FIBROGEN INC
Form 10-Q
August 13, 2015
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015

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)**

Registrant s telephone number, including area code: (415) 978-1200

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The number of shares of common stock outstanding as of July 31, 2015 was 60,564,900.

Table of Contents

FIBROGEN, INC.

TABLE OF CONTENTS

Table of Contents

FIBROGEN, INC.

PART I FINANCIAL INFORMATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

(Unaudited)

	June 30, 2015 (Unaudited)	December 31, 2014 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 236,536	$ 165,455
Short-term investments	12,129	14,364
Accounts receivable ($10,331 and $5,033 from a related party)	12,183	13,453
Prepaid expenses and other current assets	2,731	4,966
Total current assets	263,579	198,238
Restricted cash	7,254	7,254
Long-term investments	138,310	144,269
Property and equipment, net	130,451	132,171
Other assets	1,801	1,596
Total assets	$ 541,395	$ 483,528
Liabilities, stockholders equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 3,915	$ 4,551
Accrued liabilities ($5,817 and $4,594 to related parties)	46,240	48,985
Deferred revenue	13,347	9,218
Total current liabilities	63,502	62,754
Long-term portion of lease financing obligations	96,929	96,818
Product development obligations	15,186	16,465
Deferred rent	4,917	5,131
Deferred revenue, net of current	87,273	60,988
Other long-term liabilities	702	696
Total liabilities	268,509	242,852
Commitments and Contingencies		
Stockholders equity:		

Preferred stock, $0.01 par value; 125,000 shares authorized at June 30, 2015 and December 31, 2014; no shares issued and outstanding at June 30, 2015 and December 31, 2014		
Common stock, $0.01 par value; 225,000 shares authorized at June 30, 2015 and December 31, 2014; 60,370 and 59,046 shares issued and outstanding at June 30, 2015 and December 31, 2014	604	590
Additional paid-in capital	565,229	546,247
Accumulated other comprehensive loss	(623)	(3,149)
Accumulated deficit	(311,595)	(322,283)
Total stockholders equity	253,615	221,405
Non-controlling interests	19,271	19,271
Total equity	272,886	240,676
Total liabilities and equity	$ 541,395	$ 483,528

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)

	Quarter Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue:				
License and milestone revenue (includes $4,860, $3,718, $9,552 and $6,460 from a related party)	$ 106,879	$ 82,463	$ 118,385	$ 97,148
Collaboration services and other revenue (includes $719, $866, $1,353 and $1,617 from a related party)	13,671	7,495	18,463	10,686
Total revenue	120,550	89,958	136,848	107,834
Operating expenses:				
Research and development	51,555	33,269	102,094	58,919
General and administrative	9,680	7,516	20,162	13,948
Total operating expenses	61,235	40,785	122,256	72,867
Income from operations	59,315	49,173	14,592	34,967
Interest expense	(2,762)	(2,725)	(5,520)	(5,451)
Interest and other income, net	707	383	1,550	1,075
Income before income taxes	57,260	46,831	10,622	30,591
Provision (benefit) from income taxes	205		(66)	
Net income	$ 57,055	$ 46,831	$ 10,688	$ 30,591
Net income per share:				
Basic	$ 0.95	$ 1.36	$ 0.18	$ 0.74
Diluted	$ 0.83	$ 0.58	$ 0.15	$ 0.46
Weighted average number of common shares used to calculate net income per share:				
Basic	59,798	13,347	59,499	13,279
Diluted	68,752	37,106	69,354	21,639

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

Table of Contents

FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

(Unaudited)

	Quarter Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net income	$ 57,055	$ 46,831	$ 10,688	$ 30,591
Other comprehensive income (loss):				
Foreign currency translation adjustments	508	185	2,213	195
Available-for-sale investments:				
Unrealized gain (loss) on investments, net of tax effect	(368)	(280)	343	(820)
Reclassification from accumulated other comprehensive loss	(25)		(30)	
Net change in unrealized gain (loss) on available-for-sale investments	(393)	(280)	313	(820)
Other comprehensive income (loss), net of taxes	115	(95)	2,526	(625)
Comprehensive income	$ 57,170	$ 46,736	$ 13,214	$ 29,966

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)

	Six Months Ended June 30,	
	2015	**2014**
Operating activities		
Net income	$ 10,688	$ 30,591
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	2,796	1,843
Amortization of premium on investments	1,538	307
Loss on disposal of property and equipment	100	
Stock-based compensation	13,388	1,465
Tax benefit on unrealized gain on available-for-sale securities	(66)	
Changes in operating assets and liabilities:		
Accounts receivable	1,270	1,329
Prepaid expenses and other current assets	2,235	964
Other assets	(205)	(694)
Accounts payable	(636)	190
Accrued liabilities	(3,140)	4,828
Deferred revenue	30,414	36,287
Lease financing liability	312	306
Other long-term liabilities	163	(178)
Net cash provided by operating activities	58,857	77,238
Investing activities		
Purchases of property and equipment	(989)	(3,952)
Proceeds from maturities of available-for-sale securities	7,035	33,546
Net cash provided by investing activities	6,046	29,594
Financing activities		
Repayments of lease liability	(201)	(201)
Proceeds from issuance of common stock, net	5,608	831
Payments of equity issuance costs		(1,167)
Net cash provided by (used in) financing activities	5,407	(537)
Effect of exchange rate change on cash and cash equivalents	771	35
Net increase in cash and cash equivalents	71,081	106,330

Cash and cash equivalents at beginning of period	165,455	76,332
Cash and cash equivalents at end of period	$ 236,536	$ 182,662

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. Description of Operations and Summary of Significant Accounting Policies

Description of Operations

FibroGen, Inc. (FibroGen, the Company, or we and other similar pronouns) was incorporated in 1993 in Delaware and is a research-based biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs. Our focus in the areas of fibrosis and hypoxia-inducible factor (HIF) biology has generated multiple programs targeting various therapeutic areas. Our 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). FG-3019 is our monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), pancreatic cancer and liver fibrosis. We have taken a global approach with respect to the development and future commercialization of our product candidates, and this includes development and commercialization in the People s Republic of China (China).

On November 10, 2014, we effected a 1-for-2.5 reverse split of our common stock. Upon the effectiveness of the reverse stock split, (i) every 2.5 shares of outstanding common stock were combined into one share of common stock, (ii) the number of shares of common stock for which each outstanding option or warrant to purchase common stock is exercisable was proportionally decreased on a 1-for-2.5 basis, (iii) the exercise price of each outstanding option or warrant to purchase common stock was proportionately increased on a 1-for- 2.5 basis, (iv) the exchange ratio for each share of outstanding FibroGen Europe Oy (FibroGen Europe) share of stock which is exchangeable into our common stock was proportionately reduced on a 1-for-2.5 basis, and (v) the conversion ratio for each share of outstanding preferred stock which is convertible into our common stock was proportionately reduced on a 1-for-2.5 basis. All of the outstanding common stock share numbers (including shares of common stock which our outstanding preferred stock shares were convertible into), common stock warrants, share prices, exercise prices and per share amounts have been adjusted in these condensed consolidated financial statements, on a retroactive basis, to reflect this 1-for-2.5 reverse stock split for all periods presented. The par value per share and the authorized number of shares of common stock and preferred stock were not adjusted as a result of the reverse stock split.

On November 19, 2014, we closed the initial public offering (IPO) of our common stock. In our IPO, we sold 9,315,000 shares of our common stock at a public offering price of $18.00 per share. Net proceeds from our IPO and concurrent private placement were $171.8 million, after deducting underwriting discounts and commissions of $11.7 million and offering expenses of $4.1 million. AstraZeneca AB (AstraZeneca), one of our collaboration partners, agreed to purchase from us concurrently with the closing of our IPO in a private placement shares of our common stock with an aggregate purchase price of $20.0 million at a price per share equal to the IPO price. Upon the closing of our IPO, all outstanding shares of our convertible preferred stock automatically converted into 33,919,954 shares of common stock and 958,996 shares of FibroGen Europe convertible preferred stock were converted into shares of our common stock. Our proceeds from the sale of the common stock sold in the concurrent private placement were $20.0 million.

Basis of Presentation

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

The condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial reporting and the rules and regulations of the U.S. Securities and Exchange Commission (SEC) and, therefore, do not include all information and footnote disclosures normally included in the annual consolidated financial statements. The December 31, 2014 condensed consolidated balance sheet data contained within this Form 10-Q was derived from audited consolidated financial statements included in our Form 10-K for the year ended December 31, 2014, but does not include all disclosures required by accounting principles generally accepted in the United States.

The preparation of the condensed 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. Actual results could differ from those estimates. In our opinion, the accompanying unaudited condensed consolidated financial statements include all normal recurring adjustments necessary for a fair presentation of our financial position, results of operations and cash flows for the interim periods presented.

Table of Contents

Fair Value of Financial Instruments

We define fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Our valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect our market assumptions. We classify these inputs into the following hierarchy:

Level 1 Quoted prices for identical instruments in active markets.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 Unobservable inputs and little, if any, market activity for the assets.

The assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and considers factors specific to the asset or liability. In addition, the categories presented do not suggest how prices may be affected by the size of the purchases or sales, particularly with the largest highly liquid financial issuers who are in markets continuously with non-equity instruments, or how any such financial assets may be impacted by other factors such as U.S. government guarantees. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

Carrying amounts of certain of our financial instruments including cash equivalents, investments, receivables, accounts payable and accrued liabilities approximate fair value due to their short maturities.

Revenue Recognition

Substantially all of our revenues to date have been generated from our collaboration agreements.

Our collaboration agreements include multiple deliverables, and we, therefore, follow the guidance in Accounting Standards Codification (ASC) Topic 605-25, Revenue Recognition Multiple-Element Arrangements (ASC 605-25). ASC 605-25:

- provides guidance on how revenue arrangements with multiple deliverables should be separated and how the arrangement consideration should be allocated among the separate units of accounting;

- requires an entity to determine the selling price of a separate deliverable using a hierarchy of (i) vendor-specific objective evidence (VSOE), (ii) third-party evidence (TPE), or (iii) best estimate of selling price (BESP); and

requires the allocation of the arrangement consideration, at the inception of the arrangement, to the separate units of accounting based on relative selling price.

We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. Significant judgment may be required in determining whether a deliverable provides stand-alone value, determining the amount of arrangement consideration that is fixed or determinable, and estimating the stand-alone selling price of each unit of accounting.

To date, we have determined that the selling price for the deliverables within our collaboration agreements should be determined using BESP, as neither VSOE nor TPE is available. The process for determining BESP involves significant judgment on our part 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.

Table of Contents

For each unit of accounting identified within an arrangement, we determine the period over which the deliverables are provided and the performance obligation is satisfied. Service revenue is recognized using a proportional performance method. Direct labor hours or full time equivalents are typically used as the measurement of performance. Revenue may be recognized using a straight line method when performance is expected to occur roughly consistently over a period of time.

Payments or reimbursements resulting from our research and development efforts for those arrangements where such efforts are considered as deliverables are recognized as the services are performed and are presented on a gross basis. To the extent payments are required to be made to the collaboration partners pursuant to research and development efforts, those costs are charged to research and development using the guidance pursuant to ASC Topic 605-250, Customer Payments and Incentives , which states that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling prices unless the vendor receives an identifiable benefit in exchange for the consideration that is sufficiently separable from the recipient s purchase of the vendor s products, and the vendor can reasonably estimate the fair value of the benefit.

