FIBROGEN INC
Form 10-Q
November 08, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

OR

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

Commission file number: 001-36740

FIBROGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	77-0357827
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

409 Illinois Street
San Francisco, CA 94158

(Address of Principal Executive Offices) (Zip Code)

(415) 978-1200

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

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

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

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

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

The number of shares of common stock outstanding as of October 31, 2018 was 84,978,056.

FIBROGEN, INC.

TABLE OF CONTENTS

Table of Contents

FIBROGEN, INC.

PART I—FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

(Unaudited)

	September 30, 2018	December 31, 2017 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 566,722	$ 673,658
Short-term investments	86,009	62,060
Accounts receivable ($19,434 and $4,004 from a related party)	23,187	8,452
Prepaid expenses and other current assets	2,865	4,800
Total current assets	678,783	748,970
Restricted time deposits	5,181	5,181
Long-term investments	40,602	10,506
Property and equipment, net	127,908	129,476
Other assets	3,167	4,517
Total assets	$ 855,641	$ 898,650
Liabilities, stockholders’ equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 10,131	$ 5,509
Accrued liabilities ($353 and $272 to a related party)	52,598	63,781

Deferred revenue	37,697	16,670
Total current liabilities	100,426	85,960
Long-term portion of lease financing obligations	97,323	97,763
Product development obligations	16,948	17,244
Deferred rent	3,197	3,657
Deferred revenue, net of current	136,874	138,241
Other long-term liabilities	10,291	8,047
Total liabilities	365,059	350,912
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 125,000 shares authorized; no shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value; 225,000 shares authorized at September 30, 2018 and December 31, 2017; 84,847 and 82,498 shares issued and outstanding at September 30, 2018 and December 31, 2017	848	825
Additional paid-in capital	1,209,813	1,160,094
Accumulated other comprehensive loss	(2,570)	(1,795)
Accumulated deficit	(736,780)	(630,657)
Total stockholders' equity	471,311	528,467
Non-controlling interests	19,271	19,271
Total equity	490,582	547,738

Total liabilities, stockholders' equity and non-controlling interests	$	855,641	$	898,650

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

Table of Contents

FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017 (Note 1)	2018	2017 (Note 1)
Revenue:				
License revenue (includes $0, $0, $14,323 and $0 from a related party)	$—	$9,933	$14,323	$9,933
Development and other revenue (includes $5,131, $5,322, $16,448 and $15,106 from a related party)	29,027	30,617	90,580	90,327
Total revenue	29,027	40,550	104,903	100,260
Operating expenses:				
Research and development	56,443	50,336	165,555	144,049
General and administrative	15,356	12,953	45,961	37,908
Total operating expenses	71,799	63,289	211,516	181,957
Loss from operations	(42,772)	(22,739)	(106,613)	(81,697)
Interest and other, net				
Interest expense	(2,739)	(2,769)	(8,257)	(7,901)
Interest income and other, net	3,079	1,106	7,796	2,783
Total interest and other, net	340	(1,663)	(461)	(5,118)
Loss before income taxes	(42,432)	(24,402)	(107,074)	(86,815)
Provision for income taxes	124	57	299	166
Net loss	$(42,556)	$(24,459)	$(107,373)	$(86,981)
Net loss per share - basic and diluted	$(0.50)	$(0.32)	$(1.28)	$(1.24)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	84,508	75,891	83,713	69,899

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

Table of Contents

FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017 (Note 1)	2018	2017 (Note 1)
Net loss	$(42,556)	$(24,459)	$(107,373)	$(86,981)
Other comprehensive income (loss):				
Foreign currency translation adjustments	72	(578)	503	(1,827)
Available-for-sale investments:				
Unrealized gain on investments, net of tax effect	(31)	403	(28)	1,250
Reclassification from accumulated other comprehensive loss	—	(47)	—	(72)
Net change in unrealized gain on available-for-sale investments	(31)	356	(28)	1,178
Other comprehensive income (loss), net of taxes	41	(222)	475	(649)
Comprehensive loss	$(42,515)	$(24,681)	$(106,898)	$(87,630)

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

Table of Contents

FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017 (Note 1)
Operating activities		
Net loss	$(107,373)	$(86,981)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4,693	4,582
Amortization of premium on investments	584	1,503
Unrealized loss (gain) on short-term investments	1,103	3
Loss (gain) on disposal of property and equipment	53	3
Stock-based compensation	38,432	27,608
Realized foreign currency gain	(1,074)	—
Realized gain on sales of available-for-sale securities	(87)	(143)
Changes in operating assets and liabilities:		
Accounts receivable	(14,735)	(13,180)
Prepaid expenses and other current assets	1,935	33
Other assets	1,350	(1,657)
Accounts payable	4,622	184
Accrued liabilities	(9,885)	(114)
Deferred revenue	19,660	2,021
Lease financing liability	35	474
Other long-term liabilities	2,008	337
Net cash used in operating activities	(58,679)	(65,327)
Investing activities		
Purchases of property and equipment	(4,852)	(4,992)
Proceeds from sale of property and equipment	184	5
Purchases of available-for-sale securities	(110,156)	(102)
Proceeds from sales of available-for-sale securities	8,167	21,109
Proceeds from maturities of available-for-sale securities	47,390	33,849
Net cash provided by investing activities	(59,267)	49,869
Financing activities		
Borrowings under capital lease obligations	49	—

Repayments of lease liability	(302)	(302)
Proceeds from follow-on offerings, net of underwriting discounts and commission costs	—	471,205
Cash paid for payroll taxes on restricted stock unit releases	(13,288)	(5,970)
Proceeds from issuance of common stock	24,598	28,556
Payments of deferred offering costs	—	(430)
Net cash provided by financing activities	11,057	493,059
Effect of exchange rate change on cash and cash equivalents	(47)	(10)
Net decrease in cash and cash equivalents	(106,936)	477,591
Total cash and cash equivalents at beginning of period	673,658	173,782
Total cash and cash equivalents at end of period	$566,722	$651,373

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

Table of Contents

FIBROGEN, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Significant Accounting Policies

Description of Operations

FibroGen, Inc. ("FibroGen" or the "Company") was incorporated in 1993 in Delaware and is a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics agents to treat serious unmet medical needs. The Company's focus in the areas of fibrosis and hypoxia-inducible factor ("HIF") biology has generated multiple programs targeting various therapeutic areas. The Company's most advanced product candidate, roxadustat, or FG-4592, is an oral small molecule inhibitor of HIF prolyl hydroxylases ("HIF-PHs") in Phase 3 clinical development for the treatment of anemia in chronic kidney disease ("CKD") and myelodysplastic syndromes ("MDS"). Pamrevlumab, or FG-3019, is the Company's monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer and Duchenne muscular dystrophy ("DMD"). The Company is taking a global approach with respect to the development and future commercialization of its product candidates, and this includes development and commercialization in the People's Republic of China ("China"). The Company is capitalizing on its extensive experience in fibrosis and HIF biology and clinical development to advance a pipeline of innovative medicines for the treatment of anemia, fibrotic disease cancer, corneal blindness and other serious unmet medical needs.

Basis of Presentation and Principles of Consolidation

The condensed consolidated financial statements include the accounts of FibroGen, its wholly owned subsidiaries and its majority-owned subsidiaries, FibroGen Europe Oy and FibroGen China Anemia Holdings, Ltd. ("FibroGen China"). All inter-company transactions and balances have been eliminated in consolidation. The Company operates in one segment — the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs.

The unaudited condensed consolidated financial statements and related disclosures have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") applicable to interim financial reporting and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the United States Securities and Exchange Commission ("SEC") and, therefore, do not include all information and footnote disclosures normally included in the annual consolidated financial statements. The financial information included herein should be read in conjunction with the consolidated financial statements and related notes in the Company's Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2017 ("2017 Form 10-K").

The accounting policies used by the Company in its presentation of interim financial results are consistent with those presented in Note 2 to the consolidated financial statements included in the 2017 Form 10-K, except for the following:

Revenue Recognition

Substantially all of the Company's revenues to date have been generated from its collaboration agreements.

The Company's collaboration agreements include multiple performance obligations comprised of promised services, or bundles of services, that are distinct. Services that are not distinct are combined with other services in the agreement until they form a distinct bundle of services. The Company's process for identifying performance obligations and an enumeration of each obligation for each agreement is outlined in Note 2 "Collaboration Agreements." Determining the performance obligations within a collaboration agreement often involves significant judgment and is specific to the facts and circumstances contained in each agreement.

The Company has identified the following material promises under its collaboration agreements: (1) license of FibroGen technology, (2) the performance of co-development services, including manufacturing of clinical supplies and other services during the development period, and (3) manufacture of commercial supply. The evaluation as to whether these promises are distinct, and therefore represent separate performance obligations, is described in more details in Note 2 "Collaboration Agreements."

