UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2017

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 001-36352

AKEBIA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**20-8756903**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
245 First Street, Suite 1100, Cambridge, MA	**02142**
(Address of Principal Executive Offices)	**(Zip Code)**

(617) 871-2098
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site if any, every Interactive Date File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. ☒

Class	Outstanding at July 31, 2017
Common Stock, $0.00001 par value	**47,151,429**

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that are being made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, or PSLRA, with the intention of obtaining the benefits of the "safe harbor" provisions of the PSLRA. Forward-looking statements involve risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the projected timing of (1) our clinical programs for vadadustat, (2) submission of marketing applications for vadadustat, and (3) preclinical development of AKB-5169 and other product candidates;
- enrollment in the PRO$_2$TECT and INNO$_2$VATE clinical programs;
- our development program for vadadustat, including the FO$_2$RWARD and TRILO$_2$GY clinical studies, and our other product candidates;
- our anticipated funding from our collaborations;
- the timing or likelihood of regulatory filings and approvals, including any labeling or other restrictions;
- our plans to commercialize vadadustat, if it is approved;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our competitive position;
- our intellectual property position;
- developments and projections relating to our competitors and our industry;
- our estimates regarding expenses (including those associated with the PRO$_2$TECT and INNO$_2$VATE clinical programs), future revenue, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

All forward-looking statements in this Quarterly Report on Form 10-Q involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainty and may prove inaccurate. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 125,390	$ 187,335
Available for sale securities	195,825	73,008
Unbilled receivable	—	33,823
Prepaid expenses and other current assets	11,174	2,155
Total current assets	332,389	296,321
Property and equipment, net	2,934	2,612
Other assets	1,499	1,283
Total assets	$ 336,822	$ 300,216
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,212	$ 2,039
Accrued expenses	28,851	30,261
Short-term deferred revenue	142,346	81,968
Short-term deferred rent	182	—
Total current liabilities	181,591	114,268
Deferred rent, net of current portion	2,678	2,480
Deferred revenue, net of current portion	95,531	115,321
Other non-current liabilities	24	27
Total liabilities	279,824	232,096
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock $0.00001 par value, 25,000,000 shares authorized at June 30, 2017 and December 31, 2016; 0 shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock: $0.00001 par value; 175,000,000 shares authorized at June 30, 2017 and December 31, 2016; 42,490,957 and 38,615,709 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	—	—
Additional paid-in capital	420,448	365,298
Accumulated other comprehensive loss	(254)	(42)
Accumulated deficit	(363,196)	(297,136)
Total stockholders' equity	56,998	68,120
Total liabilities and stockholders' equity	$ 336,822	$ 300,216

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Collaboration revenue	$ 28,520	$ —	$ 49,385	$ —
Operating expenses:				
Research and development	43,751	30,877	103,800	51,112
General and administrative	6,905	5,311	12,693	11,122
Total operating expenses	50,656	36,188	116,493	62,234
Operating loss	(22,136)	(36,188)	(67,108)	(62,234)
Other income (expense):				
Interest income	608	270	1,044	504
Other income	10	139	4	153
Net loss	$ (21,518)	$ (35,779)	$ (66,060)	$ (61,577)
Net loss per share - basic and diluted	$ (0.53)	$ (0.95)	$ (1.66)	$ (1.65)
Weighted-average number of common shares - basic and diluted	40,819,957	37,811,056	39,795,282	37,342,324
Comprehensive loss:				
Net loss	$ (21,518)	$ (35,779)	$ (66,060)	$ (61,577)
Other comprehensive loss - unrealized loss on securities	(75)	63	(254)	37
Comprehensive loss	$ (21,593)	$ (35,716)	$ (66,314)	$ (61,540)

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Six months ended	
	June 30, 2017	**June 30, 2016**
Operating activities:		
Net loss	$ (66,060)	$ (61,577)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	253	78
Amortization of premium/discount on investments	389	287
Stock-based compensation - equity awards	4,522	2,473
Fair value of warrants issued for license	3,413	—
Changes in operating assets and liabilities:		
Unbilled receivable	33,823	—
Prepaid expenses and other current assets	(9,019)	(1,311)
Other long-term assets	(79)	—
Accounts payable	8,173	2,830
Accrued expense	(1,547)	6,362
Deferred revenue	40,588	40,000
Deferred rent	380	1,337
Net cash provided by (used in) operating activities	14,836	(9,521)
Investing activities:		
Purchase of equipment	(575)	(1,358)
Proceeds from the maturities of available for sale securities	54,118	64,874
Purchase of available for sale securities	(177,536)	(118,684)
Net cash used in investing activities	(123,993)	(55,168)
Financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	46,912	60,869
Proceeds from the sale of stock under employee stock purchase plan	125	105
Proceeds from the exercise of stock options	178	120
Payments on capital lease obligations	(3)	(6)
Net cash provided by financing activities	47,212	61,088
Decrease in cash and cash equivalents	(61,945)	(3,601)
Cash and cash equivalents at beginning of the period	187,335	49,778
Cash and cash equivalents at end of the period	$ 125,390	$ 46,177
Non-cash financing activities		
Unpaid follow-on offering costs	$ 137	$ 131

See accompanying notes to unaudited condensed consolidated financial statements

1. Nature of Organization and Operations

The Company is a biopharmaceutical company focused on developing and delivering novel therapeutics for patients based on hypoxia-inducible factor, or HIF, biology, and building our pipeline while leveraging our development and commercial expertise in renal disease. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body, as well as other important metabolic functions. Pharmacologic modulation of the HIF pathway may have broad therapeutic applications. The Company's lead product candidate, vadadustat, is an oral therapy in Phase 3 development, which has the potential to set a new standard of care in the treatment of anemia associated with chronic kidney disease (CKD). The Company's management team has extensive experience in developing and commercializing drugs for the treatment of renal and metabolic disorders, as well as a deep understanding of HIF biology. This unique combination of HIF and renal expertise is enabling the Company to advance a pipeline of HIF-based therapies to address serious diseases.

The Company's operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing its technology, identifying potential product candidates and undertaking preclinical and clinical studies. The Company has not generated any product revenue to date and may never generate any product revenue in the future. The Company's product candidates are subject to long development cycles and the Company may be unsuccessful in its efforts to develop, obtain regulatory approval for or market its product candidates.

The Company is subject to a number of risks including possible failure of preclinical testing or clinical trials, reliance on contract manufacturing organizations, the need to obtain marketing approval for its product candidates, the development of new technological innovations by competitors, the need to successfully commercialize and gain market acceptance of any of the Company's products that are approved and uncertainty around intellectual property matters. If the Company does not successfully commercialize any of its products, it will be unable to generate product revenue or achieve profitability.

The Company believes that its existing cash resources of approximately $321.2 million at June 30, 2017, together with the net proceeds from the follow-on public offering in July 2017 of approximately $62.6 million and committed funding from its collaboration partners, will be sufficient to allow the Company to fund its current operating plan into the second quarter of 2019, and as a result, through at least twelve months from the filing of the Company's 2017 second quarter Form 10-Q. There can be no assurance, however, that the current operating plan will be achieved in the time frame anticipated by the Company, or that its cash resources will fund the Company's operating plan for the period anticipated by the Company or that additional funding will be available on terms acceptable to the Company, or at all. We will require additional capital for the further development of our existing product candidates and will need to raise additional funds sooner to pursue development activities related to additional product candidates. If and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity, debt offerings, or strategic transactions.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Akebia Therapeutics Securities Corporation and Akebia Europe Limited. All intercompany balances and transactions have been eliminated in consolidation. These condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

In the quarter ended June 30, 2017, we identified and corrected an immaterial error in the amount of research and development expenses related to our global Phase 3 study of vadadustat. This adjustment also affected the amount of revenue recognized pursuant to our license and collaboration agreements with Otsuka. The adjustments impact our results of operations in each quarter of 2016 and the first quarter of 2017. We concluded the effect of these adjustments was not material to our consolidated financial statements for any prior period.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard-setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

In May 2014, the FASB, issued a new revenue recognition standard which amends revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The new standard provides a five-step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. In August 2015, the FASB deferred the effective date of the new revenue standard from January 1, 2017 to January 1, 2018. Early adoption is permitted any time after the original effective date, which for us is January 1, 2017. The Company intends to adopt the new standard on January 1, 2018. The standard allows for adoption using a full retrospective method or a modified retrospective method. The Company's historical revenue has been derived from its collaboration agreements with Mitsubishi Tanabe Pharma Corporation, or MTPC and Otsuka Pharmaceutical Co. Ltd., or Otsuka. These arrangements contain multiple-elements and have been accounted for pursuant to ASC Topic 605-25, *Revenue Recognition Multiple-Element Arrangements* (ASC 605-25). As of June 30, 2017, the Company has not commenced revenue recognition under the MTPC arrangement as the Company is not yet able to determine all of its deliverables and the total amount of arrangement consideration. The new revenue standard provides guidance in assessing what comprises the distinct service being provided to a customer that may have implications to our performance obligations and unit of account identified in our three existing collaborations which could be defined differently under the new guidance. As a result, there could be changes to the timing of revenue recognition upon adoption of the new standard. The Company is currently assessing the impact of the new revenue recognition standard on its collaboration agreements with MTPC and Otsuka and evaluating which method it will adopt.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the business of developing and commercializing proprietary therapeutics based on HIF biology.

Derivative Financial Instruments

The Company accounts for warrants and other derivative financial instruments as either equity or liabilities in accordance with ASC Topic 815, *Derivatives and Hedging* (ASC 815) based upon the characteristics and provisions of each instrument. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. The warrant issued by the Company in connection with the Janssen Pharmaceutica NV Research and License Agreement, the Janssen Agreement, is classified as equity in the Company's condensed consolidated balance sheet. (See Note 7).

Use of Estimates

The preparation of 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 the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the

following areas, among others: prepaid and accrued research and development expense, stock-based compensation expense, revenue and income taxes.

Cash and Cash Equivalents

Cash and cash equivalents consist of all cash on hand, deposits and funds invested in available-for-sale securities with original maturities of three months or less at the time of purchase. At June 30, 2017, the Company's cash is primarily in money market funds. The Company may maintain balances with its banks in excess of federally insured limits.

Investments

Management determines the appropriate classification of securities at the time of purchase and reevaluates such designation as of each balance sheet date. Currently, the Company classifies all securities as available-for-sale which are included in current assets as they are intended to fund current operations. The Company carries available-for-sale securities at fair value. The Company conducts periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. When assessing whether a decline in the fair value of a security is other-than-temporary, the Company considers the fair market value of the security, the duration of the security's decline, and prospects for the underlying business. Based on these considerations, the Company did not identify any other-than-temporary unrealized losses at June 30, 2017. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded in accumulated other comprehensive loss, a component of stockholders' equity. The amortized cost of debt securities in this category reflects amortization of premiums and accretion of discounts to maturity computed under the effective interest method. The Company includes this amortization in the caption "Interest income" within the consolidated statements of operations and comprehensive loss. The Company also includes in net investment income, realized gains and losses and declines in value determined to be other than temporary. The Company bases the cost of securities sold upon the specific identification method, and includes interest and dividends on securities in interest income.

Revenue Recognition

To date, the Company has not generated any revenue from the sales of products. For the foreseeable future, the Company expects substantially all of its revenues will be generated from its collaborations with MTPC and Otsuka (see Note 10) and any other collaborations the Company may enter into.

Multiple-Element Arrangements

The Company recognizes revenue in accordance with ASC Topic 605, *Revenue Recognition* (ASC 605). Accordingly, revenue is recognized for each unit of accounting when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;
- The seller's price to the buyer is fixed or determinable; and
- Collectability is reasonably assured.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified in current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Revenue recognition from our MTPC collaboration will commence when all criteria as required under ASC 605 have been satisfied. Therefore, collaboration revenue in the current period is generated exclusively from our collaborations agreements with Otsuka. The terms of these arrangements contain multiple deliverables, which include at inception: (i) license, (ii) development services, (iii) rights to future intellectual property and (iv) joint committee services. Non-refundable payments to the Company under these arrangements include: (i) up-front fee, (ii) payments for development services and (iii) payments based on the achievement of certain milestones. Also, under the Otsuka U.S. Agreement, the Company and Otsuka share costs incurred with respect to jointly conducted medical affairs and commercialization and non-promotional activities under the collaboration. Additionally, the Company may receive its share of net sales and bear its share of shared costs from the sale of products containing or comprising vadadustat in the United States through its U.S. collaboration with Otsuka. The Company will recognize revenue related to amounts allocated to the License Unit of Accounting on a proportional performance basis as the underlying services are performed.

The Company evaluates multiple-element arrangements based on the guidance in ASC 605-25. Pursuant to the guidance in ASC 605-25, the Company evaluates multiple-element arrangements to determine (i) the deliverables included in the arrangement and (ii) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires the Company to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered item(s) has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. In assessing whether an item has standalone value, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can use the other deliverable(s) for their intended purpose without the receipt of the remaining deliverable(s), whether the value of the deliverable is dependent on the undelivered item and whether there are other vendors that can provide the undelivered item(s). The Company's collaboration arrangements do not contain a general right of return relative to delivered item(s).

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. The Company determines the selling price for a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, the Company determines the estimated selling price for units of accounting within each arrangement using vendor-specific objective evidence (VSOE) of selling price, if available, third-party evidence (TPE) of selling price if VSOE is not available, or best estimate of selling price (BESP) if neither VSOE nor TPE is available. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting.

The Company recognizes arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605 are satisfied for that particular unit of accounting. The Company recognizes as revenue arrangement consideration attributed to licenses that have standalone value from other deliverables to be provided in an arrangement upon delivery. The Company recognizes as revenue arrangement consideration attributed to licenses that do not have standalone value from the other deliverables to be provided in an arrangement over the contractual or estimated performance period associated with the undelivered elements included in the combined unit of accounting, which is typically the term of the Company's development obligations. If there is no discernible pattern of performance and/or objectively measurable performance measures do not exist, then the Company recognizes revenue under the arrangement on a straight-line basis over the period the Company is expected to complete its performance obligations. Conversely, if the pattern of performance in which the service is provided to the customer can be determined and objectively measurable performance measures exist, then the Company recognizes revenue under the arrangement using the proportional performance method. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line method or proportional performance method, as applicable, as of the period ending date.

The Company recognizes revenue associated with milestones in accordance with the provisions of ASC Topic 605-28, *Revenue Recognition-Milestone Method*. Accordingly, at the inception of an arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (i) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from its performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. Milestones that are considered substantive are recognized as revenue in their entirety upon achievement, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive are recognized as revenue upon achievement if there are no remaining performance obligations or over the remaining period of performance if there are remaining performance obligations, assuming all other revenue recognition criteria are met. Revenue from commercial milestone payments will be accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

Collaborative Arrangements

The Company records the elements of its collaboration agreements that represent joint operating activities in accordance with ASC Topic 808, *Collaborative Arrangements* (ASC 808). Accordingly, the elements of the collaboration agreements that represent activities in which both parties are active participants and to which both parties are exposed to the significant risks and rewards that are dependent on the commercial success of the activities are recorded as collaborative arrangements. The Company considers the guidance in ASC Topic 605-45, *Revenue Recognition—Principal Agent Considerations* (ASC 605-45) in determining the appropriate treatment for the transactions between the Company and its collaborative partner and the transactions between the Company and third parties. Generally, the classification of transactions under the collaborative arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. The Company recognizes its allocation of the shared costs incurred with respect to the jointly conducted medical affairs and commercialization and non-promotional activities under the U.S. collaboration with Otsuka as a component of the related expense in the period incurred. To the extent revenue is generated from the collaboration, the Company will recognize its share of the net sales on a gross basis if it is deemed to be the principal in the transactions with customers, or on a net basis if it is instead deemed to be the agent in the transactions with customers, consistent with the guidance in ASC 605-45.

Patents

Costs incurred in connection with the application for and issuance of patents are expensed as incurred.

Income Taxes

Income taxes are recorded in accordance with FASB Topic 740, *Income Taxes* (ASC 740), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of June 30, 2017 and 2016, the Company does not have any significant uncertain tax positions. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation* (ASC 718). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, restricted stock, restricted stock units, or RSUs, and modifications to existing stock awards, to be recognized in the statements of operations and comprehensive loss based on their fair values. The Company accounts for stock-based awards to non-employees in accordance with ASC Topic 505-50, *Equity-Based Payments to Non-Employees* (ASC 505-50), which requires the fair value of the award to be re-measured at fair value until a performance commitment is reached or counterparty performance is complete. The Company's stock-based awards are comprised of stock options, shares of restricted stock, shares of common stock and warrants. The Company estimates the fair value of options granted using the Black-Scholes option pricing model. The Company uses a blend of its stock price and the quoted market price of comparable public companies to determine the fair value of restricted stock awards and common stock awards.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of company-specific historical and implied volatility data for trading the Company's stock in the public market, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. During 2017, the Company began to estimate its volatility by using a blend of its stock price history for the length of time it has market data for its stock and the historical volatility of similar public companies for the expected term of each grant. The Company is in the product development stage with no product revenue and the representative group of companies has certain similar characteristics to the Company. The Company believes the group selected has sufficient similar economic and industry characteristics, and includes companies that are most representative of the Company. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to

calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock, which is similar to the Company's peer group.

The Company's stock-based awards are subject to service based vesting conditions. Compensation expense related to awards to employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Consistent with the guidance in ASC 505- 50, compensation expense related to awards to non-employees with service-based vesting conditions is recognized on a straight-line basis based on the then-current fair value at each financial reporting date prior to the measurement date over the associated service period of the award, which is generally the vesting term.

The Company adopted ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, effective in the first quarter of the year ended December 31, 2017. Prior to adoption, share-based compensation expense was recognized on a straight line basis, net of estimated forfeitures, such that expense was recognized only for share-based awards that are expected to vest. A forfeiture rate was estimated annually and revised, if necessary, in subsequent periods if actual forfeitures differed from initial estimates. Upon adoption, the Company will no longer apply a forfeiture rate and instead will account for forfeitures as they occur.

Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC Topic 820, *Fair Value Measurements and Disclosures* (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments, and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

- Level 1 – Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2 – Valuations based on quoted prices for similar assets or liabilities in markets that are not active, or for which all significant inputs are observable, either directly or indirectly.
- Level 3 – Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Items measured at fair value on a recurring basis include short-term investments (see Note 4). The carrying amounts of prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to their short-term maturities. The rate implicit within the Company's capital lease obligation approximates market interest rates.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash and investments are the only financial instruments that potentially subject the Company to concentrations of credit risk. The Company maintains its cash with high quality, accredited financial institutions and, accordingly, such funds are subject to minimal credit risk. The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Net Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, preferred stock, stock options, warrants, unvested restricted stock and RSUs are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

Property and Equipment

Property and equipment is stated at cost, less accumulated depreciation. Assets under capital lease are included in property and equipment. Property and equipment is depreciated using the straight-line method over the estimated useful lives of the assets, generally three to seven years. Such costs are periodically reviewed for recoverability when impairment indicators are present. Such indicators include, among other factors, operating losses, unused capacity, market value declines and technological obsolescence. Recorded values of asset groups of equipment that are not expected to be recovered through undiscounted future net cash flows are written down to current fair value, which generally is determined from estimated discounted future net cash flows (assets held for use) or net realizable value (assets held for sale).

The following is the summary of property and equipment and related accumulated depreciation as of June 30, 2017 and December 31, 2016.

	Useful Life	June 30, 2017	December 31, 2016
		(in thousands)	
Computer equipment and software	3	$ 495	$ 476
Furniture and fixtures	5	800	729
Equipment	7	72	50
Leasehold improvements	Shorter of the useful life or remaining lease term (10 years)	2,226	1,763
Office equipment under capital lease	3	36	36
		3,629	3,054
Less accumulated depreciation		(695)	(442)
Net property and equipment		$ 2,934	$ 2,612

Depreciation expense, including expense associated with assets under capital leases, was approximately $0.1 million and $46,000 for the three months ended June 30, 2017 and 2016, respectively and approximately $0.3 and $0.1 million for the six months ended June 30, 2017 and 2016, respectively.

3. Strategic Collaborations and Other Significant Agreements

Mitsubishi Tanabe Pharma Corporation Collaboration Agreement

Summary of Agreement

On December 11, 2015, the Company and MTPC entered into a collaboration agreement, the MTPC Agreement, providing MTPC with exclusive development and commercialization rights to vadadustat, the Company's product candidate for the treatment of anemia related to chronic kidney disease, in Japan and certain other Asian countries, collectively, the Territory.

Pursuant to the MTPC Agreement, MTPC has an exclusive license to develop and commercialize vadadustat in the Territory. In addition, the Company will supply vadadustat for both clinical and commercial use in the Territory. The countries included in the Territory are Japan, Taiwan, South Korea, Singapore, Malaysia, India, Indonesia, East Timor, Mongolia, the Philippines, Vietnam, Laos, Cambodia, Thailand, Brunei, Myanmar, Nepal, Sri Lanka, Bangladesh, Bhutan, Maldives, Palau and Tonga and their territories.

In consideration for the exclusive license and other rights contained in the MTPC Agreement, MTPC will make payments totaling up to $350.0 million to fund the vadadustat global Phase 3 program, including up to $100.0 million in upfront and development payments, of which $40.0 million was received in January 2016. To the extent Japanese patients are included in the Phase 3 program, MTPC will fund up the balance of $60.0 million of development costs (Global Scenario).

If Japanese patients are not included in the Phase 3 program (Local Scenario), MTPC would be responsible for the costs of local development in Japan and would make no additional funding payments for the Phase 3 program. In addition, $20.0 million of the $40.0 million received in 2016 would be used to fund local development of vadadustat in Japan. The Company is currently conducting Phase 2 studies in Japan and will, if under the Local Scenario, apply the $20.0 million against the Phase 2 costs already incurred, and MTPC will reimburse the Company for costs in excess of $20.0 million to complete the studies.

The final determination of whether Japanese patients can be included in the Phase 3 program will be made by the Company and MTPC, in consultation with the Pharmaceuticals and Medical Devices Agency, PMDA, following the results of our Phase 2 studies being conducted in Japan, which is expected in the second half of 2017.

The Company is also eligible to receive up to approximately $250.0 million in additional payments based upon achievement of certain development, regulatory and sales milestones, as well as tiered double-digit royalty payments on sales of vadadustat in the Territory.

The Company and MTPC have established a joint steering committee pursuant to the agreement to oversee development and commercialization of vadadustat in the Territory, including approval of any development or commercialization plans. Unless earlier terminated, the MTPC Agreement will continue in effect on a country-by-country basis until the later of: expiration of the last-to-expire patent covering vadadustat in such country in the Territory; expiration of marketing or regulatory exclusivity in such country in the Territory; or ten years after the first commercial sale of vadadustat in such country in the Territory. MTPC may terminate the MTPC Agreement upon twelve months' notice at any time after the second anniversary of the effective date of the MTPC Agreement. Either party may terminate the MTPC Agreement upon the material breach of the other party that is not cured within a specified time period or upon the insolvency of the other party.

Revenue Recognition

The Company has evaluated all of the development, regulatory and sales milestones that may be received in connection with the MTPC Agreement. In evaluating if a milestone is substantive, the Company assesses whether: (i) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) the consideration relates solely to past performance, and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. All development and regulatory milestones are considered substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone as well as the level of effort and investment required. Accordingly, such amounts will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. The total aggregate amount of development milestones is $10.0 million and the total aggregate amount of approval milestones is up to $65.0 million. All sales milestones, up to $175.0 million, will be accounted for in the same manner as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

As of June 30, 2017, the Company cannot determine all of its deliverables or the total amount of consideration to be received for which revenue will be recognized until it knows whether vadadustat will be developed for the Japan market under a Global Scenario or under a Local Scenario. Given the uncertainty around both deliverables and the total consideration to be received, in accordance with the provisions of ASC 605-25, as of June 30, 2017, we concluded that we lack sufficient persuasive evidence of an arrangement until these uncertainties are resolved (that is, there is uncertainty regarding our rights and obligations under the arrangement). Under a Global Scenario, our deliverable will be a Services Deliverable as we will be required to include Japanese subjects in our ongoing global Phase 3 study. Under a Local Scenario, our deliverable will be a Supply Deliverable as we will not include Japanese subjects in our ongoing Phase 3 program, but will instead provide clinical supply of vadadustat to MTPC in order for MTPC to conduct a local study. The final determination will be made by the Company and MTPC in consultation with the PMDA following the results of our Phase 2 studies being conducted in Japan. Revenue recognition for the MTPC Agreement will commence when all criteria as required under ASC 605 have been satisfied, which the Company expects will be in the second half of 2017. Therefore, the $40.0 million payment received in January 2016 is recorded as deferred revenue in the accompanying consolidated balance sheets.

Otsuka Pharmaceutical Co. Ltd. U.S. Collaboration and License Agreement

Summary of Agreement

On December 18, 2016, the Company entered into a collaboration and license agreement with Otsuka, or the Otsuka U.S. Agreement. The collaboration is focused on the development and commercialization of vadadustat in the United States. Under the terms of the Otsuka U.S. Agreement, the Company will continue to lead the development of vadadustat, including the ongoing Phase 3

development program. The Company and Otsuka will co-commercialize vadadustat in the United States, subject to the approval of vadadustat by the FDA.

Under the terms of the Otsuka U.S. Agreement, the Company granted to Otsuka a co-exclusive, non-sublicensable license under certain intellectual property controlled by the Company solely to perform medical affairs activities and to conduct non-promotional and commercialization activities related to vadadustat in accordance with the associated plans. The co-exclusive license relates to activities that will be jointly conducted by the Company and Otsuka pursuant to the terms of the Otsuka U.S. Agreement.

Pursuant to the terms of the Otsuka U.S. Agreement, the Company is responsible for performing all activities related to the development of vadadustat as outlined in the current global development plan. The current global development plan encompasses all activities with respect to the ongoing PRO_2TECT and $INNO_2VATE$ clinical programs that are necessary through the filing for regulatory approval, as well as other studies. Under the Otsuka U.S. Agreement, the Company controls and retains final decision making authority with respect to the development of vadadustat. The Company's obligations related to the conduct of the current global development plan include the associated manufacturing and supply services for vadadustat.

Under the Otsuka U.S. Agreement, the parties jointly conduct, and have equal responsibility for, all medical affairs, commercialization and non-promotional activities pursuant to underlying plans as agreed to by the parties. If approved by the FDA, the Company will provide vadadustat to Otsuka for commercialization pursuant to a separate supply agreement to be negotiated.

The activities under the Otsuka U.S. Agreement are governed by a joint steering committee, or JSC, formed by an equal number of representatives from the Company and Otsuka. The JSC coordinates and monitors the parties' activities under the collaboration. Among other responsibilities, the JSC manages the overall strategic alignment between the parties, oversees the current global development plan and reviews the other detailed plans setting forth the parties' activities under the arrangement, including the medical affairs plan and commercialization and non-promotional activities plan. Additionally, the parties established a joint development committee, or JDC, which is comprised of an equal number of representatives from the Company and Otsuka. Among other responsibilities, the JDC will share information related to, and review and discuss activities and progress under, the current global development plan and any other development that may be conducted pursuant to the collaboration. In support of the potential commercialization of vadadustat, the parties will establish a joint commercialization committee, or JCC, which will be comprised of an equal number of representatives from the Company and Otsuka. Among other responsibilities, the JCC will manage the activities and progress under the commercialization and non-promotional activities plan and all other sales and marketing activities. The Company has retained the final decision making authority with respect to all development matters, pricing strategy and certain other key commercialization matters.

Under the terms of the Otsuka U.S. Agreement, the Company received a $125.0 million up-front, non-refundable, non-creditable cash payment in December 2016. In March 2017, the Company received a payment of approximately $33.8 million which represents reimbursement for Otsuka's share of costs previously incurred by the Company in implementing the current global development plan through December 31, 2016. Going forward, Otsuka will contribute a percentage of the remaining costs to be incurred under the current global development plan subsequent to December 31, 2016, commencing upon the date on which the Company has incurred a specified amount of incremental costs. The Company estimates that Otsuka's funding of the current global development plan costs subsequent to December 31, 2016 will total $153.6 million or more. The costs associated with the performance of any development activities in addition to those outlined in the current global development plan will be subject to a cost sharing or reimbursement mechanism to be determined by the parties. Costs incurred with respect to medical affairs and commercialization and non-promotional activities will generally be shared equally by the parties. Either party's share of the medical affairs and/or commercialization activities may be increased at such party's request upon mutual agreement of the parties. In addition, if the costs incurred in completing the activities under the current global development plan exceed a certain threshold, then the Company may elect to require Otsuka to fund a higher percentage of the current global development costs. In such event, the excess of the payments made under such election and Otsuka's allocated share of the current global development costs is fully creditable against future payments due to the Company under the arrangement.

In addition, Otsuka would be required to make certain milestone payments to the Company upon the achievement of specified development, regulatory and commercial events. More specifically, the Company is eligible to receive up to $125.0 million in development milestone payments and up to $65.0 million in regulatory milestone payments for the first product to achieve the associated event. Moreover, the Company is eligible for up to $575.0 million in commercial milestone payments associated with aggregate sales of all products. Due to the uncertainty of pharmaceutical development and the high historical failure rates associated therewith, no milestone payments may ever be received from Otsuka.

Under the Otsuka U.S. Agreement, the Company and Otsuka share the costs of developing and commercializing vadadustat in the United States and the profits from the sales of vadadustat after approval by the FDA. In connection with the profit share calculation, net sales include gross sales to third-party customers net of discounts, rebates, chargebacks, taxes, freight and insurance charges and other applicable deductions. Shared costs generally include costs attributable or reasonably allocable to the manufacture of vadadustat

for commercialization purposes and the performance of medical affairs activities, non-promotional activities and commercialization activities.

Under the Otsuka U.S. Agreement, Otsuka originally had a limited period of time in which it can exercise an option to convert the arrangement from a profit share to a right to receive a mid-single digit royalty on future net sales of commercialized products (the Royalty Conversion Option). On August 4, 2017, Otsuka agreed to waive its right to exercise the Royalty Conversion Option, consequently, Otsuka has no further right to elect to exercise this option.

Unless earlier terminated, the Agreement will expire on a country-by-country and product-by-product basis on the date that one or more generic versions of vadadustat first achieves 90% market penetration. Either party may terminate the Otsuka U.S. Agreement in its entirety upon an uncured breach or insolvency on the part of the other party. Otsuka may terminate the Otsuka U.S. Agreement in its entirety upon 12 months' prior written notice at any time after the release of the first topline data from the global Phase 3 development program. In the event of termination of the Otsuka U.S. Agreement, all rights and licensees granted to Otsuka under the Otsuka U.S. Agreement will automatically terminate and the licenses granted to the Company will become freely sublicensable. In addition, the upfront payment, all development costs and milestone payments received by the Company prior to such termination will not be refunded to Otsuka.

Revenue Recognition

The Company evaluated the elements of the Otsuka US Agreement in accordance with the provisions of ASC 605-25. The Company's arrangement with Otsuka contains the following deliverables: (i) license under certain of the Company's intellectual property to develop, perform medical affairs activities with respect to and conduct non-promotional and commercialization activities related to vadadustat and products containing or comprising vadadustat (the License Deliverable), (ii) development services to be performed pursuant to the current global development plan (the Development Services Deliverable), (iii) rights to future intellectual property (the Future IP Deliverable), and (iv) joint committee services (the Committee Deliverable).

The Company has identified three units of accounting in connection with its obligations under the Otsuka U.S. Agreement. Factors considered in making the assessment of standalone value included, among other things, the capabilities of the collaboration partner, whether any other vendor sells the item separately, whether the value of the deliverable is dependent on the other elements in the arrangement, whether there are other vendors that can provide the items and if the customer could use the item for its intended purpose without the other deliverables in the arrangement. Additionally, the Otsuka U.S. Agreement does not include a general right of return. The three units of accounting identified in connection with the Company's obligations under the Otsuka U.S. Agreement are as follows:

(i) License and Development Services Combined (License Unit of Accounting)

The License Deliverable does not qualify for separation from the Development Services Deliverable, due to the contractual limitations inherent in the license conveyed. More specifically, Otsuka does not have the contractual right to manufacture vadadustat and products containing or comprising vadadustat. However, the manufacturing and supply services that are conducted as part of the services to be performed pursuant to the current global development plan are necessary for Otsuka to fully exploit the associated license for its intended purpose. The value of the rights provided through the license conveyed will be realized when the underlying products covered by the intellectual property progress through the development cycle, receive regulatory approval and are commercialized. Products containing or comprising vadadustat cannot be commercialized until the development services under the current global development plan are completed. Accordingly, Otsuka must obtain the manufacturing and supply of the associated products that is included within the development services to be performed pursuant to the current global development plan from the Company in order to derive benefit from the license which significantly limits the ability for Otsuka to utilize the License Deliverable for its intended purpose on a standalone basis.

(ii) Rights to Future Intellectual Property

The License Deliverable and the Development Services Deliverable qualify for separation from the Future IP Deliverable because Otsuka can obtain the value of the license using the clinical trial materials implicit in the development services without the receipt of any other intellectual property that may be discovered or developed in the future. The Future IP Deliverable qualifies for separation from the Committee Deliverable because the joint committee services have no bearing on the value to be derived from the rights to potential future intellectual property.

(iii) Joint Committee Services

The License Deliverable and Development Services Deliverable qualify for separation from the Committee Deliverable because Otsuka can obtain the value of the license using the clinical trial materials implicit in the development services without the joint committee services. The Committee Deliverable has standalone value from the rights to Future IP Deliverable because the joint committee services have no bearing on the value to be derived from the rights to potential future intellectual property.

The Company has determined that neither VSOE of selling price nor TPE of selling price is available for any of the units of accounting identified at inception of the arrangement with Otsuka. Accordingly, the selling price of each unit of accounting was determined based on the Company's BESP. The Company developed the BESP with the objective of determining the price at which it would sell such an item if it were to be sold regularly on a standalone basis. In developing the BESP for the Joint Committee Services Unit of Accounting, the Company considered the nature of the services to be performed and estimates of the associated effort and rates applicable to such services that would be expected to be realized under similar contracts. The Company developed the BESP for the Rights to Future Intellectual Property Unit of Accounting primarily based on the likelihood that additional intellectual property covered by the license conveyed will be developed during the term of the arrangement. The Company did not develop a BESP for the License Unit of Accounting due to the following: (i) the BESP associated with the Rights to Future Intellectual Property Unit of Accounting was determined to be immaterial and (ii) the period of performance and pattern of recognition for the License Unit of Accounting and the Joint Committee Services Unit of Accounting was determined to be similar. The Company has concluded that a change in the key assumptions used to determine the BESP for each unit of accounting would not have a significant impact on the allocation of arrangement consideration.

Allocable arrangement consideration at inception is comprised of: (i) the up-front payment of $125.0 million, (ii) the cost share payment with respect to amounts incurred by the Company through December 31, 2016 of $33.8 million and (iii) an estimate of the cost share payments to be received with respect to amounts incurred by the Company subsequent to December 31, 2016 of $153.6 million. No amounts were allocated to the Rights to Future Intellectual Property Unit of Accounting because the associated BESP was determined to be immaterial. Due to the similar performance period and recognition pattern between the License Unit of Accounting and the Joint Committee Services Unit of Accounting, the arrangement consideration totaling $312.4 million has been allocated to the License Unit of Accounting and the Joint Committee Services Unit of Accounting on a combined basis. Accordingly, the Company will recognize revenue related to the allocable arrangement consideration on a proportional performance basis as the underlying development services are performed pursuant to the current global development plan which is commensurate with the period and consistent with the pattern over which the Company's obligations are satisfied for both the License Unit of Accounting and the Joint Committee Services Unit of Accounting. Effectively, the Company has treated the arrangement as if the License Unit of Accounting and the Joint Committee Services Unit of Accounting are a single unit of accounting.

The Company has evaluated all of the development, regulatory and commercial milestones that may be received in connection with the Otsuka U.S. Agreement. In evaluating if a milestone is substantive, the Company assesses whether: (i) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) the consideration relates solely to past performance, and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. All development and regulatory milestones are considered substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone as well as the level of effort and investment required. Accordingly, such amounts will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. All commercial milestones will be recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

During the three and six months ended June 30, 2017, the Company recognized revenue totaling approximately $16.6 million and $37.5 million, respectively, with respect to the Otsuka U.S. Agreement. The revenue is classified as collaboration revenue in the accompanying consolidated statement of operations. As of June 30, 2017, there is approximately $119.8 million of deferred revenue related to the Otsuka U.S. Agreement of which $112.3 million is classified as current and $7.5 million is classified as long-term in the accompanying consolidated balance sheet based on the performance period of the underlying obligations. During the three months ended June 30, 2017, the Company did not incur any costs related to the cost-sharing provisions of the Otsuka U.S. Agreement.

The Company determined that the medical affairs and commercialization and non-promotional activities elements of the Otsuka U.S. Agreement represent joint operating activities in which both parties are active participants and of which both parties are exposed to significant risks and rewards that are dependent on the commercial success of the activities. Accordingly, the Company is accounting for the joint medical affairs and commercialization and non-promotional activities in accordance with ASC No. 808, *Collaborative Arrangements* (ASC 808). Additionally, the medical affairs and commercialization and non-promotional activities were not deemed to be deliverables under ASC No. 605-25, *Revenue Recognition–Multiple-Element Arrangements* (ASC 605-25). As a result, the activities conducted pursuant to the medical affairs and commercialization and non-promotional activities plans will be accounted for as a component of the related expense in the period incurred.

Otsuka Pharmaceutical Co. Ltd. EU Collaboration and License Agreement

Summary of Agreement

On April 25, 2017, the Company entered into a collaboration and license agreement with Otsuka, the Otsuka EU Agreement. The collaboration is focused on the development and commercialization of vadadustat in Europe, Russia, China, Canada, Australia, the

Middle East and certain other territories, collectively, the Territory. Under the terms of the Otsuka EU Agreement, the Company will continue to lead the development of vadadustat, including the ongoing global Phase 3 development program. Otsuka has the sole responsibility, at its own cost, for the commercialization of vadadustat in the Territory, subject to the approval by the relevant regulatory authorities.

Under the terms of the Otsuka EU Agreement, the Company granted to Otsuka an exclusive, sublicensable license under certain intellectual property controlled by the Company to develop and commercialize vadadustat and products containing or comprising vadadustat in the Territory.

Pursuant to the terms of the Otsuka EU Agreement, the Company is responsible for performing all activities related to the development of vadadustat as outlined in the current global development plan; however, the parties may agree to allocate certain responsibilities to Otsuka. The current global development plan encompasses all activities with respect to the ongoing PRO_2TECT and $INNO_2VATE$ program, as well as other studies, through the filing for regulatory approval. The current global development plan also includes other derivative and ancillary studies. Under the Otsuka EU Agreement, the Company controls and retains final decision-making authority with respect to the development of vadadustat other than with respect to certain development matters specific to the Territory. Per the terms of the Otsuka EU Agreement, Otsuka is generally responsible for the conduct of any development activities that may be required for regulatory approval in the Territory or otherwise performed with respect to the Territory that are incremental to those included in the current global development plan. The Company's obligations related to the conduct of the current global development plan include the associated manufacturing and supply services for vadadustat.

Under the Otsuka EU Agreement, Otsuka is to be solely responsible for the conduct of all medical affairs and commercialization activities in the Territory pursuant to underlying plans as reviewed and discussed by the parties. If approved by the relevant jurisdictional regulatory health authorities in the Territory, the Company will provide vadadustat to Otsuka for commercialization pursuant to a separate supply agreement to be negotiated.

The activities under the Otsuka EU Agreement are governed by a JSC formed by up to a specified number of representatives from the Company and Otsuka. The JSC coordinates and monitors the parties' activities under the collaboration. Among other responsibilities, the JSC manages the overall strategic alignment between the parties, oversees the current global development plan and reviews the other detailed plans setting forth any other development activities that may be conducted under the arrangement. Additionally, the parties established a JDC which is be comprised of up to a specified number of representatives from the Company and Otsuka. Among other responsibilities, the JDC shares information related to, and reviews and discusses activities and progress under, the current global development plan and any other development that may be conducted pursuant to the collaboration. The Company and Otsuka also established a joint manufacturing committee, or JMC, which is comprised of up to a specified number of representatives from each of the parties. Among other responsibilities, the JMC oversees the manufacturing plan and related manufacturing activities. In support of the potential commercialization of vadadustat, the parties established a JCC which is comprised of up to a specified number of representatives from the Company and Otsuka. Among other responsibilities, the JCC reviews and discusses the activities and progress under the commercialization plan and all other sales and marketing activities. The Company has retained the final decision making authority with respect to all development matters, other than decisions related to certain development matters specific to the Territory. Otsuka has retained the final decision making authority with respect to all commercialization matters, other than decisions related to certain marketing matters.

Under the terms of the Otsuka EU Agreement, the Company received a $73.0 million up-front, non-refundable, non-creditable cash payment. The Company also received a payment of approximately $0.2 million which represents reimbursement for Otsuka's share of costs previously incurred by the Company in implementing the current global development plan in excess of a specified threshold during the quarter-ended March 31, 2017. Additionally, Otsuka will contribute a percentage of the remaining costs to be incurred under the current global development plan subsequent to March 31, 2017. The Company estimates that Otsuka's funding of the current global development plan costs subsequent to March 31, 2017 will total roughly $163.6 million. The costs associated with the performance of any mutually agreed upon development activities in addition to those outlined in the current global development plan will be subject to a cost sharing or reimbursement mechanism to be determined by the parties. Otsuka may elect to conduct additional studies of vadadustat in the EU, subject to the Company's right to delay such studies based on its objectives outside the Territory. Otsuka will pay a percentage of the costs of any such studies, and the Company will pay its portion of the costs in the form of a credit against future amounts due to the Company under the Otsuka EU Agreement. The costs incurred related to any other development activities, which are pursued solely for obtaining or maintaining regulatory approval in the Territory or otherwise performed solely with respect to the Territory that are incremental to the development activities included in the current global development plan will be borne in their entirety by Otsuka. Otsuka will pay costs incurred with respect to medical affairs and commercialization activities in the Territory.

In addition, Otsuka would be required to make certain milestone payments to the Company upon the achievement of specified development, regulatory and commercial events. More specifically, the Company is eligible to receive up to $80.0 million in development milestone payments and up to $52.0 million in regulatory milestone payments for the first product to achieve the associated event. Moreover, the Company is eligible for up to $525.0 million in commercial milestone payments associated with

aggregate sales of all products. Additionally, to the extent vadadustat is commercialized, the Company would be entitled to receive tiered royalty payments ranging from the low double digits to the low thirties based on a percentage of net sales. Royalties are due on a country-by-country basis from the date of the first commercial sale of a licensed product in a country until the latest to occur of: (i) the expiration date in such country of the last to expire valid claim within the intellectual property covering the licensed product, (ii) the date of expiration of data or regulatory exclusivity in such country or (iii) the tenth anniversary of the first commercial sale of such licensed product in such country. Due to the uncertainty of pharmaceutical development and the high historical failure rates associated therewith, no milestone or royalty payments may ever be received from Otsuka. There are no cancellation, termination or refund provisions in the Otsuka EU Agreement that contain material financial consequences to the Company.

Unless earlier terminated, the Otsuka EU Agreement will expire upon the expiration of the royalty term in the last country in the Territory. Either party may terminate the Otsuka EU Agreement in its entirety upon an uncured material breach or insolvency on the part of the other party. Otsuka may terminate the Otsuka EU Agreement in its entirety or for a specific sub-division of the Territory upon 12 months' prior written notice at any time after the release of the first topline data from either the PRO_2TECT Phase 3 development program or the $INNO_2$VATE Phase 3 development program, whichever comes first. In the event of termination of the Otsuka EU Agreement, all rights and licensees granted to Otsuka under the Otsuka U.S. Agreement will automatically terminate and the licenses granted to the Company will become freely sublicensable, but potentially subject to a future royalty. In addition, the upfront payment, all development costs and milestone payments received by the Company prior to such termination will not be eligible for refund to Otsuka.

Revenue Recognition

The Company has accounted for the Otsuka EU Agreement separately from the collaboration arrangement with Otsuka with respect to the U.S. due to the lack of interrelationship and interdependence of the elements and payment terms within each of the contracts as it relates to the respective territories. Accordingly, the Company has applied the guidance in ASC No. 605-25, *Revenue Recognition–Multiple-Element Arrangements* (ASC 605-25) solely in reference to the terms and conditions of the Otsuka EU Agreement, while the collaboration arrangement with Otsuka related to the U.S. has continued to be accounted for as a discrete agreement in its own right. The Company evaluated the Otsuka EU Agreement in accordance with the provisions of ASC 605-25. The Company's arrangement with Otsuka related to the Territory contains the following deliverables: (i) license under certain of the Company's intellectual property to develop and commercialize (including the associated packaging) vadadustat and products containing or comprising vadadustat (the License Deliverable), (ii) development services to be performed pursuant to the current global development plan (the Development Services Deliverable), (iii) rights to future intellectual property (the Future IP Deliverable) and (iv) joint committee services (the Committee Deliverable).

The Company has identified three units of accounting in connection with its obligation under the Otsuka EU Agreement. Factors considered in making this assessment included, among other things, the capabilities of the collaboration partner, whether any other vendor sells the item separately, whether the value of the deliverable is dependent on the other elements in the arrangement, whether there are other vendors that can provide the items and if the customer could use the item for its intended purpose without the other deliverables in the arrangement. Additionally, the Otsuka EU Agreement does not include a general right of return. The three units of accounting identified in connection with the Company's obligations under the Otsuka EU Agreement are as follows:

(i) *License and Development Services Combined (License Unit of Accounting)*

The License Deliverable does not qualify for separation from the Development Services Deliverable due to the contractual limitations inherent in the license conveyed. More specifically, Otsuka does not have the contractual right to manufacture vadadustat and products containing or comprising vadadustat. However, the manufacturing and supply services that are conducted as part of the services to be performed pursuant to the current global development plan are necessary for Otsuka to fully exploit the associated license for its intended purpose. The value of the rights provided through the license conveyed will be realized when the underlying products covered by the intellectual property progress through the development cycle, receive regulatory approval and are commercialized. Products containing or comprising vadadustat cannot be commercialized until the development services under the current global development plan are completed. Accordingly, Otsuka must obtain the manufacturing and supply of the associated products that is included within the development services to be performed pursuant to the current global development plan from the Company in order to derive benefit from the license which significantly limits the ability for Otsuka to utilize the License Deliverable for its intended purpose on a standalone basis. Therefore, the License Deliverable does not have standalone value from the Development Services Deliverable. As a result, the License Deliverable and the Development Services Deliverable have been combined as a single unit of accounting (the License Unit of Accounting).

(ii) *Rights to Future Intellectual Property*

The License Deliverable and the Development Services Deliverable qualify for separation from the Future IP Deliverable because Otsuka can obtain the value of the license using the clinical trial materials implicit in the development services without the receipt of any other intellectual property that may be discovered or developed in the future. The Future IP

Deliverable qualifies for separation from the Committee Deliverable because the Committee Services Deliverable has no bearing on the value to be derived from the rights to potential future intellectual property.

(iii) *Joint Committee Services*

The License Deliverable and the Development Services deliverable qualify for separation from the Committee Deliverable because Otsuka can obtain the value of the license using the clinical trial materials implicit in the development service without the joint committee services. The Committee Deliverable qualifies for separation from the Future IP Deliverable because the Committee Deliverable has no bearing on the value to be derived from the rights to potential future intellectual property.

The Company has determined that neither VSOE of selling price nor TPE of selling price is available for any of the units of accounting identified at inception of the arrangement with Otsuka. Accordingly, the selling price of each unit of accounting was determined based on the Company's BESP. The Company developed the BESP with the objective of determining the price at which it would sell such an item if it were to be sold regularly on a standalone basis. In developing the BESP for the Joint Committee Services Unit of Accounting, the Company considered the nature of the services to be performed and estimates of the associated effort and rates applicable to such services that would be expected to be realized under similar contracts. The Company developed the BESP for the Rights to Future Intellectual Property Unit of Accounting primarily based on the likelihood that additional intellectual property covered by the license conveyed will be developed during the term of the arrangement. The Company did not develop a BESP for the License Unit of Accounting due to the following: (i) the BESP associated with the rights to future intellectual property unit of accounting was determined to be immaterial and (ii) the period of performance and pattern of recognition for the License Unit of Accounting and the joint committee services unit of accounting was determined to be similar. The Company has concluded that a change in the key assumptions used to determine the BESP for each unit of accounting would not have a significant impact on the allocation of arrangement consideration.

Allocable arrangement consideration at inception is comprised of: (i) the up-front payment of $73.0 million, (ii) the cost share payment with respect to amounts incurred by the Company during the quarter ended March 31, 2017 of $0.2 million and (iii) an estimate of the cost share payments to be received with respect to amounts incurred by the Company subsequent to March 31, 2017 of $163.6 million. No amounts were allocated to the Rights to Future Intellectual Property Unit of Accounting because the associated BESP was determined to be immaterial. Due to the similar performance period and recognition pattern between the License Unit of Accounting and the Joint Committee Services Unit of Accounting, the arrangement consideration totaling $236.7 million has been allocated to the License Unit of Accounting and the Joint Committee Services Unit of Accounting on a combined basis. Accordingly, the Company will recognize revenue related to the allocable arrangement consideration on a proportional performance basis as the underlying development services are performed pursuant to the current global development plan which is commensurate with the period and consistent with the pattern over which the Company's obligations are satisfied for both the License Unit of Accounting and the Joint Committee Services Unit of Accounting. Effectively, the Company has treated the arrangement as if the License Unit of Accounting and the Joint Committee Services Unit of Accounting are a single unit of accounting.

The Company has evaluated all of the development, regulatory and commercial milestones that may be received in connection with the Otsuka EU Agreement. In evaluating if a milestone is substantive, the Company assesses whether: (i) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) the consideration relates solely to past performance, and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. All development and regulatory milestones are considered substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone as well as the level of effort and investment required. Accordingly, such amounts will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. All commercial milestones will be accounted for in the same manner as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

During the three and six months ended June 30, 2017, the Company recognized revenue totaling approximately $11.9 million with respect to the Otsuka EU Agreement. The revenue is classified as collaboration revenue in the accompanying consolidated statement of operations. As of June 30, 2017, there is approximately $73.4 million of deferred revenue related to the Otsuka EU Agreement of which $30.1 million is classified as current and $43.3 million is classified as long-term in the accompanying consolidated balance sheet based on the performance period of the underlying obligations.

Janssen Pharmaceutica NV Research and License Agreement

Summary of Agreement

In February 2017, the Company entered into a Research and License Agreement, the Janssen Agreement, with Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson and Johnson, Janssen, pursuant to which Janssen granted the Company an exclusive license under certain intellectual property rights to develop and commercialize worldwide certain HIF-PH targeted compounds.