Each of our collaboration agreements includes milestones for which we follow ASC Topic 605-28, Revenue Recognition Milestone Method (ASC 605-28). ASC 605-28 establishes the milestone method as an acceptable method of revenue recognition for certain contingent event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can only be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us. Determining whether a milestone is substantive is a matter of judgment and that assessment must be made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is (i) commensurate with either our performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relates solely to past performance and (iii) is reasonable relative to all deliverables and payment terms in the arrangement. Payments for achieving milestones which are not considered substantive are treated as additional arrangement consideration and are allocated following the relative selling price method previously described.

Net Income per Share

Immediately prior to the IPO, the Company had authorized 125,000,000 shares of Preferred Stock with a par value of $0.01 per share. The Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series D Preferred Stock, Royalty Acquisition Preferred Stock and Series G-1 Preferred Stock are collectively referred to as the Junior Preferred Stock . The Series E Redeemable Convertible Preferred Stock and Series F Redeemable Convertible Preferred Stock are collectively referred to as the Senior Preferred Stock . As of December 31, 2014, there was no outstanding convertible preferred stock as all issued and outstanding preferred stock were converted to common stock at the closing of the Company s IPO in November 2014.

Prior to the IPO, we applied the two-class method to calculate basic and diluted net income per share of common stock. The two-class method is an earnings allocation method under which earnings per share is calculated for common stock considering a participating security s rights to undistributed earnings as if all such earnings had been distributed during the period. The Junior Preferred Stock were participating securities due to their dividend rights and the Senior Preferred Stock had stated dividend rates. During periods of net income, the calculation of basic net income per share was reclassified to exclude the income attributable to all participating securities from the numerator and exclude the dilutive impact of those shares from the denominator. During periods of net loss, all participating

securities were not included in the calculation of net loss per share because the preferred stockholders had no contractual obligation to participate in losses.

Table of Contents

The following is a reconciliation of the basic and diluted net income per share calculation for the periods presented (in thousands, except per share data):

	Quarter Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net income	$ 57,055	$ 46,831	$ 10,688	$ 30,591
Less: Undistributed earnings allocated to Junior Preferred stockholders		(25,234)		(13,790)
Net income attributable to Senior Preferred and common stockholders	$ 57,055	$ 21,597	$ 10,688	$ 16,801
Less: Undistributed earnings allocated to Senior Preferred stockholders	$	$ (3,474)	$	$ (6,948)
Net income attributable to common stockholders	$ 57,055	$ 18,123	$ 10,688	$ 9,853
Weighted average shares used to compute net income per share:				
Basic	59,798	13,347	59,499	13,279
Dilutive effect of Senior Preferred stock		15,336		
Dilutive effect of potential common shares	8,954	8,423	9,855	8,360
Diluted	68,752	37,106	69,354	21,639
Net income per share:				
Basic	$ 0.95	$ 1.36	$ 0.18	$ 0.74
Diluted	$ 0.83	$ 0.58	$ 0.15	$ 0.46

Diluted net income per share does not include the effect of 3.8 million and 18.6 million securities for the quarters ended June 30, 2015 and 2014 and 1.8 million and 33.9 million securities for the six months ended June 30, 2015 and 2014.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes the revenue recognition requirements in 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. The effective date for ASU 2014-09was initially for fiscal years beginning after December 15, 2016. In July 2015, the FASB approved a one year deferral of this standard with a new effective date for fiscal years beginning after December 15, 2017. The new guidelines can be implemented using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption. We are currently evaluating the impact of this guidance on our consolidated financial statements.

2. Collaboration Agreements

Astellas Agreements

Japan Agreement

In June 2005, we 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 (such amounts were fully received as of February 2009). The Japan Agreement also provides for additional development and regulatory approval milestone payments up to $117.5 million, a commercial sales related milestone of $15.0 million and additional consideration based on net sales (as defined) in the low 20% range after commercial launch. A clinical milestone payment of $12.5 million was received in 2013. We evaluated the criteria under ASC 605-28 (as disclosed in Note 1) and concluded that the aforementioned milestone was substantive.

Table of Contents

Europe Agreement

In April 2006, we 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). The Europe Agreement also provides for additional development and regulatory approval milestone payments up to $425.0 million. Clinical milestone payments of $40.0 million and $50.0 million were received in 2010 and 2012. We evaluated the criteria under ASC 605-28 (as disclosed in Note 1) and concluded that each of those milestones was substantive. 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.

AstraZeneca Agreements

U.S./Rest of World Agreement

Effective July 30, 2013, we entered into a collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in the United States 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 has agreed to pay upfront, non-contingent and time-based payments totaling $374.0 million, which we expect to receive in various amounts through June 2016, of which $312.0 million was received as of June 30, 2015. In addition, the U.S./RoW Agreement also provides for development and regulatory approval based milestone payments of up to $550.0 million, which include potential future indications which the companies choose to pursue, and commercial related milestone payments of up to $325.0 million. During the second quarter of 2015, we received a $15.0 million development milestone payment as a result of the finalization of our two audited pre-clinical carcinogenicity study reports. We evaluated the criteria under ASC 605-28 (as disclosed in Note 1) and concluded that each of those milestones was substantive.

Under the U.S./RoW Agreement, we and AstraZeneca will share equally in the development costs of roxadustat not already paid for by Astellas, up to a total of $233.0 million. Any additional development costs incurred by us during the development period in excess of the $233.0 million (aggregated spend) will be fully reimbursed by AstraZeneca. AstraZeneca will pay us tiered royalty payments on AstraZeneca s future net sales (as defined in the agreement) of roxadustat in the low 20% range. In addition we 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, we (through our 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 agreed to pay upfront consideration totaling $28.2 million (such amounts were fully received as of March 31, 2014). In addition, the China Agreement provides for AstraZeneca to pay regulatory approval and other approval related milestones of up to $161.0 million. The China Agreement also provides for sales related milestone payments of up to $167.5 million and contingent payments of $20.0 million related to possible future compounds. 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.

Accounting for the Astellas Agreements

For each of the Astellas agreements, we evaluated the deliverables within the respective arrangements and separated them into various units of accounting.

Deliverables that did not provide standalone value have been combined with other deliverables to form a unit of accounting that collectively has standalone value, with revenue being recognized on the combined unit of accounting, rather than the individual deliverables. There are no right-of-return provisions for the delivered items in the Astellas agreements.

For the Astellas agreements, we allocated arrangement consideration to various units of accounting based on BESP of each deliverable within each unit of accounting using the relative selling price method as we did not have VSOE or TPE of selling price for such deliverables. Arrangement consideration includes non-contingent upfront payments of $360.1 million and cumulative co-development billings of $114.5 million (for the Europe Agreement) as of June 30, 2015.

For the technology license under the Japan Agreement and Europe Agreement, BESP 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

Table of Contents

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%. Our 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. BESP also considered certain future royalty payments associated with commercial performance of our compounds, transfer prices and expected gross margins.

The units of accounting that were analyzed, along with their general timing of delivery or performance of service and general timing of revenue recognition, are as follows:

License to our 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 terms, or when the agreements were signed, and any contingencies had been removed. In both cases, we concluded at the time of the agreement that our collaboration partner, Astellas, would have the knowledge and capabilities to exploit the licenses without our further involvement. However, the Japan Agreement with Astellas has contractual limitations that might affect Astellas ability to exploit the license and therefore, potentially, the conclusion as to whether the license provides stand-alone value. 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 did not have stand-alone value, we considered the intent of the parties and the substantive reasons that led to that feature of the agreement.

Manufacturing rights. In the case of the Japan Agreement, we 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, we 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. We and Astellas could have structured the arrangement with a transfer of manufacturing rights and compensated us through a royalty or other feature without significantly diminishing the prospects of the drug product. Therefore, we determined that the license in Japan provides stand-alone value to the customer despite the lack of manufacturing rights.

License to our technology developed during the term of the agreement and development (referred to as when and if available) and information sharing services. These deliverables are generally delivered throughout the term of the agreements and are recognized as revenue as the services are provided.

Co-development services (Europe Agreement). This deliverable relates to co-development services that were reasonably expected to be performed by us at the time the collaboration agreement was signed. Revenue is recognized as reimbursements for such co-development services are earned. The period related to this deliverable represented our determination of the non-contingent performance

period, which was estimated to be 36 months for the Europe Agreement from the signing of the agreement. There was no provision for co-development services in the Japan agreement.

Manufacturing of clinical supplies of products. This deliverable is satisfied as supplies for clinical product are delivered for use in our clinical trial programs during the development period, or pre-commercialization period. Revenue is recognized based on the estimated proportion of the development services performed during the development period. These estimates are made at the beginning of each accounting period and will likely change throughout the course of the terms of both agreements. As new information related to these estimates becomes available, we may adjust the timing of revenue recognition related to this unit of accounting.

Manufacturing commercial supplies of products. This deliverable is satisfied and revenue is recognized as supplies are shipped for commercial use during the commercialization period. As this deliverable is considered a contingent deliverable, it is outside the scope of the initial allocation of upfront and other consideration.

Committee service. This deliverable is satisfied and revenue is recognized throughout the course of the various agreements as meetings are attended.

Any consideration received for each Astellas agreement after the initial proceeds on the agreement signing date were also (and will be also) allocated to the various units of accounting above per agreement using the relative selling price method under ASC 605-25-30-2 and 30-5.

Under the Japan Agreement, we are 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 substantive milestone payments upon achievement of specified

Table of Contents

clinical and development milestone events, (ii) up to $95.0 million in substantive 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.

Under the Europe Agreement, we are 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 substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $335.0 million in substantive milestone payments upon achievement of specified regulatory milestone events, including up to $25.0 million in milestone payments in connection with receipt of marketing approval in Russia.

Accounting for the AstraZeneca Agreements

We evaluated whether or not the U.S./RoW and China Agreements should be accounted for as a single arrangement 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 are a single arrangement. Accordingly, upfront and other non-contingent arrangement consideration received and to be received has been and will be pooled together and allocated to each of the units of accounting in both the U.S./RoW and China Agreements based on their relative fair values.

We evaluated the deliverables within the arrangement and separated them into various units of accounting. Deliverables that did not provide stand-alone value have been combined with other deliverables to form a unit of accounting that collectively has stand-alone value, with revenue being recognized on the combined unit of accounting, rather than the individual deliverables. There are no right-of-return provisions for the delivered items in the agreements.

For the technology license under the AstraZeneca U.S./RoW Agreement, BESP 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 IRR 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. Our 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 units of accounting that were analyzed, along with their general timing of delivery or performance of service and general timing of revenue recognition, are as follows:

License to our 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 terms as all contingencies had been removed. We concluded that AstraZeneca has the knowledge and capabilities to exploit the U.S./RoW license without our further involvement.

Co-development services. This deliverable relates to co-development services which were reasonably expected to be performed by us at the time the U.S./RoW Agreement was signed. Revenue is recognized as reimbursements for such co-development services are earned. The period related to this deliverable represented our determination of the non-contingent performance period, which was estimated to be 65 months from the signing of the U.S./RoW Agreement.