For revenue recognition purposes, the Company determines that the term of its collaboration agreements begin on the effective date and ends upon the completion of all performance obligations contained in the agreements. In each agreement, the contract term is defined as the period in which parties to the contract have present and enforceable rights and obligations. The Company believes that the existence of what it considers to be substantive termination penalties on the part of the counterparty create sufficient incentive for the counterparty to avoid exercising its right to terminate the agreement unless in exceptionally rare situations.

Table of Contents

The transaction price for each collaboration agreement is determined based on the amount of consideration the Company expects to be entitled for satisfying all performance obligations within the agreement. The Company's collaboration agreements include payments to the Company of one or more of the following: non-refundable upfront license fees; co-development billings; development, regulatory, and commercial milestone payments; and royalties on net sales of licensed products.

Upfront license fees are non-contingent and non-refundable in nature and are included in the transaction price at the point when the license fees become due to the Company. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such 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.

Co-development billings resulting from the Company's research and development efforts, which are reimbursable under its collaboration agreements, are considered variable consideration. Determining the amount of variable consideration from co-development billings requires the Company to make estimates of future research and development efforts, which involves significant judgment. Co-development billings are allocated entirely to the co-development services performance obligation when amounts are related specifically to research and development efforts necessary to satisfy the performance obligation, and such an allocation is consistent with the allocation objective.

Milestone payments are also considered variable consideration, which requires the Company to make estimates of when achievement of a particular milestone becomes probable. Similar to other forms of variable consideration, milestone payments are included in the transaction price when it becomes probable that such inclusion would not result in a significant revenue reversal. Milestone payments are therefore included in the transaction price when achievement of the milestone becomes probable.

For arrangements that include sales-based royalties and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from its collaboration arrangements.

The transaction price is allocated to performance obligations based on their relative standalone selling price ("SSP"), with the exception of co-development billings allocated entirely to co-development services performance obligations. The SSP is determined based on observable prices at which the Company separately sells the products and services. If an SSP is not directly observable, then the Company will estimate the SSP considering marketing conditions, entity-specific factors, and information about the customer or class of customer that is reasonably available. The process for determining SSP involves significant judgment and includes consideration of multiple factors, including assumptions related to the market opportunity and the time needed to commercialize a product candidate pursuant to the relevant license, estimated direct expenses and other costs, which include the rates normally charged by contract research and contract manufacturing organizations for development and manufacturing obligations, and rates that would be charged by qualified outsiders for committee services.

Significant judgment may be required in determining whether a performance obligation is distinct, determining the amount of variable consideration to be included in the transaction price, and estimating the SSP of each performance obligation. An enumeration of the Company's significant judgments is outlined in Note 2 "Collaboration Agreements."

For each performance obligation identified within an arrangement, the Company determines the period over which the promised services are transferred and the performance obligation is satisfied. Service revenue is recognized over time based on progress toward complete satisfaction of the performance obligation. The Company uses an input method to measure progress toward the satisfaction of co-development services and certain other related performance obligations, which is based on costs of labor hours or full time equivalents and out-of-pocket expenses incurred relative to total expected costs to be incurred. The Company believes this measure of progress provides a faithful depiction of the transfer of services because other measures do not measure as accurately how the Company transfers its performance obligations to its collaboration partners.

Investments

The Company’s investments consist of available-for-sale debt investments and marketable equity investments. Those investments with maturities less than 12 months are considered short-term investments. Those investments with maturities greater than 12 months are considered long-term investments. The Company’s investments classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses for available-for-sale debt investments that are deemed temporary in nature are recorded in accumulated other comprehensive income (loss) as a separate component of stockholder’ equity. Marketable equity securities are equity securities with readily determinable fair value, and are measured and recorded at fair value. Realized and unrealized gains or losses resulting from changes in value and sale of the Company’s marketable equity investments are recorded in other income (expenses) in the consolidated statement of operations.

Table of Contents

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Premiums and discounts are amortized (accreted) over the life of the related security as an adjustment to its yield. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. The more significant areas requiring the use of management estimates and assumptions include valuation and recognition of revenue, estimates of accruals related to clinical trial costs, valuation allowances for deferred tax assets, and valuation and recognition of stock-based compensation. On an ongoing basis, management reviews these estimates and assumptions. Changes in facts and circumstances may alter such estimates and actual results could differ from those estimates. In the Company's opinion, the accompanying unaudited condensed consolidated financial statements include all normal recurring adjustments necessary for a fair statement of its financial position, results of operations and cash flows for the interim periods presented.

Recently Issued and Adopted Accounting Guidance

New Revenue Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"), which supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC") 605, Revenue Recognition. ASU 2014-09 is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients; and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers (collectively, the "new revenue standards").

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs 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) the Company satisfies a performance

obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company adopted the new revenue standards as of January 1, 2018 using the full retrospective method, which required the Company to recast the prior reporting period presented in the condensed consolidated financial statements. The primary impact upon adoption of the new revenue standards relates to the manner in which revenue is recognized for co-development billings and milestone payments under the Company's collaboration arrangements. Under the new revenue standards, both of these elements of consideration are considered variable consideration which requires the Company to make estimates of when co-development billings become due or when achievement of a particular milestone becomes probable. Payments are included in the transaction price when it becomes probable that inclusion would not lead to a significant revenue reversal.

The Company has recast its condensed consolidated statement of operations and condensed balance sheet from amounts previously reported due to the adoption of the new revenue standards. The adoption of the new revenue standards had no impact to the Company's previously reported condensed consolidated statement of cash flows.

Table of Contents

Select line items from the Company's condensed consolidated statement of operations and condensed balance sheet, which reflect the adoption of the new revenue standards are as follows (in thousands):

	Three Months Ended September 30, 2017			Nine Months Ended September 30, 2017		
	As Previously Reported	New Revenue Standards Adjustment	As Recast	As Previously Reported	New Revenue Standards Adjustment	As Recast
Statement of Operations						
License revenue	$19,997	$ (10,064)	$9,933	$60,930	$ (50,997)	$9,933
Development and other revenue	7,275	23,342	30,617	22,230	68,097	90,327
Total revenue	27,272	13,278	40,550	83,160	17,100	100,260
Net loss	(37,737)	13,278	(24,459)	(104,081)	17,100	(86,981)
Net loss per share - basic and diluted	$(0.50)	$ 0.18	$(0.32)	$(1.49)	$ 0.25	$(1.24)

	December 31, 2017		
	As Previously Reported	New Revenue Standards Adjustment	As Recast
Balance Sheet			
Deferred revenue, current	$7,968	$ 8,702	$16,670
Deferred revenue, net of current	112,231	26,010	138,241
Accumulated deficit	(595,945)	(34,712)	(630,657)

The adoption of the new revenue standards resulted in an increase in revenue of $5.3 million and $3.6 million for the years ended December 31, 2017 and 2016, respectively, and an increase in the opening accumulated deficit of $43.7 million as of January 1, 2016.

ASU 2016-01

In January 2016, the FASB issued ASU 2016-01, Financial Instruments-Overall (Subtopic 825-10). This guidance requires equity investments that are not accounted for under the equity method of accounting to be measured at fair value with changes recognized in net income, simplifies the impairment assessment of certain equity investments, and updates certain presentation and disclosure requirements. This guidance was effective for the annual reporting period beginning after December 15, 2017 and interim periods within those annual periods. The Company adopted this guidance as of January 1, 2018 using the modified retrospective approach. The impacts to the Company's accumulated other comprehensive loss and accumulated deficit upon adoption of this guidance are as follows (in thousands):

	Accumulated Other Comprehensive Loss	Accumulated Deficit
Balance at December 31, 2017	$ (1,795)	$ (630,657)*
Impact of change in accounting principle upon adoption of ASU 2016-01	(1,250)	1,250
Opening balance as of January 1, 2018	$ (3,045)	$ (629,407)

*Recast to reflect the adoption of the new revenue standards. See above.

The adoption of this guidance had no impact to the Company's condensed consolidated statement of operations or condensed consolidated statement of cash flows for the nine months ended September 30, 2018.

ASU 2017-09

In May 2017, the FASB issued ASU 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting. This guidance provides guidance about which changes to the terms or conditions of a stock-based payment award require an entity to apply modification accounting in Topic 718. This guidance was effective for annual reporting period beginning after December 15, 2017, including interim periods. The Company adopted this guidance as of January 1, 2018, and the adoption of this guidance had no impact to the Company's condensed consolidated financial statements.

Table of Contents

ASU 2016-16

In October 2016, the FASB issued ASU 2016-16, Intra-Entity Transfers of Assets Other Than Inventory. This guidance requires companies to recognize the income tax effects of intercompany sales or transfer of assets, other than inventory, in the income statement as income tax expense (or benefit) in the period the sale or transfer occurs. The exception to recognizing the income tax effects of intercompany sales or transfer sales or transfer of assets remains in place for intercompany inventory sales and transfers. This guidance was effective for annual reporting period beginning after December 15, 2017, including interim periods. The Company adopted this guidance as of January 1, 2018 using the modified retrospective method. The adoption of this guidance did not result in any recognition of previously unrecognized deferred charges using a modified retrospective method, thus had no impact to the Company's condensed consolidated financial statements.