Under the terms of the Janssen Agreement, Janssen granted to the Company a license for a three-year research term to conduct research on the HIF compound portfolio, unless the Company elects to extend such research term for up to two additional one-year periods upon payment of an extension fee. During the research term, the Company may designate one or more compounds as candidates for development and commercialization. Once a compound is designated for development and commercialization, the Company will be solely responsible for the development and commercialization of the compound worldwide at its own cost and expense. The Janssen Agreement includes a license to develop and commercialize AKB-5169, a preclinical compound in development as an oral treatment for inflammatory bowel disease, or IBD.

Under the terms of the Janssen Agreement, the Company made an upfront payment of $1.0 million in cash to Janssen and issued a warrant to purchase 509,611 share of the Company's common stock, the fair value of which was approximately $3.4 million, the total of which was recorded in research and development expenses for the three months ended March 31, 2017. In addition, Janssen could be eligible to receive up to an aggregate of $16.5 million from the Company in specified development milestone payments on a product-by-product basis. Janssen will also be eligible to receive up to $215.0 million from the Company in specified commercial milestones as well as tiered, escalating royalties ranging from a low to mid-single digit percentage of net sales, on a product-by-product basis.

Unless earlier terminated, the Janssen Agreement will expire on a product-by-product and country-by-country basis upon the expiration of the last royalty term, which ends upon the longer of the expiry of the patents licensed under the Janssen Agreement, the expiry of regulatory exclusivity for such product, or 10 years from first commercial sale of such product. The Company may terminate the Janssen Agreement in its entirety or only with respect to a particular licensed compound or product upon 180 days' prior written notice to Janssen. The parties also have customary termination rights, subject to a cure period, in the event of the other party's material breach of the Janssen Agreement or in the event of certain additional circumstances.

As discussed above, the Company issued a Common Stock Purchase Warrant, the Warrant, to Johnson & Johnson Innovation – JJDC, Inc., or JJDC, an affiliate of Janssen, for 509,611 shares of the Company's common stock at an exercise price of $9.81 per share. The Warrant is exercisable by JJDC, in whole or in part, at any time prior to the fifth anniversary of the date of issuance. The Warrant and the shares issuable upon exercise of the Warrant will be sold and issued without registration under the Securities Act of 1933, or the Securities Act. The Company recorded the fair value of the warrant in the amount of $3.4 million to additional paid in capital and research and development expense in March 2017.

Vifor (International) Ltd. License Agreement

Summary of Agreement

In May 2017, the Company entered into a License Agreement with Vifor (International) Ltd., or Vifor, the Vifor Agreement, pursuant to which the Company will grant Vifor an exclusive license to sell vadadustat solely to Fresenius Kidney Care Group LLC, or FKC, an affiliate of Fresenius Medical Care North America, in the United States (the "Territory").

The parties' rights under the Vifor Agreement are conditioned upon the approval of vadadustat for DD-CKD patients by the FDA, inclusion of vadadustat in a bundled reimbursement model, and payment by Vifor of a $20.0 million milestone upon the occurrence of these two events. The Vifor Agreement is structured as a profit share arrangement between the Company and Vifor in which the Company will receive a majority of the profit from Vifor's sales of vadadustat to FKC in the Territory. The Company will share the milestone payment and the revenue from the profit share with Otsuka pursuant to the Otsuka U.S Agreement. The Company retains all rights to commercialize vadadustat for use in the NDD-CKD market and in other dialysis organizations in the Territory, which will be done in collaboration with Otsuka following FDA approval.

Prior to FDA approval of vadadustat, the Company and Vifor will enter into a commercial supply agreement for vadadustat pursuant to which the Company will supply all of Vifor's requirements for vadadustat in the Territory. In addition, Vifor will enter into a supply agreement with FKC that will govern the terms pursuant to which Vifor will supply vadadustat to FKC for use in patients at its dialysis centers. During the term of the Vifor Agreement, Vifor will not sell to FKC or its affiliates any HIF product that competes with vadadustat in the Territory.

Unless earlier terminated, the Vifor Agreement will expire upon the later of the expiration of all patents that claim or cover vadadustat, or expiration of data or regulatory exclusivity for vadadustat in the Territory. Vifor may terminate the Vifor Agreement in its entirety upon 12 months' prior written notice after the release of the first topline data in the vadadustat global Phase 3 program for dialysis-dependent CKD patients. Either party may terminate the Vifor Agreement in the event of the other party's uncured material breach. The Company may also terminate the Vifor Agreement upon the occurrence of other events, such as for specific violations of the Vifor Agreement or if there are changes in Vifor's relationship with FKC.

Investment Agreement

In connection with the Vifor Agreement, in May 2017, the Company and Vifor entered into an investment agreement, the Investment Agreement, pursuant to which the Company sold an aggregate of 3,571,429 shares of common stock, the Shares, par value $0.00001 per share, to Vifor at a price per share of $14.00 for a total of $50.0 million dollars. The amount representing the premium over the closing stock price of $12.69 on the date of the transaction, totaling $4.7 million, was determined by the Company to represent consideration related to the Vifor Agreement. As the parties' rights under the Vifor Agreement are conditioned upon (a) the approval of vadadustat for DD-CKD patients by the FDA; (b) inclusion of vadadustat in a bundled reimbursement model; and (c) payment by Vifor of a $20.0 million milestone upon the occurrence of these two events, in accordance with ASC 605, the Company cannot currently determine the extent of its responsibility to supply all of Vifor's requirements for vadadustat in the Territory. Accordingly, the $4.7 million is recorded as deferred revenue in the accompanying consolidated balance sheets. Upon the satisfaction of the aforementioned conditions, revenue will be recognized as the Company supplies vadadustat to Vifor using a proportional performance method.

Vifor has agreed to a lock-up restriction such that it agrees not to sell its shares for a period of time following the effective date of the Investment Agreement as well as a customary standstill agreement. In addition, the Investment Agreement contains voting agreements made by Vifor with respect to the Shares. The Shares have not been registered pursuant to Securities Act of 1933, the "Act", and were issued and sold in reliance upon the exemption from registration contained in Section 4(a)(2) of the Act and Rule 506 promulgated thereunder.

4. Available for sale securities

Available for sale securities at June 30, 2017 and December 31, 2016 consist of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
June 30, 2017				
Cash and cash equivalents	$ 125,390	$ —	$ —	$ 125,390
Available for sale securities:				
Certificates of deposit	$ 14,855	—	—	$ 14,855
U.S. Government debt securities	128,413	—	(187)	128,226
Corporate debt securities	52,810		(66)	52,744
Total available for sale securities	$ 196,078	$ —	$ (253)	$ 195,825
Total cash, cash equivalents, and available for sale securities	$ 321,468	$ —	$ (253)	$ 321,215

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
December 31, 2016				
Cash and cash equivalents	$ 187,335	$ —	$ —	$ 187,335
Available for sale securities:				
Certificates of deposit	$ 12,698	—	—	$ 12,698
U.S. Government debt securities	50,952	—	(32)	50,920
Corporate debt securities	9,398	—	(8)	9,390
Total available for sale securities	$ 73,048	$ —	$ (40)	$ 73,008
Total cash, cash equivalents, and available for sale securities	$ 260,383	$ —	$ (40)	$ 260,343

The estimated fair value of the Company's available for sale securities balance at June 30, 2017, by contractual maturity, is as follows:

Due in one year or less	$	191,182
Due after one year		4,643
Total available for sale securities	$	195,825

5. Fair Value of Financial Instruments

The Company utilizes a portfolio management company for the valuation of the majority of its investments. This company is an independent, third-party vendor recognized to be an industry leader with access to market information that obtains or computes fair market values from quoted market prices, pricing for similar securities, recently executed transactions, cash flow models with yield curves and other pricing models. For valuations obtained from the pricing service, the Company performs due diligence to understand how the valuation was calculated or derived, focusing on the valuation technique used and the nature of the inputs.

Based on the fair value hierarchy, the Company classifies its cash equivalents and marketable securities within Level 1 or Level 2. This is because the Company values its cash equivalents and marketable securities using quoted market prices or alternative pricing sources and models utilizing market observable inputs.

Assets measured or disclosed at fair value on a recurring basis as of June30, 2017 and December 31, 2016 are summarized below:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
June 30, 2017				
Assets:				
Cash and cash equivalents	$ 125,390	$ —	$ —	$ 125,390
Certificates of deposit	—	14,855	—	14,855
U.S. Government debt securities	—	128,226	—	128,226
Corporate debt securities	—	52,744	—	52,744
	$ 125,390	$ 195,825	$ —	$ 321,215

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
December 31, 2016				
Assets:				
Cash and cash equivalents	$ 187,335	$ —	$ —	$ 187,335
Certificates of deposit	—	12,698	—	12,698
U.S. Government debt securities	—	50,920	—	50,920
Corporate debt securities	—	9,390	—	9,390
	$ 187,335	$ 73,008	$ —	$ 260,343

The Company's corporate debt securities are all investment grade.

The Company had no assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) at June 30, 2017 and December 31, 2016.

Investment securities are exposed to various risks such as interest rate, market and credit risks. Due to the level of risk associated with certain investment securities and the level of uncertainty related to changes in the value of investment securities, it is at least reasonably possible that changes in risks in the near term would result in material changes in the fair value of investments.

6. Accrued Expenses

Accrued expenses are as follows:

	June 30, 2017	December 31, 2016
	(in thousands)	
Accrued clinical expenses	$ 22,576	$ 23,643
Accrued bonus	1,750	2,995
Accrued professional fees	761	539
Accrued vacation	681	513
Accrued payroll	646	596
Accrued other	2,437	1,975
Total accrued expenses	$ 28,851	$ 30,261

7. Warrant

In connection with the Janssen Agreement, in February 2017 the Company issued a warrant to purchase 509,611 shares of the Company's common stock at an exercise price of $9.81 per share. The warrant is fully vested upon issuance and exercisable in whole or in part, at any time prior to the fifth anniversary of the date of issuance. The warrant satisfied the equity classification criteria of ASC 815, and is therefore classified as an equity instrument. The fair value at issuance of $3.4 million was calculated using the Black Scholes option pricing model and was charged to research and development expense as it represented consideration for a license for which the underlying intellectual property was deemed to have no alternative future use. As of June 30, 2017, the warrant remains outstanding and expires on February 9, 2022.

8. Stockholders' Equity

Authorized and Outstanding Capital Stock

As of June 30, 2017, the authorized capital stock of the Company included 175,000,000 shares of common stock, par value $0.00001 per share, of which 42,490,957 and 38,615,709 shares are issued and outstanding at June 30, 2017 and December 31, 2016, respectively; and 25,000,000 shares of undesignated preferred stock, par value $0.00001 per share, of which 0 shares are issued and outstanding at June 30, 2017 and December 31, 2016.

Equity Plans

On February 28, 2014, the Company's Board of Directors adopted its 2014 Incentive Plan (the "2014 Plan") and its 2014 Employee Stock Purchase Plan (the "ESPP"), which were subsequently approved by its stockholders and became effective upon the closing of the Company's initial public offering IPO on March 25, 2014. The 2014 Plan replaced the 2008 Equity Incentive Plan (as amended, the "2008 Plan"), however, options or other awards granted under the 2008 Plan prior to the adoption of the 2014 Plan that have not been settled or forfeited remain outstanding and effective. In May 2016 the Company's Board of Directors approved an inducement award program that was separate from the Company's equity plans and which, consistent with NASDAQ listing rules, did not require shareholder approval (the 2016 program and similar programs, each an "Inducement Award Program") under which 350,000 shares were reserved to be issued in 2016 and awards relating to 255,000 shares were granted and remain eligible to vest. The Company continues to grant inducement awards to new hires under a 2017 authorization.

The 2014 Plan allows for the granting of stock options, stock appreciation rights (SARs), restricted stock, unrestricted stock, restricted stock units (RSUs), performance awards and other awards convertible into or otherwise based on shares of our common stock. Dividend equivalents may also be provided in connection with an award under the 2014 Plan. The Company's employees, officers, directors and consultants and advisors are eligible to receive awards under the 2014 Plan. The Company initially reserved 1,785,000 shares of its common stock for the issuance of awards under the 2014 Plan. The 2014 Plan provides that the number of shares reserved and available for issuance under the 2014 Plan will automatically increase annually on January 1st of each calendar year, by an amount equal to three percent (3%) of the number of shares of stock outstanding on a fully diluted basis as of the close of business on the immediately preceding December 31st (the "2014 Plan Evergreen Provision"). The Company's Board of Directors may act prior to January 1st of any year to provide that there will be no automatic increase in the number of shares available for grant under the 2014 Plan for that year (or that the increase will be less than the amount that would otherwise have automatically been made). During the first six months of 2017, the Company granted 1,043,900 stock options to employees, of which 324,500 were granted under the Inducement Award program, 439,900 RSUs to employees and 87,500 stock options to directors under the 2014 Plan.

The ESPP provides for the issuance of options to purchase shares of the Company's common stock to participating employees at a discount to their fair market value. The maximum aggregate number of shares of common stock available for purchase pursuant to the exercise of options granted under the ESPP will be the lesser of (a) 262,500 shares, increased on each anniversary of the adoption of

the ESPP by one percent (1%) of the total shares of common stock then outstanding (the "ESPP Evergreen Provision") and (b) 739,611 shares (which is equal to five percent (5%) of the total shares of common stock outstanding on the date of the adoption of the ESPP on a fully diluted, as converted basis. Under the ESPP, each offering period is six months, at the end of which employees may purchase shares of common stock through payroll deductions made over the term of the offering. The per-share purchase price at the end of each offering period is equal to the lesser of eighty-five percent (85%) of the closing price of our common stock at the beginning or end of the offering period.

Shares Reserved for Future Issuance

The Company has reserved for future issuance the following number of shares of common stock:

	June 30, 2017	December 31, 2016
Common stock options and RSU's outstanding	4,856,871	3,579,694
Shares available for issuance under the 2014 Plan (1)	739,579	885,328
Warrant to purchase common stock	509,611	—
Shares available for issuance under the ESPP (2)	677,762	803,105
Total	6,783,823	5,268,127

(1) On January 1, 2017 and January 1, 2016, the shares reserved for future grants under the 2014 Plan increased by 1,265,863 and 986,800 shares, respectively pursuant to the 2014 Plan Evergreen Provision.

(2) On February 28, 2016, the shares reserved for future issuance under the ESPP increased by 273,404 shares pursuant to the ESPP Evergreen Provision.

Stock-Based Compensation

Stock Options

On February 21, 2017, as part of the Company's annual grant of equity, the Company issued 719,400 stock options to employees. In addition, the Company issues stock options to new hires and occasionally to other employees not in connection with the annual grant process. Options granted by the Company vest over periods of between 12 and 48 months, subject, in each case, to the individual's continued service through the applicable vesting date. Options vest in installments of (i) 25% at the one year anniversary and (ii) in either 36 or 48 equal monthly or 12 equal quarterly installments beginning in the thirteenth month after the initial vesting commencement date or grant date, subject to the individual's continuous service with the Company. Options generally expire ten years after the date of grant. The Company recorded approximately $1.7 million and approximately $1.0 million of stock-based compensation expense related to stock options during the three months ended June 30, 2017 and 2016, respectively and approximately $3.3 million and $2.1 million during the six months ended June 30, 2017 and 2016, respectively.

Restricted Stock

On December 23, 2013, the Company issued 450,224 shares of restricted stock to employees and 79,067 shares of restricted stock to non-employees at a grant date fair value of $7.42 per share. The aggregate grant date fair value for the shares of restricted stock issued on December 23, 2013 totaled approximately $3.9 million. The awards of restricted stock contained a performance condition wherein vesting is contingent upon the Company's consummation of a liquidity event, as defined, prior to the fifth anniversary of the date of grant. Certain of the awards of restricted stock have a requisite service period that was complete upon grant. The remainder of the awards of restricted stock have a requisite service period of four years whereby the award vests 25% on the one year anniversary of the Vesting Commencement Date (as defined), then ratably on the first day of each calendar quarter for 12 quarters, subject to continuous service by the individual and achievement of the performance target. Due to the nature of the performance condition, the Company had concluded that the performance condition was not probable of achievement and therefore, recognition of compensation cost had been deferred until the occurrence of a liquidity event, as defined. Compensation expense related to the restricted stock awards is being recognized over the associated requisite service period which commenced on March 25, 2014. The Company recorded approximately $49,000 and $27,000 of stock-based compensation expense related to restricted stock during the three months ended June 30, 2017 and 2016, respectively and approximately $0.1 million and $13,000 during the six months ended June 30, 2017 and 2016, respectively, as a result of mark to market adjustments related to non-employees.

Restricted Stock Units

On February 21, 2017, as part of the Company's annual grant of equity, the Company issued 423,650 RSUs to employees. In addition, the Company occasionally issues RSUs not in connection with the annual grant process to employees. 100% of each RSU grant vests on the third anniversary of the grant date, subject, in each case, to the individual's continued service through the applicable vesting date. Total stock-compensation expense to be recognized over the life of the RSUs is $2.9 million and will be recognized on a straight-

line basis over the vesting period. The Company recorded approximately $0.6 million and $0.2 million of stock-based compensation expense related to the RSUs during the three months ended June 30, 2017 and 2016, respectively, and approximately $1.1 million and $0.3 million during the six months ended June 30, 2017 and 2016, respectively.

Employee Stock Purchase Plan

The first offering period under the ESPP opened on January 2, 2015. The Company issued 19,317 shares during the first quarter of 2017. The Company recorded approximately $42,000 and $16,000 of stock-based compensation expense related to ESPP during the three months ended June 30, 2017 and 2016, respectively and approximately $0.1 million and $47,000 during the six months ended June 30, 2017 and 2016, respectively.

Stock-Based Compensation Expense Summary

The Company has classified its stock-based compensation expense related to share-based awards as follows:

	Three months ended		Six months ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
	(in thousands)		(in thousands)	
Research and development	$ 997	$ 365	$ 5,171	$ 757
General and administrative	1,508	857	2,762	1,716
Total	$ 2,505	$ 1,222	$ 7,933	$ 2,473

Compensation expense by type of award:

	Three months ended		Six months ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
	(in thousands)		(in thousands)	
Stock options	$ 1,747	$ 1,021	$ 3,322	$ 2,149
Restricted stock	57	27	65	13
Restricted stock units	659	158	1,050	264
Employee stock purchase plan	42	16	83	47
Warrant	—	—	3,413	—
Total	$ 2,505	$ 1,222	$ 7,933	$ 2,473

9. Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. There were no significant income tax provisions or benefits for the three months ended June 30, 2017 and 2016. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets.

10. Commitments and Contingencies

The Company leases approximately 45,362 square feet of office and lab space in Cambridge, Massachusetts under a lease which was most recently amended in July 2016, collectively, the Lease. Total monthly lease payments for base rent are approximately $242,000 per month which is subject to annual rent escalations. In addition to such annual rent escalations, base rent payments for a portion of said premises commenced on January 1, 2017 in the monthly amount of approximately $22,000. Landlord contributions included in the Lease from the landlord totaled $2,169,920, including $70,526 in leasehold improvements not yet utilized. The landlord contributions are being accounted for as a deferred lease incentive and reduction in monthly rent expense over the term of the Lease. The term of the Lease with respect to the office space expires on September 11, 2026, with one five year extension option available. The term of the Lease for the lab space is five years, with an extension option for one additional period of two years. The total security deposit in connection with the Lease of $1,280,857 is included in other assets in the Company's condensed consolidated balance sheets as of June 30, 2017 and December 31, 2016.

The Company recognizes rent expense and records a deferred lease obligation representing the cumulative difference between actual facility lease payments and lease expense recognized ratably over the lease period, which is included in the Company's condensed consolidated balance sheets as of June 30, 2017 and December 31, 2016.

The Company leases office equipment under three year capital leases with payments commencing in February 2014, April 2015 and February 2016, respectively. The capital lease amounts are included in accrued expenses and other liabilities.

At June 30, 2017, the Company's future minimum payments required under these leases are as follows:

	Operating Lease	Lease Payments to be Received from Sublease	Net Operating Lease Payments	Capital Lease	Total
		(in thousands)			
2017	$ 1,773	$ 129	$ 1,644	$ 4	$ 1,648
2018	3,545	257	$ 3,288	5	$ 3,293
2019	3,545	—	$ 3,545	—	$ 3,545
2020	3,545	—	$ 3,545	—	$ 3,545
2021	3,510	—	$ 3,510	—	$ 3,510
Thereafter	14,666	—	$ 14,666	—	$ 14,666
Total	$ 30,584	$ 386	$ 30,198	9	$ 30,207
Less amount representing interest				—	
Present value of minimum lease payments at June 30, 2017				$ 9	

The Company recorded approximately $0.8 million and $0.7 million in rent expense for the three months ended June 30, 2017 and 2016, respectively and approximately $1.6 million and $1.0 million for the six months ended June 30, 2017 and 2016, respectively.

Under the Company's agreement with a subsidiary of Quintiles IMS Holdings, Inc., or Quintiles, to provide services for the PRO$_2$TECT and INNO$_2$VATE programs, the total remaining contract costs as of June 30, 2017 were approximately $334.7 million. The estimated period of performance for the committed work with Quintiles is through the fourth quarter of 2019. The Company contracts with various other organizations to conduct research and development activities with remaining contract costs to the Company of approximately $26.5 million and $24.9 million at June 30, 2017 and December 31, 2016, respectively. The scope of the services under these research and development contracts can be modified and the contracts cancelled by the Company upon written notice. In some instances, the contracts may be cancelled by the third party upon written notice.

The Company has had a number of positive developments in its opposition and invalidity proceedings against FibroGen, Inc., or FibroGen. With regard to the opposition that the Company filed in Europe against FibroGen's European Patent No. 1463823, or the '823 patent, an oral proceeding took place March 8 and 9, 2016. Following the oral proceeding, the European Opposition Division ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. FibroGen has appealed that decision and the appeal process is expected to take 2 to 3 years. Likewise, with regard to the invalidity proceeding that the Company filed in Japan against certain claims of FibroGen's Japanese Patent No. 4804131, or the '131 patent, which is the Japanese counterpart to the '823 patent, the Japan Patent Office, or JPO, issued a preliminary decision finding all of the challenged claims to be invalid. FibroGen subsequently amended the claims and the JPO accepted the amendments. The resulting FibroGen Japanese '131 patent does not cover vadadustat or any pyridine carboxamide compounds. To date, FibroGen has been unsuccessful in its attempts to obtain a patent in the United States covering the same claim scope as it obtained initially in Europe and Japan in the '823 and '131 patents. In the event FibroGen were to obtain such a patent in the United States, the Company may decide to challenge them like the Company has done in Europe and Japan.

With regard to the opposition that we filed in Europe against FibroGen's European Patent No. 163333, or the '333 patent, an oral proceeding took place December 8 and 9, 2016. Following the oral proceeding, the European Opposition Division ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. FibroGen has appealed that decision.

On May 13, 2015, May 20, 2015 and July 6, 2015, the Company filed oppositions to FibroGen's European Patent Nos. 2322153, 2322155, and 1633333, or the '153 patent, the '155 patent, and the '333 patent, respectively, requesting the patents be revoked in their entirety. These related patents claim, among other things, various compounds that either stabilize HIFα or inhibit a HIF hydroxylase or a HIF prolyl hydroxylase for treating or preventing various conditions, including, *inter alia*, iron deficiency, microcytosis associated with iron deficiency, anemia of chronic disease, anemia wherein the subject has a transferrin saturation of less than 20%, anemia refractory to treatment with exogenously administered erythropoietin, or EPO, and microcytosis in microcytic anemia. Such method of use patents do not prevent persons from using the compound for other uses, including any previously known use of the compound. In particular, these patents do not claim methods of using any of our product candidates for purposes of inhibiting hypoxia-inducible factor prolyl hydroxylases, or HIF-PHs, for the treatment of anemia secondary to CKD. While the Company does not believe these patents will prevent it from commercializing vadadustat for treatment of anemia secondary to CKD, the Company filed these oppositions to provide us and any future partners with maximum flexibility for developing vadadustat and our pipeline of HIF PH

inhibitors. Oppositions to the ’155 patent and to the ’153 patent were also filed by Glaxo Group Limited, or Glaxo, and by Bayer Intellectual Property GmbH, Bayer Pharma Aktiengesellschaft, and Bayer Animal Health GmbH. In oral proceedings held on May 29, 2017, the European Opposition Division ruled that the '155 patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. Subsequently, in related oral proceedings held on May 31, 2017 and June 1, 2017 for the '153 patent, FibroGen significantly narrowed the claims to an indication for which vadadustat is not intended to be developed.

The Company’s policy is to record a liability if a loss in a significant legal dispute is considered probable and an amount can be reasonably estimated. The Company provides disclosure when a loss in excess of any reserve is reasonably possible, and the Company is in a position to estimate the potential loss or range of possible loss. Significant judgment is required to assess the likelihood of various potential outcomes and the quantification of loss in those scenarios. The Company’s estimates change as litigation progresses and new information comes to light. Changes in Company estimates could have a material impact on the Company’s results and financial position.

11. Employee Retirement Plan

During 2008, the Company established a retirement plan (the Plan) authorized by Section 401(k) of the Internal Revenue Code. In accordance with the Plan, all employees who have attained the age of 21 are eligible to participate in the Plan as of the first Entry Date, as defined, following their date of employment. Each employee can contribute a percentage of compensation up to a maximum of the statutory limits per year. Company contributions are discretionary and contributions in the amount of approximately $39,000 and $29,000 were made during the three months ended June 30, 2017 and 2016, respectively, and approximately $0.2 million and $0.1 million during the six months ended June 30, 2017 and 2016, respectively.

12. Net Loss per Share

The shares in the table below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, due to their anti-dilutive effect:

	Three months ended		Six months ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Warrants	509,611	—	509,611	—
Outstanding stock options	4,027,408	2,753,908	4,027,408	2,753,908
Unvested restricted stock	28,512	159,640	28,512	159,640
Unvested restricted stock units	829,463	396,813	829,463	396,813
Total	5,394,994	3,310,361	5,394,994	3,310,361

13. Subsequent Event

In July 2017, the Company completed a follow-on-public offering whereby the Company sold 4,600,000 shares of common stock, including 600,000 shares of common stock pursuant to the full exercise of an over-allotment granted to the underwriters in connection with the offering, at a price of $14.50 per share. The aggregate net proceeds received by the Company from the offering were approximately $62.6 million, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

Under the Otsuka U.S. Agreement, Otsuka originally had a limited period of time in which it can exercise an option to convert the arrangement from a profit share to a right to receive a mid-single digit royalty on future net sales of commercialized products (the Royalty Conversion Option). On August 4, 2017, Otsuka agreed to waive its right to exercise the Royalty Conversion Option, consequently, Otsuka has no further right to elect to exercise this option.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the condensed consolidated financial statements and notes thereto for the year ended December 31, 2016, and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, contained in our annual report on Form 10-K filed with the United States Securities and Exchange Commission, or the SEC, on March 6, 2017, which we refer to as our annual report.

This report contains forward-looking statements that are being made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, or PSLRA, with the intention of obtaining the benefits of the “safe harbor” provisions of the PSLRA.

Forward-looking statements involve risks and uncertainties. In this Quarterly Report on Form 10-Q, words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution our readers that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from those expressed or implied by the forward-looking statements contained in this Quarterly Report on Form 10-Q.

The following information, including all forward-looking statements, should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks identified under Part II, Item 1A. Risk Factors.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Operating Overview

We are a biopharmaceutical company focused on developing and delivering novel therapeutics for patients based on hypoxia-inducible factor, or HIF, biology, and building our pipeline while leveraging our development and commercial expertise in renal disease. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body, as well as other important metabolic functions. Pharmacologic modulation of the HIF pathway may have broad therapeutic applications. Our lead product candidate, vadadustat, is an oral therapy in Phase 3 development, which has the potential to set a new standard of care in the treatment of anemia associated with chronic kidney disease (CKD). Our management team has extensive experience in developing and commercializing drugs for the treatment of renal and metabolic disorders, as well as a deep understanding of HIF biology. This unique combination of HIF and renal expertise is enabling us to advance a pipeline of HIF-based therapies to address serious diseases.

HIF, a pathway involving hundreds of genes, is responsible for orchestrating the body's natural response to lower levels of oxygen, or hypoxia. In response to hypoxia, a coordinated adaptive response occurs resulting in both an increase in red blood cell production, a normal biological process known as erythropoiesis, and enhancement of the delivery of iron to the bone marrow to support erythropoiesis. The significance of the HIF pathway was recognized by the 2016 Albert Lasker Basic Medical Research Award, which honored the three physician-scientists who discovered the HIF pathway and elucidated this primary oxygen sensing mechanism that is essential for survival. HIF protein is constantly being produced under normal oxygen conditions, but is quickly degraded by prolyl hydroxylases, or PH. Under hypoxic conditions, HIF-PH's are inhibited, allowing HIF to stimulate erythropoiesis. These findings have opened up new possibilities for developing therapeutics, such as HIF-PH inhibitors, which have the potential to treat many diseases.

Our lead product candidate, vadadustat, is a HIF-PH inhibitor in Phase 3 development for the treatment of anemia of CKD. Anemia is a serious medical condition in which blood is deficient in hemoglobin, which is critical for delivering oxygen to organs and tissue. Untreated anemia is associated with chronic fatigue, increased risk of progression of multiple diseases and death. Anemia is common in patients with CKD, cancer, heart failure, inflammatory diseases and other critical illnesses.

More than 30 million people in the United States have CKD, with estimates that over 1.8 million of these patients suffer from anemia. Anemia from CKD is currently treated by injectable recombinant erythropoiesis-stimulating agents, or rESAs, such as EPOGEN® and Aranesp®, as well as with iron supplementation or red blood cell transfusion. Based on the reported revenues of companies that market and sell rESAs, global sales of injectable rESAs were estimated to be between $6.5 and $7.0 billion in 2015. The vast majority of these sales were for the treatment of anemia associated with renal disease.

rESAs deliver supra-physiological levels of exogenous erythropoietin, or EPO, to stimulate production of RBCs. While injectable rESAs may be effective in raising hemoglobin levels, they carry significant potential side effects, and need to be injected under the skin (subcutaneously) or into a vein (intravenously). In particular, injectable rESAs may lead to thrombosis, stroke, myocardial infarction and death. These safety concerns, which became evident starting in 2006, have led to a significant reduction in the use of injectable rESAs. Today, anemia is either not treated or inadequately treated in the majority of non-dialysis dependent (NDD) CKD patients. We believe that novel treatment options that address these concerns are needed and would have significant market potential. Because it mimics the body's natural adaptive response to hypoxia, vadadustat's HIF-PH inhibition may raise hemoglobin levels without causing supra-physiological levels of EPO.

Vadadustat has the potential to set a new standard of care for the treatment of anemia in CKD. Early clinical studies of vadadustat demonstrated that diurnal variation of EPO was maintained resulting in predictable increases in hemoglobin in normal human

volunteers and similar results were seen in NDD-CKD. These data led us to the design of our Phase 3 clinical program. The vadadustat Phase 3 program in NDD-CKD patients with anemia, called PRO$_2$TECT, and in dialysis dependent (DD) CKD patients with anemia, called INNO$_2$VATE, is designed to enroll up to 6,300 patients evaluating once daily oral dosing of vadadustat against an rESA active comparator, darbepoetin alfa. The enrollment numbers and the completion of the Phase 3 program will be driven by the rate of major adverse cardiovascular events, or MACE. In December 2015 the first patient was dosed in PRO$_2$TECT, and the first patient was dosed in INNO$_2$VATE in August 2016. We expect the remaining cost of the Phase 3 program to aggregate in the range of $450.0 million to $480.0 million in external CRO costs for the total program. We expect to report top-line clinical data for the PRO$_2$TECT study in the second half of 2018 or the first half of 2019 and top-line clinical data for the INNO$_2$VATE study in the first half of 2019. If the results from our Phase 3 program are favorable, we currently anticipate submitting marketing applications for vadadustat for the treatment of anemia associated with CKD in the United States and Europe in the second half of 2019.

In May 2017, we initiated a Phase 2 study of vadadustat in the rESA hyporesponder population, called FO$_2$RWARD. Patients who do not adequately respond to rESA treatment represent approximately 10-15% of DD-CKD patients, yet hyporesponders account for 30-40% of total rESA use. These patients have demonstrated a persistently higher risk of mortality than non-hyporesponders, and represent a high unmet need. We believe that, given its differentiated mechanism of action, vadadustat may provide a treatment option for these patients, and we anticipate results from FO$_2$RWARD in the second half of 2018. We plan to initiate a Phase 3 dosing study, called TRILO$_2$GY, in the second half of 2017 to evaluate three-times weekly dosing of vadadustat in approximately 300 DD-CKD patients receiving hemodialysis using the same active comparator, darbepoetin alfa. This is an important dosing option for dialysis providers, and we previously investigated this dosing regimen in our Phase 2 dialysis study.

If vadadustat is approved by the United States Food and Drug Administration, or FDA, we plan to establish our own commercial organization in the United States while leveraging our collaborations with Otsuka Pharmaceutical Co. Ltd., or Otsuka, and its well-established commercial organization in the United States, Europe, China and other markets. In Japan and other countries in Asia, we plan to commercialize vadadustat through our collaboration with Mitsubishi Tanabe Pharma Corporation, or MTPC. In May 2017, we entered into an exclusive license agreement with Vifor Pharma, or Vifor, to sell vadadustat solely to Fresenius Kidney Care Group LLC Fresenius Medical Care, or FKC, dialysis clinics in the United States upon approval by the FDA and inclusion of vadadustat in a bundled reimbursement model. During the term of the license agreement, Vifor may not sell to FKC or its affiliates any HIF product that competes with vadadustat in the United States.

In addition to vadadustat, we are developing a HIF-based portfolio of product candidates that target serious diseases of high unmet need. Our portfolio includes product candidates developed internally as well as in-licensed product candidates, such as AKB-5169. In February 2017, we signed an exclusive agreement with Janssen Pharmaceutica NV, or Janssen, a subsidiary of Johnson & Johnson, for access to an extensive library of well-characterized HIF pathway compounds with potential applications across multiple therapeutic areas. The lead compound, AKB-5169, is a differentiated preclinical compound in development as an oral treatment for inflammatory bowel disease, or IBD. We intend to complete further preclinical development of this compound with the goal of submitting an Investigational New Drug application to the FDA in 2018.

Since our inception in 2007, we have devoted the largest portion of our resources to our development efforts relating to vadadustat, including preparing for and conducting clinical studies of vadadustat, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through equity offerings and strategic collaborations.

We have never been profitable and have incurred net losses in each year since inception. Our net losses were $66.1 million and $61.6 million for the six months ended June 30, 2017 and 2016, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant operating expenses and increased operating losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- complete the development of vadadustat for anemia secondary to CKD;
- conduct the FO$_2$RWARD and TRILO$_2$GY clinical studies;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- initiate and continue preclinical and clinical development of our HIF compounds and product candidates;
- initiate additional preclinical, clinical or other studies for additional indications for vadadustat;

- seek to discover and develop additional product candidates;
- acquire, in-license and develop other commercial products, product candidates and technologies;
- make royalty, milestone or other payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- create additional infrastructure to support our operations as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. We have no manufacturing facilities, and all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize third-party contract research organizations, or CROs, to carry out our clinical development activities, and we do not yet have a sales organization. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will seek to fund our operations through public or private equity or debt financings or other sources including geographic partnerships. However, we may be unable to raise additional funds or enter into other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our products.

Through June 2017, we have raised approximately $255.7 million of net proceeds, including $230.0 million from three underwritten public offerings and $25.7 million of net proceeds in an at-the-market offering, or ATM, pursuant to a Sales Agreement with Cantor Fitzgerald & Co.

In July 2017, we completed a follow-on-public offering whereby we sold 4,600,000 shares of common stock, including 600,000 shares of common stock pursuant to the full exercise of an over-allotment granted to the underwriters in connection with the offering, at a price of $14.50 per share. The aggregate net proceeds received by us from the offering were approximately $62.6 million, net of underwriting discounts and commissions and estimated offering expenses payable by us.

In addition to proceeds from our public offerings, in May 2017, we received $50.0 million from the sale of 3,571,429 shares of common stock to Vifor Pharma. Our collaborators have committed up to $373.0 million or more in license payments and cost-share funding, which the Company continues to receive on a quarterly prepaid basis.

Financial Overview

In the quarter ended June 30, 2017, we identified and corrected an immaterial error in the amount of research and development expenses related to our global Phase 3 study of vadadustat. This adjustment also affected the amount of revenue recognized pursuant to our license and collaboration agreements with Otsuka. The adjustments impact our results of operations in each quarter of 2016 and the first quarter of 2017. We concluded the effect of these adjustments was not material to our consolidated financial statements for any prior period.

Revenue

To date, we have not generated any revenue from the sales of products. Our revenues have been derived from collaboration agreements.

Revenue recognition for our MTPC collaboration commence when all criteria as required under ASC 605 have been satisfied, which the Company expects will be in the second half of 2017. Therefore, collaboration revenue in the current period is generated exclusively from our collaboration arrangements with Otsuka. The terms of the Otsuka U.S. Agreement contain multiple deliverables, which include at inception: (i) license under certain of our intellectual property to develop, perform medical affairs activities with respect to and conduct non-promotional and commercialization activities related to vadadustat (the License Deliverable), (ii) development services to be performed pursuant to the current global development plan (the Development Services Deliverable), (iii) rights to future intellectual property (the Future IP Deliverable) and (iv) joint committee services (the Committee Deliverable). We have identified three units of accounting in connection with our obligations under the U.S. collaboration agreement with Otsuka as follows: (i) License Unit of Accounting, which combines the License Deliverable and the Development Services Deliverable (ii) Rights to Future Intellectual Property Unit of Accounting and (iii) Joint Committee Services Unit of Accounting.

The terms of the Otsuka EU Agreement contain multiple deliverables, which include at inception: (i) license under certain of our intellectual property to develop and commercialization activities related to vadadustat (the License Deliverable), (ii) development services to be performed pursuant to the current global development plan (the Development Services Deliverable), (iii) rights to future

intellectual property (the Future IP Deliverable), and (iv) joint committee services (the Committee Deliverable). We have identified three units of accounting in connection with our obligations under the EU collaboration agreement with Otsuka as follows: (i) License Unit of Accounting, which combines the License Deliverable and the Development Services Deliverable (ii) Rights to Future Intellectual Property Unit of Accounting, and (iii) Joint Committee Services Unit of Accounting.

We recognize arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 605, *Revenue Recognition*, or ASC 605, are satisfied for that particular unit of accounting.

The Company will recognize revenue related to amounts allocated to the License Unit of Accounting on a proportional performance basis as the underlying services are performed.

Our ability to generate product revenue and become profitable depends upon our ability to successfully develop and commercialize products. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from the sale of our products, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

For the foreseeable future, we expect substantially all of our revenue will be generated from our collaborations with Otsuka and MTPC and any other collaborations we may enter into.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, recruiting fees, travel and stock-based compensation expense;
- expenses incurred under agreements with the CROs and investigative sites that conduct our clinical studies;
- the cost of acquiring, developing and manufacturing clinical study materials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and
- costs associated with preclinical and clinical activities.

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.

We cannot determine with certainty the duration and completion costs of the current or future clinical studies of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

The duration, costs and timing of clinical studies and development of our product candidates will depend on a variety of factors, including:

- the results of our meetings with the FDA and the EMA and other regulatory authorities and the consequential effect on our study design, study size and resulting operating costs;
- the size, rate of progress, results and costs of completing our global Phase 3 development of vadadustat;
- difficulties or delays in enrolling patients in our clinical trials;
- assuming favorable Phase 3 clinical results, the timing of, and the costs involved in, obtaining regulatory approvals for vadadustat in dialysis and non-dialysis indications, including to fund the preparation and filing of regulatory submissions for vadadustat with the FDA, the EMA and other regulatory authorities, and whether we will seek regulatory approval for both indications simultaneously;
- the cost of conducting the FO_2RWARD and TRILO$_2$GY clinical studies;
- the cost, timing and outcome of our efforts to obtain marketing approval for vadadustat in the United States, Europe and other regions;

- the scope, progress, results and costs of additional preclinical, clinical, or other studies for additional indications for vadadustat, as well as any studies of AKB-5169 and other product candidates that we may develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory approvals for AKB-5169 and other product candidates that we may develop or acquire, if clinical studies are successful;
- the cost of having our product candidates manufactured and obtaining comparator product for clinical trials;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements; and
- unanticipated changes to laws or regulations applicable to our clinical trials.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, EMA or another regulatory authority were to require us to conduct clinical studies in addition to or different from those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical studies, we could be required to expend significant additional financial resources and time on the completion of clinical development.

From inception through June 30, 2017, we have incurred $335.7 million in research and development expenses. We plan to increase our research and development expenditures for the foreseeable future as we continue the development of vadadustat and our other product candidates. Our current and/or planned research and development activities include the following:

- global development of vadadustat, including the PRO2TECT and INNO$_2$VATE clinical programs;
- research and development of compounds in our HIF portfolio, including product candidates such as AKB-5169; and
- diversification of our pipeline in kidney disease and other HIF-modulated diseases.

Our direct research and development expenses consist principally of external costs, such as fees paid to clinical trial sites, consultants, central laboratories and CROs in connection with our clinical studies, and costs related to acquiring and manufacturing clinical study materials.

We currently have four programs to which our research and development costs are attributable. Historically, we have not accumulated and tracked our research and development costs or our personnel and personnel-related costs on a program-by-program basis. Our employee and infrastructure resources, and many of our costs, were directed broadly to applicable research endeavors. As a result, we are unable to specify precisely the historical costs incurred for each of our programs on a program-by-program basis.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, fees for directors, accounting and legal services fees, recruiting fees and expenses associated with obtaining and maintaining patents.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also anticipate increased expenses related to finance, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, and our other costs associated with being a public company. Additionally, we anticipate an increase in payroll and related expenses if and when we prepare for commercial operations, especially in sales and marketing.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated 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 consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to prepaid and accrued research and development expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed 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.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue

We recognize revenue in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 605, *Revenue Recognition*, or ASC 605. Accordingly, revenue is recognized for each unit of accounting when all of the following criteria are met:

- persuasive evidence of an arrangement exists;
- delivery has occurred or services have been rendered;
- the seller's price to the buyer is fixed or determinable; and
- collectability is reasonably assured.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets.

Multiple Element Arrangements

Determination of Accounting Units

We analyze multiple element arrangements based on the guidance in ASC Topic 605-25, *Revenue Recognition—Multiple Element Arrangements*, or ASC 605-25. Pursuant to the guidance in ASC 605-25, we evaluate multiple element arrangements to determine (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separate from other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered item(s) has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially within our control. In assessing whether an item under a collaboration has standalone value, we consider factors such as the research, manufacturing, and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. We also consider whether our collaboration partner can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s), and whether there are other vendors that can provide the undelivered element(s).

Options under a collaboration are considered substantive if, at the inception of the arrangement, we are at risk as to whether the collaboration partner will choose to exercise the option. Factors that we consider in evaluating whether an option is substantive include the cost to exercise the option, the overall objective of the arrangement, the benefit the collaboration partner might obtain from the arrangement without exercising the option, and the likelihood the option will be exercised. When an option is considered substantive, we would not consider the option or item underlying the option to be a deliverable at the inception of the arrangement and the associated option fees are not included in allocable consideration, assuming the option is not priced at a significant and incremental discount. Conversely, when an option is not considered substantive, we would consider the option, including other deliverables contingent upon the exercise of the option, to be a deliverable at the inception of the arrangement and a corresponding amount would be included in allocable arrangement consideration. In addition, if the price of the option includes a significant incremental discount, the discount would be included as a deliverable at the inception of the arrangement.

Allocation of Arrangement Consideration

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. The applicable revenue recognition criteria in ASC 605 are applied to each of the separate units of accounting in determining the appropriate period and pattern of recognition. We determine the selling price of a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, we determine the estimated selling price for units of accounting within each arrangement using vendor specific objective evidence, or VSOE, of selling price, if available, third-party evidence, or TPE, of selling price if VSOE is not available, or best estimate of selling price, or BESP, if neither VSOE or TPE is available. We have only used BESP to estimate selling price, since we have not had VSOE or TPE of selling price for any units of accounting to date. Determining BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, we consider applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the applicable agreement and estimated costs. We validate BESP for units of accounting by evaluating whether changes in the key

assumptions used by us to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting.

Pattern of Recognition

We recognize the arrangement's consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605 are satisfied for that particular unit of accounting. We recognize revenue associated with licenses, license options, or the discount related to a license option upon (i) delivery of the license or (ii) the earlier of exercise or expiration of the license option, if the underlying license has standalone value from the other deliverables to be provided after delivering that license. If the license does not have standalone value, the amounts allocated to the license are combined with the related undelivered items as a single unit of accounting.

We recognize the amounts associated with collaboration research and development services, joint research committees, or other services ratably over the associated period of performance. If there is no discernible pattern of performance or objectively measurable performance measures do not exist, then we recognize revenue under the arrangement on a straight-line basis over the period that we are expected to complete our performance obligations. Conversely, if the pattern of performance in which the service is provided to the collaboration partner can be determined and objectively measureable performance exists, then we recognize revenue under the arrangement using the proportional performance method. Revenue to be recognized is limited to the lesser of the cumulative amount of payments received or the cumulative revenue earned determined using the straight line method or proportional performance, as applicable, as of the period end date.

Recognition of Milestones and Royalties

At the inception of an arrangement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (1) the consideration is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone, (2) the consideration relates solely to past performance, and (3) the consideration is reasonably relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as clinical, regulatory, commercial, and other risks that must be overcome to achieve the respective milestones and the level of effort and investment required to achieve the respective milestones in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. In accordance with ASC Topic 605-28, *Revenue Recognition—Milestone Method*, or ASC 605-28, a clinical or regulatory milestone that is considered substantive will be recognized as revenue in its entirety upon successful accomplishment of the milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive would be recognized as revenue over the remaining period of performance, assuming all other revenue recognition criteria are met. Revenue from a commercial milestone payment will be accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

We will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable, we have no remaining performance obligations, and assuming all other revenue recognition criteria are met.

Prepaid and Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our prepaid and accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our prepaid and accrued research and development expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated prepaid and accrued research and development expenses include expenses for:

- CROs in connection with clinical studies;
- investigative sites in connection with clinical studies;
- vendors in connection with preclinical development activities; and
- vendors related to product manufacturing, development and distribution of clinical materials.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. The scope of services under contracts for research and development activities can be modified and some of the agreements may be cancelled by either party upon written notice. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed we may report amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates and the amount actually incurred.

Stock-Based Compensation

Stock-Based Awards

We issue stock-based awards to employees and non-employees, generally in the form of stock options, restricted stock, RSUs, shares of common stock and warrants. We account for our stock-based compensation awards in accordance with Financial Accounting Standards Board, (FASB) ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718. ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock and modifications to existing stock awards, to be recognized in the statements of operations and comprehensive loss based on their fair values. We account for stock-based awards to non-employees in accordance with ASC Topic 505-50, *Equity-Based-Payments to Non-Employees*, or ASC 505-50, which requires the fair value of the award to be re-measured at fair value until a performance commitment is reached or counterparty performance is complete. Described below is the methodology we have utilized in measuring stock-based compensation expense. Stock option, common stock and restricted stock values are determined based on a blend of our stock price and the quoted market price of our comparable public companies.

We estimate the fair value of our stock-based awards of options to purchase shares of common stock to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of company-specific historical and implied volatility data for trading our stock in the public market, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to our company, including stage of product development and life science industry focus. During 2017, we began to estimate our volatility by using a blend of our stock price history for the length of time we have market data for our stock and the historical volatility of similar public companies for the expected term of each grant. We are a company in the product development stage with no product revenue and the representative group of companies has certain similar characteristics. We believe the group selected has sufficient similar economic and industry characteristics, and includes companies that are most representative of our company. We use the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior among our employee population. For options granted to non-employees, we utilize the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock, similar to our peer group. We estimate grant date fair value of restricted stock awards with corresponding promissory notes using the Black-Scholes option pricing model. The grant date fair value of restricted stock awards and awards of common stock has been based on the estimated value of our common stock at the date of grant.

Our stock-based awards are subject to service-based vesting conditions. Compensation expense related to awards to employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Consistent with the guidance in ASC 505-50, compensation expense related to awards to non-employees with service-based vesting conditions is recognized on a straight-line basis based on the then-current fair value at each financial reporting date prior to the measurement date over the associated service period of the award, which is generally the vesting term.

The Company adopted ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, effective in the first quarter of the year ended December 31, 2017. Prior to adoption, share-based compensation expense was recognized on a straight line basis, net of estimated forfeitures, such that expense was recognized only for share-based awards that are expected to vest. A forfeiture rate was estimated annually and revised, if necessary, in subsequent periods if actual forfeitures differed from initial estimates. Upon adoption, the Company will no longer apply a forfeiture rate and instead will account for forfeitures as they occur.

Stock-based compensation expense totaled approximately $2.5 million and $1.2 million for the three months ended June 30, 2017 and 2016, respectively, and approximately $7.9 and $2.5 million for the six months ended June 30, 2017 and 2016, respectively.

We expect the impact of our stock-based compensation expense for stock options and restricted stock granted to employees and non-employees to grow in future periods due to the potential increases in the fair value of our common stock and the increase in the number of grants as a result of an increase in headcount.

Emerging Growth Company Status

The JOBS Act permits an "emerging growth company" to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We chose to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

Results of Operations

Comparison of the Three Months Ended June 30, 2017 and 2016

	Three months ended		Increase (Decrease)
	June 30, 2017	June 30, 2016	
	(In Thousands)		
Collaboration revenue	$ 28,520	$ —	$ 28,520
Operating expenses:			
Research and development	43,751	30,877	12,874
General and administrative	6,905	5,311	1,594
Total operating expenses	50,656	36,188	14,468
Loss from operations	(22,136)	(36,188)	(14,052)
Other income, net	618	409	209
Net loss	$ (21,518)	$ (35,779)	$ (14,261)

Collaboration Revenue. Collaboration revenue was $28.5 million for the three months ended June 30, 2017 and related entirely to our agreements with Otsuka. We did not recognize any collaboration revenue in the three month period ended June 30, 2016 as the Otsuka agreements were not consummated in that time period, and all revenue recognition criteria for the MTPC Agreement, as required under ASC 605, had not been satisfied, which the Company expects will be in the second half of 2017.

Research and Development Expenses. Research and development expenses were $43.8 million for the three months ended June 30, 2017, compared to $30.9 million for the three months ended June 30, 2016, an increase of $12.9 million. The increase was primarily due to the following:

	(in millions)
PRO_2TECT and $INNO_2VATE$ Phase 3 program	$ 7.4
FO_2RWARD Phase 2 study	1.7
$TRILO_2GY$ Phase 3 study	1.2
Regulatory activities and other clinical and non-clinical	0.3
Manufacture of drug substance	(0.7)
Total increase related to the continued development of vadadustat	9.9
Headcount, consulting and facilities	2.9
Other	0.1
Total net increase	$ 12.9

The increase in the costs related to the development of vadadustat is primarily attributable to external costs related to the PRO$_2$TECT and INNO$_2$VATE Phase 3 program as well as the FO$_2$RWARD and TRILO$_2$GY studies. The increase in headcount, consulting and facility related costs relates to additional resources required in support of our expanding research and development programs, as well as rent associated with our leasing of additional office and lab space. We expect our research and development expenses to increase in future periods in support of the Phase 3 programs and other studies and our pipeline development.