Manufacturing of clinical supplies of products. This deliverable is satisfied as supplies for clinical product are delivered for use in our clinical trial programs during the development period, or pre-commercialization period. Revenue is recognized based on the estimated proportion of the development services performed during the development period. These estimates are made at the beginning of each accounting period and will likely change throughout the course of the agreements. As new information related to these estimates becomes available, we may adjust the timing of revenue recognition related to this unit of accounting.

Manufacturing commercial supplies of products. This deliverable is satisfied and revenue is recognized as supplies are shipped for commercial use during the commercialization period. As this deliverable is considered a contingent deliverable, it is outside the scope of the initial allocation of upfront and other consideration.

Committee service. This deliverable is satisfied and revenue is recognized throughout the course of the various agreements as meetings are attended.

Table of Contents

Under the terms of the U.S./RoW Agreement, AstraZeneca has agreed to pay upfront, non-contingent and time-based payments totaling $374.0 million, which we expect to receive in various amounts through June 2016, of which $82.0 million was received as of December 31, 2013 and was determined to be fixed and determinable upon the execution of the collaboration agreement. Out of the remaining payments of $292.0 million, which are contractually due, $230.0 million have extended payment terms and, accordingly, were not considered to be fixed or determinable upon the execution of the agreement. As such, for these remaining payments, the amount of revenue recognized is limited to the amount of cash consideration received; additionally, for each of the amounts received, the amount of revenue recognized is determined on the basis of applying the relative selling price method to each of the units of accounting underlying the agreement. Further, $62.0 million of the remaining payment is contingent upon the occurrence of a specified event and accordingly is also not considered fixed or determinable.

Under the U.S./RoW Agreement, we are 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 substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $325.0 million in substantive milestone payments upon achievement of specified regulatory milestone events, (iii) up to $160.0 million in a non-substantive deferred approval milestone, which would be paid if certain competitors do not launch a HIF compound in the U.S. on or before January 1, 2023, and (iv) up to approximately $325.0 million in milestone payments upon the achievement of specified commercial sales events.

China Agreement:

The units of accounting that were analyzed, along with their general timing of delivery or performance of service and general timing of revenue recognition, are as follows:

License to our technology existing at the effective date of the agreement. The license was delivered at the beginning of the agreement term as all contingencies had been removed. However, the China Agreement with AstraZeneca has contractual limitations that might affect AstraZeneca s ability to exploit the license and therefore, potentially, the conclusion as to whether the license provides stand-alone value. 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 did not have stand-alone value, we considered the intent of the parties and the substantive reasons that led to that feature of the agreement.

For the China Agreement, we 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. Because the retention of manufacturing rights by us was a significant factor in the collaboration strategy, rather than simply a mechanism to properly compensate us, we concluded that the license and development services do not have stand-alone value apart from the manufacturing rights. Accordingly, all the deliverables identified, including co-development services, under the China Agreement have been treated as a single unit of account and all revenue allocable to this unit of account is deferred until delivery of commercial drug product has begun. Upon commencement of delivery of commercial drug product, revenue would be recognized in a pattern consistent with estimated deliveries of the commercial drug product.

Under the terms of the China Agreement, AstraZeneca agreed to pay upfront consideration totaling $28.2 million, of which $16.2 million was received as of December 31, 2013 and was determined to be fixed and determinable upon the execution of the collaboration agreement. The remainder of the upfront payments of $12.0 million had extended

payment terms and, accordingly, is not considered to be fixed or determinable upon the execution of the agreement. This payment of $12.0 million was received as of March 31, 2014.

Under the China Agreement, we are also eligible to receive from AstraZeneca an aggregate of approximately $328.5 million in potential milestone payments, comprised of (i) up to $15.0 million in substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $146.0 million in substantive milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $167.5 million in milestone payments upon the achievement of specified commercial sales events.

As we are accounting for both the U.S./RoW and China Agreements as one arrangement, any consideration received after the initial proceeds on the agreement signing date were also (and will be also) allocated to the various units of accounting above using the relative selling price method under ASC 605-25-30-2 and 30-5.

Table of Contents

Summary of revenue recognized under the collaboration agreements

The table below summarizes the accounting treatment for the various deliverables pursuant to each of the Astellas and AstraZeneca agreements. License amounts identified below are included in the License and milestone revenue line item in the condensed consolidated statements of operations. All other elements identified below are included in the Collaboration services 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):

		Quarter Ended June 30,		Six Months Ended June 30,	
Agreement	**Deliverable**	**2015**	**2014**	**2015**	**2014**
Japan	License	$ 91	$ 155	$ 528	$ 230
	Milestones				
	Total license and milestone revenue	91	155	528	230
	Collaboration services revenue*	$ 42	$ 89	$ 100	$ 176

As of June 30, 2015, the total arrangement consideration has been allocated to each of the following deliverables under the Japan Agreement, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through June 30, 2015	Deferred Revenue at June 30, 2015	Total Consideration Through June 30, 2015
License	$ 41,749	$	$ 41,749
When and if available compounds	12	29	41
Manufacturing clinical supplies	1,871	72	1,943
Committee services	15	2	17
Total license and collaboration services revenue	$ 43,647	$ 103	$ 43,750

* When and if available compounds, manufacturing clinical supplies and committee services have each been identified as separate units of accounting with standalone value and amounts allocable to these elements have been recognized and classified within the collaboration services revenue line item within the condensed consolidated statements of operations.

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

		Quarter Ended June 30,		Six Months Ended June 30,	
Agreement	**Deliverable**	**2015**	**2014**	**2015**	**2014**
Europe	License	$ 4,769	$ 3,563	$ 9,024	$ 6,230
	Milestones				

Total license and milestone revenue	4,769	3,563	9,024	6,230
Collaboration services revenue*	$ 677	$ 777	$ 1,253	$ 1,441

As of June 30, 2015, the total arrangement consideration has been allocated to each of the following deliverables under the Europe Agreement, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through June 30, 2015	Deferred Revenue at June 30, 2015	Total Consideration Through June 30, 2015
License	$ 392,663	$	$ 392,663
When and if available compounds	305	442	747
Manufacturing clinical supplies	8,911	494	9,405
Development services in progress	31,460		31,460
Committee services	256	16	272
Total license and collaboration services revenue	$ 433,595	$ 952	$ 434,547

* When and if available compounds, manufacturing clinical supplies, development services in progress at the time of signing of the agreement, and committee services have each been identified as a separate unit of accounting with standalone value and amounts allocable to these units have been recognized in revenue as services are performed and classified within the collaboration services revenue line item within the condensed consolidated statements of operations.

Table of Contents

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

Agreement	Deliverable	Quarter Ended June 30, 2015	Quarter Ended June 30, 2014	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
U.S. / RoW	License	$ 87,019	$ 78,745	$ 93,833	$ 90,688
	Milestones	15,000		15,000	
	Total license and milestone revenue	102,019	78,745	108,833	90,688
	Collaboration services revenue*	12,942	6,590	17,080	9,025
	China single unit of accounting**	$	$	$	$

As of June 30, 2015, the total arrangement consideration has been allocated to each of the following deliverables under the U.S./RoW Agreement, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through June 30, 2015	Deferred Revenue at June 30, 2015	Total Consideration Through June 30, 2015
License	$ 269,207	$	$ 269,207
Co-development, information sharing & committee services	37,589	44,259	81,848
Manufacturing clinical supplies	154	126	280
China-single unit of accounting		55,180	55,180
Total license and collaboration services revenue	$ 306,950	$ 99,565	$ 406,515

* Co-development, information sharing, and committee services have been combined into a single unit of accounting because the requirements to share information and serve on committees are useful only in combination with the development services, and because all three items are delivered over the same period while manufacturing clinical supplies has been identified as a separate unit of accounting with standalone value and amounts allocable to this unit of accounting have been recognized and classified within the collaboration services revenue line item within the condensed consolidated statements of operations.

** All revenues attributable to the China unit of accounting are deferred until all deliverables are met. The China license and collaboration services elements have been combined into a single unit of accounting and consideration allocable to this unit is being deferred due to FibroGen s retention of manufacturing rights and lack of standalone value.

Other Revenues

Other revenues consist of royalty payments received, which are recorded on a monthly basis as they are reported to us, and collagen feasibility sales. Other revenues were immaterial for all periods presented.

Deferred Revenue

Deferred revenue represents amounts billed to our 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 deliverables. 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 deliverables. 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 our financial assets that are measured on a recurring basis are as follows (in thousands):

	June 30, 2015			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$	$ 150,240	$	$ 150,240
Equity investments	199			199
Sub-total	199	150,240		150,439
Money market funds	127,643			127,643
Total	$ 127,842	$ 150,240	$	$ 278,082

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$	$ 158,432	$	$ 158,432
Equity investments	201			201
Sub-total	201	158,432		158,633
Money market funds	13,802			13,802
Total	$ 14,003	$ 158,432	$	$ 172,435

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 our financial liabilities that are carried at historical cost are as follows (in thousands):

	June 30, 2015			
	Level 1	Level 2	Level 3	Total
Lease financing obligations	$	$	$ 97,332	$ 97,332

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Cease-use liability	$	$	$ 184	$ 184
Lease financing obligations			97,221	97,221
Total	$	$	$ 97,405	$ 97,405

The fair values of our 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):

	June 30, 2015	December 31, 2014
Cash	$ 108,893	$ 151,653
Money market funds	127,643	13,802
Total cash and cash equivalents	$ 236,536	$ 165,455

Table of Contents

Investments

All investments are classified as available-for-sale. The amortized cost, gross unrealized holding gains or losses, and fair value of our available-for-sale investments by major investments type are summarized in the tables below (in thousands):

	June 30, 2015			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Corporate bonds	$ 150,119	$ 287	$ (166)	$ 150,240
Equity investments	124	75		199
Total investments	$ 150,243	$ 362	$ (166)	$ 150,439

	December 31, 2014			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Corporate bonds	$ 158,692	$ 254	$ (514)	$ 158,432
Equity investments	124	77		201
Total investments	$ 158,816	$ 331	$ (514)	$ 158,633

At June 30, 2015 all of the available-for-sale investments had contractual maturities within four years. We periodically review our available-for-sale investments for other-than-temporary impairment. We consider factors such as the duration, severity and the reason for the decline in value, the potential recovery period and our intent to sell. For debt securities, we also consider whether (i) it is more likely than not that we 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 quarters and six months ended June 30, 2015 and 2014, we did not recognize any other-than-temporary impairment loss.