Recently Issued Accounting Guidance Not Yet Adopted

In August 2018, the FASB issued ASU 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. This guidance requires capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This guidance should be applied either retrospectively or prospectively, and is effective for annual reporting period beginning after December 15, 2019 including interim periods, with early adoption permitted. The Company is currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement. This guidance amends existing fair value measurement disclosure requirements by adding, changing, or removing certain disclosures. This guidance is effective for annual reporting period beginning after December 15, 2019 including interim periods, with early adoption permitted. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The Company does not anticipate a material impact to its consolidated financial statements upon adoption of this guidance.

In June 2018, the FASB issued ASU 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. This guidance expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance also specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. This guidance is effective for annual reporting period beginning after December 15, 2018, including interim periods. The Company will adopt this guidance on January 1, 2019 and does not anticipate a material impact to its consolidated financial statements upon adoption.

In February 2018, the FASB issued ASU 2018-02, Income Statement - Reporting Comprehensive Income: Reclassification of Certain Tax effects from Accumulated Other Comprehensive Income. This guidance allows for the reclassification from accumulated other comprehensive income to retained earnings for the stranded tax effects arising

from the change in the reduction of the United States ("U.S.") federal statutory income tax rate from 35% to 21%. This guidance is effective for annual reporting period beginning after December 15, 2018, including interim periods, with early adoption permitted. The Company will adopt this guidance on January 1, 2019 and does not anticipate a material reclassification between its accumulated other comprehensive loss and accumulated deficit upon adoption.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This guidance requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability. This guidance is effective for the annual reporting period beginning after December 15, 2019, including interim periods within that reporting period. The Company is currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

Table of Contents

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) ("ASU 2016-02"). Under this guidance, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements ("ASU 2018-11"), which provides entities the option to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. ASU 2016-02 and ASU 2018-11 are effective for the annual reporting period beginning after December 15, 2018, including interim periods within that reporting period. The Company will adopt this guidance as of January 1, 2019 and is currently in the stages of gathering data and assessing the impact of the new lease accounting standard. The Company anticipates that the adoption of this guidance will result in additional assets and liabilities being recorded on its consolidated balance sheet.

2. Collaboration Agreements

Astellas Agreements

Japan Agreement

In June 2005, the Company entered into a collaboration agreement with Astellas Pharma Inc. ("Astellas") for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in Japan ("Japan Agreement"). Under this agreement, Astellas paid license fees and other consideration totaling $40.1 million, which amounts were fully received as of February 2009. Under the Japan Agreement, the Company is also eligible to receive from Astellas an aggregate of approximately $132.5 million in potential milestone payments, comprised of (i) up to $22.5 million in milestone payments upon achievement of specified clinical and development milestone events, which amounts were fully received as of July 2016, (ii) up to $95.0 million in milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $15.0 million in milestone payments upon the achievement of specified commercial sales milestone.

During the second quarter of 2018, Astellas reported positive results from the final phase 3 CKD-dialysis trial of roxadustat in Japan, indicating that Astellas is ready to make an NDA submission for the treatment of anemia with roxadustat in CKD-dialysis patients in 2018. The Company evaluated the regulatory milestone payment associated with NDA submission in Japan based on variable consideration requirements under the current revenue standards and concluded that this milestone became probable of being achieved in the second quarter of 2018. Accordingly, the consideration of $15.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Japan Agreement in the second quarter of 2018, of which $14.9 million was recognized as revenue during the second quarter of 2018 from performance obligations satisfied or partially satisfied.

FibroGen and Astellas are currently negotiating an amendment to the Japan Agreement that will allow Astellas to manufacture roxadustat drug product for commercialization in Japan, and for which FibroGen would continue to manufacture and deliver to Astellas roxadustat active pharmaceutical ingredient ("API"). The commercial terms of the Japan Agreement would remain substantially the same. In the second quarter of 2018, FibroGen delivered roxadustat API to Astellas under a material transfer agreement for Astellas to conduct commercial scale manufacturing validation for roxadustat drug product in anticipation of commercial launch in Japan. The associated consideration of $20.9 million was recorded as deferred revenue because Astellas' right to use the material was limited as of September 30,

2018.

Europe Agreement

In April 2006, the Company entered into a separate collaboration agreement with Astellas for the development and commercialization of roxadustat for the treatment of anemia in Europe, the Middle East, the Commonwealth of Independent States and South Africa (“Europe Agreement”). Under the terms of the Europe Agreement, Astellas paid license fees and other upfront consideration totaling $320.0 million (such amounts were fully received as of February 2009). Under the Europe Agreement, the Company is also eligible to receive from Astellas an aggregate of approximately $425.0 million in potential milestone payments, comprised of (i) up to $90.0 million in milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $335.0 million in milestone payments upon achievement of specified regulatory milestone events. Clinical milestone payments of $40.0 million and $50.0 million were received in 2010 and 2012, respectively. Under the Europe Agreement, Astellas committed to fund 50% of joint development costs for Europe and North America, and all territory-specific costs. The Europe Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range.

Table of Contents

AstraZeneca Agreements

U.S./Rest of World ("RoW") Agreement

Effective July 30, 2013, the Company entered into a collaboration agreement with AstraZeneca AB ("AstraZeneca") for the development and commercialization of roxadustat for the treatment of anemia in the U.S. and all other countries in the world, other than China, not previously licensed under the Astellas Europe and Astellas Japan Agreements ("U.S./RoW Agreement"). It also excludes China, which is covered by a separate agreement with AstraZeneca described below. Under the terms of the U.S./RoW Agreement, AstraZeneca paid upfront, non-contingent, non-refundable and time-based payments totaling $374.0 million, which were fully received in various amounts through June 2016. Under the U.S./RoW Agreement, the Company is also eligible to receive from AstraZeneca an aggregate of approximately $875.0 million in potential milestone payments, comprised of (i) up to $65.0 million in milestone payments upon achievement of specified clinical and development milestone events, $15.0 million of which was received in 2015 as a result of the finalization of its two audited pre-clinical carcinogenicity study reports, (ii) up to $325.0 million in milestone payments upon achievement of specified regulatory milestone events, (iii) up to $160.0 million in milestone payments related to activity by potential competitors and (iv) up to approximately $325.0 million in milestone payments upon the achievement of specified commercial sales events.

Under the U.S./RoW Agreement, the Company and AstraZeneca shared equally in the development costs of roxadustat not already paid for by Astellas, up to a total of $233.0 million (i.e. the Company's share of development costs is $116.5 million, which was reached during the fourth quarter of 2015). Development costs incurred by FibroGen during the development period in excess of the $233.0 million (aggregated spend) are fully reimbursed by AstraZeneca. AstraZeneca will pay the Company tiered royalty payments on AstraZeneca's future net sales (as defined in the agreement) of roxadustat in the low 20% range. In addition, the Company will receive a transfer price for delivery of commercial product based on a percentage of AstraZeneca's net sales (as defined in the agreement) in the low- to mid-single digit range.

China Agreement

Effective July 30, 2013, the Company (through its subsidiaries affiliated with China) entered into a collaboration agreement with AstraZeneca for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in China ("China Agreement"). Under the terms of the China Agreement, AstraZeneca paid upfront, non-contingent and non-refundable payments totaling $28.2 million, which were fully received in 2014. Under the China Agreement, the Company is also eligible to receive from AstraZeneca an aggregate of approximately $348.5 million in potential milestone payments, comprised of (i) up to $15.0 million in milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $146.0 million in milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $187.5 million in milestone payments upon the achievement of specified commercial sales and other events. The China Agreement is structured as a 50/50 profit or loss share (as defined) and provides for joint development costs (including capital and equipment costs for construction of the manufacturing plant in China), to be shared equally during the development.

In October 2017, the State Drug Administration in China, now known as the National Medicine Products Administration, accepted the Company's submitted New Drug Application ("NDA") for registration of roxadustat for anemia in dialysis-dependent CKD and non-dialysis-dependent CKD ("NDD-CKD") patients. This NDA submission triggered a $15.0 million milestone payment to the Company by AstraZeneca. The Company evaluated this milestone

based on variable consideration requirements under the new revenue standards and concluded that the milestone was probable of being achieved in the third quarter of 2017. Accordingly, consideration associated with this milestone was included in the transaction price and allocated to performance obligations under the China Agreement in the same period.

Accounting for the Astellas Agreements

For each of the Astellas agreements, the Company has evaluated the promised services within the respective arrangements and has identified performance obligations representing those services and bundles of services that are distinct.