General and Administrative Expenses. General and administrative expenses were $6.9 million for the three months ended June 30, 2017, compared to $5.3 million for the three months ended June 30, 2016. The increase of $1.6 million was primarily due to an increase in costs to support our research and development programs, including headcount and compensation-related costs, and associated facility-related costs. We expect our general and administrative expenses to increase in future periods to support our continued research and development and potential commercialization of our product candidates.

Other Income, Net. Other income, net, was $0.6 million for the three months ended June 30, 2017 and $0.4 million for the three months ended June 30, 2016. Other income, net for the three months ended June 30, 2017 and 2016 is primarily comprised of interest income.

Results of Operations

Comparison of the Six Months Ended June 30, 2017 and 2016

	Six Months Ended		Increase
	June 30, 2017	June 30, 2016	(Decrease)
	(In Thousands)		
Collaboration revenue	$ 49,385	$ —	$ 49,385
Operating expenses:			
Research and development	$ 103,800	$ 51,112	$ 52,688
General and administrative	12,693	11,122	1,571
Total operating expenses	116,493	62,234	54,259
Loss from operations	(67,108)	(62,234)	$ 4,874
Other income, net	1,048	657	391
Net loss	$ (66,060)	$ (61,577)	$ 4,483

Collaboration Revenue. Collaboration revenue was $49.4 million for the six months ended June 30, 2017 under our agreement with Otsuka. We did not recognize any collaboration revenue in the six month period ended June 30, 2016 as the Otsuka agreements were not consummated in that time period, and all revenue recognition criteria for the MTPC Agreement, as required under ASC 605, had not been satisfied, which the Company expects will be in the second half of 2017.

Research and Development Expenses. Research and development expenses were $103.8 million for the six months ended June 30, 2017, compared to $51.1 million for the six months ended June 30, 2016, an increase of $52.7 million. The increase was primarily due to the following:

	(in millions)
PRO$_2$TECT and INNO$_2$VATE Phase 3 program	$ 39.9
FO$_2$RWARD Phase 2 study	1.7
Regulatory and other clinical and non-clinical activities	1.6
TRILO$_2$GY Phase 3 study	1.2
Manufacture of drug substance	(1.2)
Total increase related to the continued development of vadadustat	43.2
Headcount, consulting and facilities	4.8
Fair value of warrant issued in connection with Janssen Agreement	3.4
License fee in connection with Janssen Agreement	1.0
Other	0.3
Total net increase	$ 52.7

The increase in the costs related to the development of vadadustat is primarily attributable to external costs related to the PRO$_2$TECT and INNO$_2$VATE Phase 3 program as well as the FO$_2$RWARD and TRILO$_2$GY studies. The increase in headcount, consulting and

facility related costs relates to additional resources required in support of our expanding research and development programs, as well as rent associated with our leasing of additional office and lab space. We expect our research and development expenses to increase in future periods in support of the Phase 3 programs and other studies and our pipeline development.

General and Administrative Expenses. General and administrative expenses were $12.7 million for the six months ended June 30, 2017, compared to $11.1 million for the six months ended June 30, 2016. The increase of $1.6 million was primarily due to an increase in costs to support our research and development programs, including headcount and compensation-related costs, and associated facility-related costs partially offset by lower commercial planning costs and patent related costs. We expect our general and administrative expenses to increase in future periods to support our continued research and development and potential commercialization of our product candidates.

Other Income, Net. Other income, net, was $1.0 million for the six months ended June 30, 2017 and $0.7 million for the six months ended June 30, 2016. Other income, net for the six months ended June 30, 2017 and 2016 is primarily comprised of interest income.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception in February 2007, and as of June 30, 2017, we had an accumulated deficit of $363.2 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

We have funded our operations principally through sales of our common stock and payments received from our collaboration partners. As of June 30, 2017, we had cash and cash equivalents and available for sale securities of approximately $321.2 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Accordingly, available for sale securities, consisting principally of corporate and government debt securities stated at fair value, are also available as a source of liquidity.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Six Months Ended	
	June 30, 2017	**June 30, 2016**
	(In Thousands)	
Net cash provided by (used in):		
Operating activities	$ 14,836	$ (9,521)
Investing activities	(123,993)	(55,168)
Financing activities	47,212	61,088
Net increase in cash and cash equivalents	$ (61,945)	$ (3,601)

Operating Activities. The net cash provided by operating activities was $14.8 million for the six months ended June 30, 2017 and consisted primarily of a net loss of $66.1 million adjusted for non-cash items, including stock-based compensation expense of $7.9 million, amortization of premium/discount on investments of $0.4 million, depreciation and amortization of $0.3 million and a net increase in operating assets and liabilities of $72.3 million. The significant items in the change in operating assets and liabilities include an increase in deferred revenue of $40.6 million, a decrease in unbilled receivable of approximately $33.8 million related to unbilled payments from Otsuka received in the first quarter of 2017, an increase in accounts payable and accrued expenses of approximately $6.6 million and an increase of $0.4 million in deferred rent partially offset by an increase of approximately $9.0 million in prepaid expenses and other current assets. The net increase in accounts payable and accrued expenses is primarily driven by clinical and non-clinical study costs associated with vadadustat.

The net cash used in operating activities was $9.5 million for the six ended June 30, 2016 and consisted primarily of a net loss of $61.6 million adjusted for non-cash items, including stock-based compensation expense of $2.5 million and amortization of premium/discount on investments of $0.3 million and a net increase in operating assets and liabilities of $49.2 million. The significant items in the change in operating assets and liabilities include an increase in deferred revenue of $40.0 million attributable to payments made to us pursuant to our collaboration with Mitsubishi Tanabe and an increase in accounts payable, accrued expenses and other liabilities of approximately $10.5 million partially offset by a decrease of approximately $1.3 million in prepaid expenses and other current assets. The net increase in operating assets and liabilities is primarily driven by clinical and non-clinical study costs associated with vadadustat and AKB-6899.

Investing Activities. Net cash used in investing activities for the six months ended June 30, 2017 was $124.0 million and was comprised primarily of purchases of available for sale securities of $177.5 million and purchases of equipment of $0.6 million, offset by proceeds from the maturities of available for sale securities of $54.1 million.

Net cash used in investing activities for the six months ended June 30, 2016 was $55.2 million and was comprised primarily of purchases of available for sale securities of $118.7 million and purchases of equipment of $1.4 million, offset by proceeds from the maturities of available for sale securities of $64.9 million.

Financing Activities. Net cash provided by financing activities for the six months ended June 30, 2017 was $47.2 million and consisted primarily of net proceeds from the public issuance of common stock pursuant to our ATM facility, proceeds from the exercise of stock options and proceeds from the sale of stock under our employee stock purchase plan.

Net cash provided by financing activities for the six months ended June 30, 2016 was $61.1 million and consisted primarily of net proceeds from the public issuance of common stock, proceeds from the exercise of stock options and proceeds from the sale of stock under our employee stock purchase plan.

Operating Capital Requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate 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 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 risks incident 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. We expect to incur additional costs associated with operating as a public company, and we anticipate that we will need substantial additional funding in connection with our continuing operations.

We ended the second quarter of 2017 with cash, cash equivalents and available for sale securities of $321.2 million. The Company completed a follow-on offering in July raising approximately $62.6 million in net proceeds. Our collaborators have committed up to $373.0 million or more in license payments and cost-share funding, which the Company continues to receive on a quarterly prepaid basis. The Company expects its existing cash resources, including net proceeds from the July 2017 follow-on offering and the timing of committed research and development funding from its collaborators, to fund the Company’s current operating plan into the second of 2019. Thereafter committed research and development funding will continue to be received from Otsuka on a prepaid, quarterly basis.

We will require additional capital for the further development of our existing product candidates and will need to raise additional funds sooner to pursue development activities related to additional product candidates. If and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity, debt offerings, or strategic transactions. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Furthermore, our development milestones may not be achieved, we may not receive the anticipated funding from our collaboration partners, and we may not secure other sources of financing. Additional funds may not be available to us on acceptable terms or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders or increased fixed payment obligations, and any such securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may be substantially different than actual results, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near- and long-term, will depend on many factors including, but not limited to, those described under Part II, Item 1A. Risk Factors of this Quarterly Report on Form 10-Q.

If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K that was filed with the SEC on March 6, 2017.

Off-Balance Sheet Arrangements

As of June 30, 2017 we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. As of June 30, 2017 and December 31, 2016, we had cash and cash equivalents and available-for-sale securities of $321.2 million and $260.3 million, respectively, primarily money market mutual funds consisting of U.S. government debt securities, certificates of deposit and corporate debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our investments are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of June 30, 2017, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

During the second quarter of fiscal 2017, we identified a material weakness in our internal control over financial reporting resulting from inadequate control over expense recognition of certain cash advance payments made to one of our clinical research organizations supporting our global Phase 3 program. Specifically, we did not have adequate controls in place to properly determine the portion of the cash advance payments that should be recorded as an expense in the period and the portion that should be recorded as a prepaid expense. In addition, the amount of revenue recognized pursuant to certain of our collaboration agreements was consequently affected, as such revenue is recognized based on the percentage of expense incurred on the total of the expected cost of the global Phase 3 program. Based upon that discovery, our principal executive officer and principal financial officer have concluded that, as of June 30, 2017, our disclosure controls and procedures were not effective at a level that provides reasonable assurance.

To remediate the material weakness described above, we have initiated compensating controls and are enhancing and revising the design of existing controls and procedures to properly account for certain research and development expenses. The revised and enhanced controls will not be considered effective until they operate for a sufficient period of time and management has concluded, through testing, that these controls are operating as designed.

Changes in Internal Control over Financial Reporting

Except as noted above, during the quarter ended June 30, 2017, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

Opposition Proceeding Against Our '005 Patent

In July 2011, a third party filed an opposition to our issued European Patent No. 2044005, or the '005 Patent. During the oral proceedings, which took place on April 10, 2013, the Opposition Division of the European Patent Office maintained the '005 Patent on the basis of the third auxiliary request filed during the oral proceedings. This decision resulted in the maintenance of a claim

directed to a compound chosen from a group of eight compounds, including vadadustat, as well as claims to compositions and methods for treating various diseases, including, but not limited to, anemia. Both parties have appealed the decision of the Opposition Division and final resolution of the opposition proceedings will likely take a year or more. We cannot be assured of the breadth of the claims that will remain in the ’005 Patent or that the patent will not be revoked in its entirety.

Opposition and Invalidity Proceedings Against FibroGen Inc.

We have had a number of positive developments in our opposition and invalidity proceedings against FibroGen, Inc., or FibroGen. With regard to the opposition that we filed in Europe against FibroGen’s European Patent No. 1463823, or the ’823 patent, an oral proceeding took place March 8 and 9, 2016. Following the oral proceeding, the European Opposition Division ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. FibroGen has appealed that decision and the appeal process is expected to take 2 to 3 years. Likewise, with regard to the invalidity proceeding that we filed in Japan against certain claims of FibroGen’s Japanese Patent No. 4804131, or the ’131 patent, which is the Japanese counterpart to the ’823 patent, the Japan Patent Office, or JPO, issued a preliminary decision finding all of the challenged claims to be invalid. FibroGen subsequently amended the claims and the JPO accepted the amendments. The resulting FibroGen Japanese ’131 patent does not cover vadadustat or any pyridine carboxamide compounds. To date, FibroGen has been unsuccessful in its attempts to obtain a patent in the United States covering the same claim scope as it obtained initially in Europe and Japan in the ’823 and ’131 patents. In the event FibroGen were to obtain such a patent in the United States, we may decide to challenge the patent like we have done in Europe and Japan.

With regard to the opposition that we filed in Europe against FibroGen’s European Patent No. 163333, or the ’333 patent, an oral proceeding took place December 8 and 9, 2016. Following the oral proceeding, the European Opposition Division ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. FibroGen has appealed that decision.

On May 13, 2015, May 20, 2015 and July 6, 2015, we filed oppositions to FibroGen’s European Patent Nos. 2322153, 2322155, and 163333, or the ’153 patent, the ’155 patent, and the ’333 patent, respectively, requesting the patents be revoked in their entirety. These related patents claim, among other things, various compounds that either stabilize HIFα or inhibit a HIF hydroxylase or a HIF prolyl hydroxylase for treating or preventing various conditions, including, *inter alia*, iron deficiency, microcytosis associated with iron deficiency, anemia of chronic disease, anemia wherein the subject has a transferrin saturation of less than 20%, anemia refractory to treatment with exogenously administered erythropoietin, or EPO, and microcytosis in microcytic anemia. Such method of use patents do not prevent persons from using the compound for other uses, including any previously known use of the compound. In particular, these patents do not claim methods of using any of our product candidates for purposes of inhibiting hypoxia-inducible factor prolyl hydroxylases, or HIF-PHs, for the treatment of anemia secondary to CKD. While we do not believe these patents will prevent us from commercializing vadadustat for the treatment of anemia secondary to CKD, we filed these oppositions to provide us and any future partners with maximum flexibility for developing vadadustat and our pipeline of HIF PH inhibitors. Oppositions to the ’155 patent and to the ’153 patent were also filed by Glaxo Group Limited, or Glaxo, and by Bayer Intellectual Property GmbH, Bayer Pharma Aktiengesellschaft, and Bayer Animal Health GmbH. In oral proceedings held on May 29, 2017, the European Opposition Division ruled that the '155 patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. Subsequently, in related oral proceedings held on May 31, 2017 and June 1, 2017 for the '153 patent, FibroGen significantly narrowed the claims to an indication for which vadadustat is not intended to be developed.

Item 1A. Risk Factors

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. Please reference our “Cautionary Note Regarding Forward-Looking Statements,” which identifies certain forward-looking statements contained in this report that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred net losses each year since our inception, including net losses of $66.1 million for the six months ended June 30, 2017, and $61.6 million for the six months ended June 30, 2016. As of June 30, 2017, we had an accumulated deficit of $363.2 million. To date, we have not commercialized any products or generated any revenue from the sale of products. We do not know whether or when we will generate revenue or become profitable.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. To date, we have financed our operations primarily through our public offerings of common stock, private placements of our preferred stock and strategic collaborations. The amount of our future net losses will depend, in part, on the rate of our future expenditures, and our financial position will depend, in part, on our ability to obtain funding through equity or debt financings or strategic collaborations. Even if we obtain regulatory approval to market vadadustat, our future revenue will depend upon the timing of such approval, the size of any markets in which vadadustat receives approval, our ability to achieve sufficient market acceptance, the availability and extent of reimbursement from third-party payors and other factors.

We expect to continue to incur significant expenses and increased operating losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- conduct our development program of vadadustat for the treatment of anemia secondary to CKD, including PRO_2TECT, $INNO_2VATE$, FO_2RWARD and $TRILO_2GY$;
- develop plans for the preclinical and clinical development of AKB-5169 and our other product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical studies;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- initiate additional preclinical, clinical or other studies for additional indications for vadadustat, AKB-5169 and other product candidates that we may develop or acquire;
- seek to discover and develop additional product candidates;
- acquire, in-license and develop other commercial products, product candidates and technologies;
- make royalty, milestone or other payments under our agreement with Janssen and any future in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- continue to create additional infrastructure to support our operations as a public company.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, if at all, we will be able to achieve profitability. If we are required by the FDA, EMA, or other regulatory authorities to perform studies in addition to, different from or larger than those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

To become and remain profitable, we must succeed in developing and commercializing our product candidates, which must generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and development, conducting clinical trials of our product candidates, discovering or acquiring additional product candidates, obtaining regulatory approval for these product candidates, and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

We will require substantial additional financing. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

As of June 30, 2017, our cash and cash equivalents and available for sale securities were $321.2 million. We completed a follow-on offering in July 2017 raising approximately $62.6 million in net proceeds. We believe that we will continue to expend substantial resources for the foreseeable future developing vadadustat, AKB-5169 and any other product candidates that we may develop or acquire. These expenditures will include costs associated with research and development, potentially obtaining regulatory approvals and having our products manufactured, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise as a result of our decision to include certain elements in our programs. Because the outcome of our current and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amount of funding necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- significant costs associated with our Phase 3 clinical studies of vadadustat for the treatment of anemia secondary to CKD; we expect the remaining aggregate cost of the Phase 3 program to be in the range of $450.0 million to $480.0 million and the PRO$_2$TECT and INNO$_2$VATE Phase 3 programs are designed to enroll up to approximately 6,300 CKD patients; such estimated costs could increase significantly if the Phase 3 program takes longer to complete or if we choose to add additional investigative sites, add additional patients, modify the clinical trial protocol, or perform other studies in support of the Phase 3 program;
- the results of our meetings with the FDA and the EMA and other regulatory authorities and the consequential effect on study design, study size and resulting operating costs;
- difficulties or delays in enrolling patients in our clinical trials;
- assuming favorable Phase 3 clinical results, the timing of, and the costs involved in, obtaining regulatory approvals for vadadustat in dialysis and non-dialysis indications, including to fund the preparation and filing of regulatory submissions for vadadustat with the FDA, the EMA and other regulatory authorities, and whether we will seek regulatory approval for both indications simultaneously;
- the cost of conducting the FO$_2$RWARD and TRILO$_2$GY clinical studies;
- the cost, timing and outcome of our efforts to obtain marketing approval for vadadustat in the United States, Europe and in other jurisdictions;
- the scope, progress, results and costs of additional preclinical, clinical, or other studies for additional indications for vadadustat, as well as any studies of AKB-5169 and other product candidates that we may develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory approvals for AKB-5169 and other product candidates that we may develop or acquire, if clinical studies are successful;
- the cost of securing and validating commercial manufacturing of vadadustat;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved by regulatory authorities, including product manufacturing, marketing, sales and distribution costs;
- the costs involved in preparing, filing and prosecuting patent applications and maintaining, defending and enforcing our intellectual property rights, including litigation costs, and the outcome of such litigation; and
- the extent to which we acquire or in-license other products, product candidates or technologies.

We ended the second quarter of 2017 with cash, cash equivalents and available for sale securities of $321.2 million. We completed a follow-on offering in July 2017 raising approximately $62.6 million in net proceeds. Our collaborators have committed up to$373.0 million or more in license payments and cost-share funding, which we continue to receive on a quarterly prepaid basis. The Company expects its existing cash resources, including net proceeds from the July follow-on offering and the timing of committed research and development funding from its collaborators, to fund the Company's current operating plan into the second quarter of 2019. Thereafter committed research and development funding will continue to be received from Otsuka on a prepaid, quarterly basis. If and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity, debt offerings, or strategic transactions. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Furthermore, our development milestones may not be achieved, we may not receive the anticipated funding from our collaboration partners, and we may not secure other sources of financing.

We will require additional capital for the further development of our existing product candidates and will need to raise additional funds sooner to pursue development activities related to additional product candidates. If and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity, debt offerings, or strategic collaborations. Additional funds may not be available to us on acceptable terms or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders or increased fixed payment obligations, and any such securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to product candidates on unfavorable terms to us.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of collaboration funding, equity offerings, debt financings and strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for vadadustat, AKB-5169 or any other product candidates that we develop or acquire, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to our Business and the Clinical Development, Regulatory Review and Approval of Vadadustat Other Product Candidates

We depend heavily on the success of one product candidate, vadadustat, which is in Phase 3 development. Even if we obtain favorable clinical results in our Phase 3 studies, we may not be able to obtain regulatory approval for, or successfully commercialize, vadadustat.

We currently have only one product candidate, vadadustat, in clinical development, and our business depends almost entirely on the successful clinical development, regulatory approval and commercialization of that product candidate, which may never occur. We currently have no drug products for sale, generate no revenue from sales of any drugs, and may never be able to develop marketable drug products. Vadadustat, which is in Phase 3 development, will require substantial additional clinical development, testing, manufacturing process development, and regulatory approval before we or our collaborators are permitted to commence its commercialization. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States, the European Union, Japan, and in other countries where we and our collaborators intend to test 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 testing and clinical trials that the product candidate is safe and effective for use in each target indication. This process can take many years. Of the large number of drugs in development in the United States, only a small percentage successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite capital to continue to fund our development and clinical programs, we may be unable to successfully develop or commercialize vadadustat.

We and Otsuka, our collaboration partner, are not permitted to market vadadustat in the United States until we receive approval from the FDA, in the European Union until we receive approval from the EMA, or in any jurisdiction outside of the United States until we receive the requisite approval from regulatory authorities in such jurisdiction. MTPC, our collaboration partner in Asia, will not be permitted to market vadadustat in Japan without approval from the PMDA. As a condition to receiving regulatory approval for vadadustat, we must complete Phase 3 studies and any additional non-clinical or clinical studies required by the FDA. Vadadustat may not be successful in clinical trials or receive regulatory approval. Further, vadadustat may not receive regulatory approval even if it is successful in clinical trials. Obtaining approval of an NDA in the United States is a complex, lengthy, expensive and uncertain process that typically takes many years following the completion of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, the safety concerns associated with injectable rESAs may affect the FDA's review of the safety results of compounds of this class, including vadadustat. Further, the policies or regulations, or the type and amount of clinical data necessary to gain approval, may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that vadadustat will never obtain regulatory approval. The FDA may delay, limit or deny approval of vadadustat for many reasons including, among others:

- we may not be able to demonstrate that vadadustat is safe and effective in treating anemia secondary to CKD to the satisfaction of the FDA;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may not approve the formulation, labeling or specifications we request for vadadustat;
- the FDA may approve vadadustat for use only in a small patient population;
- the FDA may require that we conduct additional clinical trials;

- the contract research organizations, or CROs, that we retain to conduct our clinical trials may not perform effectively or take actions outside of our control that materially adversely impact our clinical trials;
- we or our contract manufacturers may fail to perform in accordance with the FDA's current good manufacturing practice, or cGMP, requirements;
- the FDA may disagree with inclusion of data obtained from certain regions outside the United States to support the NDA for potential reasons such as differences in clinical practice from United States standards;
- the FDA may disagree with our interpretation of data from our nonclinical studies and clinical trials;
- the FDA may not approve the manufacturing processes or facilities of third-party manufacturers with whom we contract; or
- the policies or regulations of the FDA may significantly change in a manner that renders our clinical data insufficient for approval, or requires us to amend or submit new clinical protocols.

In addition, similar reasons may cause the EMA or PMDA or other regulatory authorities to delay, limit or deny approval of vadadustat outside the United States.

We may find it difficult to enroll patients in our clinical studies, which could delay or prevent clinical studies of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends on the speed at which we can recruit patients to participate in testing our product candidates. Patients may be unwilling to participate in our clinical studies for vadadustat because of concerns about adverse events observed with injectable rESAs, other investigational agents and commercial products in CKD or for other reasons, including competitive clinical studies for similar patient populations. In addition, patients currently receiving treatment with injectable rESAs may be reluctant to participate in a clinical trial with an investigational drug. Finally, competition for clinical trial sites may limit our access to subjects appropriate for studies of vadadustat. As a result, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our development of vadadustat, or termination of the clinical studies altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics, to complete our clinical studies in a timely manner. Patient enrollment is affected by many factors, including:

- severity of the disease under investigation;
- design of the study protocol;
- 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;
- proximity and availability of clinical study sites for prospective patients;
- availability of competing therapies and clinical studies and clinicians' and patients' perceptions as to the potential advantages of vadadustat in relation to available therapies or other products in development;
- efforts to facilitate timely enrollment in clinical studies;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical studies if we cannot enroll a sufficient number of eligible patients to participate in the clinical studies required by regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit or terminate on-going or planned clinical studies, any of which would have an adverse effect on our business.

We may not be able to conduct clinical trials in some jurisdictions outside of the United States.

We currently expect to seek regulatory approval of vadadustat for the treatment of anemia secondary to CKD in markets outside the United States, including the European Union and Japan. Our ability to successfully initiate, enroll and complete a clinical study in any country outside of the United States is subject to numerous risks unique to conducting business in international markets, including:

- difficulty in establishing or managing relationships with qualified CROs, physicians and clinical trial sites;
- different local standards for the conduct of clinical studies; and
- the potential burden of complying with a variety of laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments.

Data obtained from studies conducted in the United States may not be accepted by the EMA, PMDA and other regulatory authorities outside of the United States. Also, certain jurisdictions require data from studies conducted in their country in order to obtain approval in that country.

We are currently in discussions with the Pharmaceuticals and Medical Devices Agency, or PMDA, in Japan regarding whether Japanese subjects may be enrolled in our global Phase 3 studies. The outcome of these discussions will have a significant impact on near-term payments that MTPC will be obligated to make to us pursuant to our collaboration agreement with MTPC.

Once the results of certain Phase 2 studies of vadadustat in Japan are available, we and MTPC, following consultation with the PMDA, will determine whether a separate Phase 3 study of vadadustat will be required in Japan, which we refer to as the Local Scenario, or whether Japanese patients can take part in our global Phase 3 clinical studies, which we refer to as the Global Scenario.

Under the Local Scenario, MTPC would be responsible for the costs of the local Phase 3 study in Japan and would make no additional funding payments for the global Phase 3 program. This would reduce the total amount of development payments that we are eligible to receive under our agreement with MTPC. In addition, $20.0 million of the $40.0 million received in 2016 would be used to fund local development of vadadustat in Japan. The Company is currently conducting Phase 2 studies in Japan and will, if under the Local Scenario, apply the $20.0 million against the Phase 2 costs already incurred, and MTPC will reimburse the Company for costs in excess of $20.0 million to complete the studies.

If we fail to successfully meet requirements for the conduct of clinical trials outside of the United States, we may be delayed in obtaining, or be unable to obtain, regulatory approval or reimbursement for vadadustat in countries outside of the United States.

Regulatory authorities outside of the United States will require compliance with numerous and varying requirements. The approval procedures vary among jurisdictions and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, a drug product must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our product is also subject to approval. Approval by the FDA does not ensure approval by regulatory or reimbursement authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by the FDA or regulatory or reimbursement authorities in other countries. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval in another jurisdiction. The regulatory approval process in countries outside of the United States may include all of the risks associated with obtaining FDA approval and, in some cases, additional risks. We may not obtain such regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive the necessary approvals to commercialize our product candidates in any market. Also, favorable pricing in certain countries depends on a number of factors, some of which are outside the Company's control.

Clinical drug development is a lengthy and expensive process with an uncertain outcome, and positive results from the clinical studies of vadadustat thus far are not necessarily predictive of the results of any future clinical studies of vadadustat. If, in our Phase 3 studies, we cannot replicate the positive clinical results observed to date, we may be unable to successfully develop, obtain regulatory approval, for and commercialize vadadustat.

Clinical testing 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 studies may not be predictive of similar results in humans during clinical trials, and successful results from early or small clinical trials may not be replicated in later and larger clinical trials. For example, our encouraging preclinical and clinical results for vadadustat thus far do not ensure that the results of any future clinical trials will demonstrate similar results. Our vadadustat Phase 3 development program will enroll a larger number of subjects and will treat subjects for longer periods than our prior trials, which will result in a greater likelihood that adverse events may be observed. Many companies in the biopharmaceutical industry have suffered significant setbacks in late-stage clinical trials after achieving positive results in early stage development, and we may face similar setbacks. If the results of our ongoing or future clinical trials for

vadadustat are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are safety concerns or adverse events, we may be prevented from or delayed in obtaining marketing approval for vadadustat.

We could encounter delays if a clinical trial is suspended or terminated by us, by the relevant independent institutional review boards at the sites at which such trials are being conducted, by the Independent Data Monitoring Committee, or IDMC, for such trial or by the FDA or other regulatory authorities. Such suspension or termination may be due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, critical findings resulting from inspection of clinical trial operations, clinical trial site or manufacturing facilities by the FDA or other regulatory authorities, the imposition of a clinical hold, unforeseen safety issues or adverse side effects, changes in laws or regulations, or lack of adequate funding to continue the clinical trial. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and prospects significantly.

Even if we receive regulatory approval for our product candidates, such products will be subject to ongoing regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or other conditions of approval, or contain requirements for potentially costly post-marketing studies and surveillance to monitor the safety and efficacy of the product. In addition, if the FDA approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, as well as continued compliance with current Good Manufacturing Practices, or cGMPs, and GCPs for any clinical trials that we conduct post-approval.

Post-approval discovery of previously unknown problems with an approved drug product, including adverse events of unanticipated severity or frequency or relating to manufacturing operations or processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the drug product, withdrawal of the drug product from the market, or drug product recalls;
- fines, warning letters or clinical holds;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- a Risk Evaluation Management Strategy program; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Risks Related to our Reliance on Third Parties

We rely on third parties to conduct preclinical and clinical studies for our product candidates. If they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We are currently relying, and expect to continue to rely, on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our current and future clinical trials, including our Phase 3 development program for vadadustat. We compete with many other companies for the resources of these third parties. The third parties on whom we rely may fail to perform effectively or terminate their engagement with us, and having to enter into alternative arrangements would delay development and commercialization of our product candidates.

We entered into an agreement with Quintiles IMS Holdings, Inc. to be our primary CRO for the PRO_2TECT and $INNO_2VATE$ programs. If Quintiles cannot perform effectively or terminates their engagement with us, the progress of our Phase 3 clinical studies may be impacted and we may incur significant added costs in identifying, qualifying and contracting with a new CRO.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, the FDA and equivalent regulatory authorities outside of the United States require compliance with regulations and standards, including GCP requirements, for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the rights, integrity and confidentiality of study subjects are protected. Although we rely on third parties to conduct our clinical trials, we are responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol in compliance with legal and regulatory requirements. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product that meets certain specifications and is manufactured under applicable cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to clinical trial protocols or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, the clinical trials of our product candidates may not meet regulatory requirements. If clinical trials do not meet regulatory requirements or if these third parties need to be replaced, preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates on a timely basis or at all.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, resulting in additional losses and depriving us of potential product revenue. In addition, we are using an active comparator in our PRO_2TECT and $INNO_2$VATE clinical programs. If our distributors are unable to obtain sufficient supply of the active comparator for any reason, or supply active comparator to clinical trial sites in a timely manner, our clinical trials may be extended, delayed, suspended or terminated.

We rely on third parties to conduct some or all aspects of our product manufacturing, and these third parties may not perform satisfactorily.

We do not have any manufacturing facilities and do not expect to independently manufacture our product candidates for research and preclinical and clinical studies. We currently rely, and expect to continue to rely, on third parties to manufacture and supply drug product for our vadadustat clinical trials, and we expect to rely on third parties for the manufacture of clinical and commercial quantities of all of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Also, these third parties may fail to perform effectively or terminate their engagement with us. We entered into agreements with Evonik Corporation and Esteve Quimica for the manufacture of the drug substance for the Phase 3 development program of vadadustat. If either of these contract manufacturers cannot perform as agreed or terminates their engagement with us, we may be required to find replacement manufacturers. We may incur significant delays and added costs in identifying, qualifying and contracting with any such replacement, as well as producing the drug substance. We also have an agreement with Gregory Pharmaceutical Holdings (d/b/a UPM Pharmaceuticals Inc., or UPM) for the manufacture of finished drug product for the Phase 3 development program. Although we believe that there are several other manufacturers who also could manufacture our drug product if UPM cannot perform as agreed or terminates their engagement with us, we may incur significant delays and added costs in identifying, qualifying, and contracting with another manufacturer. When we engage a second source for the manufacture of drug product, we will incur additional costs. In addition, we have to enter into technology transfer agreements and share our know-how with such third-party manufacturers, which can be time-consuming and may result in delays. These delays could result in a suspension of our clinical trials or, if vadadustat is approved and marketed, a failure to satisfy patient demand.

Any of these events could lead to clinical study delays or failure to obtain regulatory approval, or affect our ability to successfully commercialize our future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

The facilities and processes used by our contract manufacturers to manufacture our product candidates will be inspected by the FDA and other regulatory authorities prior to or after we submit our marketing application. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with cGMP requirements for manufacture of both drug substance and finished drug product. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and regulatory requirements, we will not be able to secure and/or maintain regulatory approval for our product

candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or other regulatory authorities do not approve these facilities for the manufacture of our product candidates, or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Moreover, the failure of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect the supply of our products or product candidates. Also, if our drug substance or drug product is damaged or lost while in our contract manufacturers' control, it may impact our ability to supply our products or product candidates and we may incur significant financial harm.

In addition, our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. Certain of these manufacturing facilities may be contractually prohibited from manufacturing our product candidates or products due to exclusivity provisions in agreements with our competitors. There are a limited number of manufacturers that operate under cGMP regulations and are capable of manufacturing our product candidates for us.

If we are unable to obtain our product candidates in sufficient quantities and at sufficient yields, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution.

Completion of our clinical trials and commercialization of our product candidates require access to facilities to manufacture our product candidates at sufficient yields and at clinical and commercial scale. We have limited experience manufacturing, or managing third parties in manufacturing, our product candidates in the volumes that will be necessary to support large-scale clinical trials or commercial sales. Our contract manufacturers may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality.

Our reliance on contract manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of contract manufacturers with the expertise, required regulatory approvals and facilities to manufacture our bulk drug substance and drug product on a commercial scale, replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in the production of our product candidates. A contract manufacturer may also encounter difficulties in production.

Any delay or interruption in our supply of product candidates or products could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We may not be successful in maintaining our strategic collaborations which could adversely affect our ability to develop and commercialize our product candidates, negatively impacting our operating results.

We plan to commercialize vadadustat in the United States, Europe, and other territories pursuant to our collaboration agreement with Otsuka and have entered into a collaboration agreement with MTPC to develop and commercialize vadadustat in Japan and certain other Asian countries. We may not be able to maintain such strategic collaborations.

In addition, our strategic collaborators may terminate any agreements they enter into with us, and we may not be able to adequately protect our rights under these agreements. Furthermore, our strategic collaborators have negotiated for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do.

If we fail to maintain our current collaborations with Otsuka or MTPC, we will bear all of the risk and costs related to the development and commercialization of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop additional expertise. This could negatively affect the development and commercialization of any such product candidate.

Risks Related to our Intellectual Property

If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market. We are currently involved in an opposition proceeding involving one of our European patents, and the outcome of that proceeding may affect our ability to establish a competitive advantage in the market or successfully commercialize our lead product candidate in the European Union.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. We will only be able to protect our product candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. Any disclosure to or

misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market.

In July 2011, a third party filed an opposition to one of our issued European patents, European Patent No. 2044005, or the ’005 Patent. During the oral proceedings, which took place on April 10, 2013, the Opposition Division of the European Patent Office decided to maintain certain claims of the patent directed to a compound chosen from a group of eight compounds, including vadadustat, as well as claims to compositions and methods for treating various diseases including, but not limited to, anemia. Both parties have appealed the decision of the Opposition Division and final resolution of the opposition proceeding will likely take a year or more. We cannot be assured of the breadth of the claims that will remain in the ’005 Patent or that the patent will not be revoked in its entirety. If the European Patent Office decides to narrow the scope of the claims or revoke the ’005 Patent, we may not be able to establish a competitive advantage in the European Union in our market or successfully commercialize our product candidates in the European Union, which could materially adversely affect our business, operating results and financial condition.

Composition-of-matter patents on the active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. Method-of-use patents protect the use of a product for the specified method. A method-of-use patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other countries. Our competitors have taken, and we expect that they will continue to undertake, formal efforts to oppose the issuance of claims in our patent applications. We do not control decisions made by the United States Patent and Trademark Office, or US PTO, or equivalent bodies outside the United States. Even if our patents do successfully issue, third parties may challenge the validity, enforceability, inventorship, or scope of these patents, such actions may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. If we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the US PTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law with the passage of the America Invents Act (2011), which brings into effect significant changes to the U.S. patent laws and introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a “first to file” system in the United States. This will require us to be cognizant of the time from invention to filing of a patent application.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how processes, and any other elements of our drug discovery and development process and information or technology that are not covered by patents. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential or proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in the market, which could materially adversely affect our business, operating results and financial condition.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to research, develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, services agreements, material transfer agreements, consulting agreements, research agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets.

Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will usually expect to be granted rights to publish data arising out of such collaboration. We often grant such rights, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration and remove confidential or trade secret information from any such publication. In the future, we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Some of the intellectual property that protects our product candidates is owned by third parties and is licensed to us. Any dispute that might arise under any such license agreement could jeopardize our rights in such product candidates and materially harm our business.

We license intellectual property rights that protect some of our product candidates from third parties. If a dispute were to arise with a licensor pursuant to such a license agreement, our rights to use the licensed intellectual property and to develop and commercialize the compounds that such intellectual property covers could be jeopardized. If we have expended significant resources developing these compounds, such a dispute could have a material adverse effect on our business.

Third-party claims of intellectual property infringement may be costly and time consuming, and may delay or harm our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. The pharmaceutical and biotechnology industries are characterized by extensive litigation over patent and other intellectual property rights. We have in the past and may in the future become a party to, or be threatened with, future adversarial litigation or other proceedings regarding intellectual property rights with respect to our drug candidates. As the pharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

While our product candidates are in preclinical studies and clinical trials, we believe that the use of our product candidates in these preclinical studies and clinical trials in the United States falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e), which provides that it shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention solely for uses reasonably related to the development and submission of information to the FDA. As our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We attempt to ensure that our product candidates and the methods we employ to manufacture them, as well as the methods for their use which we intend to promote, do not infringe other parties' patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

Third parties may hold or obtain patents or other intellectual property rights and allege in the future, that the use of our product candidates infringes these patents or intellectual property rights, or that we are employing their proprietary technology without authorization. We do not believe that there are any currently issued U.S. patents that conflict with our intellectual property rights; nor do we make any admission that any of such patents are valid, enforceable or infringed. Under U.S. law, a party may be able to patent a discovery of a new way to use a previously known compound, even if such compound itself is patented, provided the newly discovered use is novel and nonobvious. Such a method-of-use patent, however, if valid, only protects the use of a claimed compound for the specified methods claimed in the patent. This type of patent does not prevent persons from using the compound for any previously known use of the compound. Further, this type of patent does not prevent persons from making and marketing the compound for an indication that is outside the scope of the patented method. We are not aware of any valid U.S. patents issued to FibroGen, or any other person, that claim methods of using any of our product candidates for purposes of inhibiting hypoxia-inducible factor prolyl hydroxylases, or HIF-PHs, for the treatment of anemia secondary to CKD. For example, we are aware of certain patents that have been acquired by FibroGen directed to certain heterocyclic carboxamide compounds that are described as inhibitors of prolyl-4-hydroxylase. Those patents, however, are believed to have expired as of December 2014.

FibroGen has also filed other patent applications in the U.S. and other countries directed to purportedly new methods of using such previously known heterocyclic carboxamide compounds for purposes of treating or affecting specified conditions, and some of these

applications have since issued as patents. To the extent any such patents issue or have been issued, we may initiate opposition or other legal proceedings with respect to such patents. We have discussed the status of the opposition proceedings against FibroGen's European '823, '153,'155 and '333 patents above in Item 1. Legal Proceedings.

There may be other patents of FibroGen or patents of third parties of which we are currently unaware with claims to compounds, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Also, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe.

Third parties, including FibroGen, may in the future claim that our product candidates and other technologies infringe upon their patents and may challenge our ability to commercialize vadadustat. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize vadadustat, AKB-6899, AKB-5169 or other product candidates that we may develop or acquire. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or our intended methods of use, including patient selection methods, the holders of any such patent may be able to block or impair our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. We may also elect to enter into a license in order to settle litigation or in order to resolve disputes prior to litigation. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. Should a license to a third-party patent become necessary, we cannot predict whether we would be able to obtain a license or, if a license were available, whether it would be available on commercially reasonable terms. If such a license is necessary and a license under the applicable patent is unavailable on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Further, defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties or redesign our products, which may be impossible or require substantial time and monetary expenditure.

We are currently involved in opposition and invalidity proceedings and may in the future be involved in lawsuits or administrative proceedings to challenge the patents of our competitors or to protect or enforce our patents, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or misappropriate our trade secrets or confidential information. To counter infringement or unauthorized use, we may be required to file infringement or misappropriation claims, which can be expensive and time-consuming. We may not be able to prevent infringement of our patents or misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. For example, we are currently involved in five opposition proceedings in the European Patent Office. These proceedings may be ongoing for a number of years and may involve substantial expense and diversion of employee resources from our business. In addition, we may become involved in additional opposition proceedings or other legal or administrative proceedings in the future. For more information, see the other risk factors under "Risks Related to Intellectual Property" and Item 1 – Legal Proceedings.

In addition, there may be a challenge or dispute regarding inventorship or ownership of patents or applications currently identified as being owned by or licensed to us. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Various administrative proceedings are also available for challenging patents, including interference, reexamination, *inter partes* review, and post-grant review proceedings before the US PTO or oppositions and other comparable proceedings in foreign jurisdictions. Interference proceedings provoked by third parties or brought by the US PTO may be necessary to determine the priority of inventions with respect to our patents or patent applications.

An unfavorable outcome in any current or future proceeding could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on

commercially reasonable terms or at all. Even if we are successful, participation in interference or other administrative proceedings before the US PTO or a foreign patent office may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and some administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the US PTO and foreign patent agencies in several stages over the lifetime of the patent. The US PTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment (such as annuities) and other similar provisions during the patent application process. While an inadvertent lapse in many cases can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from potential collaborators, prospective licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. Consequently, the breadth of our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other countries. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own products and, further, may infringe our patents in territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain countries. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in countries outside of the United States could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Security breaches and unauthorized use of our IT systems and information, or the IT systems or information in the possession of our vendors, could damage the integrity of our clinical studies or compromise our ability to protect our intellectual property.

We are highly dependent on contract research organizations to carry out our clinical studies. A security breach, cyber-attack or unauthorized access of our clinical data could cause significant risk to our business, and could compromise our ability to protect our intellectual property. Cyber-attacks can include malware, computer viruses, hacking or other significant compromise of our computer, communications and related systems. Although we take steps to manage and avoid these risks and to be prepared to respond to attacks, our preventive and any remedial actions may not be successful. Likewise, although we believe our vendors and service providers take steps to manage and avoid information security risks and respond to attacks, we may be vulnerable to attacks against our vendors or service providers, and we may not have adequate contractual remedies against such vendors and service providers in such event. Such attacks, whether successful or unsuccessful, could result in our incurring costs related to, for example, rebuilding internal systems, defending against litigation, responding to regulatory inquiries or actions, paying damages or fines, or taking other remedial steps with respect to third parties. Publicity about vulnerabilities and attempted or successful incursions could damage the integrity of our studies or delay their completion. In addition, such attacks could compromise our ability to protect our trade secrets and proprietary information from unauthorized access or misappropriation.

Risks Related to Commercialization

Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payors and others in the medical community.

Even if we obtain marketing approval for vadadustat, AKB-5169 or any other product candidates that we may develop or acquire in the future, these product candidates may not gain market acceptance among physicians, third-party payors, patients and others in the medical community in the United States or in other countries. In addition, market acceptance of any approved product depends on a number of other factors, including:

- the safety and efficacy of the product, as demonstrated in clinical trials, and in the post-marketing setting;
- the prevalence of the disease treated by our product;
- the clinical indications for which the product is approved and the product label approved by regulatory authorities, including any warnings or limitations that may be required on the label or as a consequence of potential safety risks associated with the product;
- the claims we are able to make regarding the safety and efficacy of our products;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety and efficacy of the product in relation to alternative treatments;
- the timing of product launch relative to competing products;
- the availability of adequate coverage and reimbursement by third-party payors and governmental authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- the effectiveness of our sales and marketing efforts; and
- the restrictions on the use of our products together with other medications, if any.

Market acceptance of any of our product candidates, if approved, may also depend on factors specific to such candidates, such as our ability to contract with dialysis providers. Two of the largest operators of dialysis clinics in the United States, DaVita, Inc., or DaVita, and Fresenius Medical Care, or Fresenius, account for more than half of the injectable rESA sales in the U.S. dialysis market. We believe that it may be challenging to enter into supply agreements with certain dialysis clinics.

Market acceptance is critical to our ability to generate significant revenue. In addition, any product candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

Our products may cause 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 products or even competing products in development that utilize a common mechanism of action could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities and could lead to potential product liability claims.

The patients in our clinical studies have CKD, a serious disease that increases the risk of cardiovascular disease including heart attacks and stroke, and, ultimately may cause kidney failure. Many of patients with CKD are elderly with comorbidities making them susceptible to significant health risks. Therefore, the likelihood of these patients having adverse events, including serious adverse events, while participating in our studies is high.

Serious adverse events deemed to be possibly or probably related to vadadustat could have a material adverse effect on the development of our product candidates and our business as a whole. Our understanding of adverse events in future clinical trials of our product candidates may change as we gather more information, and additional unexpected adverse events may be observed in future clinical trials.

If we or others identify undesirable side effects caused by our product candidates, either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical trials may be put on hold;
- patient recruitment could be slowed, and enrolled patients may not want to complete the clinical trial;
- we may be unable to obtain regulatory approval for our product candidates or regulatory authorities may withdraw approvals of product candidates;
- regulatory authorities may require additional warnings on the label;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our products and could substantially increase commercialization costs.

If we are unable to establish sales, marketing and distribution capabilities or to enter into additional agreements with third parties to market and sell our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We are currently collaborating with Otsuka to develop and commercialize vadadustat in the United States, Europe and certain other regions and MTPC to develop and commercialize vadadustat in Japan. We do not have a sales or marketing infrastructure and we have not yet sold, marketed or distributed any of our products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements for sales and marketing services, either by establishing our own or entering into additional geographic collaborations.

There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force are expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If we are unable to establish our own sales, marketing and distribution capabilities for the United States and Latin America and have to enter into arrangements with third parties to perform these services, our profitability, if any, is likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We have entered into collaboration agreements with Otsuka and MTPC which are key to our success. If either Otsuka or MTPC fails to perform under these agreements, our future results could be materially harmed.

In addition to certain substantial upfront payments and development milestones, our agreement with Otsuka for the United States establishes a profit sharing arrangement with respect to net sales of vadadustat and our agreement with Otsuka for the European Union and other regions provides us with royalty payments on net sales of vadadustat. Similarly, our agreement with MTPC grants them the exclusive right to develop and commercialize vadadustat in Japan and certain Asian countries in exchange for upfront, milestone, and royalty payments. We partnered with each company, in part, because they have a well-established commercial presence and infrastructure in their territories, and we expect them to help us prepare for and execute on an optimal launch of vadadustat in those geographies. If either of these companies fails to perform their obligations diligently under their agreement with us, including failing to diligently commercialize vadadustat in their territories, our sales potential in these regions may be materially harmed and we may not have an adequate remedy for such harm under our agreements with either company. Furthermore, if a contractual dispute with either Otsuka or MTPC were to arise, it could result in costly litigation for the Company and jeopardize important revenue streams, which could materially harm our financial condition.

Coverage and reimbursement may be limited or unavailable in certain market segments for our products, if approved, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of any approved products will depend significantly on the availability of adequate coverage and reimbursement from third-party payors and may be affected by existing and future healthcare reform measures. Government authorities and third-party payors decide which drugs they will cover, as well as establish formularies or implement other mechanisms to manage utilization of products, and determine reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient; and
- cost-effective.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. Additionally, we may be required to enter into contracts with third-party payors offering rebates or discounts on our products in order to obtain favorable formulary status. We may not be able to agree upon commercially reasonable terms with such third-party payors or provide data sufficient to obtain favorable coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Even if we obtain coverage for our product candidates, third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for our product, and prompt us to have to reduce pricing for the products. If reimbursement is not available or is limited, we may not be able to commercialize certain of our products. In addition, in the United States third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage reimbursement levels for new drugs. As a result, significant uncertainty exists as to whether and how much reimbursement third-party payors will provide for newly approved drugs, which, in turn, will put downward pressure on the pricing of drugs.

In addition, if vadadustat is used in an outpatient dialysis facility, such facilities often receive fixed reimbursement for a bundle of dialysis services, including certain drugs and supplies used to treat patients with end-stage renal disease, or ESRD. For example, Medicare payments to ESRD facilities for dialysis treatments are based on a prospective payment system with a standard per treatment payment (subject to certain adjustments such as patient level-case-mix adjustment). The per treatment payment covers a bundle of items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at home and includes the cost of certain routine drugs. At this time, we believe that vadadustat, if approved, will likely be included in the bundle. We may be unable to sell vadadustat, if approved, to dialysis providers on a profitable basis if third-party payors reduce their current levels of payment or if our costs of production increase faster than increases in reimbursement levels. Patient and provider access to adequate coverage and reimbursement by government and private insurance plans is central to the acceptance of any products for which we receive regulatory approval. If vadadustat is not included in the bundle, the Vifor Agreement would not become effective. We would be required to enter into contracts with third party payors and we would be subject to the risks and uncertainties described above.

Price controls may be imposed, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further

complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices, and even, in some instances, render commercialization in a market infeasible or disadvantageous from a financial perspective. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or government authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

The impact of recent healthcare reform and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws or, regulations related to healthcare availability or the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

The U.S. healthcare industry generally and U.S. government healthcare programs in particular are highly regulated and subject to frequent and substantial changes. For example, in 2010, and as described above, the Healthcare Reform Act, which represented one of the most significant healthcare reform measures in decades, was enacted. The full impact on our business of the Healthcare Reform Act or its potential future repeal or amendment is uncertain.

As a general matter, federal and state legislatures within the United States and governments in other countries will likely continue to consider changes to existing healthcare legislation, and, in particular, we anticipate additional governmental reforms intended to control drug costs. We cannot predict the reform initiatives that may be adopted in the future. Private health plans may also increase efforts to manage utilization and control drug costs and prices. The continuing efforts of the government or private third party payors to contain or reduce costs of healthcare may adversely affect:

- the demand for any drug products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

Even prior to approval, we are subject to a complex regulatory scheme that requires Company resources to ensure compliance. Failure to comply with applicable laws could subject the Company to government scrutiny or government enforcement, potentially resulting in costly investigations and/or fines or sanctions, or impacting our relationship with key regulatory agencies such as FDA or EMA.