At June 30, 2015, a total of $30.9 million of our cash and cash equivalents were held outside of the U.S. in our foreign subsidiaries to be used primarily for our China operations.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Preclinical and clinical trial accruals	$ 32,251	$ 25,418
Payroll and related accruals	9,625	15,608

Professional services	1,121	2,401
Other	3,243	5,558
Total accrued liabilities	$ 46,240	$ 48,985

Table of Contents

5. Stock-Based Compensation

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

	Quarter Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Research and development	$ 4,434	$ 408	$ 8,656	$ 883
General and administrative	2,508	262	4,732	582
Total stock-based compensation expense	$ 6,942	$ 670	$ 13,388	$ 1,465

The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option valuation model and the resulting weighted average fair value of stock options granted during the periods presented were as follows:

	Quarter Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Stock Options				
Expected term (in years)	5.2		5.2	
Expected volatility	70%	%	70%	%
Risk-free interest rate	1.7		1.7	
Expected dividend yield				
Weighted average estimated fair value	$ 12.27	$	$ 16.68	$
Employee Stock Purchase Plans				
Expected term (in years)	1.3		1.3	
Expected volatility	65%	%	65%	%
Risk-free interest rate	0.3		0.3	
Expected dividend yield				
Weighted average estimated fair value	$ 9.75	$	$ 9.75	$

6. Income Taxes

We recorded a provision for income taxes for the quarter ended June 30, 2015 due to the discrete tax effect arising from a change in the valuation of our available-for-sale securities portfolio. We recorded a benefit for income taxes for the six months ended June 30, 2015 due to the discrete tax effect arising from other comprehensive income related to available-for-sale securities. We did not record a provision for income taxes for the quarter and six months ended June 30, 2014 as we generated a net operating loss for the year ended December 31, 2014.

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

7. Related Party Transactions

Astellas is an equity investor of ours and, therefore, considered a related party. We recorded revenue related to collaboration agreements with Astellas of $5.6 million and $4.6 million during the quarter ended June 30, 2015 and 2014 and $10.9 million and $8.1 million during the six months ended June 30, 2015 and 2014. We recorded expense related to collaboration agreements with Astellas of $1.3 million and $2.4 million during the quarter ended June 30, 2015 and 2014 and $4.4 million and $4.5 million during the six months ended June 30, 2015 and 2014.

As of June 30, 2015 and December 31, 2014, accounts receivable from Astellas were $10.3 million and $5.0 million and amounts due to Astellas were $5.8 million and $4.3 million.

Julian N. Stern, a director of ours since November 1996, is of counsel to the law firm of Goodwin Procter LLP, which he joined in 2008. He has received, and continues to receive, no compensation from Goodwin Procter LLP since joining it as of counsel. We retain Goodwin Procter LLP as legal counsel for various matters, primarily consisting of intellectual property. During the quarter and six months ended June 30, 2015 and 2014, the payments made by us to Goodwin Procter LLP were not material. As of June 30, 2015 and December 31, 2014, amounts due to Goodwin Proctor LLP were not material.

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 SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on March 26, 2015.

Special Note Regarding 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 (the Exchange Act), Section 27A of the Securities Act of 1933, as amended (the 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 expressions or 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 research-based, biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs. We have capitalized on our extensive experience in fibrosis and hypoxia-inducible factor (HIF) biology to generate multiple programs targeting various therapeutic areas. 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). FG-3019 is our monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), pancreatic cancer and liver fibrosis. We have taken a global approach with respect to our product candidates, and this includes development and commercialization of product candidates in the People s Republic of China (China).

On November 10, 2014, we effected a 1-for-2.5 reverse split of our common stock. Upon the effectiveness of the reverse stock split, (i) every 2.5 shares of outstanding common stock were combined into one share of common stock, (ii) the number of shares of common stock for which each outstanding option or warrant to purchase common stock is exercisable was proportionally decreased on a 1-for-2.5 basis, (iii) the exercise price of each outstanding option or

warrant to purchase common stock was proportionately increased on a 1-for- 2.5 basis, (iv) the exchange ratio for each share of outstanding FibroGen Europe Oy (FibroGen Europe) share of stock which is exchangeable into our common stock was proportionately reduced on a 1-for-2.5 basis, and (v) the conversion ratio for each share of outstanding preferred stock which is convertible into our common stock was proportionately reduced on a 1-for-2.5 basis. All of the outstanding common stock share numbers (including shares of common stock which our outstanding preferred stock shares were convertible into), common stock warrants, share prices, exercise prices and per share amounts have been adjusted in these condensed consolidated financial statements, on a retroactive basis, to reflect this 1-for-2.5 reverse stock split for all periods presented. The par value per share and the authorized number of shares of common stock and preferred stock were not adjusted as a result of the reverse stock split.

On November 19, 2014, we closed the initial public offering (IPO) of our common stock. In our IPO, we sold 9,315,000 shares of our common stock at a public offering price of $18.00 per share. Net proceeds from our IPO and concurrent private placement were $171.8 million, after deducting underwriting discounts and commissions of $11.7 million and offering expenses of $4.1 million. AstraZeneca AB (AstraZeneca), one of our collaboration partners, agreed to purchase from us concurrently with the closing of our IPO in a private placement shares of our common stock with an aggregate purchase price of $20.0 million at a price per share equal to the IPO price. Upon the closing of our IPO, all outstanding shares of our convertible preferred stock automatically

Table of Contents

converted into 33,919,954 shares of common stock and 958,996 shares of FibroGen Europe convertible preferred stock were converted into shares of our common stock. Our proceeds from the sale of the common stock sold in the concurrent private placement were $20.0 million.

Financial Highlights

During the quarter and six months ended June 30, 2015, we had net income of $57.1 million and $10.7 million, or net income per diluted share of $0.83 and $0.15. The increase in net income and net income per diluted share for the quarter ended June 30, 2015 compared to the same period a year ago is primarily due to an increase in revenue, partially offset by an increase in operating expenses. The decrease in net income and net income per diluted share for the six months ended June 30, 2015 is primarily due to an increase in operating expenses, partially offset by an increase in revenue. The increase in revenue is primarily due to an upfront payment of $120.0 million and a development milestone payment of $15.0 million received in the second quarter of 2015 under the collaboration agreements with AstraZeneca. The increase in operating expenses resulted primarily from the progression of our clinical trials and expenses to support our new requirements as a public company.

Cash, cash equivalents, investments and receivables, excluding restricted cash, totaled $399.2 million at June 30, 2015, an increase of $61.6 million from December 31, 2014, primarily due to payments received from AstraZeneca, partially offset by cash used in operations.

Programs

During the first half of 2015, we continued to make progress in the development of our major programs.

Roxadustat is the first HIF-PH inhibitor to enter Phase 3 clinical development and 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, continue to advance roxadustat through our global Phase 3 program to support regulatory approval of roxadustat in both dialysis-dependent CKD (DD-CKD) patients and CKD patients who are not dialysis-dependent (NDD-CKD) in multiple geographies. For the three FibroGen roxadustat Phase 3 studies we have reached approximately two-thirds of our cumulative target enrollment. Our base plan is to meet target enrollment for these studies in March to April 2016, and we believe the third study could reach target enrollment by year end 2015. We currently anticipate submitting a New Drug Application (NDA) for roxadustat in the United States in 2018 and in China in 2016. In China, we completed manufacture of our NDA registration campaign for drug substance and finished drug product for roxadustat at our Beijing manufacturing facility in the second quarter of 2015. We have been informed that technical review of our Phase 3 clinical trial application has been completed by the CDE, and we believe the remaining steps in the Clinical Trial Application approval are largely perfunctory. We plan to begin opening study sites and enrolling patients in two Phase 3 studies in China in the fourth quarter of 2015.

FG-3019 is our fully-human monoclonal antibody that inhibits the activity of connective tissue growth factor (CTGF), a critical common element in the progression of fibrosis and associated serious diseases. We continue to conduct an open-label Phase 2 extension study in IPF and continue to enroll patients in a randomized, double-blind placebo-controlled Phase 2 trial in patients with IPF. The presence of approved therapies in IPF, such as Roche s pirfenidone, which is approved for marketing in Europe, Canada, Japan and the United States, and Boehringer Ingelheim s nintedanib, which has been approved in the United States and EU, has made enrollment in our placebo-controlled Phase 2 IPF trial more challenging. Our ability to complete enrollment of this IPF trial in the expected timeframe is dependent on opening additional clinical sites outside of the United States in the third quarter of 2015. In addition, we are evaluating expanding this IPF trial to include one or more comparator arms with approved therapy, which may increase the patient number in our trial to approximately 250 subjects.

We also continue to enroll an open-label Phase 2 trial in pancreatic cancer to determine whether the FG-3019, in combination with gemcitabine and nab-paclitaxel, can convert inoperable pancreatic cancer to operable cancer. Patients with inoperable Stage 3 pancreatic cancer have survival similar to patients with metastatic cancer with studies showing only half of these patients survive approximately 8 to 12 months after diagnosis and few studies even report 5 year survival. Outlook for patients with resectable pancreatic cancer is considerably better with studies showing half survive between 17 to 27 months after diagnosis and 20% alive at 5 years. We expect to review the preliminary data from this pancreatic cancer study when we have sufficient data to detect substantial differences in the context of assessing whether to expand the program, or continue or stop the study. We plan to submit an abstract of the initial study results for presentation at the American Society of Clinical Oncology Gastrointestinal meeting, which will be held in January of 2016. We plan to open a trial, for which we recently received Food and Drug Administration (FDA) clearance for our Investigational New Drug (IND) application, to study FG-3019 in Duchenne Muscular Dystrophy (DMD) in the second half of 2015. In addition, in the second quarter of 2015 we closed a trial in subjects with liver fibrosis due to the hepatitis B virus. To date, we have retained exclusive worldwide rights for FG-3019.

We are also currently pursuing our corneal implant FG-5200 for treatment of corneal blindness resulting from partial thickness corneal damage in China.

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.

Table of Contents

Astellas

We have two agreements with Astellas for the development and commercialization of roxadustat, one for Japan, and one for Europe, the Commonwealth of Independent States, the Middle East and South Africa. Under these agreements, we provided Astellas the right to develop and commercialize roxadustat for anemia in these territories.

We share responsibility with Astellas for clinical development activities required for United States and 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 June 30, 2015 totals $462.6 million.

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.

In addition, as of June 30, 2015 Astellas has separately invested $80.5 million in the equity of FibroGen, Inc.

AstraZeneca

We also have two agreements with AstraZeneca for the development and commercialization of roxadustat for anemia, one for China (China Agreement) and one for the United States and all other countries (RoW) not previously licensed to Astellas (U.S./RoW Agreement). Under these agreements we provided AstraZeneca the right to develop and commercialize roxadustat for anemia in these territories.

We will share responsibility with AstraZeneca for clinical development activities required for United States regulatory approval of roxadustat. AstraZeneca will be responsible for all of our development costs incurred under the agreed development plan for roxadustat in the United States and EU, to the extent those costs are not covered by Astellas, after an initial 50% development cost sharing period in which our funding obligations are limited to a total of $116.5 million. Thereafter, AstraZeneca will be solely responsible for additional development costs. In China, FibroGen China Anemia Holdings, Ltd. (FibroGen China) will conduct the development work for CKD anemia and its subsidiary, FibroGen (China) Medical Technology Development Co., Ltd. (FibroGen Beijing), will hold all of the

regulatory licenses issued by China regulatory authorities and FibroGen China 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, a portion of which we have received and the remainder of which we expect to receive in various amounts through 2016, including a $62.0 million time based development milestone, which became non-contingent as of July 30, 2014. 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 June 30, 2015 totals $355.2 million.

Table of Contents

During the second quarter of 2015, we received an upfront payment of $120.0 million and a development milestone payment of $15.0 million under the under the U.S./RoW Agreement. The development milestone payment resulted from the finalization of our two audited pre-clinical carcinogenicity study reports.

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.

AstraZeneca purchased 1,111,111 shares of our common stock at the IPO price for an aggregate purchase price of $20.0 million in a private placement concurrent with our IPO.