Promised services that were not distinct have been combined with other promised services to form a distinct bundle of promised services, with revenue being recognized on the bundle of services rather than the individual services. There are no right-of-return provisions for the delivered items in the Astellas agreements.

As of September 30, 2018, the transaction price for the Japan Agreement included $40.1 million of non-contingent upfront payments, $37.5 million of variable consideration related to payments for milestones considered probable of being achieved, and $12.6 million of variable consideration related to co-development billings. The transaction price for the Europe Agreement included $320.0 million of non-contingent upfront payments, $90.0 million of variable consideration related to payments for milestones considered probable of being achieved, and $183.0 million of variable consideration related to co-development billings.

Table of Contents

For revenue recognition purposes, the Company determined that the term of each collaboration agreement with Astellas begins on the effective date and ends upon the completion of all performance obligations contained in the agreement. The contract term is defined as the period in which parties to the contract have present and enforceable rights and obligations. The Company believes that the requirement to continue funding development for a substantive period of time and loss of product rights, along with non-refundable upfront payments already remitted by Astellas, create significant disincentive for Astellas to exercise its right to terminate the agreements.

For the Astellas agreements, the Company allocated the transaction price to the various performance obligations based on the relative SSP of each performance obligation, with the exception of co-development billings allocated entirely to co-development services performance obligations.

For the technology license under the Japan Agreement and Europe Agreement, SSP was determined primarily by using the discounted cash flow (“DCF”) method, which aggregates the present value of future cash flows to determine the valuation as of the effective date of each of the agreements. The DCF method involves the following key steps: 1) the determination of cash flow forecasts and 2) the selection of a range of comparative risk-adjusted discount rates to apply against the cash flow forecasts. The discount rates selected were based on expectations of the total rate of return, the rate at which capital would be attracted to the Company and the level of risk inherent within the Company. The discounts applied in the DCF analysis ranged from 17.5% to 20.0%. The Company’s cash flow forecasts were derived from probability-adjusted revenue and expense projections by territory. Such projections included consideration of taxes and cash flow adjustments. The probability adjustments were made after considering the likelihood of technical success at various stages of clinical trials and regulatory approval phases. SSP also considered certain future royalty payments associated with commercial performance of the Company’s compounds, transfer prices and expected gross margins.

The promised services that were analyzed, along with their general timing of satisfaction and recognition as revenue, are as follows:

(1) License to the Company’s technology existing at the effective date of the agreements. For both of the Astellas agreements, the license was delivered at the beginning of the agreement term. In both cases, the Company concluded at the time of the agreement that its collaboration partner, Astellas, would have the knowledge and capabilities to fully exploit the licenses without the Company’s further involvement. However, the Japan Agreement has contractual limitations that might affect Astellas’ ability to fully exploit the license and therefore, potentially, the conclusion as to whether the license is capable of being distinct. In the Japan Agreement, Astellas does not have the right to manufacture commercial supplies of the drug. In order to determine whether this characteristic of the agreement should lead to a conclusion that the license was not distinct in the context of the agreement, the Company considered the ability of Astellas to benefit from the license together with other resources readily available to Astellas. Finally, the Company considered the fact that at the time of delivery of the license, the development services were beyond the preclinical development phase and any remaining development work in either agreement would not be expected to result in any significant modification or customization to the licensed technology. As such, the development services are separately identifiable from the licensed technology, indicating that the license is a distinct performance obligation.

Manufacturing rights. In the case of the Japan Agreement, the Company retained manufacturing rights largely because of the way the parties chose for FibroGen to be compensated under the agreement. At the time the agreement was signed, the Company believed that it was more advantageous upon commercialization to have a transfer price revenue model in place as opposed to a traditional sales-based model. The manufacturing process does not require specialized

knowledge or expertise uniquely held by FibroGen, and notwithstanding contractual restrictions, Astellas could employ manufacturing services from readily available third parties in order to benefit from the license. Therefore, along with the foregoing paragraph, the Company determined that the license in Japan is a distinct performance obligation despite the retention of manufacturing rights by the Company.

In summary, the Company concludes that item (1) represents a performance obligation. The portion of the transaction price allocated to this performance obligation based on a relative SSP basis is recognized as revenue in its entirety at the point in time the license transfers to Astellas.

Table of Contents

(2) Co-development services (Europe Agreement). This promise relates to co-development services that were reasonably expected to be performed by the Company at the time the collaboration agreement was signed and is considered distinct. Co-development billings are allocated entirely to the co-development services performance obligation as amounts are related specifically to research and development efforts necessary to satisfy the performance obligation, and such an allocation is consistent with the allocation objective. Revenue is recognized over time based on progress toward complete satisfaction of the performance obligation. The Company uses an input method to measure progress toward the satisfaction of the performance obligation, which is based on costs of labor hours and out-of-pocket expenses incurred relative to total expected costs to be incurred. The measure of progress is updated each reporting period. Co-development services are expected to continue over the development period which is currently estimated to continue through the end of 2019. There was no provision for co-development services in the Japan Agreement.

(3) License to the Company's technology developed during the term of the agreement and development (referred to as "when and if available") and information sharing services. These promises are generally satisfied throughout the term of the agreements.

(4) Manufacturing of clinical supplies of products. This promise is satisfied as supplies for clinical product are delivered for use in the Company's clinical trial programs during the development period, or pre-commercialization period.

(5) Committee service. This promise is satisfied throughout the course of the agreements as meetings are attended.

Items (3)-(5) are bundled into a single performance obligation which is distinct given the fact that all are highly interrelated during the development period (pre-commercial phase of development) such that satisfying them independently is not practicable. Revenue is recognized over time based on progress toward complete satisfaction of the performance obligation. The Company uses an input method to measure progress toward the satisfaction of the performance obligation, which is based on costs of labor hours or full time equivalents and out-of-pocket expenses incurred relative to total expected costs to be incurred. The measure of progress is updated each reporting period.

(6) Manufacturing commercial supplies of products. This promised service is distinct as services are not interrelated with any of the other performance obligations. Payments received for commercial supplies of products represent sales-based payments related predominately to the license of intellectual property under both Astellas agreements. Revenue is recognized as supplies are shipped for commercial use during the commercialization period. To date, no such revenue has been recognized.

Accounting for the AstraZeneca Agreements

The Company evaluated whether the U.S./RoW Agreement and China Agreement should be accounted for as a single or separate arrangements and concluded that the agreements should be accounted for as a single arrangement with the presumption that two or more agreements executed with a single customer at or around the same time should be presumed to be a single arrangement. The key points the Company considered in reaching this conclusion are as follows:

1. While the two agreements were largely negotiated separately, those negotiations proceeded concurrently, and were intended to be completed contemporaneously, presuming AstraZeneca decided to proceed with licenses in all regions available.
2. Throughout negotiations for both agreements, the Company and the counterparties understood and considered the possibility that one arrangement may be executed without the execution of the other arrangement. However, the preference for the Company and the counterparties during the negotiations was to execute both arrangements concurrently.

3. The two agreements were executed as separate agreements because different development, regulatory and commercial approaches required certain terms of the agreements to be structured differently, rather than because the Company or the counterparties considered the agreements to be fundamentally separate negotiations.

Accordingly, as the agreements are being accounted for as a single arrangement, upfront and other non-contingent consideration received and to be received has been and will be pooled together and allocated to each of the performance obligations in both the U.S./RoW Agreement and China Agreement based on their relative SSPs.

For each of the AstraZeneca agreements, the Company has evaluated the promised services within the respective arrangements and has identified performance obligations representing those services and bundled services that are distinct.

Promised services that were not distinct have been combined with other promised services to form a distinct bundle of promised services, with revenue being recognized on the bundle of services rather than the individual promised services. There are no right-of-return provisions for the delivered items in the AstraZeneca agreements.

Table of Contents

As of September 30, 2018, the transaction price for the U.S./RoW Agreement and China Agreement included $402.2 million of non-contingent upfront payments, $30.0 million of variable consideration related to payments for milestones considered probable of being achieved, and $669.7 million of variable consideration related to co-development billings.

For the AstraZeneca agreements, the Company allocated the transaction price to the various performance obligations based on the relative SSP of each performance obligation, with the exception of co-development billings. Co-development billings under the U.S./RoW Agreement were allocated entirely to the U.S./RoW co-development services performance obligation, and co-development billings under the China Agreement were allocated entirely to the combined performance obligation under the China Agreement.

For revenue recognition purposes, the Company determined that the term of its collaboration agreements with AstraZeneca begin on the effective date and ends upon the completion of all performance obligations contained in the agreements. The contract term is defined as the period in which parties to the contract have present and enforceable rights and obligations. The Company believes that the requirement to continue funding development for a substantive period of time and the loss of product rights, along with non-refundable upfront payments already remitted by AstraZeneca, represent substantive termination penalties that create significant disincentive for AstraZeneca to exercise its right to terminate the agreement.