Even before we have obtained approval for vadadustat or any product, certain laws apply to the Company or may otherwise restrict its activities, including the following:

- United States federal securities laws restricting the purchase or sale of any securities while in possession of material, non-public information;
- laws and regulations governing the conduct of clinical and preclinical studies in the United States and in countries in which we are conducting such studies;
- laws and regulations in the United States and in countries in which we are interacting with health care providers, patients, patient organizations and other constituencies that prohibit promoting a drug prior to approval and/or reimbursement;
- laws, regulations and industry codes that vary from country to country and govern Akebia’s relationships with health care providers, patients, patient organizations, and other constituencies, and prohibit certain types of gifts and entertainment, establish codes of conduct and, in some instances, require disclosure to, or approval by, regulatory authorities for Akebia to engage in arrangements with such constituencies;
- anti-corruption and anti-bribery laws, including the Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act and various other anti-corruption laws in countries outside of the United States. The FCPA generally prohibits companies and their intermediaries, such as the CROs, contract manufacturing organizations, and distributors with which we do business outside the United States from making improper payments to foreign government officials for the purposes of obtaining or keeping business and/or other benefits;

- data privacy laws existing in the European Union and other countries in which we operate, including the United States' federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and state privacy and data protection laws, as well as state consumer protection laws; and
- international trade laws, which are laws that regulate the sale, purchase, import, export, re-export, transfer and shipment of goods, products, materials, services and technology.

If our product candidates obtain marketing approval, we will be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

If we obtain approval for any of our product candidates and begin commercializing them, our operations may be directly, or indirectly through our customers, subject to additional healthcare regulation and enforcement by the federal government, states and governments outside of the United States in which we conduct our business. In addition to the laws mentioned above, the laws that may affect our ability to operate include:

- the Federal Food, Drug & Cosmetic Act, or FD&C Act, which among other things, strictly regulates drug product marketing and promotion and prohibits manufacturers from marketing such products for off-label use;
- the federal anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce the referral for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called "federal sunshine" law (also known as "open payments") which requires pharmaceutical and medical device manufacturers to report certain financial interactions to the federal government for re-disclosure to the public;
- the federal law known as HIPAA, which, in addition to privacy protections, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- state law equivalents of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state gift ban and transparency laws, many of which state laws differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts; and
- state laws restricting interactions with healthcare providers and other members of the healthcare community or requiring pharmaceutical manufacturers to implement certain compliance standards.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reforms have strengthened these laws. For example, the Healthcare Reform Act, among other things, amended the intent requirement of the federal anti-kickback law. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate the law. The Healthcare Reform Act also amended the False Claims Act, such that violations of the anti-kickback statute are now deemed violations of the False Claims Act.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to, on a corporate or individual basis, penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and even imprisonment, any of which could materially adversely affect our ability to operate our business and our financial results. In addition, the cost of implementing sufficient systems, controls, and processes to ensure compliance with all of the aforementioned laws could be significant.

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.

The development and commercialization of new drug products is highly competitive. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the development and commercialization of our product candidates.

Our objective is to develop and commercialize new products with superior efficacy, convenience, tolerability and/or safety. In many cases, the products that we commercialize will compete with existing, market-leading products.

If vadadustat is approved and launched commercially, competing drugs may include EPOGEN® and Aranesp®, commercialized by Amgen, Procrit® and Eprex®, commercialized by Johnson & Johnson, and Mircera®, commercialized by Roche Holding Ltd., or Roche. We may face competition from potential new anemia therapies. There are several other HIF product candidates in various stages of active development for anemia indications that may be in direct competition with vadadustat if and when they are approved and launched commercially. These candidates are being developed by such companies as FibroGen, in collaboration with AstraZeneca PLC in the United States and China and with Astellas Pharma Inc. in Europe and Asia, Japan Tobacco International, GlaxoSmithKline plc and Bayer HealthCare AG. FibroGen is currently in Phase 3 clinical development of its product candidate, roxadustat, and GlaxoSmithKline plc recently commenced Phase 3 studies of its product candidate, daprodustat. Some of these product candidates may enter certain markets as early as 2017. In addition, certain companies are developing potential new therapies for renal-related diseases that could potentially reduce rESA utilization and thus limit the market for vadadustat if and when it is approved and launched commercially. Other new therapies are in development for the treatment of conditions inclusive of renal anemia that may impact the market for anemia-targeted treatment.

Since rESAs are biologic products, the introduction of biosimilars into the rESA market in the United States will constitute additional competition for vadadustat if we are able to obtain approval for and commercially launch our product. A biosimilar product is a follow-on version of an existing, branded biologic product. The patents for the existing, branded product must expire in a given market before biosimilars may enter that market without risk of being sued for patent infringement. In addition, an application for a biosimilar product cannot be approved by the FDA until 12 years after the existing, branded product was approved under a Biologics License Application, or BLA. The patents for epoetin alfa, an rESA, expired in 2004 in the European Union, and the remaining patents expired between 2012 and 2015 in the United States. Several biosimilar versions of rESAs are available for sale in the European Union and biosimilar versions of rESAs are currently being studied in clinical trials in the United States.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. Large and established companies such as Amgen and Roche, among others, compete in the market for drug products to treat anemia. In particular, these companies have greater experience and expertise in conducting pre-clinical testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing competitive products before, or more effectively than, we do. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

Risks Related to our Business and Industry

If we fail to attract and keep senior management and key personnel, we may be unable to successfully develop our products, conduct our clinical trials and commercialize our product candidates.

Recruiting and retaining qualified scientific, clinical, medical, manufacturing and sales and marketing personnel will also be critical to our success. We are highly dependent on certain members of our senior management. The loss of the services of our executives, senior managers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executives and other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. We may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the intense competition among numerous biopharmaceutical companies for similar personnel.

We also experience competition for the hiring of personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating and executing our research and development and commercialization strategy. Our consultants and advisors may become employed by companies other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to grow and pursue our business strategy will be limited.

Our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate applicable laws, including (1) FDA and other healthcare authorities' regulations, including those laws that require the reporting of true, complete and accurate information to regulatory authorities, and those prohibiting the promotion of unapproved drugs or approved drugs for an unapproved use, (2) quality standards, including Good Laboratory Practices (GLP), GCP and GMP, (3) federal and state healthcare fraud and abuse laws and regulations, (4) anti-bribery and anti-corruption laws, such as the FCPA and the U.K. Bribery Act, that prohibit the making of improper payments to foreign officials or individuals for the purposes of obtaining any business advantage, (5) laws that require the reporting of true and accurate financial information and data, and (6) securities laws and regulations. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, or if any such action is instituted against our employees, consultants, vendors or principal investigators, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, curtailment of our operations, and imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

We may encounter difficulties in managing our growth and expanding our operations successfully

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our clinical, medical, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. We have recently entered into a number of strategic collaborations for the development and commercialization of vadadustat. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize vadadustat, if approved, and any other product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train, integrate and retain additional personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to study participants or patients;
- product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue;

- the inability to commercialize any product candidates that we may develop; and
- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the use and disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from the use of hazardous materials by our employees or consultants, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to our Common Stock

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. As a result, we intend to continue to take advantage of certain reduced disclosure requirements.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and obtaining shareholder approval of any golden parachute payments not previously approved.

Investors may find our common stock less attractive if we continue to rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We could be an emerging growth company for up to five years from our initial public offering in March 2014, although circumstances could cause us to lose that status earlier, including (1) if the market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 before that time or (2) if we have total annual gross revenue of $1 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or (3) if

we issue more than $1 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately.

Our stock price has been and may continue to be volatile, and, as a result you may not be able to resell your shares at or above the public offering price.

Our stock price has been and may continue to be volatile. Since our initial public offering in March 2014, the price of our common stock as reported on The NASDAQ Global Market has ranged from a low of $5.91 on August 25, 2015 to a high of $31.00 on June 20, 2014. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control.

In addition, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. As we operate in a single industry, we are especially vulnerable to the factors listed above to the extent that they affect our industry, markets or products. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price, and such an action was filed against us but has since been dismissed. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

Provisions in our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our Ninth Amended and Restated Certificate of Incorporation and Amended and Restated By-Laws contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions:

- authorize "blank check" preferred stock, which could be issued by our Board of Directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified Board of Directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our Board of Directors pursuant to a resolution adopted by a majority of the total number of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our Board of Directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our Board of Directors may be filled only by a majority of directors then in office, even though less than a quorum;
- require a supermajority vote of the holders of our common stock or the majority vote of our Board of Directors to amend our Amended and Restated By-Laws; and
- require a supermajority vote of the holders of our common stock to amend the classification of our Board of Directors into three classes and to amend certain other provisions of our Amended and Restated Certificate of Incorporation.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our Amended and Restated Certificate of Incorporation, our Amended and Restated By-Laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. Our existing NOLs may be subject to substantial limitations arising from previous ownership changes and our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income. As described above under "—Risks related to our financial position and need for additional capital," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs. A full valuation allowance has been provided for the entire amount of our NOLs.

Our Amended and Restated Certificate of Incorporation designates the state or federal courts located in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Amended and Restated Certificate of Incorporation provides that, subject to limited exceptions, the state and federal courts located in the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our Amended and Restated Certificate of Incorporation or our Amended and Restated By-Laws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Amended and Restated Certificate of Incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our Amended and Restated Certificate of Incorporation inapplicable to, or unenforceable with respect to, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Securities

During the quarter ended June 30, 2017, we did not have any sales of unregistered securities.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

The following disclosure is provided in accordance with and in satisfaction of the requirements of Item 2.02 " *Results of Operations and Financial Condition* " of Form 8-K:

On August 8, 2017, Akebia announced its financial results for the quarter ended June 30, 2017 and commented on certain corporate accomplishments and plans. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 hereto.

The information furnished in Item 5 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 6. Exhibits.

Exhibits

4.1#	Investment Agreement between Akebia Therapeutics, Inc. and Vifor (International) Ltd., dated May 12, 2017.
10.1#	Collaboration and License Agreement between Akebia Therapeutics, Inc. and Otsuka Pharmaceutical Co. Ltd., dated April 25, 2017.
10.2#	License Agreement between Akebia Therapeutics, Inc. and Vifor (International) Ltd., dated May 12, 2017.
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. 1350.
99.1	Press Release issued by Akebia Therapeutics, Inc. on August 8, 2017 (furnished herewith).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

# Indicates portions of the exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AKEBIA THERAPEUTICS, INC.

Date: August 8, 2017

By: /s/ John P. Butler
John P. Butler
Chief Executive Officer and President

Under the requirements of the Securities and Exchange Act of 1934, this report was signed by the following persons on behalf of the Registrant and in the capacities and on the date indicated.

Date: August 8, 2017

By: /s/ John P. Butler
John P. Butler
Chief Executive Officer and President

Date: August 8, 2017

By: /s/ Jason A. Amello
Jason A. Amello
Senior Vice President, Chief Financial Officer and Treasurer

CONFIDENTIAL

INVESTMENT AGREEMENT

By and Between

VIFOR (INTERNATIONAL) LTD.

AND

AKEBIA THERAPEUTICS, INC.

Dated as of May 12, 2017

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

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INVESTMENT AGREEMENT

THIS INVESTMENT AGREEMENT (this "**Agreement**") is dated as of May 12, 2017, by and between Vifor (International) Ltd. (together with its permitted successors and assigns, the "**Investor**"), a corporation established in accordance with Swiss laws and registered in the commercial registry under CH-107.360.718, with its premises at Rechenstrasse 37, 9014 St. Gallen, Switzerland, and Akebia Therapeutics, Inc. (together with its permitted successors and assigns, the "**Company**"), a Delaware corporation, with its principal place of business at 245 First Street, Suite 1100, Cambridge, Massachusetts 02142.

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value $0.00001 per share, of the Company (the "**Common Stock**"); and

WHEREAS, in partial consideration for Investor's willingness to enter into this Agreement, the Company and Investor are entering into the License Agreement;

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor and the Company agree as follows:

ARTICLE I
Definitions.

1.1. Defined Terms. Capitalized terms used herein but not defined shall have the respective meanings ascribed to them in the License Agreement. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"**Affiliate"** shall mean, with respect to any Person, another Person that controls, is controlled by, controlling or is under common control with such Person, with "control" meaning direct or indirect Beneficial Ownership of at least 50% of the voting stock of, or at least a 50% interest in the income of, the applicable entity. Notwithstanding the foregoing, "Affiliates" will not include with respect to the Investor, FMC or any member of the FMC Group.

"**Agreement"** shall have the meaning set forth in the Preamble, including all Exhibits attached hereto.

"**Beneficial Ownership**" shall mean, with respect to any security, the ownership of such security by any "beneficial owner," as such term is defined in Rule 13d-3 and Rule 13d-5 under the Exchange Act, except that, in calculating the beneficial ownership of any particular "person" (as that term is used in Section 13(d)(3) of the Exchange Act), such "person" will be deemed to have beneficial ownership of all securities that such "person" has the right to acquire by conversion or exercise of other securities (including derivative securities, whether such securities are settled in cash or stock), whether such right is currently exercisable or is exercisable only after the passage of time. The terms "Beneficially Own," "Beneficially Owned" and "Beneficial Owner" shall have correlative meaning.

"**Business Day"** shall mean any day (other than a Saturday or Sunday) on which the banks in Cambridge, Massachusetts and in Zurich, Switzerland are open for business.

"**Company SEC Documents**" shall mean, for the year in which the applicable Closing occurs (i) the most recently filed annual report on Form 10-K, (ii) any Current Reports on Form 8-K filed by the Company with the SEC since the first day of the then-current fiscal year, (iii) the quarterly reports on Form 10-Q filed by the Company with the SEC since the filing date of the Form 10-K referred to above, (iv) the Company's most recently filed definitive proxy statement for the annual meeting of stockholders, and (v) all other statements, reports, schedules, forms and other documents filed by the Company with the SEC since the last day of the prior fiscal year, and all amendments thereto.

"**Database Lock**" shall mean when the clinical trial database for the [***] is locked to further modifications (including additions, deletions or alterations of data).

"**DOJ"** shall mean the U.S. Department of Justice.

"**FTC"** shall mean the U.S. Federal Trade Commission.

"Global Phase 3 DD-CKD Program" means the Phase 3 global clinical studies for the treatment of anemia in dialysis patients with chronic kidney disease, known informally as the INNO2VATE studies, consisting of a conversion study and a correction study, and known formally as the "Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Maintenance Treatment of Anemia in Subjects with Dialysis-Dependent Chronic Kidney Disease (INNO2VATE – Conversion)" (AKB-6548-CI-0017) and the "Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Correction of Anemia in Subjects with Incident Dialysis-Dependent Chronic Kidney Disease (INNO2VATE – Correction)" (AKB-6548-CI-0016).

"**Governmental Authority"** shall mean any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

"**Law"** or "**Laws"** shall mean any applicable law (including common law), statute, rule, regulation, order, judgment or ordinance of any Governmental Authority, including those concerning environmental, health, regulatory and safety matters.

"**License Agreement"** shall mean the License Agreement, of even date herewith, between the Investor and the Company.

"**Lock-Up Period**" shall mean the period beginning on the date of this Agreement and extending until the earliest of (i) [***], (ii) [***] or (iii) [***].

"**Material Adverse Effect**" means any change, event or occurrence that has had or is reasonably likely to have (i) a material adverse effect on the business, condition (financial or other), assets, liabilities or results of operations of the Company and its subsidiaries, taken as a whole, or (ii) a material adverse effect on the Company's ability to timely perform its obligations

under, or timely consummate any of the transactions contemplated by, this Agreement, *except* to the extent that any such change, event or occurrence results from or arises out of changes occurring in general legal, regulatory, political, economic or business conditions or changes in GAAP or interpretations thereof occurring after such date that, in each case, generally affect the biotechnology or biopharmaceutical industries and have not had or would not be reasonably likely to have a disproportionate effect on the Company and its subsidiaries compared to other participants in the biotechnology or biopharmaceutical industries.

"**NASDAQ"** shall mean The Nasdaq Global Market LLC.

"**Organizational Documents"** shall mean (i) the Ninth Amended and Restated Certificate of Incorporation of the Company, as amended through the date of this Agreement and (ii) the Amended and Restated Bylaws of the Company, as amended through the date of this Agreement.

"**Person"** shall mean any individual, partnership, limited liability company, firm, corporation, trust, joint venture, unincorporated organization, Governmental Authority or other entity, as well as any "group" within the meaning of Rule 13d-5 of the Exchange Act.

"**Price Per Share**" shall equal $14.00.

"**Public Offering**" shall mean a public offering and sale of Common Stock pursuant to an effective registration statement under the Securities Act.

"**Sale Transaction**" shall mean a transaction between the Company and a Third Party (i) involving the direct or indirect acquisition by such Third Party of [***]% or more of the Company's outstanding shares of Common Stock or consolidated assets (including assets held by subsidiaries), *excluding* a transaction in which (a) [***] or (b) [***], or (ii) involving the sale of substantially all of the Company's rights with respect to *vadadustat*.

"**SEC**" shall mean the United States Securities and Exchange Commission.

"**Securities Act**" shall mean the Securities Act of 1933, as amended.

"**Third Party"** shall mean any Person other than a Governmental Authority, the Investor, the Company or any Affiliate of the Investor or the Company.

"**Transaction"** shall mean the issuance and sale of the Shares by the Company, and the purchase of the Shares by the Investor at the Closing.

1.2. Additional Defined Terms. In addition to the terms defined in Section 1.1, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

Defined Term	Section
Common Stock	Recitals
Company	Preamble
Exchange Act	Section 4.7(a)
Closing	Section 2.1
Closing Date	Section 3.1
Investor	Preamble
Irrevocable Proxy	Section 6.2(b)(ii)
Modified Clause	Section 7.8
Rule 144	Section 5.9
Shares	Section 2.1

ARTICLE II
Purchase and Sale of Securities

2.1. Purchase and Sale of Securities. Subject to the terms and conditions of this Agreement, at the closing (the "**Closing**") the Company shall issue and sell to the Investor, free and clear of all liens, other than any liens arising as a result of any action by the Investor, and the Investor shall purchase from the Company, 3,571,429 shares of Common Stock (the "**Shares**") at the Price Per Share, representing an aggregate purchase price of U.S. $50,000,000 (the "**Purchase Price**").

ARTICLE III
Closing; Deliveries.

3.1. Closing. The Closing shall take place by electronic exchange of documents upon execution by all Parties of this Agreement (the date of such Closing, the "**Closing Date**").

3.2. Deliveries by the Company. At the Closing, simultaneously with the execution of this Agreement, the Company shall deliver to the Investor the Shares, registered in the name of the Investor, by instructing its transfer agent to register such issuance in book-entry form at the time of issuance and by causing its transfer agent to deliver a statement evidencing such issuance as soon as practicable following the Closing. The Company shall also deliver at the Closing: (i) a certificate of the Secretary of the Company dated as of the Closing Date certifying (A) that attached thereto is a true and complete copy of the Amended and Restated Bylaws of the Company as in effect at the time of the actions by the Board of Directors of the Company referred to in clause (B) below, and on the Closing Date; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board of Directors of the Company authorizing the execution, delivery and performance of this Agreement and the Transaction and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby as of the Closing Date; (C) that attached thereto is a true and complete copy of the Company's Ninth Amended Restated Certificate of Incorporation as in effect at the time of

the actions by the Board of Directors of the Company referred to in clause (B) above, and on the Closing Date; and (D) as to the incumbency and specimen signature of any officer of the Company executing this Agreement on behalf of the Company and (ii) an opinion of counsel to the Company substantially in the form attached hereto as Exhibit B and (iii) a certificate of the Chief Executive Officer of the Company substantially in the form attached hereto as Exhibit A.

3.3. Deliveries by the Investor. At the Closing, the Investor shall deliver, or cause to be delivered, to the Company the Purchase Price by wire transfer of immediately available United States funds to an account designated by the Company. The Company shall notify the Investor in writing of the wiring instructions for such account not less than [***] before the Closing Date.

ARTICLE IV
Representations and Warranties of the Company.

The Company hereby represents and warrants to the Investor as of the date of this Agreement that:

4.1. Organization, Corporate Power and Authority. The Company is a corporation duly incorporated, validly existing and in good standing under the laws of the jurisdiction of its incorporation, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. The Company has all requisite corporate power and corporate authority to own, lease and operate its properties and assets, to carry on its business as described in the Company SEC Documents and as contemplated to be conducted by this Agreement. The Company has and will have all requisite power and corporate authority to enter into this Agreement and to perform its obligations under and to carry out the Transaction.

4.2. Authorization.

(a) All requisite corporate action required by applicable Law for the authorization, execution and delivery by the Company of this Agreement, and the performance of all obligations of the Company hereunder and thereunder, including the authorization, issuance and delivery of the Closing Shares, has been taken.

(b) This Agreement has been duly executed and delivered by the Company and, upon the due execution and delivery thereof by the Investor, will constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms (except as such enforceability may be limited by (i) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights and (ii) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).

4.3. No Conflicts. The execution, delivery and performance of this Agreement, and compliance with the provisions hereof and thereof by the Company do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument,

whether written or oral, by which the Company is bound or (c) violate or conflict with any of the provisions of the Company's Organizational Documents, except in each case as would not have a Material Adverse Effect.

4.4. No Governmental Authority or Third Party Consents. No consent, approval, authorization or other order of or filing with any Governmental Authority is required to be obtained by the Company in connection with the authorization, execution and delivery of this Agreement or with the issuance and sale of the Shares at the Initial Closing, except the filing of a Current Report on Form 8-K and a Notice of Sale of Securities on Form D with the Securities and Exchange Commission to the extent required by applicable Law.

4.5. Capitalization. The authorized capitalization of the Company consists of 175,000,000 shares of Common Stock, of which 38,891,483 shares were issued and outstanding as of May 5, 2017, and 25,000,000 shares of preferred stock, $0.00001 par value, of which no shares are issued and outstanding. The sale and issuance of the Shares will not obligate the Company to issue shares of Common Stock or other securities to any other person and will not result in a right of any holder of securities issued by the Company to adjust the exercise, conversion, or exchange price or ratio under any such securities. Other than as set forth in the Company SEC Documents, the Company is not a party to any stockholders, voting or similar agreement with any other person.

4.6. Valid Issuance of Shares. When issued and delivered in accordance with the terms hereof against payment therefor, the Shares shall be validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal or other similar rights, other than as arising pursuant to this Agreement, as a result of any action by the Investor or under federal or state securities Laws. Assuming the accuracy of the representations and warranties of the Investor in this Agreement, the Shares will be issued in compliance with all applicable federal and state securities Laws.

4.7. Company SEC Documents; Financial Statements.

(a) During the one year preceding the date of this Agreement, the Company has filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein), and any required amendments to any of the foregoing, with the SEC. As of their respective filing dates (or date of amendment, if amended), each of the Company SEC Documents (i) complied as to form in all material respects with the requirements of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") (as the case may be), and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents, and (ii) contained no untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) When filed, the financial statements of the Company included in its most recently filed Annual Report on Form 10-K and, if the Annual Report on Form 10-K is not the Company's most recently filed periodic report, in its most recently filed quarterly report on Form 10-Q, complied as to form in all material respects with the published rules and regulations of the SEC applicable with respect thereto, were prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (except as

may be indicated in the notes thereto or, in the case of unaudited financial statements, as permitted by Form 10-Q, Form 8-K or any successor form under the Exchange Act, and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments that will not, individually or in the aggregate, be material in amount) and fairly present in all material respects the financial position of the Company and its consolidated subsidiaries as of the dates thereof and the results of its operations and cash flows for the periods then ended.

(c) From January 1, 2017 to the date hereof, (i) there have been no events, occurrences or developments that have had or would reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect and (ii) the Company has not incurred any liabilities other than (A) trade payables, accrued expenses and other liabilities incurred in the ordinary course of business consistent with past practice, (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission and (C) liabilities that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

4.8. Litigation. There is no action, suit, proceeding or investigation pending, or to the knowledge of the Company, threatened which (i) would reasonably be expected to materially adversely affect or successfully challenge the legality, validity or enforceability of this Agreement or (ii) except as specifically disclosed in the Company SEC Documents, would, if there were an unfavorable decision, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect. Except as disclosed in the Company SEC Documents, neither the Company nor, to the knowledge of the Company, any director or officer thereof is or has been since January 1, 2016 the subject of any action, suit, proceeding or investigation involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty relating to actions taken at the Company.

4.9. Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Shares, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended.

4.10. No General Solicitation. Neither the Company nor any Person acting on behalf of the Company has offered or sold any of the Shares by any form of general solicitation or general advertising (within the meaning of Regulation D of the Securities Act). The Company has offered the Shares for sale only to the Investor.

ARTICLE V
Representations and Warranties of the Investor.

The Investor hereby represents and warrants to the Company as of the date of this Agreement that:

5.1. Organization; Good Standing. The Investor is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of formation. The Investor has and will have all requisite power and authority to enter into this Agreement and to perform its obligations under and to carry out the Transaction.

5.2. Authorization. All requisite action required by applicable Law for the authorization, execution and delivery by the Investor of this Agreement, and the performance of all of its obligations hereunder and thereunder, including the subscription for and purchase of the Shares, has been taken. This Agreement has been duly executed and delivered by the Investor and, upon the due execution and delivery thereof by the Company, will constitute valid and legally binding obligations of the Investor, enforceable against the Investor in accordance with their respective terms (except as such enforceability may be limited by (a) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights and (b) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).

5.3. No Conflicts. The execution, delivery and performance of this Agreement and compliance with the provisions thereof by the Investor do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Investor is bound, or (c) violate or conflict with any of the provisions of the Investor's organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents), except as would not have a material adverse effect on the Investor's ability to perform its obligations or consummate the Transaction in accordance with the terms of this Agreement.

5.4. No Governmental Authority or Third Party Consents. No consent, approval, authorization or other order of any Governmental Authority or other Third Party is required to be obtained by the Investor in connection with the authorization, execution and delivery this Agreement or with the subscription for and purchase of the Shares.

5.5. Purchase Entirely for Own Account. The Shares shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and the Investor has no, and will have no, intention of selling, granting any participation or otherwise distributing the Shares. The Investor does not have and will not have as of the Closing any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participation to a Person any of the Shares.

5.6. Disclosure of Information. The Investor has received all the information from the Company and its management that the Investor considers necessary or appropriate for deciding whether to purchase the Shares hereunder. The Investor further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the Company, its financial condition, results of operations and prospects and the terms and conditions of the offering of the Shares sufficient to enable it to evaluate its investment.

5.7. Investment Experience and Accredited Investor Status. The Investor is an "accredited investor" (as defined in Regulation D under the Securities Act). The Investor has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder.

5.8. Acquiring Person. Neither the Investor nor any of its Affiliates Beneficially Owns any securities of the Company, except for securities that may be owned by employee benefit plans of the Investor or any of its Affiliates.

5.9. Restricted Securities. The Investor understands that the Shares, when issued, shall be "restricted securities" under the federal securities Laws inasmuch as they are being acquired from the Company in a transaction not involving a Public Offering and that under such Laws the Shares may be resold without registration under the Securities Act only in certain limited circumstances. The Investor represents that it is familiar with Rule 144 of the Securities Act ("**Rule 144**"), as presently in effect.

5.10. Legends. The Investor understands that any certificates representing the Shares shall bear the following legends:

(a) "THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF A REGISTRATION STATEMENT IN EFFECT WITH RESPECT TO THE SECURITIES UNDER THE SECURITIES ACT OR AN OPINION OF COUNSEL (WHICH COUNSEL SHALL BE REASONABLY SATISFACTORY TO THE COMPANY) THAT SUCH REGISTRATION IS NOT REQUIRED OR UNLESS SOLD PURSUANT TO RULE 144 OF THE SECURITIES ACT."; and

(b) "THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO AND SHALL BE TRANSFERABLE ONLY UPON THE TERMS AND CONDITIONS OF AN INVESTMENT AGREEMENT DATED AS OF MAY 12, 2017, BY AND BETWEEN AKEBIA THERAPEUTICS, INC. AND VIFOR (INTERNATIONAL) LTD., A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF AKEBIA THERAPEUTICS, INC."

ARTICLE VI
Additional Covenants and Agreements.

6.1. Lock-Up.

(a) During the Lock-Up Period, except in the case of a transfer to an Affiliate that agrees to bound by the same restrictions as the Investor described in this ARTICLE VI, the Investor shall not (i) transfer, offer, pledge, sell, contract to sell, or otherwise dispose of, directly or indirectly any option or contract to purchase, purchase any option or contract to sell, or otherwise dispose of, directly or indirectly and shares of Common Stock or any securities convertible into, exercisable for, or exchangeable for shares of Common Stock, or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction is to be settled by delivery of securities, cash or otherwise.

(b) Following the expiration of the Lock-Up Period, the Investor may transfer any Shares only as follows: (i) in a Public Offering, (ii) in accordance with Rule 144 (including the volume limitations contained in clause (e) thereof, regardless of whether such limitations would

then be applicable to any such transfer), (iii) pursuant to a tender offer initiated by the Company, (iv) in a privately negotiated transaction (other than [***]) so long as the transferee agrees to be bound by the same restrictions as the Investor described in this ARTICLE VI or (v) in any transaction between the Company and a Third Party (including a third party tender offer or other business combination transaction) which has been approved by the Company's Board of Directors.

6.2. Additional Agreements of Investor.

(a) Standstill. Except in connection with the acquisition of Shares by the Investor pursuant to the terms of this Agreement, the Investor shall not, without the written consent of the Company, acquire directly or indirectly, in a public or private transaction, including by purchase in the open market, any Common Stock if the Investor's Beneficial Ownership of the Common Stock would thereafter exceed [***] percent ([***]%). In addition, unless approved in advance in writing by the Company, the Investor agrees that it will not, directly or indirectly:

(i) Make any statement or proposal to the Company, other than a non-public statement or proposal delivered directly to the Chief Executive Officer or Chairman of the Board of Directors, or to any of the Company's stockholders regarding, or make any public announcement, proposal or offer (including an "solicitation" of "proxies" as such terms are defined or used in Regulation 14A of the Exchange Act) with respect to, or otherwise solicit, seek or offer to effect (including, for the avoidance of doubt, indirectly by means of communication with the press or media) (A) any business combination, merger, tender offer, exchange offer or similar transaction in the Company, (B) any restructuring, recapitalization, liquidation or similar transaction involving the Company, (C) any acquisition of any of the Company's equity securities or assets or rights or options to acquire equity securities or assets, (D) any proposal to seek representation on the board of directors of the Company or otherwise seek to control or influence the management, board of directors or policies of the Company or (E) any proposal, arrangement or other statement that is inconsistent with this Section 6.2;

(ii) Instigate, encourage or assist any Third Party (including forming a "group" with any such third party) to do, or enter into any discussions or agreements with any Third Party with respect to, any of the actions set forth in clause (i) above;

(iii) Take any action which would reasonably be expected to require the Company or any of is Affiliates to make a public announcement regarding any of the actions set forth in clause (i) above;

Notwithstanding the foregoing provisions, the restrictions set forth in this Section 6.2(a) shall terminate and be of no further force and effect (x) if [***], provided that the provisions of this Section 6.2(a) shall be revived if [***]; (y) upon [***]; or (z) so long as the Investor's Beneficial Ownership remains less than [***] percent ([***]%) of the Company's Common Stock, provided that the provisions of this Section 6.2(a) shall be revived at any time when the Investor's Beneficial Ownership equals [***] percent ([***]%) or more of the Company's Common Stock.

(b) Voting Agreements.

(i) Until the expiration of the standstill provisions of Section 6.2(a), Investor shall vote (or cause to be voted) all shares of Common Stock at meetings of the Company's stockholders, (A) as recommended by the Company in its definitive proxy statement or (B) in the same proportion as votes cast by the stockholders of the Company with respect to the applicable matter (such proportion determined without inclusion of the votes cast by Investor) on any matter presented for approval by the Company's stockholders. Any such vote shall be cast by Investor in accordance with such procedures relating thereto so as to ensure that it is duly counted, including for purposes of determining that a quorum is present and for purposes of recording the results of such vote.

(ii) Until the expiration of the period described in the foregoing clause (i), Investor appoints [***] of the Company, or their respective designees, and each of them individually, its proxy and attorneys-in-fact, with full power of substitution and resubstitution (the "**Irrevocable Proxy**") to vote the Shares as recommended by the Company in its definitive proxy statement. Investor shall take such further action or execute such other instruments as may be necessary to effectuate the intent of this proxy. This proxy and power of attorney shall be irrevocable during the term of this Agreement, and shall revoke any and all prior proxies granted by Investor with respect to the Shares. The proxy and power of attorney granted hereunder shall terminate upon the termination of the voting agreements in Section 6.2(b)(i). Notwithstanding the foregoing, the Irrevocable Proxy shall be effective if, at any annual or special meeting of stockholders of the Company and at any adjournments or postponements of any such meeting, the Investor (A) fails to appear or otherwise fails to cause the Shares to be counted as present for purposes for calculating a quorum, or (B) fails to vote such Shares in accordance with this Section 6.2, in each case, at least [***] prior to the date of such stockholders' meeting.

(c) Information Black Outs. From time to time, material non-public information (including information the Company has designated as material and non-public) regarding the Company may be available to Investor but not publicly disclosed. While in possession of such material non-public information and until, (i) the second trading day following the date on which the material non-public information has been publicly disclosed or (ii) the Company notifies the Investor that the information is no longer material (which it shall do promptly after it has made such determination), Investor shall not effect any sales of Common Stock on NASDAQ, regardless of whether the standstill provisions of Section 6.2(a) are then currently in effect or the Lock-Up Period has then expired.

6.3. Form D; Blue Sky Filings. If an offering hereunder qualifies under Regulation D, the Company agrees to timely file a Form D with respect to the Shares as required under Regulation D and to provide a copy thereof, promptly upon request of the Investor. If an offering hereunder does not qualify under Regulation D, the Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Shares for, sale to the Investor at the Closing under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of the Investor.

6.4. Public Disclosure. On the date of this Agreement or within [***] thereafter, the Company and Investor shall jointly issue a press release in a form mutually agreed to by the Company and the Investor. The parties hereto agree that the provisions of Section 14.3 of the License Agreement shall be applicable to the parties to this Agreement with respect to any public disclosures regarding the Transaction or regarding the parties hereto or their Affiliates (it being understood that the provisions of Section 14.3 of the License Agreement shall be read to apply to disclosures of information relating to this Agreement and the transactions contemplated hereby).

6.5. Rule 144. The Company shall use its reasonable best efforts to file the reports required to be filed by it under the Securities Act and the Exchange Act and the rules and regulations adopted by the SEC thereunder in a timely manner in accordance with the requirements of the Securities Act and the Exchange Act (and, if at any time the Company is not required to file such reports, the Company will, upon the request of the Investor, make available such information necessary to permit sales pursuant to Rule 144).

ARTICLE VII
Miscellaneous.

7.1. Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this Agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 7.3 or in such other manner as may be permitted by Law, shall be valid and sufficient thereof.

7.2. Waiver. Waiver by a party of a breach hereunder by the other party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

7.3. Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth below and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission or electronic mail, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or

communication shall be deemed to have been delivered upon receipt if delivered by hand, [***] after it is sent by registered or certified mail, return receipt requested, postage prepaid, [***] after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile or electronic mail (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either party may change its address by giving notice to the other party in the manner provided above.

If to the Investor:

Vifor Pharma
Flughofstrasse 61, 8152 Glattbrugg, Switzerland
Facsimile: [***]
Attention: [***]

With a copy to: Group General Counsel

If to the Company:

Akebia Therapeutics, Inc.
245 First Street, Suite 1100
Cambridge, MA 02142
Attention: [***]

with a copy to:

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199
Attention: [***]
E-Mail: [***]

7.4. Specific Performance. The parties hereto agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with the specific terms hereof or were otherwise breached. It is accordingly agreed that the parties shall be entitled, without posting a bond or similar indemnity, to an injunction or injunctions to prevent breaches of this Agreement or to enforce specifically the performance of the terms and provisions hereof, in addition to any other remedy to which it is entitled at law or in equity. Each of the Company and Investor agrees that it will not oppose the granting of an injunction, specific performance and other equitable relief when expressly available pursuant to the terms of this Agreement on the basis that the other party has an adequate remedy at law or an award of specific performance is not an appropriate remedy for any reason at law or equity.

7.5. Entire Agreement. This Agreement contains the entire agreement among the parties with respect to the subject matter hereof and thereof and supersedes all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.

7.6. Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the Investor and the Company.

7.7. Headings; Nouns and Pronouns; Section References. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

7.8. Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("**Modified Clause**"), then this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

7.9. Assignment. Except for an assignment of this Agreement or any rights hereunder by the Investor to an Affiliate or by the Company to a successor or direct or indirect parent company in connection with a transaction that does not give rise to a termination of this Agreement, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either the Investor or the Company without (a) the prior written consent of Company in the case of any assignment by the Investor or (b) the prior written consent of the Investor in the case of an assignment by the Company.

7.10. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

7.11. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

7.12. Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.

7.13. No Strict Construction. This Agreement has been prepared jointly and will not be construed against either party.

7.14. Survival of Warranties. The representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing and expire on [***] of the effective date of this Agreement.

7.15. Remedies. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

7.16. Expenses. Each party shall pay its own fees and expenses in connection with the preparation, negotiation, execution and delivery of this Agreement and the Transaction.

7.17. Term. If not earlier terminated by mutual written consent of the Company and the Investor, the obligations set forth in this Agreement shall expire at such times as set forth herein.

(Signature Page Follows)

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

VIFOR (INTERNATIONAL) LTD.

By: /s/ Dr. Christoph Springer
Name: Dr. Christoph Springer
Title: Global Head of Business Development

By: /s/ Dr. Oliver P. Kronenberg
Name: Dr. Oliver P. Kronenberg
Title: Group General Counsel

AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler
Name: John P. Butler
Title: President & Chief Executive Officer

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

EXHIBIT A

FORM OF OFFICER'S CERTIFICATE

[***]

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

EXHIBIT B

FORM OF OPINION OF COUNSEL

[***]

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

CONFIDENTIAL

COLLABORATION AND LICENSE AGREEMENT

BY AND BETWEEN

AKEBIA THERAPEUTICS, INC.

AND

OTSUKA PHARMACEUTICAL CO. LTD.

Dated April 25, 2017

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

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COLLABORATION AND LICENSE AGREEMENT

This **COLLABORATION AND LICENSE AGREEMENT** (this "**Agreement**") is made and entered into as of April 25, 2017 (the "**Effective Date**") between Akebia Therapeutics, Inc., a company organized and existing under the laws of the State of Delaware, United States of America with its principal offices at 245 First Street, Cambridge, MA 02142 ("**Akebia**"), and Otsuka Pharmaceutical Co. Ltd., a company organized and existing under the laws of Japan, having a registered office located at 2-9, Kanda Tsukasa-machi, Chiyoda-ku, Tokyo 101-8535, Japan ("**Licensee**").

Akebia and Licensee may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Akebia is the owner of, or otherwise controls, the Akebia Technology, the Licensed Compound, and the Licensed Products in the Territory;

WHEREAS, prior to the Effective Date the Parties entered into the U.S. Collaboration and License Agreement pursuant to which the Parties will collaborate to Develop, perform Medical Affairs, and Commercialize the Licensed Compound and the Licensed Products in the U.S.;

WHEREAS, Licensee (itself and through its Affiliates) has expertise in the development of biopharmaceutical products and has regulatory, development, and commercial capabilities in the Territory, and is interested in obtaining an exclusive license to Develop and Commercialize the Licensed Compound and the Licensed Products in the Territory; and

WHEREAS, the Parties desire to expand their relationship and collaborate to Develop and Commercialize the Licensed Compound and the Licensed Products in the Territory, and Akebia wishes to grant Licensee an exclusive license to Develop and Commercialize the Licensed Compound and the Licensed Products in the Territory as set forth in this Agreement.

NOW THEREFORE, the Parties agree as follows:

Article I
DEFINITIONS

1.1 "**AAA**" has the meaning set forth in Section 16.2.3 (Arbitration Procedure).

1.2 "**Accounting Standards**" means (a) International Financial Reporting Standards, or (b) U.S. GAAP.

1.3 "**Acquiror**" has the meaning set forth in Section 17.3.1 (Exception for Acquisition by a Third Party).

1.4 "**Additional Development**" has the meaning set forth in Section 4.3 (Additional Development).

1.5 "**Affiliate**" means, with respect to a Party, any corporation, or other business entity controlled by, controlling, or under common control with such Party, with "control" meaning (a) direct or indirect beneficial ownership of at least 50% of the voting stock or other ownership interest of, or at least a 50% interest in the income of, the applicable entity, or (b) the possession, directly or indirectly, of the power to direct the management or policies of the applicable entity, whether

through the ownership of voting securities or other equity rights, by contract relating to voting rights or corporate governance, or otherwise. Notwithstanding the foregoing, "Affiliates" will not include, with respect to an entity, *bona fide* venture capital investors in such entity or *bona fide* institutional investors in such entity, which institutional investors routinely make venture capital investments for the potential financial return on such investments and not with any view to acquisition or for other strategic purpose, or Affiliates of such venture capital or institutional investors.

1.6 "**Akebia Housemarks**" means (a) the corporate logo of Akebia, (b) the trademarks "AKEBIA," "PRO2TECT," "INNO2VATE," and "O2XYGEN," (c) any other trademark, trade name, or service mark (whether registered or unregistered) containing the word "Akebia," (d) any trademark, trade name, or service mark (whether registered or unregistered) used as the name of any clinical trial for any Licensed Product, (e) any other corporate logo or trademark of Akebia used by Akebia to identify Akebia or its Affiliates, (f) all registrations, applications for registrations, and other intellectual property rights associated with any of the foregoing, and (g) all goodwill associated with any and all of the foregoing in clauses (a) through (f).

1.7 "**Akebia Improvement**" means any Improvement that is made during the Term in the course of performance of activities undertaken by Akebia pursuant to this Agreement or pursuant to the license grants in Section 2.3 (Grant of Licenses to Akebia), solely by one or more employees of Akebia or any Affiliate of Akebia, or persons contractually required to assign or license such Improvement (or Patents Covering such Improvement) to Akebia or any Affiliate of Akebia, but excluding any Joint Know-How.

1.8 "**Akebia Indemnitees**" has the meaning set forth in Section 14.2 (Indemnification by Licensee).

1.9 "**Akebia Know-How**" means all Know-How (excluding Joint Know-How) that (a) is Controlled as of the Effective Date or during the Term by Akebia or any of its Affiliates; and (b) is either (i) disclosed to Licensee or any of its Affiliates pursuant to this Agreement; or (ii) necessary or reasonably useful for the Development, Packaging, or Commercialization of the Licensed Compound or a Licensed Product in the Field in the Territory.

1.10 "**Akebia Patents**" means all Patents (excluding Joint Patents) that (a) are Controlled as of the Effective Date or during the Term by Akebia or any of its Affiliates in the Territory, and (b) (i) [***] or (ii) are [***] of the Licensed Compound or a Licensed Product in the Field. Akebia Patents include any and all [***] and all Patents Controlled by Akebia or any of its Affiliates in the Territory that Cover Akebia Improvements. All Akebia Patents as of the Effective Date are set forth on Schedule 1.10.

1.11 "**Akebia Reserved Disputes**" means any dispute of the [***] with respect to matters within the [***] jurisdiction that is not resolved following escalation to the [***] (if applicable) and the [***] related to (a) the [***] of the Licensed Compound or the Licensed Products in the Territory in accordance with [***], (b) the [***] for each Licensed Product and [***] for use in the Territory, (c) any [***] of the Licensed Compound or the Licensed Products (*other than* [***]), including (i) whether to [***], and (ii) whether to [***], and (d) [***] only to the extent described in Section 1.11.1 through Section 1.11.4:

with respect to [***]*:*

1.11.1 *prior to* the [***], in each case, any [***] of [***] Licensed Product in such indication or such formulation to be [***] that is reasonably likely [***] for such indication or such formulation, including [***]; and

1.11.2 *after* the [***], in each case, if [***] in effect, then [***] of [***] Licensed Product in such indication or such formulation to be [***] for such indication or such formulation.

For clarity, *after* the [***], if the [***], then the [***] Licensed Product for such indication or such formulation to be [***] will be an Expert Reserved Matter, and not an Akebia Reserved Dispute.

with respect to [***]:

1.11.3 *prior to* the [***]:

(a) [***] (subject to Section 1.11.1 or Section 1.11.2, as applicable, with respect [***] that is reasonably likely [***] for such indication or such formulation, including [***], and

(b) [***], in each case, that [***] of any applicable [***] for such indication or such formulation; and

1.11.4 *after* the [***], in each case, [***] in effect, then [***] of [***] Licensed Product in such indication or such formulation [***] for such indication or such formulation.

For clarity, *after* the [***], if [***] in effect, then, [***] of [***] Licensed Product for such indication or such formulation [***] will be an Expert Reserved Matter, and not an Akebia Reserved Dispute.

Further for clarity, if the [***] of [***], in each case, [***] of such [***] will not be an Akebia Reserved Dispute, *unless*, prior to the [***] such indication or such formulation [***] is reasonably likely [***], in which case [***] will be an Akebia Reserved Dispute to the extent described above.

Notwithstanding the foregoing, an Akebia Reserved Dispute will not include any dispute regarding (A) whether to [***], (B) whether to [***], or (C) any Expert Reserved Matter.

In addition, if Akebia, [***], is (i) [***], or (ii) [***], an Akebia Reserved Dispute will not include any dispute regarding a [***] pursuant to Section [***].

1.12 "**Akebia Technology**" means Akebia Know-How, Akebia Patents, Assigned Product Improvements, Akebia Improvements, and Akebia's interest in Joint Technology.

1.13 "**Alliance Manager**" has the meaning set forth in Section 3.9 (Alliance Managers).

1.14 "**Anti-Slavery and Human Trafficking Laws**" has the meaning set forth in Section 12.4.6 (Additional Covenants).

1.15 "**API**" means active pharmaceutical ingredient, which is also commonly referred to as drug substance. For the avoidance of doubt, API will include any prodrug form.

1.16 "**Applicable Law**" means any applicable law (including common law), statute, rule, regulation, order, judgment, or ordinance of any Governmental Authority (including any Regulatory Authority), including those concerning environmental, health, regulatory, privacy, and safety matters.

1.17 "**Approved Labeling**" means, with respect to each Licensed Product: (a) the Regulatory Authority-approved full prescribing information for such Licensed Product; and (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for such Licensed Product.

1.18 "**Arbitration Request**" has the meaning set forth in Section 16.2.1 (Arbitration Request).

1.19 "**Assigned Product Improvement Patents**" means any Patent that Covers an Assigned Product Improvement.

1.20 "**Assigned Product Improvements**" means all Licensee Improvements that solely relate to the Licensed Compound or a Licensed Product.

1.21 "**Breaching Party**" has the meaning set forth in Section 15.2 (Termination for Breach).

1.22 "**Business Day**" means any day (*other than* a Saturday or Sunday) on which the banks in Cambridge, Massachusetts, Tokyo, Japan, and London, England are open for business.

1.23 "**Clinical Supply Agreement**" has the meaning set forth in Section 8.3 (Supply Agreements).

1.24 "**Combination Product**" means any Licensed Product that is comprised of two or more APIs, at least one of which is the Licensed Compound.

1.25 "**Commercial Operations**" means, with respect to a country, a country in which Licensee or any of its Affiliates conducts sales activities either itself or jointly with a Third Party.

1.26 "**Commercial Supply Agreement**" has the meaning set forth in Section 8.3 (Supply Agreements).

1.27 "**Commercialization**" means, with respect to a Licensed Product, Combination Product, or Co-Packaged Product, any and all activities directed to the marketing, promotion, distribution, pricing, reimbursement, offering for sale, and sale of such Licensed Product, Combination Product, or Co-Packaged Product, and interacting with Regulatory Authorities following Regulatory Approval in the applicable country or region for such Licensed Product, Combination Product, or Co-Packaged Product, regarding the foregoing, including seeking any required Reimbursement Approval, but excluding activities directed to the manufacture (including Packaging) and Development of the Licensed Compound or a Licensed Product. "**Commercialize**," "**Commercializing**," and "**Commercialized**" will be construed accordingly.

1.28 "**Commercialization Plan**" means a [***] plan for the Commercialization of a Licensed Product, Combination Product, or Co-Packaged Product in the Territory that is prepared, updated, and amended by Licensee in accordance with Section 7.2 (Commercialization Plan).

1.29 "**Commercially Reasonable Efforts**" means, with respect to the Development, manufacture, and Commercialization of the Licensed Compound or a Licensed Product by a Party, those efforts and resources, including reasonably necessary personnel, equivalent to the efforts that a research-

based biopharmaceutical company or a pharmaceutical company that is comparable to such Party would typically devote to a product of similar market potential, profit potential, and strategic value and at a comparable stage in development or product life to such Licensed Product, based on conditions then prevailing and taking into account all relevant factors, including issues of safety and efficacy, anticipated or actual product labeling, the competitiveness of alternative Third Party products in the marketplace, the nature and extent of expected and actual market exclusivity (including Patent coverage and regulatory exclusivity), the expected likelihood of regulatory approval, the expected and actual reimbursability and pricing, the potential profitability of such Licensed Product marketed or to be marketed, and other relevant scientific, technical, and commercial factors.

1.30 "**Comparable Quarter**" has the meaning set forth in Section 9.3.3(a) (Sub-Territory A and Sub-Territory B).

1.31 "**Competing Product**" means a product that is approved by an applicable Regulatory Authority for the treatment of anemia associated with chronic kidney disease, including any HIF Product, but excluding (a) the Licensed Products, (b) all products that [***], and (c) all [***].

1.32 "**Confidential Disclosure Agreement**" has the meaning set forth in Section 17.7 (Entire Agreement; Amendment).

1.33 "**Confidential Information**" means Know-How and any technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other information that may be disclosed by one Party to the other Party pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the Confidential Disclosure Agreement or the U.S. Collaboration and License Agreement), regardless of whether such information is specifically designated as confidential and regardless of whether such information is in written, oral, electronic, or other form.

1.34 "**Controlled**" means, with respect to a Party or its Affiliate, any Know-How, Patent, or other intellectual property right that such Party or Affiliate, as the case may be, owns or has a license to and has the ability to grant to the other Party a license or sublicense to, or a right of access with respect to, such Know-How, Patent, or other intellectual property right, without violating the terms of any agreement or other arrangements with any Third Party or incurring any additional payment obligations to a Third Party other than payment obligations incurred under licenses taken pursuant to Section 10.10.4 (Responsibility for Third Party Licenses). Notwithstanding the foregoing, no Patent, Know-How, or other intellectual property right will be "Controlled" by either Party hereunder if such Patent, Know-How, or other intellectual property right is owned or in-licensed by a Third Party that becomes an Affiliate of such Party after the Effective Date as a result of such Party being acquired by such Third Party, whether by merger, stock purchase, or purchase of assets; *provided that* prior to the date of such transaction, neither such Party nor any of its Affiliates had any rights to any such Patent, Know-How, or other intellectual property right. Notwithstanding the foregoing, any such Patent, Know-How, or other intellectual property right that is owned or in-licensed by such an acquiring Third Party and that is necessary for or used following the date of such transaction by such Third Party or acquired Party in connection with the Development, manufacture, or Commercialization of the Licensed Compound or any Licensed Product will be "Controlled" by such Third Party (as an Affiliate) or acquired Party for purposes of this Agreement.