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 United States commercialization of roxadustat, with FibroGen undertaking specified promotional activities in the end stage renal disease (ESRD) segment in the United States. 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, 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 will 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.

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 to pay for a substantial portion of the post-termination development costs under the agreed development plan until regulatory approval.

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 to pay 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.

Results of Operations

Revenue

Our revenue to date has been generated primarily from our collaboration agreements with Astellas and AstraZeneca. The sources of our revenue for the periods presented were as follows:

	Quarter Ended June 30,		Change		Six Months Ended June 30,		Change	
	2015	2014	$	%	2015	2014	$	%

	(In thousands)							
Revenue:								
License and milestone revenue	$ 106,879	$ 82,463	$ 24,416	30%	$ 118,385	$ 97,148	$ 21,237	22%
Collaboration services and other revenue	13,671	7,495	6,176	82	18,463	10,686	7,777	73
Total revenue	$ 120,550	$ 89,958	$ 30,592	34%	$ 136,848	$ 107,834	$ 29,014	27%

Under our revenue recognition policy, license revenue includes amounts from upfront, non-refundable license payments and amounts allocated pursuant to the relative selling price method from other consideration received (other than substantive milestone payments) during the periods. This revenue is generally recognized as deliverables are met and services are performed. Milestone revenue includes payments from milestones which are deemed to be substantive in nature and is recognized in its entirety in the period in which the milestone is achieved. License and milestone revenues represented 89% and 92% of total revenue for the quarter ended June 30, 2015 and 2014 and 87% and 90% of total revenue for the six months ended June 30, 2015 and 2014.

Collaboration services include co-development services, manufacturing of clinical supplies, committee services and information sharing. Collaboration services revenues are recognized over the non-contingent performance period, ranging from 36 to

Table of Contents

65 months. Other revenues consist of royalty payments received, which are recorded on a monthly basis as they are reported to us, and have been included with collaboration services and other revenue in the condensed consolidated statements of operations, as they have not been material for any of the periods presented. Collaboration services and other revenues represented 11% and 8% of total revenue for the quarter ended June 30, 2015 and 2014 and 13% and 10% of total revenue for the six months ended June 30, 2015 and 2014.

The increase in total revenue for the quarter and six months ended June 30, 2015 compared to the same periods a year ago is more fully discussed in the sections below.

Total cash consideration received through June 30, 2015 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 (in thousands):

	Cash Received Through June 30, 2015	Additional Potential Cash Payments	Total Potential Cash Payments
Astellas related-party:			
Japan Agreement	$ 52,593	$ 120,000	$ 172,593
Europe Agreement	410,000	335,000	745,000
Total Astellas	462,593	455,000	917,593
AstraZeneca:			
U.S. / RoW Agreement	327,000	922,000	1,249,000
China Agreement	28,200	348,500	376,700
Total AstraZeneca	355,200	1,270,500	1,625,700
Total revenue	$ 817,793	$ 1,725,500	$ 2,543,293

These collaboration agreements also provide for reimbursement of certain fully burdened research and development costs as well as direct out of pocket expenses.

License and Milestone Revenue

	Quarter Ended June 30,		Change		Six Months Ended June 30,		Change	
	2015	2014	$	%	2015	2014	$	%
	(In thousands)				(In thousands)			
License and milestone revenue:								
Astellas	$ 4,860	$ 3,718	$ 1,142	31%	$ 9,552	$ 6,460	$ 3,092	48%
AstraZeneca	102,019	78,745	23,274	30	108,833	90,688	18,145	20
Total license and milestone revenue	$ 106,879	$ 82,463	$ 24,416	30%	$ 118,385	$ 97,148	$ 21,237	22%

License and milestone revenue recognized under our collaboration agreements with AstraZeneca increased primarily due to an upfront payment of $120.0 million and a development milestone payment of $15.0 million received during the second quarter of 2015 compared to an upfront payment of $110.0 million received during the second quarter of 2014. A portion of each of the upfront payments received under the collaboration agreements with AstraZeneca were deferred as a result of applying the relative selling price method and assessing the timing of the provision of various deliverables. The milestone payment was recognized in its entirety upon receipt. In addition, license and milestone revenue recognized under our collaboration agreements with both Astellas and Astra Zeneca increased due to an increase in reimbursable co-development costs allocated to license and milestone revenue.

Collaboration Services and Other Revenue

Collaboration services revenue increased $6.2 million and $7.8 million for the quarter and six months ended June 30, 2015 compared to the same periods a year ago primarily due to the allocation of the upfront payment of $120.0 million received during the second quarter of 2015 and an increase in reimbursable co-development costs under our collaboration agreements with AstraZeneca and Astellas.

Table of Contents

Operating Expenses

	Quarter Ended June 30,		Change		Six Months Ended June 30,		Change	
	2015	2014	$	%	2015	2014	$	%
	(In thousands)				(In thousands)			
Operating expenses								
Research and development	$ 51,555	$ 33,269	$ 18,286	55%	$ 102,094	$ 58,919	$ 43,175	73%
General and administrative	9,680	7,516	2,164	29	20,162	13,948	6,214	45
Total operating expenses	$ 61,235	$ 40,785	$ 20,450	50%	$ 122,256	$ 72,867	$ 49,389	68%

Research and Development Expenses

Research and development expenses consist of third party research and development costs and the fully-burdened amount of costs associated with work performed under collaboration agreements. Research and development costs include employee-related expenses for research and development functions, expenses incurred under agreements with clinical research organizations (CROs), other clinical and preclinical costs and allocated direct and indirect overhead costs, such as facilities costs, information technology costs and other overhead. Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

Research and development expenses incurred by program for the periods presented were as follows (in thousands):

		Quarter Ended June 30, 2015		Six Month Ended June 30,	
Product Candidate	Phase of Development	2015	2014	2015	2014
Roxadustat	Phase 3	$ 36,336	$ 20,713	$ 72,393	$ 34,468
FG-3019	Phase 2	8,374	5,171	15,707	10,286
FG-6874	Phase 1	472	1,051	974	1,915
FG-5200	Preclinical	1,331	1,029	2,661	1,866
Other research and development expenses		5,042	5,305	10,359	10,384
Total research and development expenses		$ 51,555	$ 33,269	$ 102,094	$ 58,919

The program-specific expenses summarized in the table above include costs we directly attribute to our product candidates. We allocate research and development salaries, benefits, stock-based compensation and other indirect costs to our product candidates on a program-specific basis, and we include these costs in the program-specific expenses.

Research and development expenses increased for the quarter and six months ended June 30, 2015 compared to the same periods a year ago. The increase for the quarter ended June 30, 2015 was primarily due to an increase in clinical trial, outside services and drug development related costs of $12.2 million, stock-based compensation expense of $4.0 million and employee-related costs of $1.9 million. The increase for the six months ended June 30, 2015 was primarily due to an increase in clinical trial, outside services and drug development related costs of $29.7 million, stock-based compensation expense of $7.8 million and employee-related costs of $4.6 million. Clinical trial, outside

services and drug development related costs increased as a result of the progression of the Phase 3 trials for FG-4592 and the ongoing Phase 2 trials for FG-3019. Stock-based compensation expense increased primarily due to a higher valuation for stock option grants and expense related to the Employee Share Purchase Program (ESPP), which we implemented in November 2014. Employee-related costs increased as a result of additional headcount to support our clinical trials.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses for executive, operational, finance, legal, compliance and human resource functions. Other general and administrative expenses include facility-related costs and professional fees, accounting and legal services, other outside services, recruiting fees and expenses associated with obtaining and maintaining patents.

Table of Contents

General and administrative expenses increased for the quarter and six months ended June 30, 2015 compared to the same periods a year ago. The increase for the quarter ended June 30, 2015 was primarily due to an increase in stock-based compensation expense of $2.2 million. The increase for the six months ended June 30, 2015 was primarily due to an increase in stock-based compensation expense of $4.2 million, legal fees of $1.2 million and employee-related costs of $1.0 million. Stock-based compensation expenses increased primarily due to a higher valuation of stock option grants and expense related to the ESPP. Legal fees increased for the six months ended June 30, 2015 compared to the same period a year ago primarily as a result of incremental maintenance costs associated with our intellectual property portfolio. Employee-related costs increased primarily as a result of additional headcount to support being a public company.

Operating Expenses for Roxadustat Covered Under Collaboration Agreements

We share responsibility with AstraZeneca for clinical development activities required for United States regulatory approval of roxadustat. AstraZeneca is responsible for all of our development costs incurred under the agreed development plan for roxadustat in the United States, Europe, Japan and all other markets outside of China, to the extent those costs are not covered by Astellas, after an initial 50% development cost sharing period in which our funding obligations are limited to a total of $116.5 million, of which $83.4 million has been incurred as of June 30, 2015. We expect to reach this $116.5 million cap in late 2015. After we have reached the $116.5 million cap, AstraZeneca will be solely responsible for all future development costs. In China, our subsidiary FibroGen China will conduct the development work for CKD anemia and its subsidiary, FibroGen Beijing, will hold all of the regulatory licenses issued by China regulatory authorities and FibroGen China will be primarily responsible for regulatory, clinical and manufacturing. All development and commercialization costs for roxadustat in China will be shared equally with AstraZeneca.

Interest and Other Income (Expense), Net

	Quarter Ended June 30,		Change		Six Months Ended June 30,		Change	
	2015	2014	$	%	2015	2014	$	%
	(In thousands)				(In thousands)			
Interest and other income (expense), net:								
Interest expense	$ (2,762)	$ (2,725)	$ (37)	1%	$ (5,520)	$ (5,451)	$ (69)	1%
Interest and other income, net	707	383	324	85	1,550	1,075	475	44
Total interest and other income (expense), net	$ (2,055)	$ (2,342)	$ 287	(12)%	$ (3,970)	$ (4,376)	$ 406	(9)%

Interest expense approximated the same periods a year ago and includes payments made for imputed interest related to the facility lease financing obligations for our leased facilities in San Francisco and China as well as interest related to the TEKES product development obligations.

Interest and other income, net increased primarily due to higher average balances of cash equivalents and investments.

Provision (Benefit) from Income Taxes

We recorded a provision for income taxes for the quarter ended June 30, 2015 due to the discrete tax effect arising from a change in the valuation of our available-for-sale securities portfolio. We recorded a benefit for income taxes

for the six months ended June 30, 2015 primarily due to the discrete tax effect arising from other comprehensive income related to available-for-sale securities. We did not record a provision for income taxes for the quarter and six months ended June 30, 2014 as we generated a net operating loss for the year ended December 31, 2014.

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

Liquidity and Capital Resources

We have historically funded our operations principally from the sale of convertible preferred stock and common stock and from the execution of certain collaboration agreements involving license payments, milestones and reimbursement for development services. On November 19, 2014, we closed our IPO and concurrent private placement in which we issued and sold a total of 10,426,111 shares of common stock, resulting in net proceeds of $171.8 million, after deducting underwriting discounts and commissions of $11.7 million and offering expenses of $4.1 million for our IPO. Upon the closing of our IPO, all of our outstanding convertible preferred stock automatically converted into 33,919,954 shares of common stock, based on the shares of convertible preferred stock outstanding as of November 18, 2014.