For the technology license under the AstraZeneca U.S./RoW Agreement, SSP was determined based on a two-step process. The first step involved determining an implied royalty rate that would result in the net present value of future cash flows to equal to zero (i.e. where the implied royalty rate on the transaction would equal the target return for the investment). This results in an upper bound estimation of the magnitude of royalties that a hypothetical acquirer would reasonably pay for the forecasted cash flow stream. The Company’s cash flow forecasts were derived from probability-adjusted revenue and expense projections. Such projections included consideration of taxes and cash flow adjustments. The probability adjustments were made after considering the likelihood of technical success at various stages of clinical trials and regulatory approval phases. The second step involved applying the implied royalty rate, which was determined to be 40%, against the probability-adjusted projected net revenues by territory and determining the value of the license as the net present value of future cash flows after adjusting for taxes. The discount rate utilized was 17.5%.

U.S./RoW Agreement:

The promised services that were analyzed, along with their general timing of satisfaction and recognition as revenue, are as follows:

(1) License to the Company’s technology existing at the effective date of the agreements. For the U.S./RoW Agreement, the license was delivered at the beginning of the agreement term. The Company concluded that AstraZeneca has the knowledge and capabilities to fully exploit the license under the U.S./RoW Agreement without the Company’s further involvement. Finally, the Company considered the fact that at the time of delivery of the license, the development services were beyond the preclinical development phase and any remaining development work would not be expected to result in any significant modification or customization to the licensed technology. As such, the development services are separately identifiable from the licensed technology, indicating that the license is a distinct performance obligation. Therefore, the Company has concluded that the license is distinct and represents a performance obligation. The portion of the transaction price allocated to this performance

obligation based on a relative SSP basis is recognized as revenue in its entirety at the point in time the license transfers to AstraZeneca.

(2) Co-development services. This promise relates to co-development services that were reasonably expected to be performed by the Company at the time the collaboration agreement was signed and is distinct. Co-development billings are allocated entirely to the co-development services performance obligation as amounts are related specifically to research and development efforts necessary to satisfy the performance obligation, and such an allocation is consistent with the allocation objective. Revenue is recognized over time based on progress toward complete satisfaction of the performance obligation. The Company uses an input method to measure progress toward the satisfaction of the performance obligation, which is based on costs of labor hours or full time equivalents and out-of-pocket expenses incurred relative to total expected costs to be incurred Co-development services are expected to continue over the development period which is estimated to continue through the end of 2020.

(3) Manufacturing of clinical supplies of products. This promise is satisfied as supplies for clinical product are delivered for use in the Company’s clinical trial programs during the development period, or pre-commercialization period.

(4) Information sharing and committee service. These promises are satisfied throughout the course of the agreement as services are provided.

Table of Contents

Items (3)-(4) are bundled into a single performance obligation which is distinct given the fact that all are highly interrelated during the development period (pre-commercial phase of development) such that delivering them independently is not practicable. Revenue is recognized over time based on progress toward complete satisfaction of the performance obligation. The Company uses an input method to measure progress toward the satisfaction of the performance obligation, which is based on costs of labor hours or full time equivalents and out-of-pocket expenses incurred relative to total expected costs to be incurred. The measure of progress is updated each reporting period.

(5) Manufacturing commercial supplies of products. This promise is distinct as services are not interrelated with any of the other performance obligations. Payments received for commercial supplies of products represent sales-based royalties related predominately to the license of intellectual property under the agreement. Revenue is recognized as supplies are shipped for commercial use during the commercialization period. To date, no such revenue has been recognized.

China Agreement:

The performance obligation that were analyzed, along with their general timing of satisfaction and recognition as revenue, are as follows:

- License to the Company's technology existing at the effective date of the agreement. The license was delivered at the beginning of the agreement term. However, the China Agreement with AstraZeneca has contractual limitations that might affect AstraZeneca's ability to fully exploit the license and therefore, potentially, the conclusion as to whether the license is distinct in the context of the agreement. In the China Agreement, AstraZeneca does not have the right to manufacture commercial supplies of the drug. In order to determine whether this characteristic of the arrangement should lead to a conclusion that the license was not distinct in the context of the agreement, the Company considered the ability of AstraZeneca to benefit from the license on its own or together with other resources readily available to AstraZeneca.

For the China Agreement, the Company retained manufacturing rights as an essential part of a strategy to pursue domestic regulatory pathway for product approval which requires the regulatory licensure of the manufacturing facility in order to commence commercial shipment. The prospects for the collaboration as a whole would have been substantially different had manufacturing rights been provided to AstraZeneca. Due to certain regulatory restrictions in China, manufacturing services of commercial drug product in China are not readily available to AstraZeneca or any other parties. Therefore, AstraZeneca cannot benefit from the license on its own or together with other readily available resources. Accordingly, all the promises identified, including co-development services, under the China Agreement have been bundled into a single performance obligation and amounts of the transaction price allocable to this performance obligation are deferred until control of the manufactured commercial drug product has begun to transfer to AstraZeneca. Upon commencement of the transfer of control to commercial drug product, revenue would be recognized in a pattern consistent with estimated deliveries of the commercial drug product.

Table of Contents

Summary of Revenue Recognized Under the Collaboration Agreements

The table below summarizes the accounting treatment for the various performance obligations pursuant to each of the Astellas and AstraZeneca agreements. License amounts identified below are included in the "License revenue" line item in the condensed consolidated statements of operations. All other elements identified below are included in the "Development and other revenue" line item in the condensed consolidated statements of operations.

Amounts recognized as revenue under the Japan Agreement were as follows (in thousands):

		Three Months Ended September 30,		Nine Months Ended September 30,	
Agreement	Performance Obligation	2018	2017 *	2018	2017 *
Japan	License revenue	$ —	$ —	$ 14,323	$ —
	Development revenue	$ 474	$ 517	$ 2,065	$ 1,130

* Recast to reflect the adoption of the new revenue standards. See Note 1.

The transaction price related to consideration received and accounts receivable has been allocated to each of the following performance obligations under the Japan Agreement, along with any associated deferred revenue as follows (in thousands):

Japan Agreement	Cumulative Revenue Through September 30, 2018	Deferred Revenue at September 30, 2018	Total Consideration Through September 30, 2018
License	$ 74,089	$ —	$ 74,089
Development revenue	13,572	386	13,958
Total license and development revenue	$ 87,661	$ 386	$ 88,047

The true-up relating to prior periods resulting from changes to estimated variable consideration was immaterial in the quarter ended September 30, 2018. The remainder of the transaction price related to the Japan Agreement includes $2.1 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period.

Amounts recognized as revenue under the Europe Agreement were as follows (in thousands):

Agreement	Performance Obligation	Three Months Ended September 30, 2018	2017 *	Nine Months Ended September 30, 2018	2017 *
Europe	License revenue	$—	$—	$—	$—
	Development revenue	$4,658	$4,805	$14,384	$13,976

*Recast to reflect the adoption of the new revenue standards. See Note 1.

The transaction price related to consideration received and accounts receivable has been allocated to each of the following performance obligations under the Europe Agreement, along with any associated deferred revenue as follows (in thousands):

Europe Agreement	Cumulative Revenue Through September 30, 2018	Deferred Revenue at September 30, 2018	Total Consideration Through September 30, 2018
License	$ 370,481	$ —	$ 370,481
Development revenue	198,717	4,350	203,067
Total license and development revenue	$ 569,198	$ 4,350	$ 573,548

Table of Contents

The revenue recognized under the Europe Agreement in the quarter ended September 30, 2018 included a decrease in revenue of $0.1 million as true-up relating to prior periods resulting from changes to estimated variable consideration in the current period. The remainder of the transaction price related to the Europe Agreement includes $19.4 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period.

Amounts recognized as revenue under the U.S./RoW Agreement were as follows (in thousands):

		Three Months Ended September 30,		Nine Months Ended September 30,	
Agreement	Performance Obligation	2018	2017 *	2018	2017 *
U.S. / RoW and China	License revenue	$—	$9,933	$—	$9,933
	Development revenue	23,895	25,295	74,096	75,218
	China performance obligation	$—	$—	$—	$—

*Recast to reflect the adoption of the new revenue standards. See Note 1.

The transaction price related to consideration received and accounts receivable has been allocated to each of the following performance obligations under the U.S./RoW Agreement and China Agreement, along with any associated deferred revenue as follows (in thousands):

U.S. / RoW and China Agreements	Cumulative Revenue Through September 30, 2018	Deferred Revenue at September 30, 2018	Total Consideration Through September 30, 2018
License	$ 286,216	$ —	$ 286,216
Co-development, information sharing & committee services	377,765	29,163	406,928
China performance obligation	—	119,744	119,744
Total license and development revenue	$ 663,981	$ 148,907	$ 812,888

The revenue recognized under the U.S./RoW Agreement in the quarter ended September 30, 2018 included a decrease in revenue of $0.1 million as true-up relating to prior periods resulting from changes to estimated variable consideration in the current period. The remainder of the transaction price related to the U.S./RoW Agreement and

China Agreement includes $223.7 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period, except for amounts allocated to the China performance obligation, which are expected to be recognized in a pattern consistent with estimated deliveries of the commercial drug product.