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

1.35 "**Co-Packaged Product**" means a product that contains a Licensed Product and one or more Other Components and that is either (a) packaged together for sale or shipment as a single unit or sold at a single price, or (b) marketed or sold collectively as a single product.

1.36 "**Cost of Goods Sold**" or "**COGS**" (a) with respect to any Licensed Product in API form, U.S. Finished Form, or Tablet Formulation (in bulk form) that is manufactured and supplied by a Third Party, the actual prices paid by Akebia to such Third Party for released batches of such Licensed Product; and (b) to the extent any Licensed Product in API form, U.S. Finished Form, or Tablet Formulation (in bulk form) is manufactured and supplied by Akebia or its Affiliates, the fully-burdened cost of all direct materials and labor and fully-allocated manufacturing overhead directly attributable to the manufacture, storage, packaging, and shipping of such Licensed Product, calculated in accordance with the Accounting Standards applicable to Akebia or its Affiliates, including all Licensed Product testing and yield loss costs (to the extent within typical yield loss, as agreed by the Parties and set forth in the Manufacturing Plan or a Supply Agreement), quality control, quality assurance, or other testing of such Licensed Product, together with all reasonably allocated indirect costs and overhead applicable to the manufacturing of such Licensed Product (including internal FTE costs associated with supply thereof), or technical operations functions, less costs of goods returned in accordance with Akebia's or its Affiliates' or suppliers' return policy; *provided that*, with respect to manufacturing overhead attributable to such Licensed Product, COGS calculated in accordance with clause (b) [***].

1.37 "**Cost Share Notice**" means the notice provided by Akebia to Licensee under Section 4.1.4(a) (Initial Cost Share Notice) or Section 4.1.4(b) (Cost Share Notices).

1.38 "**Cover**" means, with respect to a particular subject matter at issue and a relevant Patent, that the manufacture, use, sale, offer for sale, or importation of the subject matter would fall within the scope of a claim in such Patent.

1.39 "**Credit Amount**" has the meaning set forth in Section 9.3.4(d) (Maximum Supply Price Reduction).

1.40 "**Creditable [***] Costs**" has the meaning set forth in Section 4.1.3(b) (Credit for [***] Costs).

1.41 "**Current Formulation**" means the [***] and any other formulation of a Licensed Product used for any clinical or non-clinical study set forth on Schedule 1.44.

1.42 "**Current Global Development Costs**" means the fully-allocated internal and external costs incurred by Akebia in implementing the Current Global Development Plan, calculated in accordance with the Accounting Standards applicable to Akebia, consistently applied and reflected in its audited financial statements.

1.43 "**Current Global Development Plan**" means the plan setting forth the Development activities that have been undertaken and will be undertaken by or on behalf of Akebia, and its Affiliates and licensees (including Licensee, if applicable pursuant to Section 4.1 (Current Global Development)), for the purpose of Developing the Licensed Compound and the Licensed Products and obtaining Regulatory Approval from [***] for the Licensed Products for the DD-CKD Indication and the NDD-CKD Indication [***], together with the budget and timelines for such activities including the proposed clinical trials and regulatory plans, as well as outlining the key elements involved in obtaining Regulatory Approval of the Licensed Products from the [***] in the DD-CKD Indication and the NDD-CKD Indication in the [***], as the same may be amended from time-to-time in accordance with this Agreement.

1.44 "**Current Global Development Program**" means the Global Phase 3 NDD-CKD Program and the Global Phase 3 DD-CKD Program, the other clinical and non-clinical studies set forth on Schedule 1.44, and any other Development activity for the purpose of obtaining Regulatory Approval from [***] for the Licensed Products for each of the DD-CKD Indication and the NDD-CKD Indication in the [***] that is conducted pursuant the Current Global Development Plan, as the same may be amended in accordance with this Agreement. For clarity, [***] are not included in the Current Global Development Program.

1.45 "**DD-CKD Indication**" means the treatment of anemia in pediatric and adult dialysis patients with chronic kidney disease.

1.46 "**Debarred/Excluded**" has the meaning set forth in Section 12.1.11 (Mutual Representations and Warranties).

1.47 "**Design-Around Product**" means any pharmaceutical product, drug product, preparation, formulation, or dosage form thereof (*other than* a Licensed Product or a [***]) sold by a Third Party (*other than* a sublicensee of Licensee) that (a) has the Licensed Compound as [***], and (b) is not Developed, Packaged, or Commercialized by Licensee, or any of its Affiliates or sublicensees.

1.48 "**Development**" means all internal and external research, development, and regulatory activities regarding the Licensed Compound or the Licensed Products. This includes (a) research, non-clinical testing, toxicology, route of synthesis, non-clinical activities, formulation, and clinical studies of a Licensed Compound or any Licensed Product, and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct clinical trials and to obtain or maintain Regulatory Approval of a Licensed Product. Development will include development and regulatory activities for additional forms, formulations, or indications for a Licensed Product after Regulatory Approval of such Licensed Product, including clinical trials initiated following receipt of Regulatory Approval or any clinical trial to be conducted after a Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved indication (such as post-marketing studies and observational studies, if required by any Regulatory Authority in any country in the Territory to maintain Regulatory Approval for a Licensed Product in such country). "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

1.49 "**Dialysis Organization**" means any dialysis organization that conducts activities in the Territory and in the U.S., either itself or through its affiliates or related entities (together with all such affiliates and related entities).

1.50 "**Divestiture Notice**" has the meaning set forth in Section 17.3.1 (Exception for Acquisition by a Third Party).

1.51 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.52 "[***] **Plan**" has the meaning set forth in Section 4.1.2(a) (Agreement of the JDC).

1.53 "[***]" means any clinical or non-clinical study that is [***] as of the Effective Date and is (a) [***] obtaining Regulatory Approval in [***], or (b) [***], in each case ((a) or (b)), for any Licensed Product for the DD-CKD Indication and the NDD-CKD Indication in the [***]. For clarity, [***] are [***] in [***] or the Current Global Development Program.

1.54 "[***]" means all costs and expenses incurred by or on behalf of a Party in connection with any [***].

1.55 "**ESA Hyporesponder**" means subjects with (a) [***], or (b) [***] (i) [***], or (ii) [***].

1.56 "**Establishing Committee**" has the meaning set forth in Section 3.5.3 (Operational Teams).

1.57 "**E.U.**" means the European Union.

1.58 "**Excess COGS**" has the meaning set forth in Section 9.3.4(b) (Maximum Supply Price Reduction).

1.59 "**Executive Officer**" means the chief executive officer of a Party or any of its Affiliates or his or her designee.

1.60 "**Expert Reserved Matter**" means, (a) *after* the [***] for a Licensed Product in [***], a disagreement of the [***] that is not resolved following escalation to the [***] (if applicable) and the [***] regarding [***] of a [***] Licensed Product in such indication or such formulation [***] for such indication or such formulation, and (b) *after* the [***], a disagreement of the [***] or any [***] that is not resolved following escalation to the [***] (if applicable) and the [***] regarding [***] of a [***] Licensed Product in such indication or such formulation [***] for such indication or such formulation.

For clarity, (i) *after* the [***] in effect, then the [***] any [***] Licensed Product for such indication or such formulation to be [***] for such indication or such formulation will be an Akebia Reserved Dispute, and not an Expert Reserved Dispute, and (ii) *after* the [***] in effect, then the [***] of any [***] Licensed Product for such indication or such formulation [***] for such indication or such formulation will be an Akebia Reserved Dispute, and not an Expert Reserved Dispute.

Further for clarity, if the [***] of any [***] of a Licensed Product in [***], in each case, [***], then [***] will not be an Expert Reserved Matter.

1.61 "**FD&C Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended from time-to-time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.62 "**FDA**" means the U.S. Food and Drug Administration or any successor agency thereto.

1.63 "**Field**" means the treatment, prevention, or diagnosis of any diseases or conditions in humans, including the Initial Indications.

1.64 "**Finished Form**" means a Licensed Product in the Tablet Formulation in finished form and with all applicable Packaging and Labeling.

1.65 "**First Commercial Sale**" means, for each Licensed Product in a country in the Territory, the first sale for end use or consumption to a Third Party of such Licensed Product in such country by Licensee, its Affiliates, or its permitted sublicensees after the granting of Regulatory Approval in the Field for such Licensed Product by the relevant Regulatory Authority in such country. First Commercial Sale excludes any sale or other distribution for use in a clinical trial or other Development activity or for compassionate or named-patient use sold at or below Seller's costs.

1.66 "**FTE**" means the equivalent of the work of one duly qualified employee of a Party full time for one year (consisting of a total of [***] hours per year) carrying out Development, manufacturing, or other regulatory, distribution, scientific, or technical work under this Agreement. Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution, and no individual may be charged at greater than one FTE, regardless of that individual's hours worked during that year. The portion of an FTE billable by a Party for one employee during a given accounting period will be determined by dividing the number of hours worked directly by such employee on the work to be conducted under this Agreement during such accounting period by the number of FTE hours applicable for such accounting period based on [***] working hours per calendar year.

1.67 "**Generic Product**" means, on a Licensed Product-by-Licensed Product (including Combination Product-by-Combination Product) and country-by-country basis in a particular country in the Territory, any pharmaceutical product sold by a Third Party in such country that: (a) contains [***] as the applicable Licensed Product in the same [***] as the applicable Licensed Product, and (b) is categorized by the applicable Regulatory Authority in such country to be [***], or [***], such Licensed Product, such that the pharmaceutical product may be substituted for such Licensed Product at the point of dispensing without any intervention by the prescribing physician in such country.

1.68 "**Global Brand Plan**" has the meaning set forth in Section 7.8 (Global Brand Plan and Promotional Materials).

1.69 "**Global Mark**" means any Marks selected by Akebia, its Affiliates, or licensees under which Akebia, its Affiliates, or licensees will market any Licensed Product outside of the Territory in the Field, and all trademark registrations and applications therefor, and all goodwill associated therewith. Global Marks exclude all Local Marks.

1.70 "**Global Medical Affairs Plan**" has the meaning set forth in Section 6.1 (Medical Affairs Plans).

1.71 "**Global Phase 3 DD-CKD Program**" means the Phase 3 global clinical studies for the DD-CKD Indication, known informally as the INNO2VATE studies, consisting of a conversion study and a correction study, and known formally as the "Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Maintenance Treatment of Anemia in Subjects with Dialysis-Dependent Chronic Kidney Disease (INNO2VATE – Conversion)" (AKB-6548-CI-0017) and the "Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Correction of Anemia in Subjects with Incident Dialysis-Dependent Chronic Kidney Disease (INNO2VATE – Correction)" (AKB-6548-CI-0016).

1.72 "**Global Phase 3 NDD-CKD Program**" means the Phase 3 global clinical studies for the NDD-CKD Indication, known informally as the PRO2TECT studies, consisting of a conversion study and a correction study, and known formally as the "Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Maintenance Treatment of Anemia in Subjects with Non-Dialysis Dependent Chronic Kidney Disease (PRO2TECT – Conversion)" (AKB-6548-CI-0015) and the "Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Correction of Anemia in Subjects with Non-Dialysis-Dependent Chronic Kidney Disease (PRO2TECT – Correction)" (AKB-6548-CI-0014).

1.73 "**Global Trade Control Laws**" means the U.S. Export Administration Regulations, the U.S. International Traffic in Arms Regulations, the economic sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, E.U. Council Regulations on export controls, including Nos. 428/2009, 267/2012, other E.U. Council sanctions regulations, as implemented in the E.U. member states, United Nations sanctions policies, and all relevant regulations made under any of the foregoing.

1.74 "**Good Clinical Practices**" or "**GCP**" means the then-current good clinical practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time.

1.75 "**Good Laboratory Practices**" or "**GLP**" means the then-current good laboratory practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time.

1.76 "**Good Manufacturing Practices**" or "**GMP**" means the then-current good manufacturing practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time.

1.77 "**Government Official**" means any official, officer, employee, or representative of: (a) any federal, state, provincial, administrative division, county, or municipal government or any department or agency thereof; (b) any public international organization or any department or agency thereof; or (c) any company or other entity owned or controlled by any government or Governmental Authority.

1.78 "**Governmental Authority**" means any court, agency, department, authority, tribunal, or other instrumentality of any supra-national, national, state, provincial, county, city, or other political subdivision. For clarity, Governmental Authorities include all Regulatory Authorities.

1.79 "**HIF Product**" means any product or product candidate that is a hypoxia-inducible factor prolyl-hydroxylase inhibitor for the treatment of anemia related to chronic kidney disease. For the avoidance of doubt, "HIF Product" includes [***], and each Licensed Product.

1.80 "**Housemarks**" means the Akebia Housemarks and the Licensee Housemarks.

1.81 "**Hyporesponder Endpoint**" means either (a) [***], or (b) [***].

1.82 "**Hyporesponder Study**" means the study known formally as the "Phase 2, Randomized, Open-Label Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Treatment of Anemia in Subjects with Dialysis-Dependent Chronic Kidney Disease who are Hyporesponsive to Erythropoiesis-Stimulating Agents" (AKB-6548-CI-0018).

1.83 "**Improvement**" means any Invention relating to, arising from the use of, or including the Licensed Compound or a Licensed Product, including any New Formulation, or its respective Development, manufacture, use, design, registration, offer for sale, sale, or importation.

1.84 "**IND**" means an Investigational New Drug application required pursuant to 21 C.F.R. Part 312 or any comparable filings outside of the U.S. (such as an application for a Clinical Trial Authorization in the E.U.).

1.85 "**Indemnified Party**" has the meaning set forth in Section 14.3 (Indemnification Procedure).

1.86 "**Indemnifying Party**" has the meaning set forth in Section 14.3 (Indemnification Procedure).

1.87 "**Information**" has the meaning set forth in Section 11.1 (Information).

1.88 "**Infringement Claim**" has the meaning set forth in Section 10.10.1 (Infringement Claim).

1.89 "**Initial Indications**" means the DD-CKD Indication and the NDD-CKD Indication, and any other indication in the Field for which the initial label of a Licensed Product is approved based on the data generated from the performance of the Current Global Development Program or any [***].

1.90 "**Invention**" means any process, method, composition of matter, article of manufacture, discovery, or finding that is conceived or reduced to practice (whether or not patentable).

1.91 "**JCC**" has the meaning set forth in Section 3.4.1 (Formation and Purpose of the JCC).

1.92 "**JDC**" has the meaning set forth in Section 3.2.1 (Formation and Purpose of the JDC).

1.93 "**JMC**" has the meaning set forth in Section 3.3.1 (Formation and Purpose of the JMC).

1.94 "**Joint Know-How**" means any Know-How that is made during the Term in the course of performance of any activities undertaken pursuant to this Agreement (including under the licenses granted hereunder) jointly by at least one employee of Akebia or its Affiliate or any Third Party contractually required to assign or license such Know-How to Akebia and at least one employee of Licensee or its Affiliate or Third Party contractually required to assign such Know-How to Licensee, but excluding any Akebia Improvements, Assigned Product Improvements, and Retained Licensee Improvements.

1.95 "**Joint Patents**" means all Patents that Cover the Joint Know-How.

1.96 "**Joint Publication Plan**" has the meaning set forth in Section 13.4.2 (After Release of Data by Akebia).

1.97 "**Joint Technology**" means Joint Know-How and Joint Patents.

1.98 "**Jointly-Agreed Regulatory Submissions**" means, for each Licensed Product in each Initial Indication, (a) the [***], (b) the [***], (c) the [***], (d) the [***], and (e) [***] submissions (including [***]), in each case, to be submitted to the EMA, and (f) [***] relating to any of the foregoing submissions.

1.99 "**JSC**" has the meaning set forth in Section 3.1.1 (Formation and Purpose of the JSC).

1.100 "**Know-How**" means Inventions, discoveries, trade secrets, information, experience, data, formulas, procedures, technology, and results (whether or not patentable), including practices, knowledge, know-how, experience and test data (including physical, chemical, biological, toxicological, pharmacological, clinical and veterinary data), dosage regimens, control assays,

product specifications, analytical and quality control data and marketing, pricing and distribution cost, and sales data or descriptions.

1.101 "**Knowledge**" means, with respect to a Party, the actual knowledge of such Party's and its European headquarters' [***] as of the Effective Date, without any inquiry or investigation. For this purpose, [***] means [***].

1.102 "**Launch Countries**" has the meaning set forth in Section 7.2 (Launch Sequence and Commercialization Plan).

1.103 "**Launch Sequence**" has the meaning set forth in Section 7.2 (Commercialization Plan).

1.104 "**Licensed Compound**" means the API referred to as vadadustat, formerly known as AKB-6548, and any salt or crystal form thereof. Licensed Compound includes any prodrug form of vadadustat.

1.105 "**Licensed Product**" means any pharmaceutical product, drug product, preparation, formulation, or dosage form thereof that has the Licensed Compound as at least one API.

1.106 "**Licensee Contributed Technology**" means (a) any Licensee Patent anywhere in the world that includes one or more claims that Covers a Licensed Product that Licensee Develops, Packages, or Commercializes pursuant to this Agreement, and (b) any Licensee Know-How.

1.107 "**Licensee Housemarks**" means (a) the corporate logo of Licensee or any of its Affiliates, (b) the trademark "Otsuka," (c) any other trademark, trade name, or service mark (whether registered or unregistered) containing the word "Otsuka," and (d) any other corporate logo or trademark used by Licensee to identify Licensee or its Affiliates, (e) all registrations, applications for registrations, and other intellectual property rights associated with any of the foregoing, and (f) all goodwill associated with any and all of the foregoing in clauses (a) through (e).

1.108 "**Licensee Improvement**" means any Improvement that is made during the Term in the course of performance of activities undertaken by Licensee pursuant to this Agreement or pursuant to the license grants in Section 2.1 (Grant of Licenses to Licensee), solely by one or more employees of Licensee or any Affiliate of Licensee, or persons contractually required to assign or license such Improvement (or Patents Covering such Improvement) to Licensee or any Affiliate of Licensee (including all sublicensees), but excluding any Joint Know-How.

1.109 "**Licensee Indemnitees**" has the meaning set forth in Section 14.1 (Indemnification by Akebia).

1.110 "**Licensee Know-How**" means all Know-How (excluding Joint Know-How) that is (a) Controlled as of the Effective Date or during the Term by Licensee or any of its Affiliates, and (b) either (i) disclosed to Akebia or any of its Affiliates pursuant to this Agreement, or (ii) necessary or reasonably useful for the Development, manufacture, or Commercialization of the Licensed Compound or a Licensed Product.

1.111 "**Licensee Patents**" means all Patents (excluding Joint Patents) that (a) are Controlled as of the Effective Date or during the Term by Licensee or any of its Affiliates in the Territory, and (b) (i) include one or more claims that Cover the Licensed Compound or a Licensed Product or their respective Development, manufacture, or Commercialization, or (ii) are necessary or reasonably useful (or, with respect to patent applications, would be necessary or reasonably useful if such patent applications were to issue as patents) for the Development, manufacture, or

Commercialization of the Licensed Compound or a Licensed Product. Licensee Patents include any and all Retained Licensee Improvement Patents.

1.112 "**Licensee R&D Cost Share**" has the meaning set forth in Section 4.1.3(a) (Licensee R&D Cost Share).

1.113 "**Licensee Reserved Dispute**" means any dispute of the [***] with respect to matters within the [***] that is not resolved following escalation to the [***] (if applicable) and the [***] related to (a) [***], (b) [***], (c) [***], and (d) the [***] of a Licensed Product, including any dispute with respect to any [***].

1.114 "**Licensee Technology**" means Licensee Know-How, Licensee Patents, Retained Licensee Improvement Technology, and Licensee's interest in Joint Technology.

1.115 "**Limited Recall**" means a recall or retrieval of a Licensed Product on grounds of product quality or manufacturing defect or public health or safety that is limited as to lots or batches of a Licensed Product.

1.116 "**Local Marks**" has the meaning set forth in Section 7.9.1 (Brand Name in the Territory).

1.117 "**Local Medical Affairs Plan**" has the meaning set forth in Section 6.2 (Medical Affairs Activities).

1.118 "**Losses**" has the meaning set forth in Section 14.1 (Indemnification by Akebia).

1.119 "**MAA**" means (a) a marketing authorization application filed with (i) the EMA under the centralized EMA filing procedure to gain approval to market a pharmaceutical or diagnostic product in the E.U., or (ii) a Regulatory Authority in any E.U. country if the centralized EMA filing procedure is not used to gain approval to market a pharmaceutical or diagnostic product in the E.U., or (b) any other equivalent or related Regulatory Submissions filed in support of approval to market a pharmaceutical or diagnostic product in any country outside the E.U., and, in each case ((a) and (b)), including any amendments thereto, and supplemental applications, but excluding Reimbursement Approval applications.

1.120 "**MACE**" means any major adverse cardiovascular event, specifically, [***].

1.121 "**Major Countries**" means [***].

1.122 "**Manufacturing Plan**" means the manufacturing plan for Akebia's supply to Licensee of each Licensed Product in the Territory (a) [***], if applicable, (b) [***], if applicable, and (c) [***] or, solely where required by Applicable Law in a country in the Territory, [***], as such plan may be updated pursuant to this Agreement.

1.123 "**Mark**" means any trademark, trade name, service mark, service name, product name, brand, domain name, trade dress, logo, slogan, or other indicia of origin or ownership, and (a) all registrations, applications for registrations, and other intellectual property rights associated with any of the foregoing, and (b) the goodwill associated with each of the foregoing.

1.124 "**Maximum Supply Price**" has the meaning set forth in Section 9.3.4 (Maximum Supply Price Reduction).

1.125 "**Medical Affairs**" means activities conducted by Akebia's or Licensee's medical affairs departments, including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries, and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs and not to other activities that do not involve the promotion, marketing, sale, or other Commercialization of the Licensed Products and are not conducted by Akebia's or Licensee's medical affairs departments.

1.126 "**National Reimbursement Authorities**" means [***], and any other Governmental Authority in a Major Country with the authority to control, approve, recommend, or otherwise determine pricing and reimbursement of pharmaceutical products in such country.

1.127 "**NDD-CKD Indication**" means the treatment of anemia in pediatric and adult non-dialysis patients with chronic kidney disease.

1.128 "**Net Sales**" means the gross amounts invoiced by Licensee, its Affiliates, or sublicensees (each, a "**Seller**") to Third Parties in the Territory for consideration, reduced by the following amounts to the extent such items are customary under industry practices:

1.128.1 trade, cash, and quantity discounts actually allowed and taken directly with respect to such sales or transfers;

1.128.2 inventory management fees paid to wholesalers and distributors and reasonably allocated to such Licensed Product;

1.128.3 tariffs, duties, excises, value added tax, and other sales taxes imposed upon and paid with respect to the sale, transportation, delivery, use, exportation, or importation of such Licensed Product (which does not include income, withholding, or similar taxes), to the extent such amounts are included in the gross invoiced sales price;

1.128.4 amounts actually repaid or credited upon returns, rejections, defects, recalls (due to spoilage, damage, expiration of useful life), price adjustments, billing errors, or trial prescriptions;

1.128.5 invoiced freight, shipping, and insurance expenses specific to such Licensed Product and allocated accordingly, to the extent such amounts are included in the gross invoiced sales price;

1.128.6 invoiced amounts that are actually written off as uncollectible in accordance with Seller's accounting policies, as consistently applied;

1.128.7 allowances or credits actually paid or given to customers on account of price reductions affecting such Licensed Product;

1.128.8 rebates (including mandatory rebates), clawbacks, discounts (including confidential payer discounts), or charge-backs actually paid or credited to any Government Authority, or to any Third Party payor, administrator, or contractee, and including those requested by any Government Authority any time after the actual sale; and

1.128.9 discounts actually paid under state-legislated or Seller-sponsored discount prescription drug programs or reductions or coupon and voucher programs.

If Seller receives [***], then the Net Sales amount for such Licensed Product [***].

Subject to the above, Net Sales will be determined in accordance with the Accounting Standards applicable to Seller, consistently employed by Seller.

In the event of any sale of a Combination Product or a Co-Packaged Product, the Net Sales from the Combination Product or Co-Packaged Product for the purposes of determining payments hereunder based on Net Sales will be determined by multiplying the Net Sales of the Combination Product or Co-Packaged Product (as applicable), during the applicable reporting period, by the fraction, A/(A+B), where A is the average sale price of a Licensed Product when sold separately in Finished Form and B is either (a) the average sale price of the other APIs included in the Combination Product when sold separately in finished form (in the case of a Combination Product), or (b) the average sales price of the Other Components included in the Co-Packaged Product when sold separately (in the case of a Co-Packaged Product), in each case, during the applicable royalty reporting period or, if sales of both a Licensed Product and the other APIs or Other Components (as applicable) did not occur in such period, then in the most recent reporting period in which sales of both occurred. If such average sale price cannot be determined for both a Licensed Product and all other APIs included in such Combination Product or all Other Components included in the Co-Packaged Product (as applicable), then Net Sales for the purposes of determining royalties based on Net Sales will be determined by multiplying the Net Sales of the Combination Product or Co-Packaged Product (as applicable) during the applicable reporting period by the fraction of C/(C+D) where C is the fair market value of a Licensed Product and D is either (i) the fair market value of all other APIs included in the Combination Product (in the case of a Combination Product), or (ii) the average sales price of the Other Components included in the Co-Packaged Product when sold separately (in the case of a Co-Packaged Product). In such event, Seller will in good faith make a determination of the respective fair market values of a Licensed Product and all other APIs or Other Components, as applicable, included in the Combination Product or Co-Packaged Product (as applicable).

If a Licensed Product is sold as part of a Co-Packaged Product, then Seller [***] of a Licensed Product included in such Co-Packaged Product [***].

1.129 "**New Formulation**" means any formulation of a Licensed Product other than the Current Formulation.

1.130 "**New Indication**" means any indication for a Licensed Product other than the Initial Indications.

1.131 "**Non-Breaching Party**" has the meaning set forth in Section 15.2 (Termination for Breach).

1.132 "**OFAC**" means the Office of Foreign Assets Control of the United States Department of the Treasury or any successor agency thereto.

1.133 "**Ongoing E.U. Opposition Hearings**" has the meaning set forth in Section 10.10.2(a) (Initiation).

1.134 "**Operational Team**" has the meaning set forth in Section 3.5.3 (Operational Teams).

1.135 "**Other Component**" means other devices or components (besides the Licensed Compound and the Licensed Products).

1.136 "**Other Covered Party**" means any political party or party official, or any candidate for political office.

1.137 "**Other Global Development**" means Development activities for the Licensed Products that are conducted pursuant to an Other Global Development Plan, as the same may be amended in accordance with this Agreement. [***] are not included in Other Global Development.

1.138 "**Other Global Development Plan**" means a plan setting forth the Development activities that are (a) not included in the Current Global Development Plan, (b) not [***], and (c) to be undertaken by or on behalf of Akebia and its Affiliates, licensees (including Licensee, if applicable), and sublicensees in Developing the Licensed Compound and the Licensed Products and obtaining or maintaining Regulatory Approval from [***] for New Indications or New Formulations, as set forth in Section 4.3 (Additional Development), together with the budget and timelines for such activities including the proposed clinical trials and regulatory plans, as well as outlining the key elements involved in obtaining and maintaining Regulatory Approval of the Licensed Products from [***] (*other than* as contemplated in the Current Global Development Plan or [***] or any [***] Plan).

1.139 "**Packaging**" or "**Package**" has the meaning set forth in Section 8.1 (Supply and Purchase Obligations).

1.140 "**Packaging and Labeling**" means primary, secondary, or tertiary packaging and labeling of a Licensed Product (in its commercial packaging presentation) for sale or use in the Territory, including the Approved Labeling and insertion of materials such as patient inserts, patient medication guides, and professional inserts and any other written, printed, or graphic materials accompanying a Licensed Product and any brand security or anti-counterfeiting measures included in the packaging elements for a Licensed Product considered to be part of the finished packaged Licensed Product, and all testing and release thereof.

1.141 "**Party Vote**" has the meaning set forth in Section 3.7 (Decision-Making and Committee Dispute Resolution).

1.142 "**Patents**" means (a) all patents and patent applications in any country or jurisdiction, (b) all patent applications filed either from such patents or patent applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications, and (d) any and all substitutions, renewals, registrations, confirmations, extensions, or restorations, including revalidations, reissues, and re-examinations (including any supplementary protection certificates and the like) of the foregoing patents or patent applications.

1.143 "**Pharmacovigilance Agreement**" means an agreement regarding receipt, investigation, and reporting of product complaints, adverse events, product recalls, and any other information related to the safety of a Licensed Product in the Territory.

1.144 "**Pharmacovigilance Committee**" or "**PVC**" has the meaning set forth in Section 3.5.2 (Pharmacovigilance Committee).

1.145 "**Prepayment**" has the meaning set forth in Section 4.1.4(a) (Initial Cost Share Notice).

1.146 "**Privacy Laws**" means all Applicable Laws with respect to the collection, use, transfer, storage, deletion, processing (both by computer and manually), combination, or other use of subject or other personal data.

1.147 "**Product Hyporesponder**" means subjects [***].

1.148 "**Product Marks**" means any Mark (whether registered or unregistered) selected in accordance with Section 7.9.1 (Brand Name in the Territory) for use on, with, or to refer to a Licensed Product (*other than* Akebia Housemarks and Licensee Housemarks) or used with patient support or other information or services or Product Materials associated with a Licensed Product in the Territory during the Term (including all Global Marks and Local Marks), and (a) all registrations, applications for registrations, and other intellectual property rights associated with any of the foregoing, and (b) the goodwill associated with each of the foregoing.

1.149 "**Product Materials**" means any and all promotional materials, training materials, medical education materials, Packaging and Labeling, and all other literature or other information related to a Licensed Product.

1.150 "**Product Withdrawal**" means removal of a Licensed Product from the market in any country in the Territory on the grounds of public health or safety that results in discontinuation of all or substantially all distribution of such Licensed Product in such country in the Territory. Product Withdrawal does not include a Limited Recall.

1.151 "**Professional Requirements**" means (a) the codes and standards of the European Accreditation Council for Continuing Medical Education (EACCME) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), (b) the codes of the Prescription Medicines Code of Practice Authority (PMCPA) and the Association of the British Pharmaceutical Industry (ABPI), and (c) all other accepted national and international pharmaceutical industry codes of practice in and for the relevant countries in the Territory, as any of the foregoing may be amended from time-to-time.

1.152 "**Progression of CKD**" means the time to [***].

1.153 "**Progression of CKD Endpoint**" means a [***] in the Progression of CKD in subjects dosed with a Licensed Product as compared to subjects receiving the comparator drug in the Global Phase 3 NDD-CKD Program.

1.154 "**Proposing Party**" has the meaning set forth in Section 4.3 (Additional Development).

1.155 "**Quality Agreement**" has the meaning set forth in Section 8.4 (Quality Agreement).

1.156 "**Quarterly Report**" has the meaning set forth in Section 9.3.5(b) (Quarterly Report).

1.157 "**Recall Decision-Makers**" has the meaning set forth in Section 11.5.3 (Voluntary Withdrawal or Recall in the Territory).

1.158 "**Recipient**" has the meaning set forth in Section 13.2 (Exceptions).

1.159 "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, any MAA approval or other approval, product or establishment license, registration, or authorization of any Regulatory Authority necessary for the commercial sale of a Licensed Product in such country or other regulatory jurisdiction, excluding, in each case, Reimbursement Approval.

1.160 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including (a) in the U.S., the FDA and any other applicable Governmental Authority in the U.S. having jurisdiction over the Licensed Products, (b) in the E.U., the EMA and any other applicable Governmental Authority in the countries in the E.U. having jurisdiction over the Licensed Products, and (c) in other countries, other analogous Governmental Authorities having jurisdiction over the Licensed Products.

1.161 "**Regulatory Executives**" has the meaning set forth in Section 5.7 (Decision-Making and Escalation For Certain Regulatory Matters).

1.162 "**Regulatory Responsible Party**" means (a) with respect to the E.U., (i) [***] (or its Affiliates), [***] of Regulatory Approval from the EMA for the Licensed Product for each of the DD-CKD Indication and the NDD-CKD Indication, and (ii) [***] (or its Affiliates [***]), [***] Regulatory Approval from the EMA for the Licensed Product for each of the DD-CKD Indication and the NDD-CKD Indication, and (b) [***] (or its Affiliates [***]), with respect to all other countries within the Territory, in each case ((a) and (b)), subject to Akebia's ongoing Development obligations in the Territory related to the Licensed Products.

1.163 "**Regulatory Submissions**" means all applications, filings, dossiers, and other documents submitted to a Regulatory Authority in support of Development of the Licensed Compound and the Licensed Products inside and outside of the Territory, including for the purpose of obtaining Regulatory Approval from that Regulatory Authority. Regulatory Submissions include all INDs, MAAs, and other Regulatory Approval applications and their equivalents inside and outside of the Territory.

1.164 "**Reimbursement Approval**" means an approval, agreement, determination, or other decision by the applicable Governmental Authority that establishes prices charged to end-users for biopharmaceutical products that a Licensed Product will be reimbursed by the Governmental Authorities or Regulatory Authorities in the Territory.

1.165 "**Restricted Party**" means any individual or entity on one or more of the Restricted Party Lists.

1.166 "**Restricted Party List**" means the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals and Blocked Persons List, the Foreign Sanctions Evaders List and the Sectoral Sanctions Identifications List, all administered by OFAC; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; and the entities subject to restrictive measures and the consolidated list of Persons, Groups, and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy.

1.167 "**Retained Licensee Improvement**" means any Licensee Improvement other than an Assigned Product Improvement.

1.168 "**Retained Licensee Improvement Patent**" means any Patent Controlled by Licensee or any of its Affiliates during the Term that Covers a Retained Licensee Improvement.

1.169 "**Retained Licensee Improvement Technology**" means Retained Licensee Improvements and Retained Licensee Improvement Patents.

1.170 "**Royalty Amount**" has the meaning set forth in Section 9.3.4(a) (Maximum Supply Price Reduction).

1.171 "**Royalty Amount Exceeding [***]**" has the meaning set forth in Section 9.3.4(c) (Maximum Supply Price Reduction).

1.172 "**Royalty Term**" means, on a country-by-country basis, the period commencing on the date of First Commercial Sale of a Licensed Product in a country in the Territory and continuing until the latest to occur of (a) the date of expiration of the last-to-expire Valid Claim of any Akebia Patent or Joint Patent that Covers a Licensed Product in the form and for the indication approved by the Regulatory Authority in such country in the Territory, (b) the date of expiration of data or regulatory exclusivity in such country in the Territory, or (c) the date that is 10 years from First Commercial Sale of such Licensed Product in such country in the Territory.

1.173 "**Safety Data**" has the meaning set forth in Section 11.3 (Pharmacovigilance Agreement).

1.174 "**Sale Transaction**" has the meaning set forth in Section 17.2 (Standstill).

1.175 "[***]" has the meaning set forth in Section 5.3.1 ([***]).

1.176 "**Seller**" has the meaning set forth in Section 1.128 (Net Sales).

1.177 "**Shared Development Costs**" has the meaning set forth in Section 4.1.3 (Development Cost Sharing).

1.178 "**SmPC**" means the Summary of Product Characteristics that sets forth a description of the manner in which a Licensed Product is to be used for a specific treatment and that is approved in connection with the receipt of Regulatory Approval from the EMA.

1.179 "**Statistically Significant**" means a p-value [***].

1.180 "**Study Data**" means all research data and reports, material regulatory materials and correspondence (including INDs and MAAs in the U.S.), clinical and non-clinical data, and chemistry, manufacturing, and controls data.

1.181 "**Sub-Committee**" has the meaning set forth in Section 3.5.1 (Sub-Committees).

1.182 "**Sub-Territory A**" means [***].

1.183 "**Sub-Territory B**" means [***]. The countries included in Sub-Territory B as of the Effective Date are set forth on Schedule 1.183.

1.184 "**Sub-Territory C**" means all countries in the Territory other than those countries in Sub-Territory A or Sub-Territory B.

1.185 "**Supply Agreements**" means the Clinical Supply Agreement and the Commercial Supply Agreement.

1.186 "**Supply Price**" has the meaning set forth in Section 8.3 (Supply Agreements).

1.187 "**Supply Price Letter Agreement**" has the meaning set forth in Section 9.3.4 (Maximum Supply Price Reduction).

1.188 "**Tablet Formulation**" means a Licensed Product containing the Licensed Compound as its sole API in the solid, oral tablet form in the dosage strength used in the Current Global Development Program as of the Effective Date or in any other dosage strength of the solid, oral tablet form manufactured by or on behalf of Akebia at any time during the Term. For clarity, the Tablet Formulation excludes [***].

1.189 "**Term**" has the meaning set forth in Section 15.1 (Term).

1.190 "**Territory**" means all of the countries of the world and their territories and possessions, except the U.S., Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Guyana, Paraguay, Peru, Uruguay, Suriname, Venezuela, Costa Rica, Guatemala, Nicaragua, Honduras, El Salvador, Panama, Belize, Mexico, Antigua and Barbuda, Bahamas, Barbados, Cuba, Dominica, Dominican Republic, Grenada, Haiti, Jamaica, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Trinidad and Tobago, [***], and their respective territories and possessions.

1.191 "**Territory-Specific Development**" means Development activities for the Licensed Compound and the Licensed Products in the [***] solely for the Territory and for obtaining or maintaining Regulatory Approval for the Licensed Product solely from the EMA or any other Regulatory Authority in the Territory that are conducted pursuant to a Territory-Specific Development Plan, as the same may be amended in accordance with this Agreement.

1.192 "**Territory-Specific Development Plan**" means a plan setting forth the Development activities that are (a) not included in the Current Global Development Plan or in any Other Global Development Plan, (b) not [***], and (c) to be undertaken by or on behalf of Licensee and its Affiliates and permitted sublicensees in Developing the Licensed Compound and the Licensed Products in the [***] solely for the Territory and for obtaining or maintaining Regulatory Approval for the Licensed Products solely from the EMA or any other Regulatory Authority in the Territory, together with timelines for such activities, including the high-level study design of proposed clinical trials, as well as outlining the key elements involved in obtaining and maintaining Regulatory Approval for the Licensed Products from the applicable Regulatory Authorities in the Territory.

1.193 "**Third Party**" means any person or entity other than a Party or its Affiliates.

1.194 "**U.S.**" means the United States of America (including all possessions and territories thereof, including Puerto Rico).

1.195 "**U.S. Collaboration and License Agreement**" has the meaning set forth in the Recitals.

1.196 "**U.S. Dollars**" or "**$**" means the legal tender of the U.S.

1.197 "**U.S. Finished Form**" means the Finished Form of a Licensed Product that is made commercially available in the U.S.

1.198 "**Valid Claim**" means a claim in any issued and unexpired Akebia Patent or Joint Patent in the Territory, which claim has not lapsed, been cancelled or revoked, become abandoned, or been held invalid or unenforceable by a non-appealed or un-appealable decision of a court or government agency or other appropriate body of competent jurisdiction and has not been disclaimed or admitted to be invalid or unenforceable through reissue, reexamination, disclaimer, or otherwise, or has not been made unenforceable due to failure to pay maintenance fees.

1.199 "**Withholding Party**" has the meaning set forth in Section 9.7 (Taxes).

1.200 "**Year A**" has the meaning set forth in Section 9.3.4 (Maximum Supply Price Reduction).

1.201 "**Year B**" has the meaning set for in Section 9.3.4 (Maximum Supply Price Reduction).

1.202 **Interpretation**. (a) Whenever any provision of this Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" and "including but not limited to" (or "includes without limitations" and "includes but is not limited to") regardless of whether the words "without limitation" or "but not limited to" actually follow the term "including" (or "includes"); (b) "herein," "hereby," "hereunder," "hereof," and other equivalent words will refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used; (c) all definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural; (d) wherever used herein, any pronoun or pronouns will be deemed to include both the singular and plural and to cover all genders; (e) the recitals set forth at the start of this Agreement, along with the schedules and exhibits to this Agreement, and the terms and conditions incorporated in such recitals and schedules and exhibits will be deemed integral parts of this Agreement and all references in this Agreement to this Agreement will encompass such recitals and schedules and exhibits and the terms and conditions incorporated in such recitals and schedules and exhibits; *provided that* in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions set forth in the recitals, schedules, or exhibits, the terms of this Agreement will control; (f) in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement, or otherwise, the terms and conditions of this Agreement will govern; (g) this Agreement will be construed as if both Parties drafted it jointly, and will not be construed against either Party as principal drafter; (h) unless otherwise provided, all references to Sections, Articles, and Schedules in this Agreement are to Sections, Articles, and Schedules of and to this Agreement; (i) any reference to any federal, national, state, local, or foreign statute or law will be deemed to also refer to all rules and regulations promulgated thereunder, unless the context requires otherwise; (j) wherever used, the word "shall" and the word "will" are each understood to be imperative or mandatory in nature and are interchangeable with one another; (k) the word "or" will not be exclusive; (l) references to a particular person include such person's successors and assigns to the extent not prohibited by this Agreement; and (m) the section headings and captions used herein are inserted for convenience of reference only and will not be construed to create obligations, benefits, or limitations.

Article II
LICENSES

2.1 **Grant of Licenses to Licensee**. Subject to the terms and conditions of this Agreement (including Section 2.7 (No Other Rights and Retained Rights)), Akebia hereby grants to Licensee and its Affiliates:

2.1.1 an exclusive, royalty-bearing license, with the right to grant sublicenses only as provided in Section 2.2 (Rights of Licensee to Grant Sublicenses), under the Akebia Technology to Develop (solely in accordance with Article IV (Development)) and Commercialize (including to import, export, distribute, offer for sale, and sell), but not [***], the Licensed Compound and the Licensed Products in the Field in the Territory during the Term;

2.1.2 a non-exclusive license, with the right to grant sublicenses only as provided in Section 2.2 (Rights of Licensee to Grant Sublicenses), under the Akebia Technology to [***] the Licensed Products inside and outside of the Territory during the Term, subject to and solely in accordance with Section 8.1 (Supply and Purchase Obligations) and solely for use in exercising the licenses in Section 2.1.1 and Section 2.1.3; and

2.1.3 a non-exclusive license under the Akebia Technology to [***] in the Field outside of the Territory during the Term, solely to the extent that the conduct of such activities is allocated to Licensee under the Current Global Development Plan or any [***] Plan or Other Global Development Plan.

2.2 **Rights of Licensee to Grant Sublicenses**. Subject to the terms and conditions of this Agreement, upon Akebia's written consent, [***], Licensee will have the right to enter into one or more sublicenses under this Agreement with Third Parties to Develop (solely in accordance with Article IV (Development)), Commercialize, and [***] the Licensed Products in the Field in the Territory during the Term; *provided*, *however*, that Licensee's right to sublicense to Third Parties, including through multiple tiers, is conditioned on every sublicense agreement with a Third Party entered into after the Effective Date including a sublicenseable license back to Licensee of all Patents made or generated by the sublicensee that are necessary or reasonably useful to manufacture, use, sell, offer for sale, or import the Licensed Compound and the Licensed Products (such that Licensee Controls such Patents for the purposes of this Agreement). Licensee will provide prior written notification to Akebia identifying Licensee's intention to grant such sublicense, the purpose of such sublicense, and the identity of the Third Party to whom Licensee intends to grant such sublicense. Each sublicensee will hold its rights contingent on the rights licensed to Licensee under the terms of this Agreement and each sublicense will be consistent with the terms and conditions of this Agreement. Any loss by Licensee of its rights under this Agreement due to an early termination of this Agreement pursuant to Article XV (Term and Termination) will cause the permitted sublicensees to [***].

2.3 **Grant of Licenses to Akebia**. Subject to the terms and conditions of this Agreement, including Section 15.7.6 (Termination by Licensee for Breach), Licensee hereby grants to Akebia a royalty-free, fully paid-up, perpetual, irrevocable license (with the right to grant sublicenses through multiple tiers, subject to Section 2.4 (Rights of Akebia to Grant Sublicenses)) under (a) Licensee's interest in Joint Technology, (b) the Retained Licensee Improvement Technology, and (c) any Licensee Contributed Technology solely to:

2.3.1 Develop, manufacture, have manufactured, and Commercialize (including to import, export, distribute, offer for sale, and sell) the Licensed Compound and the Licensed Products outside of the Territory;

2.3.2 Develop, manufacture, and have manufactured the Licensed Compound and the Licensed Products in the Territory for the purpose of obtaining Regulatory Approval and Commercializing the Licensed Products outside of the Territory; and

2.3.3 Develop, manufacture, and have manufactured the Licensed Compound and the Licensed Products in the Territory to perform its obligations under this Agreement.

(a) The license granted in Section 2.3.1 under Licensee's interest in the Joint Technology and the Retained Licensee Improvement Technology is exclusive (even as to Licensee) during the Term (subject to the rights retained by Licensee in Section 2.7 (No Other Rights and Retained Rights)) and non-exclusive after the Term, (b) the licenses granted in Section 2.3.2 and Section 2.3.3 under Licensee's interest in the Joint Technology and the Retained Licensee Improvement Technology are non-exclusive during and after the Term, and (c) the licenses granted in Section 2.3.1, Section 2.3.2, and Section 2.3.3 under the Licensee Contributed Technology are non-exclusive during and after the Term.

2.4 **Rights of Akebia to Grant Sublicenses**. Akebia will have the right to grant sublicenses under the licenses granted in Section 2.3 (Grant of Licenses to Akebia) through multiple tiers without Licensee's consent; *provided that* Akebia will, promptly after granting any such sublicense, provide written notification to Licensee identifying Akebia's grant of such sublicense, the purpose of such sublicense, and the Third Party to whom Akebia has granted such sublicense. All sublicensees will hold their rights contingent on Akebia's rights under this Agreement. Any termination of the licenses granted to Akebia in Section 2.3 (Grant of Licenses to Akebia) as a result of a termination of this Agreement pursuant to Section 15.7.6 (Termination by Licensee for Breach) will [***].

2.5 **Responsibility for Sublicensees**. Each Party agrees that it will be fully responsible and liable for any breach of the terms of this Agreement by any of its sublicensees to the same extent as if such Party itself has committed any such breach.

2.6 **Subcontracting**. Each Party may subcontract with a Third Party to perform services in connection with the performance of its obligations and exercise of its rights under this Agreement; *provided that* (a) no such permitted subcontractor will be Debarred/Excluded, (b) no such permitted subcontracting will relieve the subcontracting Party of its obligations under this Agreement or any liability hereunder, and (c) the agreement pursuant to which Licensee engages any Third Party subcontractor must (i) be consistent in all material respects with this Agreement, (ii) contain obligations of confidentiality and non-use no less stringent than the confidentiality terms of this Agreement, and (iii) contain terms that are consistent with the intellectual property provisions set forth in this Agreement.

2.7 **No Other Rights and Retained Rights**. Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party, including Akebia Technology or Licensee Technology, in each case, that are not expressly granted herein, whether by implication, estoppel, or otherwise, and Licensee will not practice the Akebia Technology and Akebia will not practice the Licensee Technology, in each case, other than as expressly licensed and permitted under this Agreement. Any rights not expressly granted to Licensee by Akebia under this Agreement are hereby retained by Akebia and any rights not

expressly granted to Akebia by Licensee under this Agreement are hereby retained by Licensee. For clarity, Akebia retains (on behalf of itself and its licensees) the right to Develop, manufacture, and have manufactured the Licensed Compound and the Licensed Products inside the Territory (a) to perform its obligations under this Agreement, and (b) for the purpose of obtaining and maintaining Regulatory Approval and Commercializing the Licensed Compound and the Licensed Products outside of the Territory.

Article III
GOVERNANCE

3.1 Joint Steering Committee.

3.1.1 **Formation and Purpose of the JSC**. The Joint Steering Committee ("**JSC**") will coordinate and oversee or monitor the Parties' activities hereunder in accordance with this Section 3.1 (Joint Steering Committee). As of the Effective Date, the JSC will be the joint steering committee established under the U.S. Collaboration and License Agreement. At any time during the Term the Parties may, and upon the conclusion of the term of the U.S. Collaboration and License Agreement the Parties will, establish a JSC that is separate from the joint steering committee established under the U.S. Collaboration and License Agreement. The JSC will have the responsibilities set forth herein, and, for so long as the JSC is the joint steering committee under the U.S. Collaboration and License Agreement, will also have the responsibilities set forth in the U.S. Collaboration and License Agreement. If the Parties establish a JSC that is separate from the joint steering committee established under the U.S. Collaboration and License Agreement, then the terms of Section 3.1.2 (Membership) will apply to the membership of the JSC and the terms of Section 3.1.3 (Meetings) and Section 3.1.4 (Meeting Agendas) will apply to meetings and minutes of the JSC. The JSC may establish a charter that will include details regarding the operation of the JSC consistent with this Article III (Governance). The JSC will dissolve upon the expiration of the Term. Notwithstanding anything to the contrary set forth in this Article III (Governance), during the term of the U.S. Collaboration and License Agreement, at the request of Licensee, the joint steering committee and sub-committees (including the joint development committee and joint commercialization committee) established under the U.S. Collaboration and License Agreement may oversee, monitor, review, discuss, and to the extent provided herein, approve Licensee's activities under this Agreement that are conducted in [***].

3.1.2 **Membership**. Each Party will designate up to three representatives with appropriate knowledge and expertise to serve as members of the JSC. The members of the JSC may also be members of the joint steering committee under the U.S. Collaboration and License Agreement. Each Party may replace its JSC representatives at any time upon written notice to the other Party. Akebia will designate one of its JSC members as one of the co-chairpersons of the JSC and Licensee will designate one of its members as the other co-chairperson of the JSC. [***] The lead co-chairperson or his or her designee, in collaboration with the Alliance Managers, will be responsible for calling meetings, preparing, and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within 30 days thereafter. Such minutes will not be finalized until all JSC members have had an adequate opportunity to review and confirm the accuracy of such minutes.

3.1.3 **Meetings**. The JSC will hold meetings at such times as it elects to do so, but in no event will such meetings be held less frequently than quarterly, unless otherwise agreed by the

Parties. The JSC will meet alternatively at Licensee's Affiliate's facilities in the United States or Europe and Akebia's facilities in Cambridge, Massachusetts, or at such locations as the Parties may otherwise agree. Meetings of the JSC may be held by audio or video teleconference with the consent of each Party; *provided*, *however*, that at least one JSC meeting per year will be held in person. If the members of the JSC and the joint steering committee under the U.S. Collaboration and License Agreement are the same or overlap, then the Parties may hold joint meetings of the JSC and the joint steering committee under the U.S. Collaboration and License Agreement. The Alliance Manager of each Party will attend each meeting of the JSC as [***]. Each Party will be responsible for all of its own expenses of participating in any JSC meeting.

3.1.4 **Meeting Agendas**. Each Party will disclose to the other Party the proposed agenda items along with appropriate information at least five Business Days in advance of each meeting of the JSC; *provided that* under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a lesser period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting.