Table of Contents

During the second quarter of 2015, we received a $120.0 million upfront payment and a $15.0 million development milestone payment under the U.S./RoW Agreement. The development milestone payment was related to the finalization of our two audited pre-clinical carcinogenicity study reports.

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one or more of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all the risks related to the development and commercialization of novel therapeutics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. As a newly public company, we expect to incur additional costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

As of June 30, 2015, we had cash and cash equivalents of $236.5 million. Cash is invested in accordance with our investment policy, primarily to provide liquidity and preserve capital. Investments, consisting principally of corporate debt securities stated at fair value, are also available as a source of liquidity. As of June 30, 2015, we had short- and long-term investments of $12.1 million and $138.3 million. As of June 30, 2015, a total of $30.9 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries to be used primarily for our China operations.

We believe our existing cash and cash equivalents, investments and payments due under our license and collaboration agreements will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months. However, our liquidity assumptions may change over time, and we could utilize our available financial resources sooner than we currently expect. In addition, we may elect to raise additional funds at any time through equity, equity-linked or debt financing arrangements. Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth under Part I, Item 1A: Risk Factors in this Quarterly Report on Form 10-Q. We may not be able to secure additional financing to meet our operating requirements on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, the ownership of our existing stockholders will be diluted. If we raise additional financing by the incurrence of indebtedness, we will be subject to increased fixed payment obligations and could also be subject to restrictive covenants, such as limitations on our ability to incur additional debt, and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to obtain needed additional funds, we will have to reduce our operating expenses, which would impair our growth prospects and could otherwise negatively impact our business.

Cash Flows

The following table sets forth the primary sources and uses of cash (in thousands):

	Six Months Ended June 30,		
	2015	**2014**	**Change**
Net cash provided by (used in):			
Operating activities	$ 58,857	$ 77,238	$ (18,381)
Investing activities	6,046	29,594	(23,548)
Financing activities	5,407	(537)	5,944

Effect of exchange rate changes on cash	771	35	736
Net change in cash and cash equivalents	$ 71,081	$ 106,330	$ (35,249)

Operating Activities

Net cash provided by operating activities was $58.9 million for the six months ended June 30, 2015 and consisted primarily of net income of $10.7 million adjusted for non-cash items of $17.8 million, which includes stock-based compensation expense of $13.4 million, depreciation expense of $2.8 million, amortization of the premium on investments of $1.5 million, and a net increase in operating assets and liabilities of $30.4 million. The significant items in the change in operating assets and liabilities include an increase in deferred revenue of $30.4 million, an increase in prepaid expenses and other current assets of $2.2 million, an increase in accounts receivable of $1.3 million, a decrease in accrued liabilities of $3.1 million and a decrease in accounts payable of $0.6 million. The change in deferred revenue relate to the timing of the receipt of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The change in accounts receivable and prepaid expenses and other current assets relates to the timing of payments. The changes in accounts payable and accrued liabilities is driven by clinical trial activity related to upcoming Phase 3 trials for roxadustat and the timing of payments.

Table of Contents

Net cash provided by operating activities was $77.2 million for the six months ended June 30, 2014, and consisted primarily of net income of $30.6 million adjusted for non-cash items including stock-based compensation expense of $1.5 million, depreciation expense of $1.8 million, amortization of bond premium/discount of $0.3 million and a net increase in operating assets and liabilities of $43.0 million. The significant items in the change in operating assets and liabilities include an increase in deferred revenue of $36.3 million and an increase in accounts payable and accrued expenses of $5.0 million. The increase in deferred revenue relates to the timing of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The increase in accrued expenses is driven by the increase in clinical trial activity related to upcoming Phase 3 trials for roxadustat.

Investing Activities

Investing activities consist primarily of purchases of property and equipment and proceeds from the maturities of investments.

Financing Activities

Financing activities primarily reflect proceeds from the issuance of our common stock, repayments of our lease liability and payments of equity issuance costs associated with the planned public offering of our securities.

Off-Balance Sheet Arrangements

During the quarter and six months ended June 30, 2015, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements.

Contractual Obligations and Commitments

There have been no material changes in our contractual obligations compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

Critical Accounting Policies and Estimates

Our management s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no material changes in our critical accounting policies, estimates and judgments during the quarter ended June 30, 2015 compared with the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2014. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management s judgments and estimates.

Revenue Recognition

Substantially all of our revenues to date have been generated from our collaboration agreements.

Our collaboration agreements include multiple deliverables, and we follow the guidance in Accounting Standards Codification (ASC) Topic 605-25, Revenue Recognition Multiple-Element Arrangements, (ASC 605-25). ASC 605-25:

- provides guidance on how revenue arrangements with multiple deliverables should be separated and how the arrangement consideration should be allocated among the separate units of accounting;

- requires an entity to determine the selling price of a separate deliverable using a hierarchy of (i) vendor-specific objective evidence (VSOE), (ii) third-party evidence (TPE), or (iii) best estimate of selling price (BESP); and

- requires the allocation of the arrangement consideration, at the inception of the arrangement, to the separate units of accounting based on relative selling price.

Table of Contents

We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. Significant judgment may be required in determining whether a deliverable provides stand-alone value, determining the amount of arrangement consideration that is fixed or determinable, and estimating the stand-alone selling price of each unit of accounting.

To date, we have determined that the selling price for the deliverables within our collaboration agreements should be determined using BESP, as neither VSOE nor TPE is available. The process for determining BESP involves significant judgment on our part 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.

For each unit of accounting identified within an arrangement, we determine the period over which the deliverables are provided and the performance obligation is satisfied. Service revenue is recognized using a proportional performance method. Direct labor hours or full time equivalents are used as the measurement of performance. Revenue may be recognized using a straight line method when performance is expected to occur consistently over a period of time.

Payments or reimbursements resulting from our research and development efforts for those arrangements where such efforts are considered as deliverables are recognized as the services are performed and are presented on a gross basis. To the extent payments are required to be made to our collaboration partners pursuant to research and development efforts, those costs are charged to research and development using the guidance pursuant to ASC Topic 605-250, Customer Payments and Incentives , which states that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling prices unless the vendor receives an identifiable benefit in exchange for the consideration that is sufficiently separable from the recipient s purchase of the vendor s products, and the vendor can reasonably estimate the fair value of the benefit.

Each of our collaboration agreements includes milestones for which we follow ASC Topic 605-28, Revenue Recognition Milestone Method (ASC 605-28). ASC 605-28 establishes the milestone method as an acceptable method of revenue recognition for certain contingent event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can only be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us. Determining whether a milestone is substantive is a matter of judgment and that assessment must be made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone (i) is commensurate with either our performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relates solely to past performance and (iii) is reasonable relative to all deliverables and payment terms in the arrangement. Payments for achieving milestones which are not considered substantive are treated as additional arrangement consideration and are allocated following the relative selling price method previously described.

Recently Issued and Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes the revenue recognition requirements in 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. The effective date for ASU 2014-09was initially for fiscal years beginning after December 15, 2016. In July 2015, the FASB approved a one year deferral of this standard with a new effective date for fiscal years beginning after December 15, 2017. The new guidelines can be implemented using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption. We are currently evaluating the impact of this guidance on our consolidated financial statements.

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We believe there has been no material change in our exposure to market risks as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q.

Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of June 30, 2015, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Table of Contents

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below in addition to the other information included or incorporated by reference in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Although we have discussed all known material risks, the risks described below are not the only ones that we may face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described under Part I, Item 1A Risk Factors included in our Annual Report on Form 10-K for the year ended December 31, 2014.

Risks Related to Our Financial Condition and History of Operating Losses

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future and may never achieve or sustain profitability. We may require additional financings in order to fund our operations.*

We are a clinical-stage biopharmaceutical company with two lead product candidates in clinical development, roxadustat, or FG-4592 in anemia in chronic kidney disease (CKD), and FG-3019 in idiopathic pulmonary fibrosis (IPF), pancreatic cancer and liver fibrosis. Pharmaceutical product development is a highly risky undertaking. To date, we have focused our efforts and most of our resources on hypoxia-inducible factor, or HIF, and fibrosis biology research, as well as developing our lead product candidates. We are not profitable and, other than in 2006 and 2007 due to income received from our Astellas collaboration, have incurred losses in each year since our inception. We have not generated any significant revenue based on product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. Although we had net income of $10.7 million for the six months ended June 30, 2015, our net loss for the years ended December 31, 2013 and 2014 was $14.9 million and $59.5 million. As of June 30, 2015, we had an accumulated deficit of $311.6 million. As of June 30, 2015, we had capital resources consisting of cash, cash equivalents and short-term investments of $248.7 million plus $138.3 million of long-term investments classified as available for sale securities. Despite contractual development and cost coverage commitments from our collaboration partners, AstraZeneca AB (AstraZeneca) and Astellas Pharma Inc. (Astellas), and the potential to receive milestone and other payments from these partners, we anticipate we will continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, and seek regulatory approval for our product candidates. If we do not successfully develop and obtain regulatory approval for our existing or any future product candidates and effectively manufacture, market and sell any product candidates that are approved, we may never generate product sales, and even if we do generate product sales,

we may never achieve or sustain profitability on a quarterly or annual basis. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and working capital. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We believe that we will continue to expend substantial resources for the foreseeable future as we continue late-stage clinical development of roxadustat, grow our operations in China, expand our clinical development efforts on FG-3019, seek regulatory approval, prepare for the commercialization of our product candidates, and pursue additional indications. These expenditures will include costs associated with research and development, conducting preclinical trials and clinical trials, obtaining regulatory approvals in various jurisdictions, and manufacturing and supplying products and product candidates for ourselves and our partners. In particular, in our planned Phase 3 clinical trial program for roxadustat, which we believe will be the largest Phase 3 program ever conducted for an anemia product candidate, we are expecting to enroll approximately 7,000 to 8,000 patients worldwide. We are conducting this Phase 3 program in conjunction with Astellas and AstraZeneca, and we are substantially dependent on Astellas and AstraZeneca for the funding of this large program. The outcome of any clinical trial and/or regulatory approval process is highly uncertain and we are unable to fully estimate the actual costs necessary to successfully complete the development and regulatory approval process for our compounds in development and any future product candidates. We believe that the net proceeds from our initial public offering (IPO), our existing cash, cash equivalents and short-term investments and expected third party collaboration revenues will allow us to fund our operating plans through at least the next 12 months. Our operating plans or third party

Table of Contents

collaborations may change as a result of many factors, which are discussed in more detail below, and other factors that may not currently be known to us, and we therefore may need to seek additional funds sooner than planned, through offerings of public or private securities, debt financings or other sources, such as royalty monetization or other structured financings. Such financings may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect our business. We may also seek additional capital due to favorable market conditions or strategic considerations even if we currently believe that we have sufficient funds for our current or future operating plans.

Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress in the development of our product candidates;
- the costs of development efforts for our product candidates, such as FG-3019, that are not subject to reimbursement from our collaboration partners;
- the costs necessary to obtain regulatory approvals, if any, for our product candidates in the United States, China and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the continuation of our existing collaborations and entry into new collaborations;
- the time and unreimbursed costs necessary to commercialize products in territories in which our product candidates are approved for sale;
- the revenues from any future sales of our products as well as revenue earned from profit share, royalties and milestones;
- the level of reimbursement or third party payor pricing available to our products;
- the costs of establishing and maintaining manufacturing operations and obtaining third party commercial supplies of our products, if any, manufactured in accordance with regulatory requirements;
- the costs we incur in maintaining domestic and foreign operations, including operations in China;
- regulatory compliance costs; and

the costs we incur in the filing, prosecution, maintenance and defense of our extensive patent portfolio and other intellectual property rights.

