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.

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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

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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

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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

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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

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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.

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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.

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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.

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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