3.1.5 **Specific Responsibilities of the JSC**. The responsibilities of the JSC will be to:

(a) manage the overall strategic alignment between the Parties under this Agreement and maintain the relationship between the Parties;

(b) [***] any allocation to Licensee of Development activities in the Territory under the Current Global Development Plan, as described in Section 4.1 (Current Global Development);

(c) [***] the Current Global Development Plan and [***] any material amendments or updates thereto (including any amendments to the budgets set forth therein greater than [***]), in each case, which will be prepared by Akebia, as described in Section 4.1.1 (Current Global Development Plan);

(d) [***] any determination by the JDC (or attempt to resolve any dispute or disagreement at the JDC) as to whether to conduct any [***] pursuant to Section 3.2.3(c);

(e) [***] each initial [***] Plan and any material amendments or updates thereto (including any amendments to the budgets set forth therein greater than [***]), as described in Section 4.1.2(a) (Agreement of the JDC) and Section 4.1.2(c) ([***] Plan Amendments);

(f) [***] the initial [***] Development Plan, as described in Section 4.2.1(a) (Initial [***] Development Plan);

(g) subject to Section 3.1.5(i) with respect to the non-clinical studies, [***], and, [***], any amendment or update to the Territory-Specific Development Plan (or portion thereof) related to such indication or such formulation, as described in Section 4.2.1(b)(i) (Prior to the Receipt of Regulatory Approval);

(h) [***] a study design or protocol of any clinical study for a Licensed Product in such Initial Indication in the Current Formulation or New Indication or New Formulation that is [***];

(i) [***] each non-clinical study to be conducted under any [***] Development Plan for such Licensed Product in such indication or such formulation, and the study design or protocol therefor, as described in Section 4.2.1(b)(ii)(2);

(j) [***] a study design or protocol of any non-clinical study for a Licensed Product in such Initial Indication in the Current Formulation or New Indication or New Formulation [***];

(k) [***] any Additional Development of the Licensed Compound or a Licensed Product, including any Other Global Development for any New Indication or New Formulation in the Territory proposed by either Party pursuant to Section 4.3 (Additional Development);

(l) [***] each Other Global Development Plan and any material amendments or updates thereto (including any amendments to the budgets set forth therein greater than [***]), in each case, which will be prepared by the Proposing Party, as described in Section 4.3.1(d) (Conduct of Additional Development);

(m) [***] whether to hold any [***], as described in Section 5.3.1 ([***]);

(n) [***] the Launch Sequence and amendments and updates thereto, in each case, to be prepared by Licensee, subject to and as described in Section 7.2.1 (Launch Sequence);

(o) [***] Licensee's decision not to launch or Commercialize a Licensed Product in a Major Country, and the portion of the initial Commercialization Plan or any amendment or update thereto that contemplates not launching or Commercializing a Licensed Product in such country, as described in Section 7.2.2 (Commercialization Plan);

(p) [***] any matters related to the Commercialization Plan (or any amendment or update thereto) referred to the JSC by either Party's representatives to the JCC;

(q) [***] any Territory-specific brand strategy for a Licensed Product, which will be developed by the JCC, subject to and as described in Section 7.2.3 (Consistency with Global Brand Plan);

(r) [***] the Global Brand Plan and any material amendments or updates thereto, which, in each case, will be prepared by [***], as described in Section 7.8 (Global Brand Plan and Promotional Materials);

(s) [***] the Manufacturing Plan and any material amendments or updates thereto (including any amendments to the budgets set forth therein greater than [***]), as described in Section 8.2 (Manufacturing Plan; Product Supply);

(t) attempt to resolve any other disputes or disagreements, including those arising from any Sub-Committee;

(u) [***] possibility of the Parties [***]; and

(v) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.

3.2 Joint Development Committee.

3.2.1 **Formation and Purpose of the JDC**. The Joint Development Committee ("**JDC**") will be a Sub-Committee of the JSC. As of the Effective Date, the JDC will be the joint development committee established under the U.S. Collaboration and License Agreement. At any time during the Term the Parties may, and upon the conclusion of the term of the U.S. Collaboration and License Agreement the Parties will, establish a JDC that is separate from the joint development committee established under the U.S. Collaboration and License Agreement. The JDC will have the responsibilities set forth herein, and, for so long as the JDC is the joint development committee under the U.S. Collaboration and License Agreement, will also have the responsibilities set forth in the U.S. Collaboration and License Agreement; *provided that* the JSC established under this Agreement (and not the U.S. Collaboration and License Agreement, if the joint steering committees are not the same committee) will approve or attempt to resolve any dispute related to Territory-Specific Development matters (as applicable). If the Parties establish a JDC that is separate from the joint development committee established under the U.S. Collaboration and License Agreement, then the terms of Section 3.2.2 (Membership and Meetings of the JDC) will apply to the membership and meetings of the JDC. The JDC will dissolve upon completion of all Development activities and Medical Affairs with respect to the Licensed Products in the Territory.

3.2.2 **Membership and Meetings of the JDC**. Each Party will designate up to three representatives with appropriate knowledge and expertise to serve as members of the JDC. The members of the JDC may also be members of the joint development committee under the U.S. Collaboration and License Agreement. Akebia will designate a co-chairperson of the JDC and Licensee will designate a co-chairperson of the JDC, each of whom will be a Party's representative who is a member of the JDC. Each Party may replace its JDC representatives and co-chairpersons at any time upon written notice to the other Party. The Alliance Manager of each Party (or his or her designee) will attend each meeting of the JDC as a [***]. The JDC will hold meetings at such times as it elects to do so (but in any event at least quarterly, unless the Parties agree otherwise), and at such locations as the Parties may agree upon or, if agreed by the Parties, by audio or video teleconference. If the members of the JDC and the joint development committee under the U.S. Collaboration and License Agreement are the same or overlap, then the Parties may hold joint meetings of the JDC and the joint development committee under the U.S. Collaboration and License Agreement. Each Party will be responsible for all of its own expenses of participating in any JDC meeting.

3.2.3 **Specific Responsibilities of the JDC**. The responsibilities of the JDC will be to:

(a) [***] the roles of the Parties with respect to the activities under the Current Global Development Program and the ways in which Licensee can provide assistance to Akebia with respect to the Current Global Development Program;

(b) [***] any amendments or updates to the Current Global Development Plan (*provided that* material amendments or updates will be subject to JSC approval in

accordance with Section 3.1.5(c) (Specific Responsibilities of the JSC)), as described in Section 4.1.1 (Current Global Development Plan);

(c) [***] any [***], and, if applicable, discuss the Development strategy for each such [***], and the roles and responsibilities of each Party in conducting each such [***] (including which Party will be the sponsor for such study), and the associated budget, in each case, as described in Section 4.1.2 ([***] Plan);

(d) [***] each [***] Plan and any amendments and updates thereto (*provided that* each initial [***] Plan and any material amendments or updates will be subject to JSC [***] in accordance with Section 3.1.5(e) (Specific Responsibilities of the JSC)), as described in Section 4.1.2(a) (Agreement of the JDC) and Section 4.1.2(c) ([***] Plan Amendments);

(e) [***] updates from Akebia of Development, manufacturing, and regulatory activities related to the Licensed Compound and the Licensed Products outside of the Territory, as described in Section 4.1.5 (Global and EMA Development Reports);

(f) [***], the Current Global Development Plan, the [***] Development Plan, any [***] Plan, and any Other Global Development Plan, including through each Party's updates of the status of Development in the Territory, as described in Section 4.1.5 (Global and [***] Reports), Section 4.2.2 ([***] Development Reports), and Section 4.3.2 (Additional Development Reports; Information);

(g) subject to Section 3.2.3(h) with respect to non-clinical studies included in any [***] Development Plan, [***] the initial [***] Development Plan and amendments and updates thereto; *provided that*:

(i) [***], the initial [***] Development Plan and material amendments or updates thereto (or portion thereof) related to such indication or such formulation will be subject to JSC [***] in accordance with Section 3.1.5(g) (Specific Responsibilities of the JSC), as described in Section 4.2.1(a) (Initial [***] Development Plan) and Section 4.2.1(b)(i) (Prior to the Receipt of Regulatory Approval); and

(ii) [***], the study design or protocol of any clinical study for a Licensed Product in such Initial Indication in the Current Formulation or New Indication or New Formulation [***] for such indication or such formulation will, in each case, be subject to JSC [***] in accordance with Section 3.1.5(h) (Specific Responsibilities of the JSC), as described in Section 4.2.1(b)(ii)(1);

(h) [***] whether to conduct any non-clinical study of a Licensed Product in an Initial Indication in the Current Formulation or in any New Indication or New Formulation, and the study design or protocol therefor included in any Territory-Specific Development Plan; *provided that*:

(i) [***], in each case, all non-clinical studies to be conducted under any Territory-Specific Development Plan for such indication or such formulation will be subject to JSC [***] in accordance with Section

3.1.5(i) (Specific Responsibilities of the JSC), as described in Section 4.2.1(b)(ii)(2); and

(ii) [***], the study design or protocol of any non-clinical study for a Licensed Product in such Initial Indication in the Current Formulation or New Indication or New Formulation [***] for such indication or such formulation will, in each case, be subject to JSC [***] in accordance with Section 3.1.5(j) (Specific Responsibilities of the JSC), as described in Section 4.2.1(b)(ii)(3);

(i) [***] for [***] in the Territory and other [***];

(j) [***] Development activities of the Parties related to any Additional Development in the Territory proposed by either Party pursuant to Section 4.3 (Additional Development);

(k) [***] (at a joint meeting with the JSC) whether to hold any [***], as described in Section 5.3.1 ([***]);

(l) [***] the Global Medical Affairs Plan and the Local Medical Affairs Plan, and any amendments or updates thereto, as described in Section 6.1 (Medical Affairs Plans);

(m) [***] updates from the Parties of Medical Affairs and progress under the Global Medical Affairs Plan (with respect to Akebia) and the Local Medical Affairs Plan (with respect to Licensee), as described in Section 6.2 (Medical Affairs Activities);

(n) [***] the Joint Publication Plan, as described in Section 13.4.2 (After Release of Data by Akebia); and

(o) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.

3.3 Joint Manufacturing Committee.

3.3.1 **Formation and Purpose of the JMC**. At an appropriate time (but no later than [***] after the Effective Date, or earlier if Akebia is to manufacture and supply to Licensee any Licensed Product for Development purposes), the JSC will establish a Joint Manufacturing Committee ("**JMC**"), which JMC will be a Sub-Committee of the JSC and will have the responsibilities provided for herein; *provided that*, if the Parties establish a joint manufacturing committee as a sub-committee of the joint steering committee under the U.S. Collaboration and License Agreement, then, unless the Parties agree otherwise, the JMC under this Agreement will be the same as the joint manufacturing committee established under the U.S. Collaboration and License Agreement. Notwithstanding the foregoing, at any time during the Term the Parties may, and upon the conclusion of the term of the U.S. Collaboration and License Agreement the Parties will, establish a JMC that is separate from the joint manufacturing committee established under the U.S. Collaboration and License Agreement. The JMC will have the responsibilities set forth herein, and, for so long as the JMC is the joint manufacturing committee under the U.S. Collaboration and License Agreement, will also have the

responsibilities delegated to the joint manufacturing committee under the U.S. Collaboration and License Agreement. The JMC will dissolve upon the termination or expiration of the Supply Agreements.

3.3.2 **Membership and Meetings of the JMC**. Each Party will designate up to three representatives with appropriate knowledge and expertise to serve as members of the JMC. Akebia will designate a co-chairperson of the JMC and Licensee will designate a co-chairperson of the JMC, each of whom will be a Party's representative who is a member of the JMC. Each Party may replace its JMC representatives and co-chairpersons at any time upon written notice to the other Party. The Alliance Manager of each Party (or his or her designee) will attend each meeting of the JMC as a [***]. The JMC will hold meetings at such times as it elects to do so (but in any event at least two times each year, unless the Parties agree otherwise), and at such locations as the Parties may agree upon or, if agreed by the Parties, by audio or video teleconference. Each Party will be responsible for all of its own expenses of participating in any JMC meeting.

3.3.3 **Specific Responsibilities of the JMC**. The responsibilities of the JMC will be to:

(a) [***] the Manufacturing Plan, and any amendments or updates thereto (*provided that* the initial Manufacturing Plan and material amendments or updates thereto will be subject to JSC [***] in accordance with Section 3.1.5(s) (Specific Responsibilities of the JSC)), as described in Section 8.2 (Manufacturing Plan; Product Supply);

(b) [***] the [***] of each contract manufacturing organization that Akebia desires to engage to manufacture and supply the Licensed Products in API form or Tablet Formulation, as described in Section 8.2 (Manufacturing Plan; Product Supply); and

(c) [***] activities under the Manufacturing Plan related to the manufacture and supply of the Licensed Products for Development and Commercialization purposes, as described in Section 8.7 (Manufacturing Reports).

3.4 Joint Commercialization Committee.

3.4.1 **Formation and Purpose of the JCC**. At an appropriate time (but at least [***] prior to the anticipated First Commercial Sale of the first Licensed Product in the Territory, unless otherwise agreed by the Parties), the JSC will establish a Joint Commercialization Committee ("**JCC**"), which JCC will be a Sub-Committee of the JSC and will have the responsibilities provided for herein. The JCC will dissolve upon the completion of all Commercialization activities with respect to the Licensed Products.

3.4.2 **Membership and Meetings of the JCC**. Each Party will designate up to three representatives with appropriate knowledge and expertise to serve as members of the JCC. Akebia will designate a co-chairperson of the JCC and Licensee will designate a co-chairperson of the JCC, each of whom will be a Party's representative who is a member of the JCC. Each Party may replace its JCC representatives and co-chairpersons at any time upon written notice to the other Party. The Alliance Manager of each Party (or his or her designee) will attend each meeting of the JCC as a [***]. The JCC will hold meetings at such times as it elects to do so (but in any event at least two times each year, unless the Parties agree otherwise), and at such locations as the Parties may agree upon

or, if agreed by the Parties, by audio or video teleconference. Each Party will be responsible for all of its own expenses of participating in any JCC meeting.

3.4.3 **Specific Responsibilities of the JCC**. The responsibilities of the JCC will be to:

(a) [***] the Launch Sequence and any amendments or updates thereto prepared by Licensee in accordance with Section 7.2.1 (Launch Sequence);

(b) [***] the Commercialization Plan and any amendments or updates thereto (*provided that* any amendment or update that contemplates not launching or Commercializing a Licensed Product in a Major Country will be subject to JSC [***] in accordance with Section 3.1.5(o) (Specific Responsibilities of the JSC)), as described in Section 7.2.2 (Commercialization Plan);

(c) upon request of a Party, [***] a Territory-specific brand strategy for a Licensed Product, as described in Section 7.2.3 (Consistency with Global Brand Plan);

(d) [***] Commercialization activities and progress under the Commercialization Plan through Licensee's updates as described in Section 7.3 (Commercialization Reports);

(e) [***] the Global Brand Plan and any material amendments or updates thereto, which, in each case, will be prepared by [***], as described in Section 7.8 (Global Brand Plan and Promotional Materials); and

(f) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.

3.5 Additional Committees.

3.5.1 **Sub-Committees**. The JSC will establish and delegate specifically-defined duties to the JDC, the JMC, the JCC, the PVC, and other operational committees or *ad hoc* sub-committees, on an "as needed" basis to oversee particular projects or activities (the JDC, the JMC, the JCC, the PVC, and such other operational committees and sub-committees, each a "**Sub-Committee**"). Each Sub-Committee may establish a charter that will include details regarding its operation and that is consistent with this Article III (Governance). In addition, the JSC or the co-chairpersons of the JSC may delegate to the JDC, the JMC, or the JCC any responsibilities of the JSC set forth in Section 3.1.5 (Specific Responsibilities of the JSC), and in such case, any agreement reached by unanimous Party Vote of the JDC, the JMC, or the JCC with respect to such delegated responsibilities will be deemed [***] by the JSC (to the extent such [***] is required hereunder). The JSC or the co-chairpersons of the JSC acting together may also reallocate any responsibility of a Sub-Committee to any other Sub-Committee. Each such Sub-Committee, other than the JDC, the JMC, the JCC, and the PVC, will be constituted and will operate as the JSC determines. Akebia will designate a co-chairperson of each Sub-Committee and Licensee will designate a co-chairperson of each Sub-Committee, each of whom will be a Party's representative who is a member of such Sub-Committee. [***] The lead co-chairperson or his or her designee, in collaboration with the Alliance Managers, will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within 30 days thereafter. Such minutes will not be finalized until all Sub-

Committee members have had an adequate opportunity to review and confirm the accuracy of such minutes in writing. Each Party may replace its representatives and co-chairpersons on each such Sub-Committee at any time upon written notice to the other Party. The Alliance Manager of each Party (or his or her designee) will attend each meeting of each Sub-Committee as a [***]. Each Sub-Committee will hold meetings at such times as it elects to do so (but in any event at least two times each year, unless the Parties agree otherwise), and at such locations as the Parties may agree upon or, if agreed by the Parties, by audio or video teleconference. Each Party will be responsible for all of its own expenses of participating in any Sub-Committee meeting. Each Sub-Committee and its activities will be subject to the oversight of, and will report to, the JSC. No Sub-Committee's authority may exceed that specified for the JSC in this Article III (Governance). Any disagreement between the representatives of the Parties on a Sub-Committee will be referred to the JSC for resolution in accordance with Section 3.7 (Decision-Making and Committee Dispute Resolution).

3.5.2 **Pharmacovigilance Committee**. Without limiting the generality of, and subject to, Section 3.5.1 (Sub-Committees), the pharmacovigilance committee (the "**Pharmacovigilance Committee**" or "**PVC**") will be a Sub-Committee of the JSC. As of the Effective Date, the PVC will be the pharmacovigilance committee established under the U.S. Collaboration and License Agreement. At any time during the Term the Parties may, and immediately upon the conclusion of the term of the U.S. Collaboration and License Agreement the Parties will, establish a PVC that is separate from the pharmacovigilance committee established under the U.S. Collaboration and License Agreement. If the Parties establish a PVC that is separate from the pharmacovigilance committee established under the U.S. Collaboration and License Agreement, then the Parties will establish such PVC at an appropriate time, but in any event prior to the earlier of (a) [***], or (b) [***]. In addition to any other matters that the JSC may delegate to the PVC, the PVC will provide a forum for the Parties to discuss and share information regarding the safety of the Licensed Products and other pharmacovigilance matters worldwide, including safety and pharmacovigilance matters arising under this Agreement in accordance with the Pharmacovigilance Agreement.

3.5.3 **Operational Teams**. From time-to-time, the JSC or any Sub-Committee (whether the JSC or any Sub-Committee is the same as the joint steering committee or applicable sub-committee under the U.S. Collaboration and License Agreement) may establish and delegate specific matters or duties within its responsibilities to directed teams (each, an "**Operational Team**"), the composition, operation, and responsibilities of which will be determined by the JSC or the applicable establishing Sub-Committee (the "**Establishing Committee**"). Operational Teams may be established on an *ad hoc* basis for purposes of a specific activity or on such other basis as the applicable Establishing Committee may determine. Each Operational Team will report to, and its activities will be subject to the oversight of, the applicable Establishing Committee. No Operational Team's authority may exceed that specified for the applicable Establishing Committee. Any disagreement between the representatives of the Parties on any Operational Teams will be referred to the applicable Establishing Committee for resolution in accordance with Section 3.7 (Decision-Making and Committee Dispute Resolution).

3.6 **Additional Participants**. Regardless of whether the JSC or any Sub-Committee is the same as the joint steering committee or applicable sub-committee under the U.S. Collaboration and License Agreement, (a) at the request of either Party, other employees of such Party or any of its Affiliates involved in the Development, manufacturing, Medical Affairs, or Commercialization of

the Licensed Compound or the Licensed Products may attend meetings of the JSC or any Sub-Committee as [***], and (b) with the consent of each Party, consultants, representatives, or advisors involved in the same activities may attend meetings of the JSC or any Sub-Committee as [***]; *provided*, *however*, that such Third Party [***] are under written obligations of confidentiality and non-use applicable to the Confidential Information of each Party that are at least as stringent as those set forth in Article XIII (Confidentiality).

3.7 **Decision-Making and Committee Dispute Resolution**. Each Party's representatives on the JSC and each Sub-Committee will, [***] (the "**Party Vote**") on all matters brought before such committee for a decision by consensus. The JSC and each Sub-Committee will make decisions as to matters within its jurisdiction by unanimous Party Vote, which may either be reflected in the minutes of the committee meeting or by an action by written consent signed by the co-chairperson appointed by each Party or his or her designee identified in writing; *provided*, *however*, that neither the JSC nor any Sub-Committee will have the authority to amend, modify, or waive compliance with this Agreement. Any disagreement between the representatives of Licensee and Akebia with respect to matters within the scope of authority of the Alliance Managers, or any Sub-Committees that cannot be resolved after good faith efforts will, at the election of either Party, be submitted to the JSC for resolution. If, after good faith efforts, the JSC is unable to resolve any such disagreement referred to it by any Sub-Committee or any disagreement with respect to the matters within the scope of the JSC's authority or any other disagreement between the Parties that may be referred to the JSC within a period of [***], then, except as set forth in Section 7.2.1 (Launch Sequence), and Section 7.2.3 (Consistency with Global Brand Plan), at the election of either Party, a Party may refer such matter to the Party's respective Executive Officer. The Executive Officers will use good faith efforts to resolve any such disagreement so referred to them as soon as practicable, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties. If the Executive Officers are unable to resolve any disagreement so referred within [***] after such matter is referred to them (or such longer period as the Executive Officers may agree upon), then the Parties will continue to operate under existing plans until the Parties reach agreement on the applicable matter; *provided*, *however*, that (a) if the disagreement is [***], then the Executive Officer of Akebia will have the final say on such dispute, (b) if the disagreement is [***], then the Executive Officer of Licensee will have the final say on such dispute, and (c) if the disagreement is an Expert Reserved Matter, then such matter will be resolved by binding baseball arbitration pursuant to Section 16.4 (Baseball Arbitration for Expert Reserved Matters). Notwithstanding the foregoing, neither the JSC, nor the [***] will have the authority to (i) amend or modify, or waive compliance with this Agreement, (ii) obligate either Party to violate Applicable Law or the requirements of any Regulatory Authority, or (iii) impose any obligation on either Party that would be in violation of such Party's written standard operating procedures, written business policies, or written compliance policies or procedures. For the avoidance of doubt, matters that are specified in Section 3.1.5 (Specific Responsibilities of the JSC), Section 3.2.3 (Specific Responsibilities of the JDC), Section 3.3.3 (Specific Responsibilities of the JMC), or Section 3.4.3 (Specific Responsibilities of the JCC) to be [***] (as opposed to [***]) do not require any agreement or decision by either Party and are not subject to the voting and decision-making procedures set forth in this Section 3.7 (Decision-Making and Committee Dispute Resolution).

3.8 **Interactions Between Committees and Internal Teams**. The Parties recognize that while they will establish the JSC, the JDC, the JMC, the JCC, the PVC, and other Sub-Committees under this Agreement, each Party possesses an internal structure (including with various committees, teams, and review boards) that will be involved in administering such Party's activities under this Agreement. If requested by a Party, the JSC, and any Sub-Committees will establish procedures to facilitate communications between the JSC, the JDC, the JMC, the JCC, the PVC, or such

other Sub-Committee and the relevant internal committee, team, or board of the requesting Party. Such procedures may include, to the extent reasonably necessary, requiring appropriate members of the JSC or any other Sub-Committee to be available at reasonable times and places and upon reasonable prior notice to make appropriate reports to or respond to reasonable inquiries from, the relevant internal committee, team, or board.

3.9 **Alliance Managers**. Each of the Parties will appoint a single individual to manage Development and Commercialization obligations between the Parties (each, an "**Alliance Manager**"), which individual may also be the alliance manager under the U.S. Collaboration and License Agreement. The role of the Alliance Manager is to act as a single point of contact between the Parties to ensure a successful relationship under this Agreement. The Alliance Managers will attend all JSC meetings and the Alliance Managers or their respective designees will attend all Sub-Committee meetings and will support the co-chairpersons of the JSC and each Sub-Committee in the discharge of his or her responsibilities. Alliance Managers will be [***] in all JSC and Sub-Committee meetings; *provided*, *however*, that an Alliance Manager may bring any matter to the attention of the JSC or any Sub-Committee if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will designate its initial Alliance Manager promptly after the Effective Date and each Party may change its designated Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Alliance Manager will also: (a) be the point of first referral in all matters of conflict resolution; (b) provide a single point of communication for seeking consensus between the Parties regarding key strategy and plan issues; (c) identify and bring disputes to the attention of the JSC in a timely manner; (d) plan and coordinate cooperative efforts and internal and external communications; and (e) take responsibility for ensuring that governance activities, such as the conduct of required JSC and Sub-Committee meetings and production of meeting minutes, occur as set forth in this Agreement, and that the relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

Article IV
DEVELOPMENT

4.1 **Current Global Development**. Subject to Licensee's performance of its obligations and fulfillment of its responsibilities, in each case, with respect to regulatory affairs in accordance with Article V (Regulatory Affairs), Akebia will use Commercially Reasonable Efforts to perform the Current Global Development Program, and Licensee will provide assistance reasonably requested by Akebia in connection with the activities under the Current Global Development Plan. If Licensee agrees to perform any activities under the Current Global Development Plan and the JSC [***] the allocation of such activities to Licensee pursuant to Section 3.1.5(b) (Specific Responsibilities of the JSC), then Licensee will use Commercially Reasonable Efforts to perform such activities, and Akebia will provide all assistance reasonably requested by Licensee in connection therewith.

4.1.1 **Current Global Development Plan**. Prior to the Effective Date, Akebia has provided to Licensee the Current Global Development Plan (including the corresponding budget disclosed by Akebia to Licensee at the meeting of the joint steering committee under the U.S. Collaboration and License Agreement on February 23, 2017). Akebia may prepare amendments or updates to the Current Global Development Plan, including any (a) new protocols proposed by Akebia for any additional clinical or non-clinical study that is not an [***] and is to be included in the Current Global Development Program, and (b) material revisions proposed by Akebia to the protocol of any clinical or non-clinical

study included in the Current Global Development Program as of the Effective Date. Akebia will provide each such amendment or update to the Current Global Development Plan (or corresponding budget) to the JDC for its [***] as set forth in Section 3.2.3(b) (Specific Responsibilities of the JDC), *provided that* material amendments or updates will be provided to the JSC for its [***] as set forth in Section 3.1.5(c) (Specific Responsibilities of the JSC). Each such material amendment or update to the Current Global Development Plan (and corresponding budget) will become effective and will supersede the previous Current Global Development Plan (and corresponding budget) upon [***] of the JSC.

4.1.2 **[***]**. The Parties anticipate that the studies included in the Current Global Development Program as of the Effective Date will be the pivotal studies that are necessary to obtain Regulatory Approval from [***] for the Licensed Product in an Initial Indication in the Current Formulation in [***]

(a) Agreement of the JDC. If, following completion of the [***], and [***] at the JDC of the advice received from [***] at such meetings, Licensee desires to conduct any [***], then Licensee may propose such [***] to the JDC, and the JDC will [***] such [***] as set forth in Section 3.2.3(c) (Specific Responsibilities of the JDC). If the JDC [***] conduct an [***], then the JDC will [***] the Development strategy for such [***], the roles and responsibilities of each Party in conducting such [***], and the associated budget pursuant to Section 3.2.3(c) (Specific Responsibilities of the JDC). Unless the Parties agree otherwise, Licensee will prepare a development plan for such [***] (each, an "[***] **Plan**"), which plan will include the protocols for such [***], and the Development strategy, roles and responsibilities of each Party (including which Party will be the sponsor of such study), and associated budget, in each case, for such [***] as discussed by the JDC. Licensee will submit such [***] Plan to the JDC for its [***] as provided in Section 3.2.3(d) (Specific Responsibilities of the JDC), and to the JSC for its [***] as provided in Section 3.1.5(e) (Specific Responsibilities of the JSC). Thereafter, Licensee may conduct (or if the Parties agree that Akebia will be the sponsor, Akebia will conduct) such [***] pursuant to the [***] Plan, as the same may be amended from time-to-time in accordance with this Agreement.

(b) Failure of the JDC to Agree. If, after escalation to the JSC and the Executive Officers, the Parties are unable to agree (A) as to [***], or (B) on any [***] (including the roles and responsibilities of each Party in conducting such [***]), then, in either case ((A) or (B)), Licensee may conduct (and will be the sponsor of) such [***] pursuant to an [***] Plan prepared by Licensee and provided to Akebia; *provided that*, prior to Regulatory Approval from the FDA in the U.S. for a Licensed Product in an Initial Indication in the Current Formulation, Akebia may require Licensee to delay [***]

(c) [***] Plan Amendments. Licensee may prepare amendments or updates to any [***] Plan, and will provide each such amendment or update to the JDC for its [***] as set forth in Section 3.2.3(d) (Specific Responsibilities of the JDC); *provided that* material amendments or updates will be provided to the JSC for its [***] as set forth in Section 3.1.5(e) (Specific Responsibilities of the JSC). Each such material amendment or update to an [***] Plan will become effective and will supersede the previous [***] Plan upon [***] of the JSC.

(d) Performance. Each Party agrees to use Commercially Reasonable Efforts to perform the activities allocated to such Party under each [***] Plan, and the other Party will provide all assistance reasonably requested by the performing Party in connection therewith.

4.1.3 **Development Cost Sharing**. Commencing on and after January 1, 2017, Akebia and Licensee will each be responsible for [***]% of all [***] Costs, and Licensee will be responsible for [***]% of all Current Global Development Costs and Akebia will be responsible for the remaining [***]% of all Current Global Development Costs, in each case, incurred on and after January 1, 2017 (the [***] Costs and Current Global Development Costs, collectively, the "**Shared Development Costs**"), in accordance with the following:

(a) Licensee R&D Cost Share. Licensee will be responsible for paying (i) [***]% of all [***] Costs, subject to Licensee's right to credit Akebia's [***]% share of such costs as described in Section 4.1.3(b) (Credit for [***] Costs), and (ii) [***]% of all Current Global Development Costs (collectively, the "**Licensee R&D Cost Share**", as such definition may be amended pursuant to Section 15.7.7 (Termination for Sub-Territory A)), and Akebia will be responsible for paying [***]% of all Current Global Development Costs, in each case, in accordance with Section 4.1.4 (Payment of Licensee R&D Cost Share). If Licensee agrees to perform any activities under the Current Global Development Plan and the JSC [***] such allocation of activities pursuant to Section 3.1.5(b) (Specific Responsibilities of the JSC), then Licensee will perform such activities in accordance with the estimated budget for such activities, and the costs incurred by Licensee in connection with such activities will be credited against the Licensee R&D Cost Share.

(b) Credit for [***] Costs. Licensee may credit an amount equal to [***]% of the actual [***] Costs incurred by or on behalf of either Party (the "**Creditable [***] Costs**") against future payments due to Akebia under this Agreement as follows: (i) *first*, Licensee may credit $[***] of Creditable [***] Costs incurred against [***] due to Akebia under this Agreement (including the Licensee R&D Cost Share), and (ii) *then* Licensee may credit any further Creditable [***] Costs (if applicable) only against [***] due to Akebia pursuant to Section [***] and [***] due to Akebia pursuant to Section [***]. Notwithstanding the foregoing, Licensee may not credit any such Creditable [***] Costs against amounts due to Akebia in any calendar quarter to the extent that doing so would cause the amount due to Akebia in such [***] (whether as Licensee R&D Cost Share, milestone payments, or royalties) to be less than [***]% of the amount otherwise due to Akebia for such [***]; *provided that* Licensee may carry forward any such uncreditable amount of Creditable [***] Costs in any [***] into future [***] and apply such amount against applicable future payments due to Akebia in accordance with this Section 4.1.3(b) (Credit for [***] Costs) in such future [***] until all Creditable [***] Costs are fully credited.

(c) Report of [***] Costs. On a [***] basis prior to end of each [***] during which Licensee conducts any [***], Licensee will provide Akebia with a written notice that includes (i) the estimated budget for any such [***] for the next [***] following the date of such notice, and (ii) a report of actual [***] Costs incurred by or on behalf of Licensee during the [***].

(d) Separate Obligations. For clarity, the Licensee R&D Cost Share under this Agreement is in addition to and separate from Licensee's research and development cost share obligations under the U.S. Collaboration and License Agreement.

4.1.4 **Payment of Licensee R&D Cost Share**.

(a) Initial Cost Share Notice. No later than [***], Akebia will provide Licensee with a Cost Share Notice that includes (i) the estimated budget for the Current Global Development Program for the next [***] following the date of such Cost Share Notice, (ii) an invoice for the estimated amount of the applicable Licensee R&D Cost Share for the [***], and (iii) a report of actual Current Global Development Costs incurred by or on behalf of Akebia during the [***].

(b) Cost Share Notices. Following Akebia's delivery to Licensee of the initial Cost Share Notice in accordance with Section 4.1.4(a) (Initial Cost Share Notice), on a [***] basis prior to the end of each [***], Akebia will provide Licensee with a Cost Share Notice that includes (i) the estimated budget for the Current Global Development Program and any [***] to be conducted by or on behalf of Akebia for the next [***] following the date of such Cost Share Notice, (ii) an invoice for the estimated amount of the applicable Licensee R&D Cost Share for the [***] following such Cost Share Notice, and (iii) a report of actual [***].

(c) Prepayment. Within [***] of receipt of each Cost Share Notice, Licensee will pay to Akebia the estimated amount of the Licensee R&D Cost Share for the applicable [***], as set forth in the invoice provided pursuant to Section 4.1.4(a)(ii) (Initial Cost Share Notice) or Section 4.1.4(b)(ii) (Cost Share Notices), as applicable, (the "**Prepayment**"). If the Prepayment paid by Licensee to Akebia for a [***] exceeds the Licensee R&D Cost Share of the actual Shared Development Costs incurred by Akebia for such [***] (based on the [***] reports provided pursuant to Section 4.1.4(b)(iii) (Cost Share Notices)), then such overpayment will be credited to the next Prepayment, or, if there are no subsequent Prepayments owed to Akebia, then Licensee may credit the amount of such overpayment to [***] due to Akebia under Section 9.2 (Milestone Payments). If the Prepayment paid by Licensee to Akebia is less than the applicable Licensee R&D Cost Share of the actual Shared Development Costs incurred by Akebia for such [***] (based on the [***] reports provided pursuant to Section 4.1.4(b)(iii) (Cost Share Notices)), then Licensee will pay to Akebia the amount of such underpayment within [***] of Akebia's invoice therefor.

(d) Current Global Development Costs for First Calendar Quarter of 2017. If the Licensee R&D Cost Share of the actual Current Global Development Costs incurred by Akebia during the [***] (based on the initial Cost Share Notice provided pursuant to Section 4.1.4(b)(iii) (Initial Cost Share Notice)) is greater than $[***], then Licensee will pay to Akebia an amount equal to the difference between the Licensee R&D Cost Share of such actual Current Global Development Costs incurred by Akebia during the first calendar quarter of 2017 and $[***] within [***] of Akebia's invoice therefor. Likewise, if the Licensee R&D Cost Share of the actual Current Global Development Costs incurred by Akebia during the [***] (based on the initial Cost Share Notice provided pursuant to Section 4.1.4(b)(iii) (Initial Cost Share Notice)) is less than $[***],

then the amount equal to the difference between $[***] and the Licensee R&D Cost Share of such actual Current Global Development Costs incurred during the [***] will be credited to the next Prepayment pursuant to Section 4.1.4(c) (Prepayment).

4.1.5 **Global and [***] Development Reports**. At each JDC meeting, Akebia and Licensee (if applicable) will each provide the JDC with an update (by means of a slide presentation or otherwise) summarizing the Development activities executed under the Current Global Development Plan and any [***] Plan or Other Global Development Plan for the Territory during the prior [***], including [***] and the ongoing status of [***] under any such plan, the status of each pending and proposed [***] set forth in the Current Global Development Plan, or any [***] Plan or Other Global Development Plan for each Licensed Product for the Territory (to the extent not already provided, and without limiting the obligations under Article V (Regulatory Affairs)). In addition, each Party will promptly provide written notice to the other Party, through the JDC or Alliance Managers, of any significant Development events in the Territory (*e.g.*, clinical trial initiation or completion, clinical holds, Regulatory Approvals, and Study Data) that the reporting Party reasonably believes is of interest to the other Party. In addition to the foregoing, on [***] basis, Akebia will provide the JDC with a written summary of any Development, manufacturing, and regulatory activities related to the Licensed Compound and the Licensed Products outside of the Territory that materially impact the Current Global Development Program. Notwithstanding the foregoing, the Parties acknowledge and agree that any information and updates provided pursuant to this Section 4.1.5 (Global and [***] Development Reports) will be subject to the rules and regulations set forth by the relevant Regulatory Authorities.

4.2 **Territory-Specific Development**. Subject to Section 4.1 (Current Global Development) and this Section 4.2 (Territory-Specific Development), [***] will be responsible for all Territory-Specific Development at its [***], including all [***]. Except as may otherwise be permitted under this Agreement (including pursuant to Section 4.3 (Additional Development) and as provided in Section 3.1.5(b) (Specific Responsibilities of the JSC)), [***] will conduct Development of the Licensed Compound and the Licensed Products only (a) in accordance with the applicable Territory-Specific Development Plan that has been [***] by the JDC and the JSC, or, as applicable, any portion thereof that has been [***] by the JSC as set forth in Section 3.1.5(f) (Specific Responsibilities of the JSC), in each case, as required under Section 4.2.1 (Territory-Specific Development Plan), and (b) only for the [***], unless the Parties agree to conduct [***] pursuant to Section 4.3.1 (Approval of Additional Development). [***] will use Commercially Reasonable Efforts to Develop, and obtain and maintain Regulatory Approval and Reimbursement Approval (where required) for, the Licensed Products in the Initial Indications in the Territory. In no event will Akebia have the right or authority, [***] or otherwise, to require Licensee to conduct any [***] Development, but Akebia may [***] Licensee from conducting certain [***] Development pursuant to the exercise of its [***] in accordance with Section 1.11(d) (Akebia Reserved Disputes), in each case, at any time.

4.2.1 **Territory-Specific Development Plan**.

(a) Initial Territory-Specific Development Plan. No later than [***] after the Effective Date, [***] will prepare and submit to the JDC for its [***] as set forth in Section 3.2.3(g) (Specific Responsibilities of the JDC), and subsequently to the JSC for its [***] as set forth in Section 3.1.5(f) (Specific Responsibilities of the JSC) the initial Territory-Specific Development Plan that summarizes the

Development activities that [***] or its Affiliates or permitted sublicensees will undertake for each country or region in the Territory for purposes of obtaining Regulatory Approval.

(b) Amendments and Updates. From time-to-time as necessary (*e.g.*, following receipt of guidance from a Regulatory Authority in the Territory), [***] will prepare amendments or updates to the then-current Territory-Specific Development Plan, including any amendment approved by the JSC pursuant to 3.1.5(g) (Specific Responsibilities of the JSC) that sets forth any Additional Development that is to be conducted as Territory-Specific Development, and provide each such amendment or update to the Territory-Specific Development Plan to the JDC for its [***] as set forth in Section 3.2.3(g) (Specific Responsibilities of the JDC), and subsequently to the JSC for its [***] as set forth in Section 3.1.5(g) (Specific Responsibilities of the JSC), Section 3.1.5(h) (Specific Responsibilities of the JSC), Section 3.1.5(i) (Specific Responsibilities of the JSC) or Section 3.1.5(j) (Specific Responsibilities of the JSC). Each amendment or update to the Territory-Specific Development Plan will become effective and will supersede such previous Territory-Specific Development Plan upon [***], thereof by the JSC.

(i) Prior to [***]. Prior to [***], the JDC will [***] as set forth in Section 3.2.3(g) (Specific Responsibilities of the JDC), and the JSC will [***] as set forth in Section 3.1.5(g) (Specific Responsibilities of the JSC) any amendment or update to the Territory-Specific Development Plan (or portion thereof) related to such indication or such formulation for which the [***].

(ii) After [***]. After [***], the JDC and JSC will each [***], but the JSC need not [***], any amendment or update to the Territory-Specific Development Plan (or portion thereof) related to such indication or such formulation for which the [***], *unless* such amendments or updates (or portions thereof) includes a study design or protocol set forth in the following clauses (1), (2), or (3), in which case such study design or protocol will be subject to [***] by the JSC as set forth in Section 3.1.5(h) (Specific Responsibilities of the JSC), with respect to clinical studies, or Section 3.1.5(i) (Specific Responsibilities of the JSC) or Section 3.1.5(j) (Specific Responsibilities of the JSC), in each case, with respect to non-clinical studies:

(1) a study design or protocol of any clinical study [***] conducted under the Current Global Development Plan (or any Other Global Development Plan with respect to New Indications or New Formulations) for such indication or such formulation;

(2) *prior to* [***] for such Licensed Product in such indication or such formulation; or

(3) *after* [***] for such Licensed Product in such Initial Indication in the Current Formulation or New Indication or New Formulation that is [***] conducted under the Current Global Development Plan (or any Other Global Development Plan with respect to

New Indications or New Formulations) for such indication or such formulation.

4.2.2 **Territory-Specific Development Reports**. At each meeting of the JDC, [***] will provide [***] with a written update (by means of a slide presentation or otherwise) summarizing the activities executed under the Territory-Specific Development Plan in each country in the Territory during the period since the last JDC meeting, including the status of each pending and proposed Regulatory Submission for the Licensed Products in such countries. In addition, [***] will provide prompt written notice to [***], through the JDC or Alliance Managers, of any significant Development events in the Territory (*e.g.*, clinical trial initiation or completion, clinical holds, Regulatory Submissions for the Licensed Products, Regulatory Approvals, or Study Data that Licensee reasonably believes is of interest to [***]). Notwithstanding the foregoing, the Parties acknowledge and agree that any information and updates provided pursuant to this Section 4.2.2 (Territory-Specific Development Reports) will be subject to the rules and regulations set forth by the relevant Regulatory Authorities.

4.3 Additional Development. If either Party (the "**Proposing Party**") desires to conduct Other Global Development or any other additional Development of the Licensed Compound or a Licensed Product in its territory that is not included in any [***] Plan or the then-current Current Global Development Plan or the then-current Territory-Specific Development Plan (including for any New Indication, New Formulation, or any Other Global Development, but excluding any [***], "**Additional Development**"), then the Proposing Party will present a proposal to the JSC for its [***] pursuant to Section 3.1.5(k) (Specific Responsibilities of the JSC), including a synopsis of the Development activities related to such Additional Development, the potential role of the non-Proposing Party with respect to such Additional Development, the timeline for such Additional Development, and the estimated costs associated with such Additional Development. Notwithstanding the foregoing, if a Regulatory Authority in a country or jurisdiction in the Territory requires a New Formulation for a Licensed Product in order for such Regulatory Authority to grant Regulatory Approval for such Licensed Product in an Initial Indication in such country or jurisdiction, then all Development related to such New Formulation will not be Additional Development and instead will be conducted as Territory-Specific Development pursuant to Section 4.2 (Territory-Specific Development).

4.3.1 **[***] Additional Development**.

(a) JSC [***]; Agreement. If the JSC [***] any Additional Development as Other Global Development and both Parties agree to participate in such Additional Development, then the Parties will enter into a co-development agreement (or an amendment to this Agreement) regarding such Additional Development, including the allocation of costs and responsibilities related to such Additional Development and the reporting of information regarding such Additional Development, and each Party will receive a right of reference pursuant to Section 5.5 (Rights of Reference; Further Assurances) to the data generated from such Additional Development for the purposes of obtaining Regulatory Approval and Commercializing the Licensed Product in its territory. If the JSC [***] any Additional Development as new Territory-Specific Development and [***] agrees to conduct such Additional Development, then [***] will receive a right of reference pursuant to Section 5.5 (Rights of Reference; Further Assurances) to the data generated from such Additional Development for the purposes of

obtaining Regulatory Approval and Commercializing the Licensed Product outside of the Territory.

(b) JSC [***]; Failure to Agree. If the JSC [***] Additional Development and the non-Proposing Party does not agree to participate in such Additional Development, then the Proposing Party may conduct such Additional Development in its own territory as [***] (in the case of [***]) or [***] (in the case of [***]); *provided*, *however*, that if [***] is the Proposing Party, then [***] may conduct such Additional Development inside the Territory for the purpose of [***]. Subject to Section 4.3.2 (Additional Development Reports; Information) and Section 4.3.4 (Rights to IP and Data), the non-Proposing Party will not receive a [***] to any data generated from such Additional Development that is conducted as Other Global Development and that the JSC [***], but in which the non-Proposing Party does not agree to participate.

(c) No JSC [***].

(i) Licensee Proposal. With respect to any Additional Development proposed by Licensee, if the JSC does not [***] such Additional Development and, after escalation of the dispute to the Executive Officers pursuant to Section 3.7 (Decision-Making and Committee Dispute Resolution), [***] ultimately determines not to [***] such Additional Development [***], then Licensee will not conduct any Development activities related to such Additional Development.

(ii) Akebia Proposal. With respect to any Additional Development that is conducted as Other Global Development and that is proposed by Akebia, if the Licensee's representatives on the JSC do not [***] such Additional Development and, after escalation of the dispute to the Executive Officers pursuant to Section 3.7 (Decision-Making and Committee Dispute Resolution), Akebia ultimately determines to [***] such Additional Development [***], then Akebia may [***] such Additional Development inside the Territory for the purpose of [***], in each case, at its cost and expense. Subject to Section 4.3.2 (Additional Development Reports; Information) and Section 4.3.4 (Rights to IP and Data), Licensee will not receive a [***] to any data generated from such Additional Development that is conducted as Other Global Development and that the JSC does not [***] (due to Licensee's representatives' disapproval), but that Akebia ultimately determines to conduct.

(d) Conduct of Additional Development. In all cases, and subject to a Party's right to conduct any Additional Development as set forth under this Section 4.3.1 (Approval of Additional Development), the Proposing Party (with respect to Additional Development that is conducted as Other Global Development) and Licensee (with respect to Additional Development that is conducted by Licensee as Territory-Specific Development) will conduct any such Additional Development in accordance with the terms of this Agreement and pursuant to (i) an applicable Other Global Development Plan or amendment thereto that is prepared by the Proposing Party and [***] by the JSC pursuant to Section 3.1.5(l) (Specific Responsibilities of the JSC), or (ii) an applicable Territory-Specific Development Plan or amendment thereto prepared by [***] and

submitted to the JDC for its [***] as set forth in Section 3.2.3(g) (Specific Responsibilities of the JDC), and subsequently to the JSC for its [***] as set forth in Section 3.1.5(g) (Specific Responsibilities of the JSC). In addition, nothing in this Agreement will prevent the non-Proposing Party from [***] with the Proposing Party regarding any [***] generated from any Additional Development (to the extent such non-Proposing Party does not obtain rights thereto pursuant to Section 4.3.3 (Reimbursement for Additional Development)).

4.3.2 **Additional Development Reports; Information**.

(a) By Licensee.

(i) All Additional Development. If Licensee conducts any Additional Development and the Parties do not enter into a co-development agreement (or amendment to this Agreement) with respect to such Additional Development in accordance with Section 4.3.1(a) (JSC [***]; Agreement), then, at each JDC meeting, Licensee will provide the JDC with an update (by means of a slide presentation or otherwise) summarizing the Additional Development in each country performed by Licensee or its Affiliates during the prior [***] (with the level of information set forth in Section 4.2.2 (Territory-Specific Development Reports)). In addition, Licensee will promptly provide written notice, through the JDC, to Akebia of any significant Development events that arise in the course of conducting such Additional Development, and will provide to Akebia copies of all material documentation and information related to such Additional Development, including any research data and reports and Study Data and reports that are necessary or reasonably useful for Akebia to satisfy any reporting obligations with Regulatory Authorities inside or outside of the Territory or to obtain or maintain Regulatory Approval for the Licensed Products outside of the Territory; *provided that* unless such Additional Development is conducted pursuant to Section 4.3.1(a) (JSC Approval; Agreement), or Akebia [***] in accordance with Section 4.3.3 (Reimbursement for Additional Development) to any Additional Development conducted by Licensee pursuant to Section 4.3.1(b) (JSC Approval; Failure to Agree), Akebia will use such information, data, and reports solely for the foregoing purposes and Akebia will not use such information, data, or reports to [***].

(ii) Jointly Agreed; Opt-In. In addition, if Licensee conducts Additional Development as Other Global Development pursuant to Section 4.3.1(a) (JSC [***]; Agreement) or if Akebia [***] in accordance with Section 4.3.3 (Reimbursement for Additional Development) to any Additional Development conducted by Licensee pursuant to Section 4.3.1(b) (JSC [***]; Failure to Agree), then Licensee will provide to Akebia any research data and reports and Study Data and reports that are necessary or reasonably useful for Akebia to [***], and to [***], in each case, in accordance with this Agreement, and notwithstanding the restriction in Section 4.3.2(a)(i) (All Additional Development), Akebia may use such information, data, and reports for the foregoing purposes.

(b) By Akebia.

(i) All Additional Development. If Akebia conducts Additional Development that is conducted as Other Global Development and the Parties do not enter into a co-development agreement (or amendment to this Agreement) with respect to such Additional Development in accordance with to Section 4.3.1(a) (JSC [***]; Agreement), then at each JDC meeting, Akebia will provide the JDC with an update (by means of a slide presentation or otherwise) summarizing such Additional Development performed by Akebia or its Affiliates during the prior [***] (with the level of information set forth in Section 4.1.5 (Global and EMA Development Reports)). In addition, Akebia will promptly provide written notice, through the JDC, to Licensee of any significant Development events that arise in the course of conducting such Additional Development, and will provide to Licensee copies of all material documentation and information related to such Additional Development, including any research data and reports and Study Data and reports that are necessary or reasonably useful for Licensee to satisfy any reporting obligations with Regulatory Authorities in the Territory or to obtain or maintain Regulatory Approval for the Licensed Products in the Territory; *provided that* unless such Additional Development is conducted pursuant to Section 4.3.1(a) (JSC Approval; Agreement) or Licensee [***] in accordance with Section 4.3.3 (Reimbursement for Additional Development) to any Additional Development conducted by Akebia pursuant to Section 4.3.1(b) (JSC [***]; Failure to Agree) or Section 4.3.1(c)(ii) (No JSC [***]; Akebia Proposal), Licensee may use such information, data, and reports solely for the foregoing purposes and Licensee will not use such information, data, or reports to [***].

(ii) Jointly Agreed; [***]. In addition, if Akebia conducts Additional Development as Other Global Development pursuant to Section 4.3.1(a) (JSC [***]; Agreement) or if Licensee [***] in accordance with Section 4.3.3 (Reimbursement for Additional Development) to any Additional Development conducted by Akebia pursuant to Section 4.3.1(b) (JSC [***]; Failure to Agree) or Section 4.3.1(c)(ii) (No JSC [***]; Akebia Proposal), then Akebia will provide to Licensee any research data and reports and Study Data and reports that are necessary or reasonably useful for Licensee to [***] in accordance with this Agreement, and notwithstanding the restriction in Section 4.3.2(b)(i) (All Additional Development), Licensee may use such information, data, and reports to [***] in accordance with this Agreement.