Additional funds may not be available when we require them, or on terms that are acceptable to us. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate our research and development efforts or other operations or activities that may be necessary to commercialize our product candidates.

All of our recent revenue has been earned from collaboration partners for our product candidates under development.

During the years ended December 31, 2014, 2013 and 2012, 100%, 100% and 99% of our revenues recognized were from our collaboration partners.

We will require substantial additional capital to achieve our development and commercialization goals, which for our lead product candidate, roxadustat, is currently contemplated to be provided under our existing third party collaborations with Astellas and AstraZeneca.

If either or both of these collaborations were to be terminated, we could require significant additional capital in order to proceed with development and commercialization of our product candidates, or we may require additional partnering in order to help fund such development and commercialization. If adequate funds or partners are not available to us on a timely basis or on favorable terms, we may be required to delay, limit, reduce or terminate our research and development efforts or other operations.

If we are unable to continue to progress our development efforts and achieve milestones under our collaboration agreements, our revenues may decrease and our activities may fail to lead to commercial products.

Substantially all of our revenues to date have been, and a significant portion of our future revenues are expected to be, derived from our existing collaboration agreements. Revenues from research and development collaborations depend upon continuation of the collaborations, reimbursement of development costs, the achievement of milestones and royalties and profits from our product sales, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenues under our collaboration agreements will be substantially less than expected.

Table of Contents

Risks Related to the Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead product candidate, roxadustat, and our second compound in development, FG-3019.

To date, we have invested a substantial portion of our efforts and financial resources in the research and development of roxadustat, which is currently our lead product candidate. Roxadustat is our only product candidate that has advanced into a potentially pivotal trial, and it may be years before the studies required for its approval are completed, if ever. Our other product candidates are less advanced in development and may never enter into pivotal studies. We have completed 26 Phase 1 and 2 clinical studies with roxadustat in North America, Europe and Asia, in which over 1,400 subjects have participated and for which we reported favorable primary and secondary safety and efficacy endpoint results. Based on our discussions with the United States Food and Drug Administration (FDA) we believe that we have an acceptable plan for the conduct of our Phase 3 clinical trial program. We have also had discussions with China regulatory authorities regarding the conduct of Phase 3 clinical trials in China, which are part of our global Phase 3 clinical trial program for safety data. We have also discussed our Phase 3 clinical development program with three national health authorities in the EU and obtained scientific advice from the European Medicines Agency. Our near-term prospects, including maintaining our existing collaborations with Astellas and AstraZeneca, will depend heavily on successful Phase 3 development and commercialization of roxadustat.

Our other lead product candidate, FG-3019, is currently in clinical development for IPF, pancreatic cancer and liver fibrosis. FG-3019 requires substantial further development and investment. We do not have a collaboration partner for support of this compound, and, while we have promising open-label safety data and potential signals of efficacy, we would need to complete larger and more extensive controlled clinical trials to validate the results to date in order to continue further development of this product candidate. In addition, although there are many potentially promising indications beyond IPF, pancreatic cancer and liver fibrosis, we are still exploring indications for which further development of, and investment for, FG-3019 may be appropriate. Accordingly, the costs and time to complete development and related risks are currently unknown. Moreover, FG-3019 is a monoclonal antibody, which may require experience and expertise that we may not currently possess as well as financial resources that are potentially greater than those required for our small molecule lead compound, roxadustat.

The clinical and commercial success of roxadustat and FG-3019 will depend on a number of factors, many of which are beyond our control, and we may be unable to complete the development or commercialization of roxadustat or FG-3019.

The clinical and commercial success of roxadustat and FG-3019 will depend on a number of factors, including the following:

- the timely initiation, continuation and completion of our Phase 3 clinical trials for roxadustat, which will depend substantially upon requirements for such trials imposed by the FDA and other regulatory agencies and bodies and the continued commitment and coordinated and timely performance by our third party collaboration partners, AstraZeneca and Astellas;

- the timely initiation and completion of our Phase 2 clinical trials for FG-3019, including in IPF and pancreatic cancer;

our ability to demonstrate the safety and efficacy of our product candidates to the satisfaction of the relevant regulatory authorities;

whether we are required by the FDA or other regulatory authorities to conduct additional clinical trials, and the scope and nature of such clinical trials, prior to approval to market our products;

the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities, including pricing and reimbursement determinations;

the ability to successfully commercialize our product candidates, if approved, for marketing and sale by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;

our ability and the ability of our third party manufacturing partners to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability;

our success in educating health care providers and patients about the benefits, risks, administration and use of our product candidates, if approved;

acceptance of our product candidates, if approved, as safe and effective by patients and the healthcare community;

the success of efforts to enter into relationships with large dialysis organizations involving the administration of roxadustat to dialysis patients;

the achievement and maintenance of compliance with all regulatory requirements applicable to our product candidates;

Table of Contents

- the maintenance of an acceptable safety profile of our products following any approval;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competitive treatments;
- our ability to obtain and sustain an adequate level of pricing or reimbursement for our products by third party payors;
- our ability to enforce successfully our intellectual property rights for our product candidates and against the products of potential competitors; and
- our ability to avoid or succeed in third party patent interference or patent infringement claims.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will ever be able to achieve profitability through the sale of, or royalties from, our product candidates. If we or our collaboration partners are not successful in obtaining approval for and commercializing our product candidates, or are delayed in completing those efforts, our business and operations would be adversely affected.

We may be unable to obtain regulatory approval for our product candidates, or such approval may be delayed or limited, due to a number of factors, many of which are beyond our control.*

The clinical trials and the manufacturing of our product candidates are and will continue to be, and the marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to develop and, if approved, market any product candidates. Before obtaining regulatory approval for the commercial sale of any product candidate, we must demonstrate through extensive preclinical trials and clinical trials that the product candidate is safe and effective for use in each indication for which approval is sought. The regulatory review and approval process is expensive and requires substantial resources and time, and in general very few product candidates that enter development receive regulatory approval. In addition, our collaboration partners for roxadustat have final control over development decisions in their respective territories and they may make decisions with respect to development or regulatory authorities that delay or limit the potential approval of roxadustat, or increase the cost of development or commercialization. Accordingly, we may be unable to successfully develop or commercialize roxadustat or FG-3019 or any of our other product candidates.

We have not obtained regulatory approval for any of our product candidates and it is possible that roxadustat and FG-3019 will never receive regulatory approval in any country. Regulatory authorities may take actions or impose requirements that delay, limit or deny approval of roxadustat or FG-3019 for many reasons, including, among others:

- our failure to adequately demonstrate to the satisfaction of regulatory authorities that roxadustat is safe and effective in treating anemia in CKD or that FG-3019 is safe and effective in treating IPF, pancreatic cancer or liver fibrosis;

our failure to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;

the determination by regulatory authorities that additional clinical trials are necessary to demonstrate the safety and efficacy of roxadustat or FG-3019, or that ongoing clinical trials need to be modified in design, size, conduct or implementation;

our product candidates may exhibit an unacceptable safety signal as they advance through clinical trials, in particular controlled Phase 3 trials;

the contract research organizations (CROs) that conduct clinical trials on our behalf may take actions outside of our control that materially adversely impact our clinical trials;

we or third party contractors manufacturing our product candidates may not maintain current good manufacturing practices (cGMP), successfully pass inspection or meet other applicable manufacturing regulatory requirements;

regulatory authorities may not agree with our interpretation of the data from our preclinical trials and clinical trials;

collaboration partners may not perform or complete their clinical programs in a timely manner, or at all; or

principal investigators may determine that one or more serious adverse events (SAEs) is related or possibly related to roxadustat, and any such determination may adversely affect our ability to obtain regulatory approval, whether or not the determination is correct.

Any of these factors, many of which are beyond our control, could jeopardize our or our collaboration partners abilities to obtain regulatory approval for and successfully market roxadustat. Because our business and operations in the near-term are almost entirely dependent upon roxadustat, any significant delays or impediments to regulatory approval could have a material adverse effect on our business and prospects.

Table of Contents

Furthermore, in both the United States and China, we also expect to be required to perform additional clinical trials in order to obtain approval or as a condition to maintaining approval due to post-marketing requirements. If the FDA requires a risk evaluation and mitigation strategy (REMS) for any of our product candidates if approved, the substantial cost and expense of complying with a REMS or other post-marketing requirements may limit our ability to successfully commercialize our product candidates.

Our Phase 2 clinical trial results to date for roxadustat may not be indicative of the results that may be obtained in larger, controlled Phase 3 clinical trials required for approval.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical and early clinical trials may not be predictive of similar results in larger, controlled clinical trials, and successful results from early or small clinical trials may not be replicated or show as favorable an outcome, even if successful. For example, in the past we developed an earlier generation product candidate aimed at treating anemia in CKD that resulted in a clinical hold for a safety signal seen in that product in Phase 2 clinical trials. The clinical hold applied to that product candidate and roxadustat was lifted for both product candidates after submission of the requested data to the FDA. While we have not seen similar safety concerns involving roxadustat to date, our Phase 2 clinical trials have involved a relatively small number of patients exposed to roxadustat for a relatively short period of time compared to the Phase 3 clinical trials that we will be conducting, and only a fraction of the patients in the Phase 2 clinical trials were randomized to placebo. Accordingly, the Phase 2 clinical trials that we have conducted may not have uncovered safety issues, even if they exist. In addition, some of the safety concerns associated with the treatment of patients with anemia in CKD using Erythropoiesis Stimulating Agents (ESAs) did not emerge for many years until placebo-controlled studies had been conducted in large numbers of patients. The biochemical pathways that we believe are affected by roxadustat are implicated in a variety of biological processes and disease conditions, and it is possible that the use of roxadustat to treat larger numbers of patients will demonstrate unanticipated adverse effects, including possible drug interactions, which may negatively impact the safety profile, use and market acceptance of roxadustat. We studied the potential interaction between roxadustat and three statins (atorvastatin, rosuvastatin and simvastatin), which are used to lower levels of lipids in the blood. An adverse effect associated with increased statin plasma concentration is myopathy, which typically presents in a form of myalgia. The studies indicated the potential for increased exposure to those statins when roxadustat is taken simultaneously with those statins and suggested the need for statin dose reductions for patients receiving higher statin doses. We performed additional clinical pharmacology studies to evaluate if the effect of any such interaction could be minimized or eliminated by a modification of the dosing schedule that would separate the administration of roxadustat and the statin, however, such studies showed no minimization of effect. It is possible that the potential for interaction between roxadustat and statins could lead to label provisions for statins or roxadustat relating, for example, to dose scheduling or recommended statin dose limitations. In CKD patients statin therapy is often initiated earlier than treatment for anemia, and risks of myopathy have been shown to decrease with increased time on drug. While we believe the prior statin treatment history of such patients at established doses may reduce the risk of adverse effects from any interaction with roxadustat and facilitate any appropriate dose adjustments, we cannot be sure that this will be the case.