Other Revenues

Other revenues consist primarily of collagen material sold for research purposes. Other revenues were immaterial for all periods presented.

Deferred Revenue

Deferred revenue represents amounts billed to the Company’s collaboration partners for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The current portion of deferred revenue represents the amount to be recognized within one year from the balance sheet date based on the estimated performance period of the underlying performance obligations. The long term portion of deferred revenue represents amounts to be recognized after one year through the end of the non-contingent performance period of the underlying performance obligations. The long term portion of deferred revenue also includes amounts allocated to the China unit of accounting under the AstraZeneca arrangement as revenue recognition associated with this unit of accounting is tied to the commercial launch of the products within China, which is not expected to occur within the next year.

Table of Contents

3. Fair Value Measurements

The fair values of the Company's financial assets that are measured on a recurring basis are as follows (in thousands):

	September 30, 2018			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$—	$6,009	$ —	$6,009
Bond and mutual funds	10,446	—	—	10,446
Equity investments	223	—	—	223
Money market funds	495,131	—	—	495,131
Certificate of deposits	—	109,933	—	109,933
Total	$505,800	$115,942	$ —	$621,742

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$—	$53,943	$ —	$53,943
Bond and mutual funds	18,402	—	—	18,402
Equity investments	221	—	—	221
Money market funds	569,942	—	—	569,942
Total	$588,565	$53,943	$ —	$642,508

Our Level 2 investments are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar investments, issuer credit spreads, benchmark investments, prepayment/default projections based on historical data and other observable inputs.

The fair values of the Company's financial liabilities that are carried at historical cost are as follows (in thousands):

	September 30, 2018			
	Level 1	Level 2	Level 3	Total
Lease financing obligations	$—	$ —	$98,209	$98,209

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Lease financing obligations	$—	$ —	$98,476	$98,476

The fair values of the Company's financial liabilities were derived by using an income approach, which required Level 3 inputs such as discounted estimated future cash flows.

There were no transfers of assets or liabilities between levels for any of the periods presented.

4. Balance Sheet Components

Cash and Cash Equivalents

Cash and cash equivalents consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Cash	$ 71,591	$ 103,716
Money market funds	495,131	569,942
Total cash and cash equivalents	$ 566,722	$ 673,658

At September 30, 2018 and December 31, 2017, a total of $25.5 million and $32.3 million, respectively, of the Company's cash and cash equivalents were held outside of the U.S. in its foreign subsidiaries to be used primarily for its China operations.

Table of Contents

Investments

The Company's investments consist of available-for-sale debt investments and marketable equity investments. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's available-for-sale investments by major investments type are summarized in the tables below (in thousands):

	September 30, 2018			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$6,011	$ —	$ (2)	$6,009
Certificate of deposits	110,000	—	(67)	109,933
Bond and mutual funds	10,399	47	—	10,446
Equity investments	125	98	—	223
Total investments	$126,535	$ 145	$ (69)	$126,611

	December 31, 2017			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$53,985	$ 4	$ (46)	$53,943
Bond and mutual funds	17,249	1,153	—	18,402
Equity investments	126	95	—	221
Total investments	$71,360	$ 1,252	$ (46)	$72,566

At September 30, 2018, all of the available-for-sale investments had contractual maturities within one year. The Company periodically reviews its available-for-sale investments for other-than-temporary impairment. The Company considers factors such as the duration, severity and the reason for the decline in value, the potential recovery period and its intent to sell. For debt securities, the Company also considers whether (i) it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. During the three and nine months ended September 30, 2018 and 2017, the Company did not recognize any other-than-temporary impairment loss.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Preclinical and clinical trial accruals	$ 22,606	$ 32,321
Payroll and related accruals	16,626	18,810
Property taxes and other	1,900	4,201

Professional services	1,835	1,991
Other	9,631	6,458
Total accrued liabilities	$ 52,598	$ 63,781

5. Stock-Based Compensation

Stock-based compensation expense was allocated to research and development and general and administrative expense as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$8,465	$5,538	$22,729	$16,060
General and administrative	5,858	4,090	15,703	11,548
Total stock-based compensation expense	$14,323	$9,628	$38,432	$27,608

Table of Contents

The assumptions used to estimate the fair value of stock options granted and purchases under the Company's 2014 Employee Share Purchase Plan ("ESPP") using the Black-Scholes option valuation model were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock Options				
Expected term (in years)	5.3	5.3	5.4	5.7
Expected volatility	68.1%	69.5%	67.8%	71.5%
Risk-free interest rate	2.9%	1.9%	2.7%	2.2%
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$35.99	$26.47	$32.37	$16.63
ESPPs				
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Expected volatility	47.3 - 72.8%	52.8 - 76.0%	47.3 - 75.3%	52.8 - 77.2%
Risk-free interest rate	1.0 - 2.6%	0.6 - 1.3%	0.8 - 2.6%	0.5 - 1.3%
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$20.10	$9.67	$15.27	$9.15

6. Income Taxes

The provisions for income taxes for the three and nine months ended September 30, 2018 and 2017 were due to foreign taxes.

Based upon the weight of available evidence, which includes its historical operating performance, reported cumulative net losses since inception and expected continuing net loss, the Company has established and continues to maintain a full valuation allowance against its deferred tax assets as it does not currently believe that realization of those assets is more likely than not.

7. Related Party Transactions

Astellas is an equity investor in the Company and considered a related party. The Company recorded revenue related to collaboration agreements with Astellas of $5.1 million and $5.3 million during the three months ended September 30, 2018 and 2017, respectively, and $30.8 million and $15.1 million during the nine months ended September 30, 2018 and 2017, respectively. The related party revenue for the nine months ended September 30, 2018 included $14.9 million of a $15.0 million regulatory milestone under the Japan Agreement that was included in the transaction price during the second quarter of 2018. See Note 2 and below for details. The related party revenue was

recast for the three and nine months ended September 30, 2017 as a result of adoption of the new revenue standards. See Note 1 for details.

The Company recorded expense related to collaboration agreements with Astellas of $0.4 million and $0.2 million during the three months ended September 30, 2018 and 2017, respectively, and $1.1 million and $0.8 million during the nine months ended September 30, 2018 and 2017, respectively.

As of September 30, 2018 and December 31, 2017, accounts receivable from Astellas were $19.4 million and $4.0 million, respectively, and amounts due to Astellas were $0.4 million and $0.3 million, respectively. The accounts receivable from Astellas as of June 30, 2018 included $20.9 million related to a sale of roxadustat API to Astellas during the second quarter of 2018, which was received during the three months ended September 30, 2018. The sale was made pursuant to a material transfer agreement in anticipation of the execution of an amendment to the Japan Agreement allowing Astellas to manufacture roxadustat drug product, which is expected to be finalized in the fourth quarter of 2018. The sale enables Astellas to conduct the commercial scale manufacturing validation for roxadustat drug product in anticipation of commercial launch in Japan. The associated consideration was recorded as deferred revenue because Astellas' right to use the material was limited as of September 30, 2018.

Table of Contents

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and in our Securities and Exchange Commission ("SEC") filings, including our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on February 27, 2018.

FORWARD-LOOKING STATEMENTS

The following discussion and information contained elsewhere in this Quarterly Report on Form 10-Q contain "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"), Section 27A of the Securities Act of 1933, as amended ("Securities Act") and within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expression variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors," set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. New risks emerge from time to time, and it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q and are cautioned not to place undue reliance on such forward-looking statements.

BUSINESS OVERVIEW

We were incorporated in 1993 in Delaware and are a biopharmaceutical company discovering and developing first-in-class therapeutics. Roxadustat (FG-4592), our most advanced product candidate, is an oral small molecule inhibitor of hypoxia inducible factor ("HIF") prolyl hydroxylase ("HIF-PH") activity in Phase 3 clinical development for the treatment of anemia in chronic kidney disease ("CKD") and myelodysplastic syndromes ("MDS"). Pamrevlumab (FG-3019), a human monoclonal antibody that inhibits the activity of connective tissue growth factor ("CTGF") is in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, and Duchenne muscular dystrophy ("DMD"). We are taking a global approach to the development and future commercialization of our product candidates, and this includes development and commercialization in the People's Republic of China ("China"). We are capitalizing on our extensive experience in fibrosis and HIF biology and clinical development to advance a pipeline of innovative medicines for the treatment of anemia, fibrotic disease cancer, corneal blindness and other serious unmet medical needs.