4.3.3 **Reimbursement for Additional Development**. If (a) the JSC [***] any Additional Development as Other Global Development and the Proposing Party elects to proceed with such Additional Development as permitted under Section 4.3.1(b) (JSC [***]; Failure to Agree) without the non-Proposing Party's agreement to participate in such Additional Development at such time, or (b) Akebia elects to proceed with any Additional Development, notwithstanding the failure of Licensee's representatives on the JSC to [***] such Additional Development, as permitted under Section 4.3.1(c)(ii) (No JSC [***]; Akebia Proposal), then, in each case ((a) and (b)), at any time, the non-Proposing Party may request, in its discretion and upon written notice to the Proposing

Party, to [***] with respect to such Additional Development and [***] to compensate the Proposing Party for conducting such Additional Development at risk and for the time value of money at such time. Such [***] will become effective upon the Parties' agreement to such [***] amount.

4.3.4 **Rights to IP and Data**. Except as set forth under Section 4.3.2(a)(i) (By Licensee; All Additional Development) and Section 4.3.2(b)(i) (By Akebia; All Additional Development), the non-Proposing Party will not have any rights with respect to any information, data, or intellectual property rights generated from any Additional Development conducted pursuant to Section 4.3.1(b) (JSC [***]; Failure to Agree) or Section 4.3.1(c)(ii) (No JSC [***]; Akebia Proposal), including pursuant to the licenses granted in Article II (Licenses) or the [***] granted in Section 5.5 (Rights of Reference; Further Assurances), unless the non-Proposing Party [***] to such Additional Development in accordance with Section 4.3.3 (Reimbursement for Additional Development). If the non-Proposing Party [***] to any Additional Development conducted pursuant to Section 4.3.1(b) (JSC [***]; Failure to Agree) or Section 4.3.1(c)(ii) (No JSC [***]; Akebia Proposal), then following the non-Proposing Party's payment of such [***], the Party conducting such Additional Development will provide any information, data, or intellectual property generated from such Additional Development to the other Party in accordance with Section 4.3.2(a)(ii) (Jointly Agreed; [***]) or Section 4.3.2(b)(ii) (Jointly Agreed; [***]), as applicable, and such information, data, and intellectual property will be included in the licenses granted to the non-Proposing Party under Article II (Licenses) and the [***].

4.4 Performance of [***]. [***] will (a) [***] related to the Licensed Compound and the Licensed Products that are not part of the Current Global Development Program that are necessary to obtain or maintain Regulatory Approval for any Licensed Product in the Territory, and (b) use Commercially Reasonable Efforts to perform any other [***] related to the Licensed Compound and the Licensed Products that are not part of the Current Global Development Program. [***] will reimburse [***] for all costs and expenses incurred by or on behalf of [***] in connection with such studies within [***] of receiving [***] invoice therefor.

4.5 Standards of Conduct. Akebia and Licensee will perform, and each will ensure that their Affiliates and licensees and permitted sublicensees (as applicable), and subcontractors perform, all Development activities under the Current Global Development Plan, Other Global Development Plan, Territory-Specific Development Plan, or any [***] Plan, as the case may be, in a good scientific manner, in accordance with GLP, GMP, and GCP, as applicable, and in compliance with Applicable Law.

4.6 Development Efforts. Akebia and Licensee, each directly or through their Affiliates, licensees (with respect to Akebia), permitted sublicensees (with respect to Licensee), or subcontractors, will use Commercially Reasonable Efforts to Develop, or support the Development of, Licensed Products in the Territory.

4.7 Development Records. Each Party and its Affiliates will maintain written or electronic records, in sufficient detail, in a good scientific manner (in accordance with GLP, GCP, and GMP, as applicable), and appropriate for regulatory and patent purposes, and that are complete and accurate in all material respects and reflect all Development work performed and results achieved, in each case, by or on behalf of such Party and its Affiliates, licensees, or permitted sublicensees (as applicable) under the Current Global Development Plan and any Other Global Development Plan, [***] Plan, or Territory-Specific Development Plan.

Article V
REGULATORY AFFAIRS

5.1 Regulatory Submissions.

5.1.1 **Submissions in the E.U.** Subject to Section 5.2.2 (Responsibility), until receipt of Regulatory Approval from the EMA for a Licensed Product in each Initial Indication in the Current Formulation, [***] will be responsible in collaboration with a representative from Licensee's regulatory team for (a) preparing, filing, and submitting, directly or through its Affiliates, all Regulatory Submissions in the E.U. relating to the Current Global Development Program and any [***], and each material amendment or update thereto; *provided that* [***] for a Licensed Product in each Initial Indication for the E.U. (and each material amendment or update thereto) in the name of [***], and for each such MAA, [***], and (b) preparing briefing packages [***] relating to Regulatory Submissions in the E.U. for such Licensed Product in each Initial Indication (*other than* the briefing package for any [***]). Following receipt of Regulatory Approval from the EMA for the Licensed Product in each Initial Indication, Licensee will be responsible for preparing, filing, and submitting, directly or through its Affiliates and permitted sublicensees, all Regulatory Submissions in the E.U. relating to the Current Global Development Program.

5.1.2 **Submissions Outside of the E.U.** From and after the Effective Date, [***] will be responsible for (a) preparing, filing, and submitting, directly or through its Affiliates and permitted sublicensees, all Regulatory Submissions in all countries and jurisdictions in the Territory outside of the E.U., and each material amendment or update thereto, [***]; *provided that*, upon [***] request, a representative from [***] regulatory team will provide reasonable assistance to [***] in connection with [***] preparation of each IND and MAA for a Licensed Product in countries and jurisdictions in the Territory outside of the E.U. (including each material amendment or update thereto), and (b) briefing packages for meetings with Regulatory Authorities relating to Regulatory Submissions in each such country and jurisdiction in the Territory for such Licensed Product in each Initial Indication.

5.2 Collaboration With Respect to Regulatory Interactions.

5.2.1 **Correspondence**. The Parties' regulatory teams will collaborate with respect to substantive correspondence in support of Jointly-Agreed Regulatory Submissions and other Regulatory Submissions in the E.U. on which the Parties have collaborated pursuant to Section 5.1 (Regulatory Submissions). In addition, the Regulatory Responsible Party will provide the other Party with (a) copies (without translation) of any material written correspondence submitted to or received from (i) the EMA and (ii) Regulatory Authorities in the Major Countries and, (iii) upon [***] request, Regulatory Authorities in other countries in the Territory, and (b) summaries of any material oral communications with (i) the EMA and (ii) Regulatory Authorities in the Major Countries and, (iii) upon [***] request, Regulatory Authorities in other countries in the Territory, in each case ((a) and (b)), relating to Regulatory Submissions or Development of the Licensed Compound or any Licensed Product in such country, reasonably promptly after receipt or delivery by such Regulatory Responsible Party of such correspondence or communication, as the case may be (but in any event, with respect to correspondence or communications with the EMA, no later than [***] after receipt or delivery).

5.2.2 **Responsibility**. Notwithstanding Section 5.1 (Regulatory Submissions) or Section 5.2.1 (Correspondence), (a) the Regulatory Responsible Party will be responsible for, and will have final decision-making authority on the content of, all Regulatory Submissions, communications, and other dealings with the Regulatory Authorities in the applicable countries in the Territory relating to Development of the Licensed Products; *provided that* the Parties will agree, and [***], on the content of all Jointly-Agreed Regulatory Submissions, and (b) the Regulatory Responsible Party will not be required to delay any submission, correspondence, or communication with any Regulatory Authorities in the Territory in a manner that affects such Regulatory Responsible Party's ability to comply with any Regulatory Authority requirement or deadline or Applicable Law in the Territory or that would delay receipt of Regulatory Approval. At a mutually convenient time after the Effective Date as agreed to by the Parties, the Parties' regulatory teams will meet and agree on the strategy and procedures for authoring, publishing, reviewing, approving, and submitting Jointly-Agreed Regulatory Submissions.

5.3 Regulatory Meetings.

5.3.1 **[***]**. Prior to [***], either Party may request that the JDC and JSC hold a joint meeting to [***] whether or not to [***] (the "[***]"). Such requested joint meeting of the JDC and JSC will be held [***] after such Party's request and each Party's Regulatory Executive will be present at such meeting. If the Parties determine (or [***]) to hold a [***], then, subject to Section 5.7 (Decision-Making and Escalation For Certain Regulatory Matters), the Parties' regulatory teams will collaborate [***].

5.3.2 **Other Regulatory Meetings**. The Regulatory Responsible Party will [***] with (a) [***] and (b) [***], in each case ((a) and (b)), to the extent [***]. Without limiting the foregoing, representatives of each Party will [***].

5.4 Additional Development. The Party that is the Regulatory Responsible Party will have those responsibilities allocated to such Party under this Article V (Regulatory Affairs) with respect to any Additional Development conducted by or on behalf of either Party.

5.5 Rights of Reference; Further Assurances.

5.5.1 **Rights Granted to Licensee**. Subject to Section 4.3.2 (Additional Development Reports; Information) and Section 4.3.4 (Rights to IP and Data), Akebia will provide access to a complete electronic copy of all relevant Regulatory Submissions Controlled by Akebia that are necessary or reasonably useful to Licensee in support of Licensee's preparation and filing of any Regulatory Submissions with respect to any Licensed Product in the Territory in accordance with this Agreement. Subject to Section 4.3.2 (Additional Development Reports; Information) and Section 4.3.4 (Rights to IP and Data), Akebia will make available to Licensee copies of material documentation related to the Licensed Compound or the Licensed Products, including all Study Data from any [***] and any other Study Data if such other Study Data is necessary or reasonably useful to conduct clinical studies or obtain or maintain Regulatory Approvals for any Licensed Product in the Territory, in each case, in accordance with this Agreement. Subject to Section 4.3.2 (Additional Development Reports; Information) and Section 4.3.4 (Rights to IP and Data), Licensee and its Affiliates and permitted sublicensees will be entitled [***] to access, use, and reference the Regulatory Submissions and Study Data Controlled by Akebia for the Development and Commercialization of the Licensed Compound and the Licensed Products in the Territory. In furtherance of the foregoing, and subject to the

rules of the relevant Regulatory Authority and the terms and conditions of this Agreement, Akebia hereby grants to Licensee a right of reference to any Regulatory Approval Controlled by Akebia during the Term relating to the Licensed Compound or any Licensed Product (including the right to rely upon, access, inspect, copy, and otherwise use all information and data included in or used to support any such Regulatory Approval), solely for Licensee's or its Affiliates' or its permitted sublicensees' use in the [***] of the Licensed Products in the Territory during the Term in accordance with this Agreement. All Regulatory Submissions and Study Data will be considered Confidential Information of Akebia pursuant to Article XIII (Confidentiality).

5.5.2 **Rights Granted to Akebia**. Subject to Section 4.3.2 (Additional Development Reports; Information) and Section 4.3.4 (Rights to IP and Data), in support of Akebia's Development and Commercialization of the Licensed Compound and the Licensed Products outside of the Territory, Licensee will provide access to a complete electronic copy of all relevant Regulatory Submissions that are necessary or reasonably useful to Akebia in preparing its own IND, MAA, or other Regulatory Submissions for a Licensed Product for use outside of the Territory. Subject to Section 4.3.2 (Additional Development Reports; Information) and Section 4.3.4 (Rights to IP and Data), Licensee will make available to Akebia copies of material documentation related to the Licensed Compound and each Licensed Product, including all Study Data from any [***] and any other Study Data if such Study Data is necessary or reasonably useful to conduct clinical studies or obtain or maintain Regulatory Approvals of the Licensed Compound or any Licensed Product outside of the Territory. Subject to Section 4.3.2 (Additional Development Reports; Information) and Section 4.3.4 (Rights to IP and Data), Akebia and its Affiliates, licensees, and sublicensees will be entitled [***] to access, use, and reference the Regulatory Submissions and Study Data Controlled by Licensee for the Development, manufacture, and Commercialization of the Licensed Compound and each Licensed Product outside of the Territory. In furtherance of the foregoing and subject to the rules of the relevant Regulatory Authority and the terms and conditions of this Agreement, Licensee hereby grants to Akebia a right of reference to any Regulatory Approval Controlled by Licensee relating to the Licensed Compound or any Licensed Product (including the right to rely upon, access, inspect, copy, and otherwise use all information and data included in or used to support any such Regulatory Approval), solely for Akebia's or its Affiliates', licensees', or sublicensees' use in the [***] of the Licensed Products outside the Territory.

5.5.3 **Further Assurances**. The Party granting rights to the other Party under Section 5.5.1 (Rights Granted to Licensee) and Section 5.5.2 (Rights Granted to Akebia) will take such actions as may be reasonably requested by the other Party to give effect to the intent of such Sections and to give the other Party the benefit of the granting Party's Regulatory Approvals in the other Party's territory as provided in this Section 5.5 (Rights of Reference; Further Assurances). Such actions may include providing [***], and that the Regulatory Authority may access, in support of the other Party's application for Regulatory Approval in its territory or providing any underlying raw data or information submitted by such Party to the Regulatory Authority with respect to any Regulatory Submissions, Regulatory Approval, or other Regulatory Submissions Controlled by such Party or its Affiliates that relates to any Licensed Product.

5.6 **Cooperation**. The Parties will cooperate with each other to achieve the regulatory objectives contemplated herein in a timely, accurate, and responsive manner. The non-Regulatory Responsible Party will assist the Regulatory Responsible Party, as is reasonably necessary, in

order for such Regulatory Responsible Party to obtain and maintain each applicable MAA for each Licensed Product in the Territory, including in connection with the preparation, filing, and submission of all Regulatory Submissions by such Regulatory Responsible Party.

5.7 **Decision-Making and Escalation For Certain Regulatory Matters**. Any disagreement between the Parties' regulatory teams with respect to (a) the contents of the [***] described in Section 5.3.1 ([***]), or (b) the contents of any [***], in each case ((a) and (b)), that cannot be resolved after good faith efforts will, at the election of either Party, be submitted for resolution to [***] (each, a "**Regulatory Executive**"). If, after good faith efforts, the [***] are unable to resolve any such disagreement set forth in clauses (a) or (b) within a period of [***], then, at the election of either Party, a Party may refer such matter to the Parties' respective Executive Officers for resolution in accordance with Section 16.1 (Executive Officers; Disputes). For clarity, neither Party will have [***] on the [***] or on the contents of [***] in the event that the Parties' Executive Officers do not agree.

Article VI
MEDICAL AFFAIRS

6.1 **Medical Affairs Plans**. Akebia will prepare a reasonably detailed, [***] plan for global Medical Affairs (the "**Global Medical Affairs Plan**"), and Licensee will prepare a reasonably detailed, [***] plan for Medical Affairs in the Territory (the "**Local Medical Affairs Plan**"), in each case, no later than [***] following the Effective Date. The strategic objectives in the Local Medical Affairs Plan will be consistent with the strategic objectives in the Global Medical Affairs Plan, unless otherwise agreed by the Parties. In order to ensure consistency between the Global Medical Affairs Plan and the Local Medical Affairs Plan and coordination and alignment between the Parties with respect to the Medical Affairs to be conducted by Akebia in the Territory pursuant to the Global Medical Affairs Plan and by Licensee in the Territory pursuant to the Local Medical Affairs Plan (including with respect to each Party's communications with key opinion leaders in the Territory), the Global Medical Affairs Plan and the Local Medical Affairs Plan, and any amendments or updates thereto, will be [***] simultaneously by the JDC as provided in Section 3.2.3(l) (Specific Responsibilities of the JDC), with the first such [***] occurring no later than [***] following the Effective Date. Any subsequent [***], to the extent required, will occur [***] thereafter at an appropriate time as agreed by the JDC, or more frequently as may be required during the Term.

6.2 **Medical Affairs Activities**. Licensee will be responsible for Medical Affairs in the Territory, and will conduct such activities in accordance with the Local Medical Affairs Plan. In addition, each Party will conduct all Medical Affairs in the Territory in a professional and ethical business manner and in compliance with Applicable Law and applicable Professional Requirements. Each Party will provide the other Party with reasonable cooperation, support, and assistance with respect to preparing such Party's Medical Affairs plan, and conducting activities under each such plan, in order to coordinate Medical Affairs inside and outside of the Territory. In addition, each Party will provide to the JDC an update (by means of a slide presentation or otherwise) summarizing its Medical Affairs and progress under the Global Medical Affairs Plan (with respect to Akebia) and the Local Medical Affairs Plan (with respect to Licensee) during the period since the last JDC meeting as provided in Section 3.2.3(m) (Specific Responsibilities of the JDC).

Article VII
COMMERCIALIZATION

7.1 **General**. Subject to the Launch Sequence and the Commercialization Plan as [***] by the JCC, or [***] by the JSC (if applicable), Licensee and its Affiliates and permitted sublicensees will be solely responsible for the Commercialization of the Licensed Products in the Territory. Licensee and its Affiliates and permitted sublicensees will be responsible for all costs associated with the Commercialization of the Licensed Products in the Territory, and will have sole responsibility and authority for [***] for the Licensed Products, detailing, marketing and promotion activities, booking sales, distributing the Licensed Product, processing, invoicing, and collecting inventory and receivables, and providing customer support.

7.2 **Launch Sequence and Commercialization Plan**.

7.2.1 **Launch Sequence**. No later than [***] following the Effective Date, Licensee will prepare a list of those countries in the Territory in which Licensee intends to commence Commercialization of each Licensed Product within the first [***] after receipt of Regulatory Approval for such Licensed Product from the FDA and the EMA and timelines reflecting potential date ranges for First Commercial Sale following receipt of Regulatory Approval and Reimbursement Approval (if applicable) in such countries, (the "**Launch Sequence**" and the countries included in the Launch Sequence, the "**Launch Countries**"). Licensee will amend or update the Launch Sequence [***] thereafter, including updating such sequence with additional countries in the Territory in which Licensee plans to commence Commercialization of a Licensed Product. The Launch Sequence and all amendments and updates thereto will be [***] by the JCC pursuant to Section 3.4.3(a) (Specific Responsibilities of the JCC), and subsequently [***] by the JSC pursuant to Section 3.1.5(n) (Specific Responsibilities of the JSC); *provided that* if the JSC is unable to [***] the Launch Sequence or any amendment or update thereto, then such matter will not be referred for resolution by the Executive Officers, and instead Licensee's representatives on the JSC will [***] the Launch Sequence (including the Launch Countries).

7.2.2 **Commercialization Plan**. At least [***] prior to the anticipated First Commercial Sale of a Licensed Product in each Launch Country in the Territory, but not earlier than [***] after the Effective Date, Licensee will prepare and submit to the JCC for its [***] pursuant to Section 3.4.3(a) (Specific Responsibilities of the JCC), and, if applicable, to the JSC for its [***] pursuant to Section 3.1.5(o) (Specific Responsibilities of the JSC) an initial Commercialization Plan. Such initial Commercialization Plan will be a [***] for Commercialization in the [***]. At least [***] prior to the anticipated First Commercial Sale of a Licensed Product in each Launch Country, Licensee will prepare and submit to the JCC for its [***] pursuant to Section 3.4.3(a) (Specific Responsibilities of the JCC), and, if applicable, to the JSC for its [***] pursuant to Section 3.1.5(o) (Specific Responsibilities of the JSC) an update to the Commercialization Plan for the launch of each Licensed Product in the [***] that will include an update to the initial [***], the then-current Launch Sequence [***], and general descriptions with respect to [***] for each Licensed Product, [***] of each Licensed Product by Licensee's [***], [***], and [***] for each Licensed Product. On [***] basis thereafter, Licensee will prepare and submit to the JCC for its [***] pursuant to Section 3.4.3(a) (Specific Responsibilities of the JCC), and, if applicable, to the JSC for its [***] pursuant to Section 3.1.5(o) (Specific Responsibilities of the JSC) an update to the Commercialization Plan, which update will include the then-current [***]. If the initial Commercialization Plan or any amendment or

update thereto reflects a decision by Licensee not to launch or Commercialize a Licensed Product in a Major Country, then such decision (and the portion of the Commercialization Plan or amendment or update relating thereto) must be [***] by the JSC pursuant to Section 3.1.5(o) (Specific Responsibilities of the JSC). In addition, upon the request of either Party's JCC representatives, such Party may refer any matter related to the Commercialization Plan (or any amendment or update thereto) to the JSC for [***] pursuant to Section 3.1.5(p) (Specific Responsibilities of the JSC).

7.2.3 **Consistency with Global Brand Plan**. Following Licensee's receipt from Akebia of the Global Brand Plan (and any update thereto) pursuant to Section 7.8 (Global Brand Plan and Promotional Materials), Licensee will ensure that the Commercialization Plan is at all times consistent with the then-current version of such Global Brand Plan; *provided, however*, that if the JCC [***] a Territory-specific [***] for a Licensed Product, including any Licensed Product [***] for the Territory that is inconsistent with the Global Brand Plan pursuant to Section 3.4.3(c) (Specific Responsibilities of the JCC), and the JSC [***] such Territory-specific [***] pursuant to Section 3.1.5(q) (Specific Responsibilities of the JSC), then Licensee will implement such Territory-specific [***] in lieu of the applicable [***] under the Global Brand Plan; *provided further that* if the JSC [***] on the Territory-specific [***], then such matter will not be referred for resolution by the Executive Officers, and instead Licensee's representatives on the JSC will [***] the Territory-specific [***].

7.3 **Commercialization Reports**. At each meeting of the JCC, Licensee will provide to the JCC an update (by means of a slide presentation or otherwise) summarizing its Commercialization activities performed in each Launch Country during the period since the last JCC meeting, and, following First Commercial Sale of a Licensed Product in a country in the Territory, sales performance reports for each such country, as set forth in Section 3.4.3(d) (Specific Responsibilities of the JCC).

7.4 **Reimbursement and Information Sharing**. Licensee will be responsible for, and will have sole authority and [***] with respect to, any [***] related to obtaining and maintaining Reimbursement Approval in the Territory (where required), and all [***] of Licensed Products in the Territory; *provided that* (a) upon Licensee's reasonable request, Akebia will [***] and Licensee will reimburse Akebia's out-of-pocket costs incurred in connection with [***], and (b) [***], upon Akebia's reasonable request, Licensee will use reasonable efforts to [***] in such country, and if Akebia is [***] reasonably promptly after such meeting. Upon either Party's reasonable request, but subject to local anti-competition laws and any obligations of confidentiality between a Party and any Third Party, the Parties will share [***] (or their equivalent), as well as other [***] as may be agreed by the Parties.

7.5 **Commercialization Efforts**. Licensee, directly or through its Affiliates or permitted sublicensees, will use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Territory and to achieve First Commercial Sale as promptly as practicable after receipt of Regulatory Approval and Reimbursement Approval (if applicable) in each country in the Territory, and, after achieving First Commercial Sale in such country, Commercialize such Licensed Product in such country in the Territory in accordance with the Commercialization Plan. The Parties acknowledge that it may be consistent with the expenditure of Commercially Reasonable Efforts [***].

7.6 **Standards of Conduct; Compliance**. Licensee will perform, or will ensure that each of its Affiliates, permitted sublicensees (as applicable), and subcontractors perform, all

Commercialization activities in a professional and ethical business manner and in compliance with Applicable Law, applicable Professional Requirements, the Approved Labeling, and the Commercialization Plan.

7.7 **Commercializing Affiliates**. If, after the Effective Date, any Licensee Affiliate commences Commercial Operations in a country that is not included on Schedule 1.183, then Licensee will promptly provide written notice thereof to Akebia and will update Schedule 1.183 to include such country.

7.8 **Global Brand Plan and Promotional Materials**. No later than [***] prior to the anticipated First Commercial Sale in the Territory, Akebia will submit to the JCC and to the JSC, for [***] pursuant to Section 3.4.3(e) (Specific Responsibilities of the JCC) and Section 3.1.5(r) (Specific Responsibilities of the JSC), a global brand plan, which plan will include the [***] for the Licensed Products (the "**Global Brand Plan**"). Akebia may amend or update the Global Brand Plan from time-to-time and will submit material amendments and updates to the JCC and to the JSC, for [***] pursuant to Section 3.4.3(e) (Specific Responsibilities of the JCC) and Section 3.1.5(r) (Specific Responsibilities of the JSC). All promotional materials for the Licensed Products used by Licensee or its Affiliates in the Territory must be consistent with the Global Brand Plan (or, if applicable, any Territory-specific [***] determined in accordance with Section 7.2.3 (Consistency with Global Brand Plan)). If Licensee seeks to use any promotional materials for any Licensed Product (whether such materials are considered "core" or country-specific) that have content or messaging that is inconsistent with the Global Brand Plan or any Territory-specific [***] determined in accordance with Section 7.2.3 (Consistency with Global Brand Plan), then, in each case, Licensee will [***]. Upon Akebia's reasonable request, Licensee will provide samples of Licensee's promotional materials for the Territory, without translation, [***] determined in accordance with Section 7.2.3 (Consistency with Global Brand Plan), and other content or format approved by Akebia. Upon Licensee's reasonable request, Akebia will provide to Licensee samples of Akebia's core promotional materials for the Licensed Products, without translation.

7.9 **Trademarks and International Nonproprietary Name**.

7.9.1 **Brand Name in the Territory**. Licensee will Commercialize each Licensed Product under the Global Marks using the global brand name for such Licensed Product selected by Akebia in the Global Brand Plan (which name will be the global brand name agreed to by the Parties pursuant to the U.S. Collaboration and License Agreement for the U.S.) and under the trade dress set forth in the Global Brand Plan, unless Licensee reasonably believes that the use or registration of any Global Mark in a particular country in the Territory (a) [***] or would violate the Applicable Laws of such country, (b) is reasonably likely to be [***], or (c) is in conflict with any [***] in such country. If Licensee is unable to use any Global Mark for any of the foregoing reasons, then Licensee will use one of two alternative Marks (which Marks will include trademarks and trade dress) selected by [***] in the Global Brand Plan, or if such alternative Marks are unacceptable for the reasons set forth in the preceding sentence, then Licensee will use other Marks (including trademarks and trade dress) to be agreed upon by Licensee and Akebia (the "**Local Marks**"). [***], including all trademark registrations and applications therefor and all goodwill associated therewith. Once the brand name for a Licensed Product has been selected for a country in the Territory pursuant to this Section 7.9.1 (Brand Name in the Territory), the Regulatory Responsible Party in such country will be responsible for obtaining Regulatory Approval of such brand name for use in the Commercialization of such Licensed Product in such country.

7.9.2 **Required Use and Compliance**.

(a) Housemarks. Licensee will Commercialize the Licensed Products only under the applicable Product Marks and each Party's Housemarks as set forth herein, and no other Marks.

(b) Ownership; Use. Each Party acknowledges that Akebia has sole and exclusive ownership of all rights, title, and interests in and to the Product Marks and Akebia Housemarks. Licensee agrees that it and its Affiliates will: (i) ensure that each use of the Product Marks and the Akebia Housemarks by Licensee is accompanied by an acknowledgement that such Product Marks and Akebia Housemarks are owned by Akebia; (ii) not use such Product Marks or Akebia Housemarks in a way that might materially prejudice their distinctiveness or validity or the goodwill of Akebia therein and includes the trademark registration symbol ® or ™ as appropriate; (iii) not use any trademarks or trade names so resembling any of such Product Marks or the Akebia Housemarks as to be likely to cause confusion or deception; and (iv) place and display the Product Marks and Akebia Housemarks on and in connection with the Licensed Products only in such form and manner as specified in the guidelines adopted from time-to-time by Akebia and provided to Licensee; *provided*, *however*, that Licensee will not be required to place or display any Akebia Housemark on promotional materials or other Product Materials used to Commercialize the Licensed Products in the Territory, except as provided in Section 8.6 (Approved Labeling).

7.9.3 **Trademark Responsibility**. [***] will be responsible for (a) registering, prosecuting, protecting, and enforcing the Product Marks in the Territory, (b) preparing any guidelines applicable to the use of Product Marks, (c) registering, in [***] name, at least [***] primary Product Mark and at least [***] alternative Product Marks, (d) if necessary pursuant to Section 7.9.1 (Brand Name in the Territory), registering, prosecuting, and enforcing any Local Marks in the Territory, (e) preparing any guidelines applicable to the use of any Local Mark, and (f) investigating and defending any infringement or threatened infringement relating to any of the foregoing, in each case, including all costs associated therewith. [***] will cooperate and assist [***] with any of the foregoing activities with respect to all Product Marks, including, if requested by [***], providing any specifications, affidavits, declarations, or other documents necessary for [***] to submit to appropriate Regulatory Authorities in order to register and prosecute Product Marks. [***] will reimburse [***] for the costs of the activities set forth in clauses (a), (c), (d), (e), and (f) to the extent related to a Product Mark in the Territory. For clarity, [***] will not be responsible for any costs associated with designing or determining any Product Mark. [***] will be responsible for securing and protecting any domain names associated with the Product Marks in [***] name, at [***] cost and expense. [***] will not obtain or hold any such domain name in its own name. Neither Party will register in its own name any trademark, corporate name, domain name, social media account, or other source identifier containing any trademark owned by the other Party or any word or mark that is confusingly similar to any such trademark. [***] will promptly notify [***] of any infringement or threatened infringement of any of the Product Marks in the Territory of which it becomes aware.

7.9.4 **Respect of Marks**. Neither Party will, and will ensure that its Affiliates do not (a) attack, challenge, oppose, petition to cancel, or initiate legal action or proceedings in connection with any Product Mark or any Housemark of the other Party during the Term, or

thereafter challenge the registration of any Product Mark or any Housemark of the other Party in any country; (b) file, register, or maintain any registrations for any trademarks or trade names that are confusingly similar to any Product Mark (*other than* for a Licensed Product) in any country without the express prior written consent of Akebia; or (c) authorize or assist any Third Party to do any of the foregoing. Licensee will not have, assert, or acquire any rights, title, or interests in or to any Product Marks or Akebia Housemarks or the goodwill pertaining thereto, except in each case for the limited licenses explicitly provided in this Agreement. Akebia will not have, assert, or acquire any rights, title, or interest in or to any Licensee Housemarks or the goodwill pertaining thereto. Licensee will maintain the quality standards of Akebia with respect to use of Product Marks and Akebia Housemarks pursuant to the licenses granted under Section 2.1 (Grant of Licenses to Licensee) and Section 7.9.5 (Trademark License), as applicable, and with respect to the goods it sells and the services it provides in connection with the Product Marks and the Akebia Housemarks hereunder. Each Party recognizes and agrees that no ownership rights are vested or created by the limited licenses granted pursuant to Section 2.1 (Grant of Licenses to Licensee), Section 2.3 (Grant of Licenses to Akebia), or Section 7.9.5 (Trademark License), as applicable, and that all goodwill developed by virtue of the use by Licensee of the Product Marks and the Akebia Housemarks inures to the benefit of Akebia.

7.9.5 **Trademark License**. Subject to the terms and conditions of this Agreement, Akebia hereby grants and agrees to grant to Licensee an exclusive, royalty-free license, with the right to sublicense to sublicensees in accordance with this Agreement, to use the Product Marks and the Akebia Housemarks solely in connection with the Commercialization of the Licensed Products in the Territory pursuant to this Agreement, including to effect the co-labeling provided for under Section 8.6 (Approved Labeling) and as part of any domain names associated with the Product Marks.

7.9.6 **International Non-Proprietary Name**. Akebia will be responsible for the selection and filing of the international nonproprietary name for the Licensed Compound and each Licensed Product with the World Health Organization and any Regulatory Authorities in the Territory, to which names Licensee will have the right to reference.

7.10 **Negotiations with [***]**. The Parties intend to collaborate and strategize together with respect to any [***] between a Party and any [***] relating to the Territory (including, if applicable, any discussions relating to both inside the Territory and outside of the Territory), and each Party will involve the other Party in [***] upon such other Party's request.

Article VIII
MANUFACTURING AND SUPPLY

8.1 **Supply and Purchase Obligations**. Subject to the terms and conditions of this Agreement, Akebia will use Commercially Reasonable Efforts to manufacture or have manufactured and supply to Licensee the Licensed Products (a) [***], (b) [***], and (c) [***], in each case ((a) through (c)), in the Territory pursuant to the Manufacturing Plan. If Licensee is to perform any non-clinical or clinical studies in the Territory under this Agreement, then Licensee will purchase from Akebia all of Licensee's requirements of such Licensed Products for such studies, which Licensed Product Akebia will supply [***], as applicable. Subject to the terms and conditions of this Agreement, Licensee will purchase from Akebia all of Licensee's requirements of each Licensed Product for commercial use in the Territory. Except with respect to any U.S. Finished Form that Akebia supplies to Licensee (where required by Applicable Law in a country in the

Territory), Licensee will be responsible, at its sole cost and expense, for all [***], and other related activities required to convert the Licensed Product supplied by Akebia into Finished Form (such activities, collectively, "**Packaging**"), including all [***] of the Licensed Products for use in the Territory and for [***] associated therewith. Upon Licensee's request, Akebia will provide [***] technology transfer to Licensee's representatives of information necessary or reasonably useful to support Licensee's [***] of the Licensed Products in furtherance of Licensee's [***] activities, including providing reasonable assistance to Licensee in connection therewith upon request; *provided that* Licensee will provide to Akebia any information, data, and reports relating to Licensee's [***] of the Licensed Products. Licensee will reimburse Akebia for all out-of-pocket costs incurred by or on behalf of Akebia in connection with such technology transfer within [***] of receiving Akebia's invoice therefor.

8.2 **Manufacturing Plan; Product Supply**. Akebia will prepare the Manufacturing Plan, and will submit such Manufacturing Plan (and any amendments or updates thereto) to the JMC for its [***] pursuant to Section 3.3.3(a) (Specific Responsibilities of the JMC), and subsequently to the JSC for its [***] pursuant to Section 3.1.5(s) (Specific Responsibilities of the JSC); *provided that* only the initial Manufacturing Plan and material amendments or updates will be subject to JSC [***]. The Parties will discuss the manufacture and supply of the Licensed Compound and the Licensed Products for Development and Commercialization purposes through the JMC pursuant to the reports provided by Akebia as set forth under Section 8.7 (Manufacturing Reports). In addition, prior to Akebia's engagement of any contract manufacturing organization for manufacture and supply of the Licensed Products [***], Akebia will reasonably consult with Licensee regarding the [***] of such contract manufacturing organization through the JMC pursuant to Section 3.3.3(b) (Specific Responsibilities of the JMC) and Akebia will include all such contract manufacturing organizations so engaged in the Manufacturing Plan.

8.3 **Supply Agreements**. If Licensee is to perform any clinical or non-clinical studies in the Territory in accordance with this Agreement, then the Parties will agree upon a supply agreement on reasonable and customary terms for the supply of the Licensed Compound or the Licensed Products by Akebia to Licensee in the Territory at its [***] (the "**Clinical Supply Agreement**"). Prior to First Commercial Sale of the Licensed Product, the Parties will agree upon a supply agreement on reasonable and customary terms for the commercial supply of such Licensed Product by Akebia to Licensee in the Territory at the Supply Price [***] (the "**Commercial Supply Agreement**"). The Commercial Supply Agreement will include provisions regarding long-range forecasting of Licensee's requirements for the Licensed Product, specifications, changes to manufacturing process or specifications, ordering, shipment and delivery, failure to supply (including appropriate remedies in the event of a failure to supply), audit and inspection, shortage allocation, acceptance and rejection, and warranties. The supply price for the Licensed Products [***] supplied by Akebia to Licensee or its manufacturer during the Term for commercial use in the Territory will be equal to [***] *plus* [***] (the "**Supply Price**").

8.4 **Quality Agreement**. Prior to delivery of any Licensed Product hereunder or under a Supply Agreement, the Parties will also enter into one or more quality technical agreements (each a "**Quality Agreement**") containing reasonable and customary terms and conditions regarding quality assurance and quality control and compliance with GMP and GCP (as applicable). Each Party agrees to provide information to the other Party regarding quality defects and quality complaints associated with the use of the Licensed Products in accordance with the timeframes and procedures for reporting and other terms and conditions set forth in the Quality Agreements. The Regulatory Responsible Party will be responsible for the management of all product quality complaints with respect to the Licensed Products in the Territory, and the Quality Agreement will define each Party's roles and responsibilities with respect to the same.

8.5 **Term of Supply Agreements and Quality Agreement**. Unless otherwise agreed by the Parties, the term of each Supply Agreement and the Quality Agreement will either (a) [***] upon termination of this Agreement (in the event of any termination of this Agreement pursuant to Section 15.2 (Termination for Breach), Section 15.3 (Termination by Licensee for Convenience), Section 15.4 (Termination by Akebia Upon Patent Challenge by Licensee), or Section 15.5 (Termination by Written Agreement)) or (b) expire [***] after the effective date of expiration of this Agreement (in the event of expiration of this Agreement pursuant to Section 15.1 (Term)).

8.6 **Approved Labeling**. The Parties agree that, to the extent permitted under Applicable Law within the Territory, the Approved Labeling will include the Akebia Housemarks and the Licensee Housemarks with equal prominence.

8.7 **Manufacturing Reports**. At each JMC meeting, Akebia will provide the JMC with an update (by means of a slide presentation or otherwise) summarizing Akebia's manufacturing activities under the Manufacturing Plan related to supply of the Licensed Products for Development purposes (if Akebia is supplying to Licensee any Licensed Product for clinical Development purposes) and Commercialization purposes as set forth in Section 3.3.3(c) (Specific Responsibilities of the JMC). Notwithstanding the foregoing, the Parties acknowledge and agree that any information and updates provided pursuant to this Section 8.7 (Manufacturing Reports) will be subject to the rules and regulations set forth by the relevant Regulatory Authorities.

Article IX
PAYMENTS

9.1 **Upfront Payment**. As partial consideration for the rights and licenses granted by Akebia to Licensee under this Agreement, no later than [***] after the Effective Date, Licensee will pay to Akebia a nonrefundable and noncreditable upfront payment of $73,000,000.

9.2 **Milestone Payments**. As additional consideration for the rights and licenses granted to Licensee under this Agreement, Licensee will pay to Akebia, in the manner set forth in Section 9.3.5 (Royalty Payments and Reports), the following nonrefundable and noncreditable milestone payments, as applicable, no later than [***] after the first occurrence of the indicated event for the Licensed Products:

9.2.1 **NDD-CKD Approval Milestones**. Upon Regulatory Approval by [***] of a Licensed Product in the Territory in the NDD-CKD Indication, Licensee will pay to Akebia [***] of the following payment amounts set forth in Table 9.2.1 below, depending upon which of the events #1-#4 in Table 9.2.1 occurs.

Table 9.2.1 – NDD-CKD Approval Milestones

Event	***Payment Amount (in U.S. Dollars)***
1. If such Licensed Product [***]:	$[***]
2. If such Licensed Product [***]:	$[***]
3. If such Licensed Product [***]:	$[***]
4. If such Licensed Product [***]:	$[***]

9.2.2 **DD-CKD Approval Milestones**. Upon Regulatory Approval by [***] of a Licensed Product in the Territory in the DD-CKD Indication, Licensee will pay to Akebia [***] of the following payment amounts set forth in Table 9.2.2 below, depending upon which of the events #1-#4 in Table 9.2.2 occurs.

Table 9.2.2 – DD-CKD Approval Milestones	
Event	***Payment Amount (in U.S. Dollars)***
1. If such Licensed Product [***]:	$[***]
2. If such Licensed Product [***]:	$[***]
3. If such Licensed Product [***]:	$[***]
4. If such Licensed Product [***]:	$[***]

9.2.3 **Data Milestones**. If the following milestone events #1-#3 set forth in Table 9.2.3 below are achieved, then Licensee will pay the applicable corresponding milestone payment (in each case, either (a) or (b)) to Licensee upon the first Regulatory Approval of the Licensed Product in the Territory, in addition to any other approval milestones set forth under Section 9.2.1 (NDD-CKD Approval Milestones) or Section 9.2.2 (DD-CKD Approval Milestones):

Table 9.2.3 – Data Milestones		
Event	***Applicable Criteria***	***Payment Amount (in U.S. Dollars)***
1. [***]	(a) [***]	$[***]
	(b) [***]	$[***]
2. [***]	(a) [***]	$[***]
	(b) [***]	$[***]
3. [***]	(a) [***]	$[***]
	(b) [***]	$[***]

9.2.4 **Sales Milestones**. Upon the first occurrence of each event set forth in Table 9.2.4 below in the Territory during the Term, Licensee will pay to Akebia the corresponding sales milestone set forth in Table 9.2.4. Licensee will not [***]. If in a given calendar year during the Term more than one of the following thresholds for the sales milestones is exceeded with respect to aggregate Net Sales of Licensed Products during the Term, then Licensee will pay to Akebia [***] with respect to each such threshold that is exceeded for the first time in such calendar year.

Table 9.2.4 – Sales Milestones	
Event	***Payment Amount (in U.S. Dollars)***
Achievement of $[***] of aggregate annual Net Sales of Licensed Products in the Territory during a calendar year	$[***]
Achievement of $[***] of aggregate annual Net Sales of Licensed Products in the Territory during a calendar year	$[***]
Achievement of $[***] of aggregate annual Net Sales of Licensed Products in the Territory during a calendar year	$[***]
Achievement of $[***] of aggregate annual Net Sales of Licensed Products in the Territory during a calendar year	$[***]
Achievement of $[***] of aggregate annual Net Sales of Licensed Products in the Territory during a calendar year	$[***]
Achievement of $[***] of aggregate annual Net Sales of Licensed Products in the Territory during a calendar year	$[***]

9.3 Royalties.

9.3.1 **Royalty Amounts**. Licensee will pay Akebia nonrefundable and noncreditable royalties based on Net Sales of Licensed Products during the Royalty Term in the Territory at the applicable incremental royalty rates set forth (a) in Table 9.3.1(a) for Net Sales of Licensed Product in countries in Sub-Territory A, (b) in Table 9.3.1(b) for Net Sales of Licensed Product in countries in Sub-Territory B, and (c) in Table 9.3.1(c) for Net Sales of Licensed Product in countries in Sub-Territory C. Net Sales for [***] in each of Sub-Territory A and Sub-Territory B will, in each case, be [***] for purposes of calculating the applicable royalty tier for Net Sales in each such sub-territory. Net Sales for [***] in Sub-Territory C, however, will be [***], and the royalty tier payable on Net Sales in [***] in Sub-Territory C will be calculated based on Net Sales in [***].

Table 9.3.1(a) – Royalty Rates: Sub-Territory A	
Portion of Annual Net Sales (in U.S. Dollars in Sub-Territory A)	***Royalty Rate***
$[***] to ≤$[***]	[***]%
>$[***] to ≤$[***]	[***]%
>$[***] to ≤$[***]	[***]%
>$[***] to ≤$[***]	[***]%
>$[***] to ≤$[***]	[***]%
>$[***]	[***]%

Table 9.3.1(b) – Royalty Rates: Sub-Territory B	
Portion of Annual Net Sales (in U.S. Dollars in Sub-Territory B)	***Royalty Rate***
$[***] to ≤$[***]	[***]%
>$[***] to ≤$[***]	[***]%
>$[***] to ≤$[***]	[***]%
>$[***] to ≤$[***]	[***]%
>$[***] to ≤$[***]	[***]%
>$[***]	[***]%

Table 9.3.1(c) – Royalty Rates: Sub-Territory C	
Portion of Annual Net Sales (in U.S. Dollars in each country in Sub-Territory C)	***Royalty Rate***
$[***] to ≤$[***]	[***]%
>$[***] to ≤$[***]	[***]%
>$[***] to ≤$[***]	[***]%
>$[***] to ≤$[***]	[***]%
>$[***]	[***]%

For example, if there is $[***] in [***] annual Net Sales in Sub-Territory A in a given calendar year, after conversion to U.S. Dollars of the Net Sales in each country in the Territory, then Licensee would owe a royalty of ($[***] x [***]%) + ($[***] x [***]%) + ($[***] x [***]%) + ($[***] x [***]%) + ($[***] x [***]%) = $[***].

9.3.2 **Royalty Term**. Running royalties paid by Licensee under Section 9.3.1 (Royalty Amounts) will be paid on a country-by-country basis during the Royalty Term in such country. Upon expiration of the Royalty Term in [***] in Sub-Territory A or in Sub-Territory B, the Net Sales in [***] Net Sales for purposes of calculating the applicable royalty tier for Net Sales in such sub-territory.

9.3.3 **[***] Competition Reduction**.

(a) Sub-Territory A and Sub-Territory B. On a country-by-country and Licensed Product-by-Licensed Product basis in each of Sub-Territory A and Sub-Territory B, during the Royalty Term for such Licensed Product in such country following the first to occur of: (i) [***] for such Licensed Product in such country, if, upon [***] for such Licensed Product in such country, Applicable Law in such country requires a [***] that causes a [***] of such Licensed Product; (ii) [***] for such Licensed Product in such country; or (iii) the first date on which, [***] for such Licensed Product in such country, (A) Net Sales of such Licensed Product in such country in a calendar quarter are at least [***]% less than the Net Sales of such Licensed Product in such country during the same full [***] in the [***] immediately preceding the [***] during which the first commercial sale of such [***] for such Licensed Product in such country occurred (the "**Comparable** [***]", *e.g.*, if [***] occurred in the second [***] of [***], then the Comparable [***] would be the second [***] of [***]), or (B) the average net selling price of such Licensed Product in such country during a [***] is at least [***]% less than the average net selling price of such Licensed Product in such country during the applicable Comparable [***] (where average net selling price is determined by dividing the Net Sales of such Licensed Product in such country in such [***] or [***] Quarter, as applicable, by the number of units of such Licensed Product sold in such country in such [***] or Comparable [***], as applicable), the Net Sales of such Licensed Product in such country that will be included in the aggregate annual Net Sales for purposes of calculating the applicable royalty tier for Net Sales in such sub-territory pursuant to Section 9.3.1 (Royalty Amounts) and for purposes of the royalty payments required under Section 9.3.5 (Royalty Payments and Reports) will be reduced by [***]% for the remainder of the Royalty Term for such Licensed Product in such country.

(b) Sub-Territory C. On a country-by-country and Licensed Product-by-Licensed Product basis in Sub-Territory C, during the Royalty Term for such Licensed Product in such country following the first to occur of: (i) [***] for such Licensed Product in such country, if, [***] for such Licensed Product in such country, Applicable Law in such country requires a [***] that causes a [***] of such Licensed Product; (ii) [***] for such Licensed Product in such country; or (iii) the first date on which, [***] for such Licensed Product in such country, (A) Net Sales of such Licensed Product in such country in a [***] are at least [***]% less than the Net Sales of such Licensed Product in such country during the applicable [***], or (B) the average net selling price of such Licensed Product in such country during a [***] is at least [***]% less than the average net selling price of such Licensed Product in such country during the applicable [***] (where average net selling price is determined by dividing the Net Sales of such Licensed Product in such country in such [***] or [***], as applicable, by the number of units of such Licensed Product sold in such country in such [***] or [***], as applicable), royalty payments on Net Sales in such country (based on the royalty rate applicable as set forth in Table 9.3.1(c) before taking into account any reduction) will be reduced by [***]% for the remainder of the Royalty Term for such Licensed Product in such country.

9.3.4 **Maximum Supply Price Reduction**. If in any calendar year ("**Year A**") the [***] of Licensed Product [***], in each case, [***] set forth in [***] dated as of the Effective

Date by and between the Parties (the "**Maximum Supply Price**") for Year A, then Licensee may credit against the royalties due to Akebia pursuant to Section 9.3.1 (Royalty Amounts) for Year A an amount equal to [***] and the [***] *multiplied by* the [***] of Licensed Product [***] in Year A, in accordance with the steps set forth below in Section 9.3.4(a) through Section 9.3.4(d); *provided that* such credit against the royalties due to Akebia for Year A will be applied against any and all royalties due to Akebia in the next calendar year ("**Year B**") as set forth below in Section 9.3.4(d). Notwithstanding the foregoing, Licensee may not credit such amount to the extent that doing so would cause the effective royalties paid by Licensee to Akebia in Year A in any sub-territory to be less than [***]% of Net Sales in such sub-territory in Year A. If the [***], then the Maximum Supply Price will be increased or decreased (as applicable) on a *pro-rata* basis.

(a) Calculate the total royalties in U.S. Dollars due to Akebia pursuant to Section 9.3.1 (Royalty Amounts) in all sub-territories for Year A (the "**Royalty Amount**").

(b) Calculate the difference in U.S. Dollars between the [***] in Year A and the [***], *multiplied by* the [***] of Licensed Product [***] during Year A (the "**Excess COGS**").

(c) Calculate the portion of the Royalty Amount due in each of Sub-Territory A, Sub-Territory B, and Sub-Territory C, in each case that exceeds [***]% of Net Sales in each such sub-territory in Year A, and add each such amount that exceeds [***]% of Net Sales in each such sub-territory (such sum, the "**Royalty Amount Exceeding [***]%**").

(d) Licensee will receive a credit in an amount equal to the Excess COGS in Year A but not exceeding (*i.e.* capped at) the Royalty Amount Exceeding [***]% in Year A (the "**Credit Amount**"), which Credit Amount Licensee will apply against royalties payable to Akebia pursuant to Section 9.3.1 (Royalty Amounts) in Year B on [***] from the first dollar payable to Akebia as royalties in Year B as follows: [***] of Year B Licensee will credit [***]% of the Credit Amount for Year A against royalties due to Akebia in such [***] in Year B, and, to the extent that such [***]% of the Credit Amount exceeds the royalties due to Akebia in a particular [***] in Year B, then [***]; *provided that* Akebia will have no obligation to make any payment to Licensee for any portion of the Credit Amount that cannot be credited in full due to there being insufficient royalties to credit against in [***].

For example (and for illustrative purposes only), if in Year A the Credit Amount is $[***], then in each [***] in Year B Licensee may credit $[***] against the royalties due to Akebia for such [***]. If in the [***] of Year B, the royalties due to Akebia are only $[***], then Licensee may carry forward into the [***] of Year B the $[***] that Licensee was unable to credit against royalties due to Akebia in the [***], and Licensee may credit such amount against royalties due to Akebia in such [***]. Accordingly, in such [***] Licensee may credit a total of $[***] against royalties due to Akebia in such [***].

For further example (and for illustrative purposes only), if in a calendar year:

The Royalty Amount due to Akebia is $[***] on $[***] of Net Sales (royalties of $[***], based on $[***] in Net Sales in Sub-Territory A; royalties of $[***], based on $[***] in Net Sales in Sub-Territory B; and royalties of $[***], based on $[***] in Net Sales in Sub-Territory C); and

The Excess COGS is $[***]; and

The Royalty Amount Exceeding [***]*% is $*[***] ($[***] above [***]% in Sub-Territory A; $[***] above [***]% in Sub-Territory B; and $[***] above [***]% in Sub-Territory C);

then

Licensee may credit the Excess COGS against the Royalty Amount Exceeding [***]%, but as the Excess COGS ($[***]) is greater than the Royalty Amount Exceeding [***]% ($[***]), accordingly Licensee may only credit the portion of the Excess COGS up to the amount of the Royalty Amount Exceeding [***]% ($[***]) and therefore, Licensee may only credit against royalties payable to Akebia in the next calendar year $[***] (and not the full $[***] of Excess COGS). For the avoidance of doubt, Licensee [***] apply the uncredited amount of the Excess COGS ($[***]), or any portion thereof [***].

