months ended September 30, 2018 would have been approximately $30,000. At September 30, 2018, we had $21.3 million of this zero-cost inventory.

We expect that cost of goods sold will increase during the fourth quarter of 2018 as compared to the third quarter of 2018 primarily as a result of an expected increase in ONPATTRO sales in the United States and the beginning of commercial sales of ONPATTRO in Europe, initially in Germany and subsequently in additional European countries in the fourth quarter of 2018.

Research and development. The following tables summarize the components of our research and development expenses for the periods indicated, in thousands and as a percentage of total research and development expenses, together with the changes, in thousands:

Description	Three Months Ended September 30, 2018	% of Expense Category	Three Months Ended September 30, 2017	% of Expense Category	Dollar Change
Research and development					
Stock-based compensation	$ 45,784	33 %	$ 15,090	16 %	$30,694
Compensation and related	28,008	20 %	24,888	26 %	3,120
Clinical trial	21,355	15 %	24,587	26 %	(3,232)
External services	12,302	9 %	11,054	12 %	1,248
Facilities-related	11,811	8 %	7,798	8 %	4,013
Manufacturing	8,002	6 %	6,999	7 %	1,003
Lab supplies and materials	3,697	3 %	2,929	3 %	768
Other	8,986	6 %	1,907	2 %	7,079
Total research and development expenses	$ 139,945	100 %	$ 95,252	100 %	$44,693

Research and development expenses increased significantly during the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 due primarily to increased stock-based compensation expense related to the accounting for performance-based stock awards as a result of the approval and launch of ONPATTRO and clinical achievements with respect to our givosiran Phase 3 study. In addition, other research and development expenses increased primarily due to license payments due to third parties as a result of the regulatory approval and commercial launch of ONPATTRO in the third quarter of 2018.

Description	Nine Months Ended September 30, 2018	% of Expense Category	Nine Months Ended September 30, 2017	% of Expense Category	Dollar Change
Research and development					
Compensation and related	$ 88,453	24 %	$ 71,406	26 %	$17,047
Stock-based compensation	67,537	18 %	37,035	14 %	30,502
Clinical trial	65,159	17 %	65,271	24 %	(112)
Manufacturing	57,734	15 %	36,466	13 %	21,268
External services	37,649	10 %	26,568	10 %	11,081
Facilities-related	30,046	8 %	23,324	8 %	6,722
Lab supplies and materials	9,423	3 %	7,800	3 %	1,623
Other	18,383	5 %	4,993	2 %	13,390
Total research and development expenses	$ 374,384	100 %	$ 272,863	100 %	$101,521

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Research and development expenses increased significantly during the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 due primarily to increased stock-based compensation expense related to the accounting for performance-based stock awards as a result of the approval and launch of ONPATTRO and clinical achievements with respect to our givosiran Phase 3 study. In addition, manufacturing expenses increased significantly as a result of our late stage programs. Compensation and related expenses increased as a result of an increase in headcount during the period as we expand and advance our development pipeline. In addition, external services expenses increased during the nine months ended September 30, 2018 as a result of increased pre-clinical services related to early stage programs to support our Alnylam 2020 strategy, as well as increased expenses related to regulatory submissions.

During the three and nine months ended September 30, 2018 and 2017, in connection with advancing the activities under our collaboration agreements, we incurred significant research and development expenses, primarily related to external development and manufacturing services. The 2018 amendment to the 2014 Sanofi Genzyme collaboration, together with the Exclusive TTR License and the AT3 License Terms, provide us with the exclusive right to pursue the further global development and commercialization of all TTR products and any back-up products and provide Sanofi Genzyme with the exclusive right to pursue the further global development and commercialization of fitusiran and any back-up products. As a result, we expect aggregate costs incurred under our collaboration agreements to decrease. The following table summarizes the expenses incurred under our collaboration agreements by collaboration partner for the periods indicated, in thousands:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Sanofi Genzyme	$5,291	$45,668	$38,643	$134,509
Vir	1,823	—	15,205	—
MDCO	940	374	1,581	5,493
Total	$8,054	$46,042	$55,429	$140,002

We expect to continue to devote a substantial portion of our resources to research and development expenses to support our goals for 2020. We expect that research and development expenses, excluding stock-based compensation expenses, will increase during the fourth quarter of 2018 as compared to the third quarter of 2018 as we continue to develop our pipeline and advance our product candidates into later-stage development, hire additional employees and prepare regulatory submissions. We expect that stock-based compensation expenses will decrease significantly during the fourth quarter of 2018 as compared to the third quarter of 2018 as a result of significant non-recurring stock-based compensation expense recorded in the third quarter of 2018 related to the accounting for certain of our performance-based equity awards. However, we expect that certain expenses will be variable depending on the timing of manufacturing batches, clinical trial enrollment and results, regulatory review of our product candidates and programs, and stock-based compensation expenses due to our determination regarding the probability of vesting for performance-based awards.

A significant portion of our research and development costs are not tracked by project as they benefit multiple projects or our technology platform. However, certain of our collaboration agreements contain cost-sharing arrangements pursuant to which certain costs incurred under the project are reimbursed. Costs reimbursed under the agreements typically include certain direct external costs and a negotiated full-time equivalent labor rate for the actual time

worked on the project. As a result, although a significant portion of our research and development expenses are not tracked on a project-by-project basis, we do track direct external costs attributable to, and the actual time our employees worked on, our collaborations.

Selling, general and administrative. The following tables summarize the components of our selling, general and administrative expenses for the periods indicated, in thousands and as a percentage of total selling, general and administrative expenses, together with the changes, in thousands:

Description	Three Months Ended September 30, 2018	% of Expense Category	Three Months Ended September 30, 2017	% of Expense Category	Dollar Change
Selling, general and administrative					
Stock-based compensation	$ 42,170	36 %	$ 10,865	23 %	$31,305
Compensation and related	28,968	25 %	14,386	30 %	14,582
Consulting and professional services	28,844	25 %	14,871	31 %	13,973
Facilities-related	7,680	6 %	2,802	6 %	4,878
Other	8,883	8 %	4,720	10 %	4,163
Total selling, general and administrative expenses	$ 116,545	100 %	$ 47,644	100 %	$68,901

Selling, general and administrative expenses increased significantly during the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 due primarily to an increase in stock-based compensation expense related to the accounting for performance-based stock awards as a result of the approval and launch of ONPATTRO and clinical achievements with respect to our givosiran Phase 3 study. In addition, selling, general and administrative expenses increased significantly due to an increase in commercial and medical affairs headcount and commercial-related services to support corporate growth and prepare for the launch of ONPATTRO in 2018, and potential additional country launches of ONPATTRO in 2019, as well as future worldwide product launches assuming regulatory approval of givosiran and other product candidates.

Description	Nine Months Ended September 30, 2018	% of Expense Category	Nine Months Ended September 30, 2017	% of Expense Category	Dollar Change
Selling, general and administrative					
Consulting and professional services	$ 92,042	34 %	$ 42,435	32 %	$49,607
Compensation and related	78,819	29 %	40,327	30 %	38,492
Stock-based compensation	62,242	23 %	28,667		