22

Table of Contents

Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017 *	2018	2017 *
	(in thousands, except for per share data)			
Result of Operations				
Revenue	$29,027	$40,550	$104,903	$ 100,260
Operating expenses	$71,799	$63,289	$211,516	$ 181,957
Net loss	$(42,556)	$(24,459)	$(107,373)	$ (86,981)
Net loss per share - basic and diluted	$(0.50)	$(0.32)	$(1.28)	$ (1.24)

	September 30, 2018	December 31, 2017
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$566,722	$ 673,658
Short-term and long-term investments	$126,611	$ 72,566
Accounts receivable	$23,187	$ 8,452

* Recast to reflect the adoption of the new revenue standards. See Note 1 to the condensed consolidated financial statements.

Our revenue for the three months ended September 30, 2018 decreased compared to the same period a year ago primarily due to the revenue related to a $15.0 million regulatory milestone recognized in prior year period. In October 2017, then the China Food and Drug Administration (now known as the National Medicine Products Administration (“NMPA”)) accepted our New Drug Application (“NDA”) for registration of roxadustat for anemia in DD CKD and NDD-CKD patients. This NDA submission triggered a $15.0 million milestone payment to FibroGen by AstraZeneca, which became probable of being achieved and therefore partially recognized as revenue under the new revenue standards during the third quarter of 2017.

Our revenue for the nine months ended September 30, 2018 increased compared to the same period a year ago primarily related to the recognition of $14.9 million of a $15.0 million regulatory milestone associated with NDA submission in Japan under the collaboration agreement with Astellas for roxadustat for the treatment of anemia in Japan (“Japan Agreement”) that was included in the transaction price during the second quarter of 2018 when this milestone became probable of being achieved, as compared to the above mentioned partial recognition of a $15.0 million regulatory milestone in the prior year period.

Operating expenses for the three and nine months ended September 30, 2018 increased compared to the same periods a year ago primarily due to higher stock-based compensation due to the cumulative impact of stock option grant activities, higher drug development expenses associated with drug substance manufacturing activities related to pamrevlumab, and higher employee-related expenses resulting from higher average compensation level and higher

headcount, partially offset by lower clinical trial activities related to roxadustat and pamrevlumab. Operating expenses for nine months ended September 30, 2018 were also impacted by higher facility related expenses relative to the prior period in which our property taxes were reduced as a result of a final settlement we obtained related to historical property tax payments.

During the three months ended September 30, 2018, we had a net loss of $42.6 million, or net loss per basic and diluted share of $0.50, as compared to a net loss of $24.5 million for the same period a year ago, due to an decrease in revenue and an increase in operating expenses. During the nine months ended September 30, 2018, we had a net loss of $107.4 million, or net loss per basic and diluted share of $1.28, as compared to a net loss of $87.0 million for the same period a year ago, due to an increase in operating expenses, partially offset by an increase in revenue.

Cash and cash equivalents, investments and accounts receivable totaled $716.5 million at September 30, 2018, a decrease of $38.2 million from December 31, 2017, primarily due to the cash used in operations.

Table of Contents

Programs

Roxadustat for the Treatment of Anemia in Chronic Kidney Disease

Roxadustat, the most advanced HIF-PH inhibitor in clinical development, acts by stimulating the body's natural pathway of erythropoiesis, or red blood cell production. We, along with our collaboration partners, Astellas Pharma Inc. ("Astellas") and AstraZeneca AB ("AstraZeneca"), are nearing completion of a global Phase 3 program to support regulatory approvals of roxadustat in the United States ("U.S."), Europe, Japan, and China for anemia in both dialysis-dependent CKD ("DD-CKD") patients and non-dialysis-dependent CKD ("NDD-CKD") patients. These Phase 3 programs are studying multiple patient populations, including incident dialysis patients and stable dialysis patients in which roxadustat is compared to epoetin alfa, as well as non-dialysis patients in which roxadustat is compared to placebo.

For our U.S. and European CKD anemia programs, we have completed treatment of all Phase 3 patients (other than for a European reimbursement study), and expect to report topline individual study results in the fourth quarter of 2018, subject to adequate progress in our MACE adjudication procedures, and report pooled safety data prior to the submission of the NDA for roxadustat in the first half of 2019. In the third quarter of 2018, Astellas announced positive topline results for its ALPS study, a global Phase 3 trial of roxadustat in CKD anemia patients not on dialysis. Astellas has also completed its Phase 3 study in DD-CKD comparing roxadustat to darbepoetin or epoetin alfa.

In China, the NMPA continues to review our NDA submission for the registration of roxadustat to treat anemia for DD-CKD patients and NDD-CKD patients. While there is no fixed regulatory timeline for an NDA approval decision, we currently anticipate a market approval decision for our NDA in China by year-end for anemia in DD-CKD patients. We expect a decision regarding whether anemia in NDD-CKD will be added to the label in the first half of 2019 after the clinical site inspections have been completed for NDD-CKD.

In Japan, Astellas has reported positive results from four of its six Phase 3 anemia studies and has filed an NDA for roxadustat in anemia associated with DD-CKD. This NDA triggered a $15 million milestone payment from Astellas. Astellas has also completed one of its two Phase 3 NDD-CKD studies in Japan.

Astellas presented results from two of its four DD-CKD studies at ASN Kidney Week 2018. In the 303 patient double-blind Phase 3 hemodialysis study, treatment with oral roxadustat was as effective as darbepoetin alfa in maintaining hemoglobin levels within the target range of 10.0–12.0 g/dL in hemodialysis patients previously treated with erythropoiesis-stimulating agents ("ESAs"). The average hemoglobin levels at Weeks 18–24 was 11.00 (± 0.60) g/dL and 10.95 (± 0.63) g/dL in the roxadustat and darbepoetin alfa groups, respectively; the difference between the groups was 0.05 (95% CI: -0.10, ± 0.20) g/dL. The maintenance rate of target hemoglobin levels (10.0–12.0 g/dL) during Weeks 18–24 was 79.3% and 83.4% in the roxadustat and darbepoetin alfa groups, respectively; the difference between the 2 groups was -4.1% (95% CI: -13.6, ± 5.3). Among patients with at least one hemoglobin value during Weeks 18–24, the maintenance rate was 95.2% and 91.3% in the roxadustat and darbepoetin alfa groups, respectively; the difference between the 2 groups was 3.9% (95% CI: -2.9, ± 10.7). Roxadustat was well tolerated with a safety profile similar to that of darbepoetin alfa and consistent with previous reports. The proportions of patients who reported TEAEs were similar in the roxadustat and darbepoetin alfa groups. There was no increased risk of ophthalmological abnormalities, including retinal hemorrhages, observed in patients treated with roxadustat compared to darbepoetin alfa.

In Astellas's 56 patient open-label Phase 3 peritoneal dialysis ("PD") study in Japan, roxadustat was effective in achieving and maintaining hemoglobin levels within the target range of 10.0-12.0 g/dL at Weeks 18-24. This open-label trial treated two groups of patients with roxadustat: patients not previously treated with ESAs ("ESA-Naïve") and patients previously treated with ESAs ("ESA-Conversion"). The hemoglobin maintenance rate was 92.3% (95% CI: 64.0-99.8) for ESA-Naïve patients and 74.4% (95% CI: 58.8-86.5) for ESA-Conversion patients. Maintenance rates of patients with at least one hemoglobin value at Weeks 18-24 were 92.3% (95% CI: 64.0-99.8; ESA-Naïve) and 86.5% (95% CI: 71.2-95.5; ESA-Conversion). The mean of average hemoglobin levels at Weeks 18-24 was 11.05 g/dL (± 0.62) for ESA-Naïve patients and 10.93 g/dL (± 0.61) for ESA-Conversion patients. The mean change in average hemoglobin at Weeks 18-24 from baseline was 1.69 g/dL (± 1.05) for ESA-Naïve patients; and 0.14 g/dL (± 0.76) for ESA-Conversion patients. All iron parameters remained clinically stable despite robust erythropoiesis and without the need for IV iron supplementation, and hepcidin decreased in a manner consistent with previous Phase 2 and Phase 3 studies of roxadustat. Roxadustat was well tolerated with no safety concerns.

Table of Contents

Pamrevlumab (FG-3019) – Monoclonal Antibody Against Connective Tissue Growth Factor (CTGF)

Pamrevlumab is our human monoclonal antibody that inhibits the activity of CTGF, a central mediator and critical common element in the progression of fibrotic and fibro-proliferative diseases. We are currently conducting Phase 2 trials in pancreatic cancer and DMD and we have completed our Phase 2 trial in IPF. In the U.S., pamrevlumab has received orphan drug designation for IPF and Fast Track designation for the treatment of both IPF patients and patients with locally advanced unresectable pancreatic cancer from the U.S. Food and Drug Administration ("FDA").