The FDA has informed us that our Phase 3 trials must include, as a safety endpoint, a major adverse cardiac events (MACE) endpoint, which is a composite endpoint designed to identify major safety concerns, in particular relating to cardiovascular events such as cardiovascular death, myocardial infarction and stroke. In addition, we expect that our Phase 3 clinical trials supporting approval in Europe will be required to include MACE+ as a safety endpoint which, in addition to the MACE endpoints, also incorporates measurements of hospitalization rates due to heart failure or unstable angina. As a result, our ongoing and planned Phase 3 clinical trials may identify unanticipated safety concerns in the patient population under study. The FDA has also informed us that the MACE endpoint will need to be evaluated separately for our Phase 3 trials in non-dialysis dependent-CKD patients and our Phase 3 trials in dialysis

dependent-CKD patients. The MACE endpoint will be evaluated in pooled analysis across Phase 3 studies of similar study populations and requires demonstration of non-inferiority relative to comparator, which means that the MACE event rate in roxadustat-treated patients must have less than a specified probability of exceeding the rate in the comparator trial by a specified hazard ratio. The number of patients necessary in order to permit a statistical analysis with adequate ability to detect the relative risk of MACE or MACE+ events in different arms of the trial, referred to as statistical power, depends on a number of factors, including the rate at which MACE or MACE+ events occur per patient-year in the trial, treatment duration of the patients, the required hazard ratio, and the required statistical power and confidence intervals.

In addition, we cannot be sure that the potential advantages that we believe roxadustat may have for treatment of patients with anemia in CKD as compared to the use of ESAs will be substantiated by our Phase 3 clinical trials or that we will be able to include a discussion of such advantages in our labeling should we obtain approval. We believe that roxadustat may have certain benefits as compared to ESAs based on the data from our Phase 2 clinical trials conducted to date, including safety benefits, the absence of a hypertensive effect, the potential to lower cholesterol levels and the potential to correct anemia without the use of IV iron. However, our belief that roxadustat may offer those benefits is based on a limited amount of data from our Phase 2 clinical trials and our understanding of the likely mechanisms of action for roxadustat. Some of these benefits, such as those associated with the apparent effects on blood pressure and cholesterol, are not fully understood and, even if roxadustat receives marketing approval, we do not expect that it will be approved for the treatment of high blood pressure or high cholesterol based on the data from our Phase 3 trials,

Table of Contents

and we may not be able to refer to any such benefits in the labeling. While the data from our Phase 2 trials suggests roxadustat may reduce LDL, or low-density lipoprotein, and reduce the ratio of LDL to HDL, or high-density lipoprotein, the data show it may also reduce HDL, which may be a risk to patients. In addition, causes of the safety concerns associated with the use of ESAs to achieve specified target Hb levels have not been fully elucidated. While we believe that the issues giving rise to these concerns with ESAs are likely due to factors other than the Hb levels achieved, we cannot be certain that roxadustat will not be associated with similar, or more severe, safety concerns.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early stage development, and we may face similar setbacks. In addition, the CKD patient population has many afflictions that may cause severe illness or death, which may be attributed to roxadustat in a manner that negatively impacts the safety profile of our product candidate. If the results of our ongoing or future clinical trials for roxadustat are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are unanticipated safety concerns or adverse events that emerge during clinical trials, we may be prevented from or delayed in obtaining marketing approval for roxadustat, and even if we obtain marketing approval, any sales of roxadustat may suffer.

Our Phase 2 results to date for FG-3019 may not be indicative of the results that may be obtained in larger, controlled Phase 2 clinical trials or Phase 3 clinical trials required for approval.

We have conducted only a limited number of Phase 2 clinical trials with FG-3019. We have conducted an open-label Phase 2 dose escalation study of FG-3019 for IPF in 89 patients and a Phase 2 dose finding trial of FG-3019 combined with gemcitabine plus erlotinib in 75 patients with pancreatic cancer. We cannot be sure that the results of these trials will be substantiated in double-blinded trials with larger numbers of patients, that larger trials will demonstrate the efficacy of FG-3019 for these or other indications or that safety issues will not be uncovered in further trials. In the Phase 2 clinical trial for IPF, we used quantitative high resolution computed tomography, or HRCT, to measure the extent of lung fibrosis. While we believe that quantitative HRCT is an accurate measure of lung fibrosis, it is a novel technology that has not yet been accepted by the FDA as a primary endpoint in pivotal clinical trials. In addition, while we believe that the animal studies that we have conducted to date demonstrate that FG-3019 has the potential to arrest or reverse fibrosis and reduce tumor mass, we cannot be sure that these results will be indicative of the effects of FG-3019 in human trials. In addition, the IPF and pancreatic cancer patient populations are extremely ill and routinely experience SAEs, including death, which may be attributed to FG-3019 in a manner that negatively impacts the safety profile of our product candidate. If the additional Phase 2 clinical trials that we are planning for FG-3019 in IPF and pancreatic cancer do not show favorable efficacy results or result in safety concerns, or if we do not meet our clinical endpoints with statistical significance, or demonstrate an acceptable risk-benefit profile, we may be prevented from or delayed in obtaining marketing approval for FG-3019 in one or both of these indications.

We do not know whether our ongoing or planned Phase 3 clinical trials in roxadustat or Phase 2 clinical trials in FG-3019 will need to be redesigned based on interim results, be able to achieve sufficient enrollment or be completed on schedule, if at all.

Clinical trials can be delayed or terminated for a variety of reasons, including delay or failure to:

address any physician or patient safety concerns that arise during the course of the trial;

obtain required regulatory or institutional review board (IRB) approval or guidance;

reach timely agreement on acceptable terms with prospective CROs and clinical trial sites;

recruit, enroll and retain patients through the completion of the trial;

maintain clinical sites in compliance with clinical trial protocols;

initiate or add a sufficient number of clinical trial sites; and

manufacture sufficient quantities of product candidate for use in clinical trials.

In addition, we could encounter delays if a clinical trial is suspended or terminated by us, by the relevant IRBs at the sites at which such trials are being conducted, or by the FDA or other regulatory authorities. A suspension or termination of clinical trials may result from any number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, changes in laws or regulations, or a principal investigator s determination that a serious adverse event could be related to our product candidates. Any delays in completing our clinical trials will increase the costs of the trial, delay the product candidate development and approval process and jeopardize our ability to commence marketing and generate revenues. Any of these occurrences may materially and adversely harm our business and operations and prospects.

Table of Contents

Our product candidates may cause or have attributed to them undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.

Undesirable side effects caused by our product candidates or that may be identified as related to our product candidates by physician investigators conducting our clinical trials or even competing products in development that utilize a similar mechanism of action or act through a similar biological disease pathway could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Adverse events and SAEs that emerge during treatment with our product candidates or other compounds acting through similar biological pathways may be deemed to be related to our product candidate and may result in:

- our Phase 3 clinical trial development plan becoming longer and more extensive;
- regulatory authorities increasing the data and information required to approve our product candidates and imposing other requirements; and
- our collaboration partners terminating our existing agreements.

The occurrence of any or all of these events may cause the development of our product candidates to be delayed or terminated, which could materially and adversely affect our business and prospects. Refer to Business Our Development Program for Roxadustat and Business FG-3019 for the Treatment of Fibrosis and Cancer in our Annual Report on Form 10-K for the year ended December 31, 2014 for a discussion of the adverse events and serious adverse events that have emerged in clinical trials of roxadustat and FG-3019.

Clinical trials of our product candidates may not uncover all possible adverse effects that patients may experience.

Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur. There have been other products, including ESAs, that have been approved by the regulatory authorities but for which safety concerns have been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of ESAs products from the market, and any of our product candidates may be subject to similar risks. For example, roxadustat for use in anemia in CKD is being developed to address a very diverse patient population expected to have many serious health conditions at the time of administration of roxadustat, including diabetes, high blood pressure and declining kidney function.

Although to date we have not seen evidence of significant safety concerns with our product candidates currently in clinical trials, patients treated with our products, if approved, may experience adverse reactions and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our product candidates. If safety problems occur or are identified after our product

candidates reach the market, we may, or regulatory authorities may require us to amend the labeling of our products, recall our products or even withdraw approval for our products.

We may fail to enroll a sufficient number of patients in our clinical trials in a timely manner, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the rate at which we can recruit and enroll patients in testing our product candidates. Patients may be unwilling to participate in clinical trials of our product candidates for a variety of reasons, some of which may be beyond our control:

severity of the disease under investigation;

availability of alternative treatments;

size and nature of the patient population;

eligibility criteria for and design of the study in question;

perceived risks and benefits of the product candidate under study;

ongoing clinical trials of competitive agents;

physicians and patients perceptions as to the potential advantages of our product candidates being studied in relation to available therapies or other products under development;

Table of Contents

our, our CRO s, and our trial sites efforts to facilitate timely enrollment in clinical trials;

patient referral practices of physicians; and

ability to monitor patients and collect patient data adequately during and after treatment.

Patients may be unwilling to participate in our clinical trials for roxadustat due to adverse events observed in other drug treatments of anemia in CKD, and patients currently controlling their disease with existing ESAs may be reluctant to participate in a clinical trial with an investigational drug. We may not be able to successfully initiate or continue clinical trials if we cannot rapidly enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate on-going or planned clinical trials, any of which could have a material and adverse effect on our business and prospects.

If we or third party manufacturers on which we rely cannot manufacture our product candidates and/or products at sufficient yields, we may experience delays in development, regulatory approval and commercialization.

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our product candidates at sufficient yields and at commercial scale. We have limited experience manufacturing, or managing third parties in manufacturing any of our product candidates in the volumes that are expected to be necessary to support large-scale clinical trials and sales. Our efforts to establish these capabilities may not meet our requirements as to scale-up, yield, cost, potency or quality in compliance with cGMP. Our clinical trials must be conducted with product produced under applicable cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Even an experienced third party manufacturer may encounter difficulties in production, which difficulties may include:

costs and challenges associated with scale-up and attaining sufficient manufacturing yields, in particular for biologic products such as FG-3019, which is a monoclonal antibody;

supply chain issues, including the timely availability and shelf life requirements of raw materials and supplies;

quality control and assurance;

shortages of qualified personnel and capital required to manufacture large quantities of product;

compliance with regulatory requirements that vary in each country where a product might be sold;

capacity limitations and scheduling availability in contracted facilities; and

natural disasters that affect facilities and possibly limit production.

For example, we have a limited amount of FG-3019 in storage and there are long lead times required to manufacture and scale-up the manufacture of additional supply. If we are unable to manufacture sufficient quantities of FG-3019 on a timely basis, it may limit our ability to replenish inventory or delay our development of FG-3019 in some or all indications. Any delay or interruption in the supply of our product candidates or products could have a material adverse effect on our business and operations.

Even if we are able to obtain regulatory approval of our product candidates, the label we obtain may limit the indicated uses for which our product candidates may be marketed.

With respect to roxadustat, we expect that regulatory approvals, if obtained at all, will limit the approved indicated uses for which roxadustat may be marketed, as ESAs have been subject to significant safety limitations on usage as directed by the Black Box warnings included in their labels. Refer to Business Roxadustat For the Treatment of Anemia in Chronic Kidney Disease Limitations of the Current Standard of Care for Anemia in CKD in our Annual Report on Form 1