We plan to begin enrolling a double-blind placebo controlled Phase 3 trial of pamrevlumab as a neoadjuvant therapy for pancreatic cancer in the first quarter of 2019. We intend to enroll approximately 260 patients, randomized 1:1 to receive either pamrevlumab, in combination with gemcitabine and nab-paclitaxel, or chemotherapy with placebo.

We also plan to begin enrolling our double-blind, placebo-controlled Phase 3 trial of pamrevlumab in approximately 500 IPF patients in the first quarter of 2019. This study is powered to meet the FDA requirement of a highly statistically-significant result in the primary efficacy endpoint of change from baseline in forced vital capacity (FVC).

In DMD, all 21 non-ambulatory patients from our fully enrolled Phase 2 trial will have completed one year of study in March 2019.

Collaboration Partnerships for Roxadustat

Our current and future research, development, manufacturing and commercialization efforts with respect to roxadustat and our other product candidates currently in development depend on funds from our collaboration agreements with Astellas and AstraZeneca as described below.

Astellas

In June 2005, we entered into the Japan Agreement with Astellas for roxadustat for the treatment of anemia in Japan. In April 2006, we entered into the Europe Agreement with Astellas for roxadustat for the treatment of anemia in Europe, the Commonwealth of Independent States, the Middle East, and South Africa. Under these agreements, we provide Astellas the right to develop and commercialize roxadustat for anemia indications in these territories.

We share responsibility with Astellas for clinical development activities required for the United States ("U.S.") and the European Union ("EU") regulatory approval of roxadustat, and share equally those development costs under the agreed development plan for such activities. Astellas will be responsible for clinical development activities and all associated costs required for regulatory approval in all other countries in the Astellas territories. Astellas will own and have responsibility for regulatory filings in its territories. We are responsible, either directly or through our contract manufacturers, for the manufacture and supply of all quantities of roxadustat to be used in development and commercialization under the agreements.

The Astellas agreements will continue in effect until terminated. Either party may terminate the agreements for certain material breaches by the other party. In addition, Astellas will have the right to terminate the agreements for certain specified technical product failures, upon generic sales reaching a particular threshold, upon certain regulatory actions, or upon our entering into a settlement admitting the invalidity or unenforceability of our licensed patents. Astellas may also terminate the agreements for convenience upon advance written notice to us. In the event of any termination

of the agreements, Astellas will transfer and assign to us the regulatory filings for roxadustat and will assign or license to us the relevant trademarks used with the products in the Astellas territories. Under certain terminations, Astellas is also obligated to pay us a termination fee.

Consideration under these agreements includes a total of $360.1 million in upfront and non-contingent payments, and milestone payments totaling $557.5 million, of which $542.5 million are development and regulatory milestones and $15.0 million are commercial-based milestones. Total consideration, excluding development cost reimbursement and product sales-related payments, could reach $917.6 million. The aggregate amount of such consideration received through September 30, 2018 totals $472.6 million. During the second quarter of 2018, Astellas reported positive results from the final Phase 3 CKD-dialysis trial of roxadustat in Japan, indicating that Astellas will be ready to make an NDA submission for the treatment of anemia with roxadustat in CKD-dialysis patients in 2018. We evaluated the regulatory milestone payment associated with NDA submission in Japan based on variable consideration requirements under the current revenue standards and concluded that this milestone became probable of being achieved in the second quarter of 2018. Accordingly, the consideration of $15.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Japan Agreement in the second quarter of 2018. Additionally, under these agreements, Astellas pays 100% of the commercialization costs in its territories. Astellas will pay us a transfer price, based on net sales, in the low 20% range for our manufacture and delivery of roxadustat.

Table of Contents

FibroGen and Astellas are currently negotiating an amendment to the Japan Agreement that will allow Astellas to manufacture roxadustat drug product for commercialization in Japan, and for which FibroGen would continue to manufacture and deliver to Astellas roxadustat API. The commercial terms of the Japan Agreement would remain substantially the same. In the second quarter of 2018, FibroGen delivered roxadustat API to Astellas under a material transfer agreement for Astellas to conduct commercial scale manufacturing validation for roxadustat drug product in Japan.

In addition, as of September 30, 2018, Astellas had separate investments of $80.5 million in the equity of FibroGen, Inc.

AstraZeneca

In July 2013, we entered into the U.S./RoW Agreement, a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in the U.S. and all territories not previously licensed to Astellas, except China. In July 2013, through our China subsidiary and related affiliates, we entered into the China Agreement, a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in China. Under these agreements we provide AstraZeneca the right to develop and commercialize roxadustat for anemia in these territories. We share responsibility with AstraZeneca for clinical development activities required for U.S. regulatory approval of roxadustat.

Now that we have reached the $116.5 million cap on our initial funding obligations (during which time we shared 50% of the joint initial development costs), all development and commercialization costs for roxadustat for the treatment of anemia in CKD in the U.S., Europe, Japan and all other markets outside of China have been paid by Astellas and AstraZeneca since reaching the cap.

In China, FibroGen (China) Medical Technology Development Co., Ltd. (“FibroGen Beijing”) will conduct the development work for CKD anemia, will hold all of the regulatory licenses issued by China regulatory authorities, and will be primarily responsible for regulatory, clinical and manufacturing. China development costs are shared 50/50. AstraZeneca is also responsible for 100% of development expenses in all other licensed territories outside of China. We are responsible, through our contract manufacturers, for the manufacture and supply of all quantities of roxadustat to be used in development and commercialization under the AstraZeneca agreements.

Under the AstraZeneca agreements, we will receive upfront and subsequent non-contingent payments totaling $402.2 million. Potential milestone payments under the agreements total $1.2 billion, of which $571.0 million are development and regulatory milestones and $652.5 million are commercial-based milestones. Total consideration under the agreements, excluding development cost reimbursement, transfer price payments, royalties and profit share, could reach $1.6 billion. The aggregate amount of such consideration received through September 30, 2018 totals $432.2 million.

Payments under these agreements include over $500.0 million in upfront, non-contingent and other payments received or expected to be received prior to the first U.S. approval, excluding development expense reimbursement.

Under the U.S./RoW Agreement, AstraZeneca will pay for all commercialization costs in the U.S. and RoW and AstraZeneca will be responsible for the U.S. commercialization of roxadustat, with FibroGen undertaking specified promotional activities in the end-stage renal disease segment in the U.S. In addition, we will receive a transfer price for delivery of commercial product based on a percentage of net sales in the low- to mid-single digit range and

AstraZeneca will pay us a tiered royalty on net sales of roxadustat in the low 20% range.

Under the China Agreement, which is conducted through FibroGen China Anemia Holdings, Ltd. ("FibroGen China"), the commercial collaboration is structured as a 50/50 profit share. AstraZeneca will conduct commercialization activities in China as well as serve as the master distributor for roxadustat and fund roxadustat launch costs in China until FibroGen Beijing has achieved profitability. At that time, AstraZeneca will recoup 50% of their historical launch costs out of initial roxadustat profits in China.

In September 2016, AstraZeneca approved the protocol related to the development of roxadustat for the treatment of anemia in patients with MDS, for which we have received approval from the NMPA for our clinical trial application in China for a Phase 2/3 trial and acceptance of our IND from the FDA for a Phase 3 trial in the U.S. As a result, for revenue recognition purposes, during the third quarter of 2016, we extended the estimated joint development service period for the AstraZeneca agreements from the end of 2018 to the end of 2020, to allow for development of MDS.

AstraZeneca may terminate the U.S./RoW Agreement upon specified events, including our bankruptcy or insolvency, our uncured material breach, technical product failure, or upon 180 days prior written notice at will. If AstraZeneca terminates the U.S./RoW Agreement at will, in addition to any unpaid non-contingent payments, it will be responsible for paying for a substantial portion of the post-termination development costs under the agreed development plan until regulatory approval.

Table of Contents

AstraZeneca may terminate the China Agreement upon specified events, including our bankruptcy or insolvency, our uncured material breach, technical product failure, or upon advance prior written notice at will. If AstraZeneca terminates our China Agreement at will, it will be responsible for paying for transition costs as well as make a specified payment to FibroGen China.

In the event of any termination of the agreements, but subject to modification upon termination for technical product failure, AstraZeneca will transfer and assign to us any regulatory filings and approvals for roxadustat in the affected territories that they may hold under our agreements, grant us licenses and conduct certain transition activities.

Additional Information Related to Collaboration Agreements

Total cash consideration received through September 30, 2018 and potential cash consideration, other than development cost reimbursement, transfer price payments, royalties and profit share, pursuant to our existing collaboration agreements are as follows:

	Cash Received Through September 30, 2018	Additional Potential Cash Payments	Total Potential Cash Payments
	(in thousands)		
Astellas--related-party:			
Japan Agreement	$62,593	$ 110,000	$ 172,593
Europe Agreement	410,000		