9.3.5 **Royalty Payments and Reports**.

(a) Flash Reports. Within [***] after the end of each calendar quarter during the Term, Licensee will provide to Akebia "flash" reports that will set forth (i) for the first and second month of such calendar quarter: (A) the actual gross sales of the Licensed Products sold by Licensee or its Affiliates in the Territory in such months; and (B) the actual total aggregate Net Sales of the Licensed Products sold by Licensee or its Affiliates in the Territory in such months, and (ii) for the third month of such calendar quarter, Licensee's good faith estimate of the amounts set forth in the foregoing clauses (i)(A) and (i)(B) of this Section 9.3.5(a) (Flash Reports). The amounts and calculations set forth in the foregoing clauses (i) and (ii) will be broken down for each of Sub-Territory A, Sub-Territory B, and Sub-Territory C.

(b) Quarterly Report. In addition to the "flash" reports to be provided in accordance with Section 9.3.5(a) (Flash Reports), within [***] after the end of each calendar quarter during the Term, Licensee will provide to Akebia a written report (each, a "**Quarterly Report**") setting forth in reasonable detail (i) the gross sales of the Licensed Products sold by Licensee or its Affiliate in the Territory in such calendar quarter; (ii) the aggregate Net Sales of the Licensed Products sold by Licensee or its Affiliates in the Territory in such calendar quarter; (iii) the exchange rates used to calculate the royalties payable in U.S. Dollars; (iv) any withholding taxes required to be made from such royalties; and (v) the quantity and description of the Licensed Products sold by such Party or its Affiliate in the Territory during such calendar quarter comprising such Net Sales, including detailed sales reports for each Licensed Product for each month of the calendar quarter in each country in the Territory. The amounts, calculations, and information set forth in the foregoing clauses (i) through (v) will be broken down on a monthly basis for each country in the Territory. The Parties will seek to

resolve any questions or issues related to a Quarterly Report within [***] following receipt by each Party of the other Party's Quarterly Report.

(c) Royalty Payments. The information contained in each flash report and Quarterly Report will be considered Confidential Information of Licensee. Within [***] after the end of each calendar quarter, Licensee will make the royalty payment due hereunder for the calendar quarter covered by the applicable Quarterly Report.

9.4 **Accounting; Audit**. Each Party agrees to keep full, clear, and accurate records in accordance with the Accounting Standards applicable to such Party, consistently applied, for a period of at least three years after the relevant payment is owed pursuant to this Agreement, setting forth Development costs, including Shared Development Costs, COGS, and sales of the Licensed Products in sufficient detail to enable amounts owed or payable to the other Party hereunder, to be determined. Each Party further agrees to permit its books and records to be examined by an independent accounting firm selected by the auditing Party and reasonably acceptable to the audited Party to verify (a) with respect to Licensee's right to audit, the Quarterly Reports and the reports provided for in Section 4.1.4 (Payment of Licensee R&D Cost Share), reports of any costs and expenses associated with any Additional Development performed by Akebia that Licensee [***] in accordance with Section 4.3.3 (Reimbursement for Additional Development), and COGS charged pursuant to Section 8.3 (Supply Agreements), and (b) with respect to Akebia's right to audit, the reports provided for in Section 4.1.4 (Payment of Licensee R&D Cost Share) related to any [***] Costs, reports of any costs and expenses associated with any Additional Development performed by Licensee that Akebia [***] in accordance with Section 4.3.3 (Reimbursement for Additional Development), and royalty payments based on Net Sales (subject to such independent accounting firm's written obligations of confidentiality and non-use applicable to each Party's Confidential Information that are at least as stringent as those set forth described in Article XIII (Confidentiality)). Such auditor will be bound by a legal agreement obligating it to maintain the confidentiality of such information. Such audit will not be (i) performed more frequently than once per calendar year, (ii) conducted for any calendar year more than three years after the end of such year, or (iii) repeated for any calendar year. Such examination is to be made at the expense of the auditing Party, except in the event that the results of the audit reveal an underpayment (or excess credit in the case of [***] Costs that may be credited pursuant to Section 4.1.3 (Development Cost Sharing) or overcharge in the case of COGS charged pursuant to Section 8.3 (Supply Agreements)) by the audited Party of [***]% or more during the period being audited, in which case reasonable audit fees for such examination will be paid by the audited Party.

9.5 **Currency Conversion**. Any Net Sales that are invoiced or incurred in a currency other than U.S. Dollars, and all other payments by Licensee to Akebia, will be converted into U.S. Dollars at the applicable rate of exchange to U.S. Dollars as listed in the *Wall Street Journal*, Eastern Edition on the last Business Day of the reporting calendar quarter.

9.6 **Method of Payment**. All payments due to a Party under this Agreement will be made in U.S. Dollars by wire transfer to a U.S. bank account of such Party designated from time-to-time in writing by the relevant Party.

9.7 **Taxes**. If under any law or regulation of any country of the Territory withholding of taxes of any type, levies or other charges is required with respect to any amounts payable hereunder to a Party, the other Party ("**Withholding Party**") will apply the withholding or deduction as so required and will promptly pay such tax, levy, or charge to the proper Governmental Authority, and will promptly furnish the Party with proof of such payment. The Withholding Party will have the

right to withhold or deduct any such tax, levy, or charge actually paid from payment due the Party or be promptly reimbursed by the Party if no further payments are due the Party. Any amounts so withheld or deducted from the payment due the Party pursuant to the relevant law or regulation will be deemed paid to such Party for all purposes of this Agreement. Each Withholding Party agrees to assist the other Party in claiming exemption from (or reduction in) such deductions or withholdings under double taxation or similar agreement or treaty from time-to-time in force and in minimizing the amount required to be so withheld or deducted. Notwithstanding the foregoing, all sums payable by either Party hereunder are stated exclusive of any sales tax, value added tax, or other similar taxes, assessments, and charges imposed by the jurisdiction of the Withholding Party or the payee and any such taxes will be paid by the Withholding Party.

9.8 **Late Payments; Disputed Payments**. Any amount owed by a Party to the other Party under this Agreement that is not paid within the applicable time period set forth herein will accrue interest at the lesser of (a) the London Interbank Offered Rate *plus* [***]%, or (b) the highest rate permitted under Applicable Law. If a Party disputes an invoice or other payment obligation under this Agreement, then such Party will timely pay the undisputed amount of the invoice or other payment obligation, and the Parties will resolve such dispute in accordance with Article XVI (Dispute Resolution; Governing Law).

Article X
OWNERSHIP OF INTELLECTUAL PROPERTY

10.1 **Akebia Intellectual Property**. Ownership of the Akebia Know-How, Akebia Improvements, Assigned Product Improvements, and Akebia Patents will be and remain vested at all times in Akebia. Licensee hereby assigns its entire right, title, and interest in any Assigned Product Improvements to Akebia. Licensee will promptly disclose to Akebia any Assigned Product Improvements conceived or reduced to practice, but no later than [***] after Licensee's intellectual property department receives notice of such conception or reduction to practice. Licensee and its Affiliates will provide and will cause its employees and contractors to provide all further cooperation that Akebia reasonably determines is necessary to accomplish the complete transfer of such Assigned Product Improvements and all associated rights to Akebia, including executing further assignments, consents, releases, and other commercially reasonable documentation and providing good faith testimony by affidavit, declaration, in-person, or other proper means in support of any effort by Akebia to establish, perfect, defend, or enforce its rights in any Assigned Product Improvements through prosecution of governmental filings, regulatory proceedings, litigation, and other means, including through the filing, prosecution, maintenance, and enforcement of Assigned Product Improvement Patents. Without limitation, Licensee will cooperate with Akebia if Akebia applies for U.S. or foreign patent protection for such Assigned Product Improvements and will obtain the cooperation of the individual inventors of any such Assigned Product Improvements assigned to Akebia under this Agreement. If Licensee is unable to assign any Assigned Product Improvement or Assigned Product Improvement Patent, then Licensee hereby grants and agrees to grant to Akebia a royalty-free, fully paid-up, exclusive (even as to Licensee), perpetual, irrevocable license (with the right to grant sublicenses through multiple tiers) under such Assigned Product Improvement and Assigned Product Improvement Patent for any and all purposes.

10.2 **Licensee Intellectual Property**. Ownership of the Licensee Know-How, Retained Licensee Improvement Technology, Licensee Contributed Technology, and Licensee Patents will be and remain vested at all times in Licensee.

10.3 Joint Technology.

10.3.1 **Invention Disclosure**. The Parties will promptly disclose to each other any Joint Know-How conceived or reduced to practice, but no later than [***] after the applicable Party's intellectual property department receives notice of such conception or reduction to practice.

10.3.2 **Ownership**. All Joint Technology will be jointly owned by the Parties, with each Party entitled to the free use and enjoyment of such Joint Technology, but subject to the terms and conditions of this Agreement, including the license grants under Article II (Licenses). Subject to such terms and conditions of this Agreement, neither Party will have a duty to account to the other or seek any consent with respect to the licensing or exploitation of Joint Technology. To the extent any further consent is required to enable a Party to so license or exploit its interest in the Joint Technology, the other Party will grant such consent promptly upon request.

10.4 Prosecution of Akebia Patents.

10.4.1 **Akebia's First Right to Prosecute**. Akebia will have the first right, but not the obligation, to file, prosecute, and maintain the Akebia Patents. On the reasonable request of Akebia, Licensee will cooperate in connection with the filing, prosecution, and maintenance of all Akebia Patents.

10.4.2 **Status Updates**. On a semi-annual basis [***], Akebia will provide to Licensee a written summary of the status of all Akebia Patents, including patent applications, being prosecuted and maintained by Akebia in the Territory. Furthermore, upon Licensee's request, but no more than [***], Akebia will reasonably discuss and consult with Licensee and will provide updates to Licensee by audio or video teleconference regarding Akebia Patents being prosecuted and maintained by Akebia in the Territory, including the strategies for the filing, prosecution, and maintenance of such Akebia Patents.

10.4.3 **Assistance; Costs**. Licensee undertakes without cost to Akebia to obtain all necessary assignment documents for Akebia with respect to prosecution and maintenance of Akebia Patents, to render all signatures that will be necessary for Akebia Patent filings, and to assist Akebia in all other reasonable ways that are necessary for the issuance of the Akebia Patents as well as for the prosecution and maintenance of such patents. Akebia will be responsible for [***]% of the costs incurred with respect to the filing, prosecution, and maintenance of Akebia Patents.

10.4.4 **Abandonment**. If Akebia decides that it is no longer interested in prosecuting or maintaining a particular Akebia Patent in any country in the Territory during the Term, then it will promptly provide written notice to Licensee of this decision. Licensee may, upon written notice to Akebia, assume such prosecution and maintenance at its sole expense. Akebia will assign such Akebia Patent to Licensee at [***]. Following such assignment, (a) such patent or patent application will no longer be considered an Akebia Patent and will be considered a Licensee Patent, (b) Akebia will undertake [***] to obtain all necessary assignment documents for Licensee with respect to prosecution of such Licensee Patent, to render all signatures that will be necessary for such Licensee Patent filings and to assist Licensee in all other reasonable ways that are necessary for the issuance of such Licensee Patent as well as for the maintenance and prosecution of such

Licensee Patent, and (c) Licensee will be responsible for [***]% of the costs incurred with respect to the prosecution and maintenance of such Licensee Patent.

10.5 Prosecution of Joint Patents.

10.5.1 **Filing of Joint Patents**. Akebia will have the first right of election to file patent applications claiming Joint Know-How. If Akebia declines to file such applications, then Licensee may do so.

10.5.2 **Akebia's First Right to Prosecute**. Regardless of which Party files patent applications claiming Joint Know-How, Akebia will have the first right, but not the obligation, to prosecute and maintain the Joint Patents. On the reasonable request of Akebia, Licensee will cooperate in connection with the prosecution and maintenance of all Joint Patents.

10.5.3 **Status Updates**. On a semi-annual basis [***], Akebia will provide to Licensee a written summary of the status of all Joint Patents, including patent applications, being prosecuted and maintained by Akebia. Furthermore, upon Licensee's request, but no more than [***], Akebia will reasonably discuss and consult with Licensee and will provide updates to Licensee by audio or video teleconference regarding Joint Patents being prosecuted and maintained by Akebia, including the strategies for the filing, prosecution, and maintenance of such Joint Patents.

10.5.4 **Assistance; Costs**. Licensee undertakes without cost to Akebia to obtain all necessary assignment documents for Akebia with respect to prosecution and maintenance of Joint Patents, to render all signatures that will be necessary for Joint Patent filings and to assist Akebia in all other reasonable ways that are necessary for the issuance of the Joint Patents as well as for the prosecution and maintenance of such patents. [***] will be responsible for [***]% of the costs incurred with respect to the filing, prosecution, and maintenance of such Joint Patents in the Territory, and Licensee will reimburse Akebia for Licensee's [***]% share of such costs incurred by Akebia in the Territory within [***] of receiving Akebia's invoice therefor. Akebia will be responsible for [***]% of the costs incurred with respect to the filing, prosecution, and maintenance of Joint Patents outside of the Territory.

10.5.5 **Abandonment**. If Akebia decides that it is no longer interested in prosecuting or maintaining a particular Joint Patent in any country during the Term, then it will promptly provide written notice to Licensee of this decision. Licensee may, upon written notice to Akebia, assume such prosecution and maintenance at its sole expense. Akebia will assign such Joint Patent to Licensee at [***]. Following such assignment, (a) such patent or patent application will no longer be considered a Joint Patent and will be considered a Licensee Patent, (b) Akebia will undertake [***] to obtain all necessary assignment documents for Licensee with respect to prosecution of such Licensee Patent, to render all signatures that will be necessary for such Licensee Patent filings and to assist Licensee in all other reasonable ways that are necessary for the issuance of such Licensee Patent as well as for the maintenance and prosecution of such Licensee Patent, and (c) Licensee will be responsible for [***]% of the costs incurred with respect to the prosecution and maintenance of such Licensee Patent.

10.6 Prosecution of Retained Licensee Improvement Patents.

10.6.1 **Filing of Retained Licensee Improvement Patents**. Licensee will have the first right of election to file patent applications claiming Retained Licensee Improvements. If Licensee declines to file such applications, then Akebia may do so.

10.6.2 **Licensee's First Right to Prosecute**. Regardless of which Party files patent applications claiming Retained Licensee Improvements, Licensee will have the first right, but not the obligation, to prosecute and maintain Retained Licensee Improvement Patents. On the reasonable request of Licensee, Akebia will cooperate in connection with the prosecution and maintenance of all Retained Licensee Improvement Patents.

10.6.3 **Territory-Related Status Updates**. On a semi-annual basis, [***], Licensee will provide to Akebia a written summary of the status of all Retained Licensee Improvement Patents being prosecuted and maintained by Licensee in the Territory. Furthermore, upon Akebia's request, but no more than [***], Licensee will reasonably discuss and consult with Akebia and will provide updates to Akebia by audio or video teleconference regarding Retained Licensee Improvement Patents being prosecuted and maintained by Licensee in the Territory, including the strategies for the filing, prosecution, and maintenance of such Retained Licensee Improvement Patents in the Territory.

10.6.4 **Assistance; Costs**. Akebia undertakes without cost to Licensee to obtain all necessary assignment documents for Licensee with respect to prosecution and maintenance of Retained Licensee Improvement Patents, to render all signatures that will be necessary for Retained Licensee Improvement Patent filings, and to assist Licensee in all other reasonable ways that are necessary for the issuance of Retained Licensee Improvement Patents as well as for the prosecution and maintenance of such patents. Licensee will be responsible for [***]% of the costs incurred with respect to the filing, prosecution, and maintenance of the Retained Licensee Improvement Patents.

10.6.5 **Abandonment**. If Licensee decides that it is no longer interested in maintaining or prosecuting a particular Retained Licensee Improvement Patent during the Term, then it will promptly provide written notice to Akebia of this decision. Akebia may, upon written notice to Licensee, assume such prosecution and maintenance at its sole expense. License will assign such Retained Licensee Improvement Patent to Akebia at [***]. Following such assignment, (a) such patent or patent application will no longer be considered a Retained Licensee Improvement Patent and will be considered an Akebia Patent, (b) Licensee will undertake [***] to obtain all necessary assignment documents for Akebia with respect to prosecution of such Akebia Patent, to render all signatures that will be necessary for such Akebia Patent filings and to assist Akebia in all other reasonable ways that are necessary for the issuance of such Akebia Patent as well as for the maintenance and prosecution of such Akebia Patent, and (c) Akebia will be responsible for [***]% of the costs incurred with respect to the prosecution and maintenance of such Akebia Patent.

10.7 Enforcement of [***] Patents in the Territory.

10.7.1 **Notice of Infringement**. If either Party becomes aware of any Third Party activity in the Territory, including any Development activity in the Territory (whether or not an exemption from infringement liability for such Development activity is available under Applicable Law), that infringes (or that is directed to the Development of a product that

would infringe) an Akebia Patent, a Joint Patent, or a Retained Licensee Improvement Patent, then the Party becoming aware of such activity will give prompt written notice to the other Party regarding such alleged infringement.

10.7.2 **Rights to Enforce [***] in the Territory**. As between the Parties, [***] will have the first right, but not the obligation, to attempt to resolve such Third Party activity in the Territory that infringes (or that is directed to the Development of a product that would infringe) [***] by commercially appropriate steps at its own expense, including the filing of an infringement suit to enforce the [***] using counsel of its own choice; *provided that* [***] will be entitled to [***] related to such infringement suit (to the extent relevant, together with its own counsel, at its own expense). If [***] fails to initiate a suit or take other action to terminate such alleged infringement within [***] after the notice provided under Section 10.7.1 (Notice of Infringement) and [***], then [***] will have the second right, but not the obligation, to attempt to resolve such Third Party activity in the Territory by commercially appropriate steps at its own expense, including the filing of an infringement suit to enforce the [***] using counsel of its own choice. Notwithstanding the foregoing, in the event either Party receives a [***], [***] will either file an action or enable [***] to file an action pursuant to such regulations within [***] after the [***] or other applicable deadline under a similar Applicable Law in any other country in the Territory.

10.7.3 **Rights to Enforce [***] in the Territory**. As between the Parties, [***] will have the first right, but not the obligation, to attempt to resolve such Third Party activity in the Territory that infringes (or that is directed to the Development of a product that would infringe) a [***] by commercially appropriate steps at its own expense, including the filing of an infringement suit to enforce the [***] using counsel of its own choice; *provided that* [***] will be entitled to attend any [***] related to such infringement suit (to the extent relevant, together with its own counsel, at its own expense). If [***] fails to initiate a suit or take other action to terminate any such alleged infringement by a product that competes with a Licensed Product in the Territory within [***] after the notice provided under Section 10.7.1 (Notice of Infringement), then [***] will have the second right, but not the obligation, to attempt to resolve such Third Party activity in the Territory at its own expense, including the filing of an infringement suit to enforce the [***] using counsel of its own choice.

10.7.4 **Allocation of Recoveries in the Territory**. Any amounts recovered by a Party as a result of an action pursuant to this Section 10.7 (Enforcement of [***] in the Territory), whether by settlement or judgment, will be allocated as follows: (a) first each Party will be reimbursed [***]; *provided that* if amounts recovered are insufficient to reimburse all such [***] incurred by both Parties, then such recovered amounts will be shared *pro-rata* in proportion to the relative amount of such [***] incurred by each Party, and (b) second, the balance of such recovered amounts will be retained by the [***].

10.7.5 **Cooperation; Procedures**. In any event, at the request and expense of the Party bringing an infringement action under this Section 10.7 (Enforcement of [***] in the Territory), the other Party will provide reasonable assistance and cooperation in any such action (including entering into a common interest agreement if reasonably deemed necessary by any Party) and agrees to be joined as a party to the suit if necessary for the initiating Party to bring or continue an infringement action hereunder. In addition, the Party bringing an infringement action under this Section 10.7 (Enforcement of [***] in the Territory) will provide the other Party with [***] during the course of the action. Neither Party may

settle any action or proceeding brought under this Section 10.7 (Enforcement of [***], Joint Patents, or [***] in the Territory) or knowingly take any other action in the course thereof, in a manner that materially adversely affects the other Party's interest in the [***] in the Territory, in each case, without the written consent of such other Party. Each Party will have the right to be represented by counsel of its own selection and its own expense in any suit or other action instituted by the other Party pursuant to this Section 10.7 (Enforcement of [***] in the Territory). In addition, the Parties will reasonably assist each other and cooperate in any such investigation, pre-litigation preparation, or litigation to ensure that there is an aligned global litigation and enforcement strategy.

10.8 Enforcement of [***] Outside of the Territory.

10.8.1 **Rights to Enforce**. As between the Parties, and subject to any other agreement between the Parties, [***] will have the exclusive right, but not the obligation, to attempt to resolve any Third Party activity outside of the Territory, including any Development activity (whether or not an exemption from infringement liability for such Development activity is available under Applicable Law), that infringes (or that is directed to the development of a product that would infringe) any [***] outside of the Territory, by commercially appropriate steps at its own expense, including the filing of an infringement suit to enforce the [***] using counsel of its own choice.

10.8.2 **Allocation of Recoveries Outside of the Territory**. Any amounts recovered by [***] as a result of an action pursuant to this Section 10.8 (Enforcement of [***] Outside of the Territory), whether by settlement or judgment, will be retained by [***].

10.8.3 **Cooperation**. In any event, at the request and expense of [***], [***] will provide reasonable assistance and cooperation in any infringement action brought under this Section 10.8 (Enforcement of [***] Outside of the Territory), including entering into a common interest agreement if [***] determines it is reasonably necessary to do so, and [***] agrees to be joined as a party to the suit if necessary for [***] to bring or continue an infringement action hereunder.

10.9 Enforcement of [***] Outside of the Territory.

10.9.1 **Rights to Enforce [***] Outside of the Territory**. As between the Parties, [***] will have the first right, but not the obligation, to attempt to resolve any Third Party activity outside of the Territory, including any Development activity (whether or not an exemption from infringement liability for such Development activity is available under Applicable Law), that infringes (or that is directed to the Development of a product that would infringe) a [***] by commercially appropriate steps at its own expense, including the filing of an infringement suit to enforce the [***] using counsel of its own choice. If [***] fails to initiate a suit or take other action to terminate such alleged infringement within [***] after being notified by [***] of such infringement and [***], then [***] will have the second right, but not the obligation, to attempt to resolve such Third Party activity outside of the Territory against a product that was competitive to the Licensed Product by commercially appropriate steps at its own expense, including the filing of an infringement suit to enforce the [***] using counsel of its own choice.

10.9.2 **Allocation of Recoveries Outside of the Territory**. Any amounts recovered by either Party as a result of an action pursuant to this Section 10.9 (Enforcement of [***] Outside of the Territory), whether by settlement or judgment, will be allocated as follows: (a)

first, each Party will be reimbursed [***]; *provided that* if amounts recovered are insufficient to reimburse all such [***] incurred by both Parties, then such recovered amounts will be shared *pro-rata* in proportion to the relative amount of such [***] incurred by each Party, and (b) second, the balance of such recovered amounts will be retained by [***].

10.9.3 **Cooperation**. In any event, at the request and expense of the Party bringing an infringement action under this Section 10.9 (Enforcement of [***] Outside of the Territory), the other Party will provide reasonable assistance and cooperation in any such action (including entering into a common interest agreement if reasonably deemed necessary by any Party) and agrees to be joined as a party to the suit if necessary for the initiating Party to bring or continue an infringement action hereunder. In addition, the Party bringing an infringement action under this under this Section 10.9 (Enforcement of [***] Outside of the Territory) will provide the other Party with [***] during the course of the action.

10.10 Defense of Third Party Infringement Claims; Third Party IP.

10.10.1 **Infringement Claim**. If a Third Party asserts that a Patent or other right controlled by it is or will be infringed by a Party's activities in the Territory under this Agreement ("**Infringement Claim**") or a Party becomes aware of a Patent or other right that might form the basis for an Infringement Claim, then the Party first obtaining knowledge of such Infringement Claim or such potential Infringement Claim will immediately provide the other Party with written notice thereof and the related facts in reasonable detail. The Parties will [***]. Notwithstanding the foregoing, the terms of this Section 10.10.1 (Infringement Claim) will not apply with respect to any [***] that is the subject of Section 10.10.2 ([***]).

10.10.2 [***].

(a) [***]. [***]

(b) **Control and Costs**. With regard to any [***], [***] will be responsible for preparing, [***] such [***] using Commercially Reasonable Efforts (including Commercially Reasonable Efforts to [***] such [***] and the counsel of its own choosing, including the right to control the strategy [***] (subject to Section [***]), any appeals, and other material factors related to such [***]. In addition, the Parties will reasonably assist each other and cooperate and share information with respect to such [***], including any appeals thereof. [***].

(c) **Cooperation**. **[***]** will keep [***] reasonably informed regarding [***], including by providing [***] with copies of all pleadings and other documents filed in [***] [***].

10.10.3 **Responsibility to Defend**. If, during the Term of this Agreement, a Third Party asserts that a Patent or other right controlled by such Third Party is infringed or will be infringed in the Territory by the exercise of the licenses granted under Article II (Licenses), then, subject to Section 10.10.2 (Challenge to Certain Third Party Patents), [***] will be responsible for defending against any such claim at its own expense using Commercially Reasonable Efforts and the counsel of its own choosing; *provided that*, (a) [***] will keep [***] reasonably informed regarding any such claim, including by providing

Licensee with [***] relating to such claim, (b) [***], and (c) [***] will be entitled to attend any [***] related to such claim (to the extent relevant, together with its own counsel, at its own expense). [***], *except that* [***], in each case, of any [***], unless the Parties agree otherwise). [***] will not [***]. In addition, the Parties will reasonably assist each other and cooperate and share information with respect to such claim.

10.10.4 **Responsibility for Third Party Licenses**. At any time during the Term, if either Party believes that it is necessary or advisable to seek to acquire or obtain a license under any Patents owned or controlled by a Third Party in order to avoid infringement thereof by the exercise of the licenses granted under Article II (Licenses), whether or not there has been the institution of any infringement claim, then the Parties will discuss whether to acquire or obtain a license under such Patents. [***] will have the sole right, but not the obligation, to negotiate and acquire or obtain a license under such Patents from such Third Party; *provided*, *however*, that [***] the Licensed Products (including Combination Products) in the Territory, then [***] to such Third Party assignor, licensor, or grantor of rights pursuant to such agreement. [***] of the Licensed Products (including Combination Products) in countries both inside and outside of the Territory, then (a) [***] of the Licensed Products (including Combination Products) in the Territory (*e.g.*, [***]), (b) [***] of the Licensed Products (including Combination Products) in the Territory or outside of the Territory (*e.g.*, [***]), and (c) [***] of the Licensed Products (including Combination Products) in countries outside of the Territory (*e.g.*, [***]). [***] will not be responsible for [***] under any license agreement that [***] of the Licensed Products (including Combination Products) in countries outside of the Territory. [***] will reimburse [***] share of such payments within [***] of [***] invoice therefor. This Section 10.10 (Defense of Third Party Infringement Claims; Third Party IP) will not be interpreted as placing on either Party a duty of inquiry regarding Third Party intellectual property rights. Each Party will keep the other Party informed of the status of any Third Party claim of infringement.

10.11 **Patent Term Extensions**. Akebia will be solely responsible for making all decisions regarding patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, that are applicable to Akebia Patents or Joint Patents licensed hereunder and that become available directly as a result of the Regulatory Approval of a Licensed Product; *provided that* Akebia will consult with Licensee with respect to such decisions and will consider the comments and concerns of Licensee in good faith.

10.12 **Unified Patent Court**. In the event that Unified Patent Court Agreement enters into force during the Term of this Agreement, Akebia will be solely responsible for making all decisions regarding Patents, including decisions regarding the opting-out or opting-in of existing European Patents into the jurisdiction of the Unified Patent Court or the registration of European Patents with Unitary Effect; *provided that* Akebia will consult with Licensee with respect to such decisions and will consider the comments and concerns of Licensee in good faith.

10.13 **Housemarks**. Licensee will be responsible for the registration and maintenance of the Licensee Housemarks throughout the Territory, as well as all expenses associated therewith. Akebia will be responsible for the registration and maintenance of the Akebia Housemarks throughout the Territory, as well as all expenses associated therewith.

Article XI
INFORMATION; PHARMACOVIGILANCE; PRODUCT WITHDRAWAL AND LIMITED RECALL

11.1 **Information**. Akebia and Licensee will use Commercially Reasonable Efforts to disclose and make available to each other in a timely manner all Regulatory Information, Study Data, post-marketing data, Commercialization information, and other information concerning the Licensed Compound or the Licensed Products, known by Akebia or Licensee at any time during the Term (the "**Information**"), subject to receipt of any required Third Party consents. Notwithstanding the foregoing, neither Party will be obligated to disclose to the other Party confidential information about its products other than the Licensed Compound or any Licensed Product.

11.2 **Data Security**. During the Term of this Agreement, each Party will maintain (and, as applicable, cause its Affiliates to maintain) environmental, safety, and facility procedures, data security procedures, and other safeguards against the disclosure, destruction, loss, or alteration of the other Party's Information in the possession of such Party or its Affiliates, including procedures to ensure compliance with Privacy Laws, that are no less rigorous than those maintained by such Party (or any of its Affiliates) for its own Information of a similar nature. In addition, each Party has implemented and will continue to implement during the Term appropriate controls to comply with Privacy Laws and maintain data privacy of its own Information, including for detecting, responding to, and reporting potential breaches in accordance with Applicable Law. Without limiting the foregoing, Akebia will put in place a "business continuity plan" to be implemented in the event of a catastrophic data loss of Akebia's primary databases.

11.3 **Pharmacovigilance Agreement**. Reasonably in advance (in any event at least [***] in advance, unless the Parties agree otherwise) of the initiation of any Development activities by Licensee in any country in the Territory, the Parties (under the guidance of their respective pharmacovigilance departments, or equivalent thereof) will define and finalize the Parties' responsibilities with respect to pharmacovigilance activities in a written Pharmacovigilance Agreement which, for so long as the U.S. Collaboration and License Agreement is in effect, may be the same pharmacovigilance agreement as is entered into by the Parties under the U.S. Collaboration and License Agreement (as amended if necessary to incorporate terms relating to the Territory). Such Pharmacovigilance Agreement will provide for the receipt, investigation, recording, communication, and exchange by the Parties of information that a Party becomes aware of in the Territory and globally concerning adverse events in or involving a research patient or subject or, in the case of non-clinical studies, an animal in a toxicology study, and the seriousness thereof, whether or not determined to be attributable to the Licensed Compound or any Licensed Product, including any such information received by either Party from a Third Party (subject to receipt of any required consents from such Third Party) (such information, the "**Safety Data**"). Such guidelines and procedures will be in accordance with, and will enable each Party and its Affiliates to fulfill, local and international regulatory reporting obligations to Regulatory Authorities. Subject to compliance with Applicable Law, each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement (as the Parties may agree to modify it from time-to-time) and to cause its Affiliates and licensees and permitted sublicensees (as applicable) to comply with such obligations. It is understood that each Party and its Affiliates or licensee or permitted sublicensees (as applicable) will have the right to disclose Safety Data if such disclosure is reasonably necessary to comply with Applicable Laws and regulations and requirements of Regulatory Authorities within the Territory (or outside of the Territory with respect to Akebia) with respect to its filings and activities related to the Licensed Compound and the Licensed Products.

11.4 **Safety Reporting and Global Safety Database**. In each case in accordance with, and subject to (once executed), the Pharmacovigilance Agreement to be entered into pursuant to Section 11.3 (Pharmacovigilance Agreement), (a) Akebia will own all of the Safety Data, and the Pharmacovigilance Agreement will include provisions requiring the establishment of a global safety database for the Licensed Products that will be owned and maintained by Akebia, (b) Akebia will have sole control and discretion with respect to the collection, assessment, and safety reporting to Regulatory Authorities with respect to the Licensed Products outside of the Territory, and (c) the Regulatory Responsible Party will have sole control and discretion with respect to the collection, assessment, and safety reporting to Regulatory Authorities with respect to the Licensed Products in the Territory; *provided*, *however*, that the PVC will review and discuss, and the Parties will consult, communicate, and cooperate with each other through the PVC with respect to the foregoing in the Territory. In addition, prior to the execution of the Pharmacovigilance Agreement (and thereafter, to the extent consistent with such Pharmacovigilance Agreement), the non-Regulatory Responsible Party will promptly (and, once executed, in accordance with the timeframes set forth in the Pharmacovigilance Agreement) forward to the Regulatory Responsible Party for handling and reporting to applicable Regulatory Authorities in the Territory all reports received by such non-Regulatory Responsible Party of adverse drug events, pregnancy reports, and any other information concerning the safety and benefit-risk profile that are or may be associated with the Licensed Products. To the extent that there are any inconsistencies between this Section 11.4 (Safety Reporting and Global Safety Database), and the Pharmacovigilance Agreement, then the Pharmacovigilance Agreement will control.

11.5 **Product Withdrawals and Limited Recalls**.

11.5.1 **Notice**. Each Party will notify the other Party promptly following the first Party's determination that any event, incident, or circumstance has occurred that may result in the need for a Product Withdrawal anywhere in the world (including in the Territory) or a Limited Recall in the Territory, which notice need not be in writing. Such Party will include in such notice the reasoning behind such determination, and any supporting facts.

11.5.2 **Mandated Withdrawal or Recall**. If a Regulatory Authority in the Territory mandates that any Product Withdrawal be implemented or that any Limited Recall be undertaken, then [***], in consultation and coordination with [***], will initiate and manage the Product Withdrawal or Limited Recall as and to the extent mandated by the Regulatory Authority in the Territory and in compliance with Applicable Law.

11.5.3 **Voluntary Withdrawal or Recall in the Territory**. With respect to any Product Withdrawal or Limited Recall within the Territory that is not mandated by a Regulatory Authority, immediately after receipt of notification thereof, (a) each Party's quality, safety, compliance, or regulatory affairs personnel with authority to make product recall decisions on behalf of such Party (the "**Recall Decision-Makers**") will discuss and attempt to agree on whether or not to voluntarily implement the Product Withdrawal or undertake the Limited Recall, and (b) if the Parties' Recall Decision-Makers fail to agree within a reasonably appropriate time period (depending upon the circumstances), whether or not to voluntarily implement or undertake a Product Withdrawal or a Limited Recall within the Territory, then [***] will have the right to determine whether or not to voluntarily undertake a Product Withdrawal or Limited Recall within the Territory. [***] will carry out all such Product Withdrawal or Limited Recall activities (as applicable) in coordination and collaboration with [***], in a manner that enables both Parties to comply with regulatory requirements as expeditiously as possible, and in compliance

with all Applicable Laws. If [***] does not choose to undertake a voluntary Product Withdrawal or Limited Recall in the Territory despite [***] notice to [***] that such Product Withdrawal or Limited Recall should be undertaken (which notice may be given to any of [***] Recall Decision-Makers), then, notwithstanding anything to the contrary herein, [***].

11.5.4 **Withdrawals and Recalls; Costs and Cooperation**. Each Party will provide all cooperation reasonably requested by the other Party in connection with any Product Withdrawal or Limited Recall in the Territory. If a Product Withdrawal or Limited Recall in the Territory is required as the sole and direct result of actions or omissions of [***], permitted sublicensees, or subcontractors (including [***]), then [***] will bear all of the costs incurred in connection with such Product Withdrawal or Limited Recall in the Territory. If a Product Withdrawal or Limited Recall in the Territory is required as the sole and direct result of [***] or its licensees' (other than [***]) or subcontractors' failure to manufacture and supply the Licensed Products in accordance with this Agreement, the Supply Agreements, or any Quality Agreement, including as a result of any failure for such Licensed Products to be manufactured in accordance with cGMP or to the applicable specifications, then [***] will bear (and will reimburse [***] for) all of the costs incurred in connection with such Product Withdrawal or Limited Recall in the Territory. If a Product Withdrawal or Limited Recall in the Territory is required, but is not clearly required as the sole and direct result of the actions or omissions of [***], as described above, then [***] incurred in connection with such Product Withdrawal or Limited Recall in the Territory.

Article XII
REPRESENTATIONS, WARRANTIES, AND COVENANTS

12.1 Mutual Representations and Warranties. Each of Licensee and Akebia hereby represents and warrants to the other Party as of the Effective Date:

12.1.1 (a) It is a corporation or entity duly organized and validly existing under the laws of the state, municipality, provinces, administrative division, or other jurisdiction of its incorporation or formation; and (b) it has full power and authority and the legal right to own and operate property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.

12.1.2 The execution, delivery, and performance of this Agreement by it has been duly authorized by all requisite corporate action.

12.1.3 This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity.

12.1.4 It has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and such performance does not conflict with or constitute a breach of any of its agreements with Third Parties.

12.1.5 It has obtained all necessary consents, approvals, and authorizations of all Regulatory Authorities and other Third Parties required to be obtained in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder.

12.1.6 The execution and delivery of this Agreement and the performance of its obligations hereunder (a) do not conflict with or violate any requirement of Applicable Law or any provision of its articles of incorporation, bylaws, limited partnership agreement, or any similar instrument, as applicable, in any material way, and (b) do not conflict with, violate, or breach or constitute a default or require any consent under, any Applicable Law or any contractual obligation or court or administrative order by which it is bound.

12.1.7 It has the right to grant the rights and licenses described in this Agreement.

12.1.8 To its Knowledge, it has not, directly or indirectly, offered, promised, paid, authorized, or given to any Government Official or Other Covered Party for the purpose, pertaining to this Agreement, of: (a) influencing any act or decision of the Government Official or Other Covered Party; (b) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (c) securing any improper advantage; or (d) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order to obtain or retain business, or direct business to, any person or entity, in each case in any way related to this Agreement.

12.1.9 It is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly, or indirectly, from this Agreement.

12.1.10 It is in compliance with all applicable global trade laws (including the Global Trade Control Laws), including those related to import controls, export controls, or economic sanctions. It is not, nor is any of its Affiliates or its or their respective directors, officers, employees, agents, or representatives, or in the last five years was, a Restricted Party.

12.1.11 It has not been debarred or suspended under 21 U.S.C. §335(a) or (b), is not the subject of a conviction described in Section 306 of the FD&C Act, has not been and is not excluded from a federal or governmental health care program, debarred from federal contracting, convicted of or pled nolo contendere to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, is not subject to OFAC sanctions or on the OFAC list of specially designated nationals, and is not subject to any similar sanction of any Government Authority in the Territory ("**Debarred/Excluded**"), and no proceeding that could result in it being Debarred/Excluded is pending, and neither it nor any of its Affiliates has used, in any capacity in the performance of obligations relating to the Licensed Product, any employee, subcontractor, consultant, agent, representative, or other person who has been Debarred/Excluded.

12.2 Additional Akebia Warranties. Except as set forth on Schedule 12.2, Akebia hereby represents and warrants as of the Effective Date to Licensee that:

12.2.1 The Akebia Patents set forth on Schedule 1.10 have been duly filed and maintained in the Territory and, to Akebia's Knowledge, are being diligently prosecuted in the Territory.

12.2.2 Other than routine patent prosecution, there is no pending, or to Akebia's Knowledge threatened, litigation relating to it or any Affiliate that seeks to invalidate or challenge the enforceability of any of the Akebia Patents set forth on Schedule 1.10 in the Territory, and no Third Party has challenged in writing, or, to the Knowledge of Akebia, has threatened to challenge, Akebia's right to use and license the Akebia Know-How in the Territory.

12.2.3 Akebia has obtained the assignment of all interests and all rights of any and all Third Parties who are named as inventors with respect to the subject matter of the Akebia Patents in the Territory.

12.2.4 To Akebia's Knowledge, there is no use, infringement, or misappropriation of the Akebia Technology in the Territory in derogation of the rights granted to Licensee in this Agreement.

12.2.5 There are no investigations, inquiries, actions, or other proceedings pending before or, to Akebia's Knowledge, threatened by any Regulatory Authority or other Government Authority in the Territory with respect to any Licensed Product arising from any default by Akebia or a Third Party acting on behalf of Akebia in the discovery or Development of the Licensed Compound, and Akebia has not received written notice threatening any such investigation, inquiry, action, or other proceeding.

12.2.6 Other than routine patent prosecution, there are no claims asserted in writing, judgments, or settlements in effect against Akebia relating to the Akebia Patents or the Akebia Know-How in the Territory.

12.2.7 There are no claims or litigation pending or, to the Knowledge of Akebia, threatened alleging that the Development, manufacture, or Commercialization of the Licensed Products in the Tablet Formulation in the manner reasonably contemplated herein as of the Effective Date, infringes or would infringe any issued patent of any Third Party in the Territory.

12.2.8 Akebia and, to Akebia's Knowledge, its contractors and consultants, have complied in all material respects with all Applicable Law, including GLP and GCP, in the Development and manufacture of the Licensed Compound and the Licensed Products prior to the Effective Date.

12.2.9 To Akebia's Knowledge, Akebia has disclosed to Licensee all material information in Akebia's possession or control as of the Effective Date pertaining to Development of the Licensed Compound and the Licensed Products in the Territory, including all briefing documents, meeting minutes, and all protocols and protocol amendments for all past and active studies in the Current Global Development Program, in each case, submitted to or received from Regulatory Authorities in the Territory relating to the Licensed Compound and the Licensed Products.

12.2.10 Akebia owns or Controls the rights, title, and interests in and to the Akebia Patents set forth on Schedule 1.10 and licensed to Licensee pursuant to Section 2.1 (Grant of Licenses to Licensee).

12.3 **Additional Licensee Warranties**. Licensee hereby represents and warrants as of the Effective Date that Licensee has immediately available funds sufficient to cover Licensee's financial obligations under this Agreement.

12.4 **Additional Covenants**. Each of Licensee and Akebia hereby covenant to the other:

12.4.1 It will, and will ensure that its Affiliates, comply with all Applicable Laws and, to the extent applicable, Professional Requirements, with respect to the performance of its obligations under this Agreement, including, as applicable, the Approved Labeling, the European Data Protection Directive 95/46/EC, the European General Data Protection Regulation (Regulation (EU) 2016/679), and any other applicable national data protection legislation.

12.4.2 It will not in the future offer, promise, pay, authorize, or give, money or anything of value, directly or indirectly, to any Government Official or Other Covered Party for the purpose, pertaining to this Agreement, of: (a) influencing any act or decision of the Government Official or Other Covered Party; (b) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (c) securing any improper advantage; or (d) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order to obtain or retain business, or direct business to, any person or entity, in each case in any way related to this Agreement.

12.4.3 Neither it nor its Affiliates will export, transfer, or sell any Licensed Product (a) to any country or territory that is subject to comprehensive economic sanctions administered by OFAC, unless the sale of such Licensed Product would be permissible if Licensee or its Affiliates or sublicensees were subject to OFAC's jurisdiction, (b) to any other country or territory in which such activity would violate Applicable Law in the U.S., (c) to any Restricted Party unless the sale of such Licensed Product would be permissible if Licensee or its Affiliates or sublicensees was subject to OFAC's jurisdiction, or (d) in such a manner that would violate the Global Trade Control Laws.

12.4.4 In performing under this Agreement, it and its Affiliates agree to comply with all applicable anti-corruption laws, including the Foreign Corrupt Practices Act of 1977 and the Bribery Act 2010, as amended from time-to-time; the anti-corruption laws of the Territory; and all laws enacted to implement the Organization for Economic Co-operation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions.

12.4.5 It will not engage, in any capacity in connection with this Agreement or any ancillary agreements, any officer, employee, contractor, consultant, agent, representative, or other person who has been Debarred/Excluded. Each Party will inform the other Party in writing promptly if it or any person engaged by it or any of its Affiliates who is performing any obligations under this Agreement or any ancillary agreements is Debarred/Excluded, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or, to each Party's Knowledge, is threatened, pursuant to which a Party, any of its Affiliates or any such person performing obligations hereunder or thereunder may become Debarred/Excluded.

12.4.6 In performing under this Agreement, it and its Affiliates agree to: (a) comply with all applicable anti-slavery and human trafficking laws, statutes, regulations, and codes in

force from time-to-time including the Modern Slavery Act 2015 (the "**Anti-Slavery and Human Trafficking Laws**"); (b) have and maintain throughout the Term its own policies and procedures to ensure its compliance with Anti-Slavery and Human Trafficking Laws; and (c) not engage in any activity, practice, or conduct that would constitute an offense under the Modern Slavery Act 2015 if such activity, practice, or conduct were carried out in the United Kingdom.

12.5 **Disclaimer**. EXCEPT AS EXPRESSLY SET FORTH HEREIN, THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY AKEBIA ARE PROVIDED "AS IS" AND WITHOUT WARRANTY. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH OF THE PARTIES EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR ENFORCEABILITY OF THEIR RESPECTIVE INTELLECTUAL PROPERTY RIGHTS, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, ARISING FROM A COURSE OF DEALING, USAGE, OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO.

12.6 **Limitation of Liability**. NEITHER OF THE PARTIES WILL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, INDIRECT, CONSEQUENTIAL, OR PUNITIVE DAMAGES OR DAMAGES FOR LOSS OF PROFIT OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT, ITS PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER, EXCEPT TO THE EXTENT THE DAMAGES RESULT FROM A PARTY'S WILLFUL MISCONDUCT OR INTENTIONAL BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT, A BREACH OF THE OBLIGATIONS OF A PARTY UNDER [***], A VIOLATION BY A PARTY OR ITS AFFILIATES OF THE [***].

Article XIII
CONFIDENTIALITY

13.1 **Generally**. During the Term of this Agreement and for a period of five years following the early termination of this Agreement, each Party (a) will maintain in confidence all Confidential Information of the other Party; (b) will not use such Confidential Information for any purpose except in connection with the activities contemplated by this Agreement or in order to further the purpose of this Agreement; and (c) will not disclose such Confidential Information to anyone other than those of its Affiliates, investors, prospective investors, lenders, prospective lenders, financing sources, prospective financing sources (including, in each case, in connection with any royalty factoring transaction), prospective acquirers, permitted sublicensees, prospective sublicensees (to the extent sublicensing is permitted), employees, consultants, financial or legal advisors, agents or subcontractors who are bound by written obligations of non-disclosure and non-use no less stringent than those set forth in this Article XIII (Confidentiality) and to whom such disclosure is necessary in connection with such Party's activities as contemplated in this Agreement or in connection with financing or acquisition activities (including its right to assign its rights hereunder pursuant to Section 17.1 (Assignment) as part of a royalty factoring transaction). Each Party will ensure that such Party's Affiliates, investors, prospective investors, lenders, prospective lenders, acquirors, prospective acquirors, financing sources, prospective financing sources, permitted sublicensees, prospective sublicensees, employees, consultants, agents, consultants, and subcontractors comply with these obligations. Each Party will notify the other Party promptly on discovery of any unauthorized use or disclosure of the other's Confidential Information, including the other's trade secrets or proprietary information. The Joint

Know-How and the terms of this Agreement will be the Confidential Information of each Party. Licensee acknowledges that (a) all Safety Data, (b) Akebia Know-How, and (c) all other information related to Akebia's and its Affiliates' and licensees' Development and Commercialization of the Licensed Compound and the Licensed Products constitutes Confidential Information of Akebia. Akebia acknowledges that all Licensee Know-How constitutes Confidential Information of Licensee.

13.2 **Exceptions**. The obligations of confidentiality, non-disclosure, and non-use set forth in Section 13.1 (Generally) will not apply to the extent the receiving Party (the "**Recipient**") can demonstrate that the disclosed information (a) was in the public domain at the time of disclosure to the Recipient by the other Party, or thereafter entered the public domain, in each case other than as a result of actions of the Recipient, its Affiliates, employees, licensees, agents, or subcontractors, in breach of this Agreement; (b) was rightfully known by the Recipient or its Affiliates (as shown by its written records) prior to the date of disclosure to the Recipient by the other Party; (c) was received by the Recipient or its Affiliates on an unrestricted basis from a Third Party rightfully in possession of such information and not under a duty of confidentiality to the other Party; or (d) was independently developed by or for the Recipient or its Affiliates without reference to or reliance on the Confidential Information of the other Party (as demonstrated by written records). Notwithstanding any other provision of this Agreement, the Recipient's disclosure of Confidential Information will not be prohibited if such disclosure: (i) is in response to a valid order of a court or other governmental body; or (ii) is otherwise required by Applicable Law or regulation or rules of a nationally recognized securities exchange. Further, notwithstanding any other provision of this Agreement, either Party may disclose the other Party's Confidential Information to the extent necessary to exercise the rights granted to or retained by the Recipient under this Agreement, including in filing or prosecuting patent applications in accordance with this Agreement, prosecuting or defending litigation, responding to an investigation by a Governmental Authority, or otherwise establishing rights or enforcing obligations under this Agreement, making Regulatory Submissions with respect to the Licensed Products in their respective territories, or conducting Development or clinical studies with respect to the Licensed Products. If a Recipient is required to disclose Confidential Information pursuant to this Section 13.2 (Exceptions), then prior to any disclosure such Recipient will provide the other Party with prior written notice of such disclosure in order to permit the other Party to seek a protective order or other confidential treatment of such Confidential Information.

13.3 **Publicity**. The Parties recognize that each Party may from time-to-time desire to issue press releases and make other public statements or disclosures regarding the terms of this Agreement. In such event, the Party desiring to issue a press release or make a public statement or disclosure will provide the other Party with a copy of the proposed press release, statement, or disclosure for review and approval as soon as practicable prior to publication, which advance approval will not be unreasonably withheld. No other public statement or disclosure of, or concerning, the terms of this Agreement will be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party. Once any public statement or disclosure has been approved in accordance with this Section 13.3 (Publicity), then either Party may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding the foregoing provisions of this Article XIII (Confidentiality), a Party may (a) disclose the terms of this Agreement where required, as reasonably determined by the disclosing Party, by Applicable Law, regulation, or legal process or by applicable stock exchange rule (with prompt notice of any such legally required disclosure to the other Party and, to the extent practicable, sufficient opportunity for the other Party to review and comment on such required disclosure and request confidential treatment thereof or a protective order therefor) and (b) disclose the terms of this Agreement under obligations of confidentiality to such Party's Affiliates, investors,

prospective investors, lenders, prospective lenders, acquirors, prospective acquirors, permitted sublicensees, prospective sublicensees (to the extent sublicensing is permitted), employees, consultants, agents, and subcontractors in connection with such Party's activities hereunder and in connection with such Party's financing activities.

13.4 Publications.

13.4.1 **Prior to Release of Data by Akebia**. Until the [***], Akebia will have the sole right to publish any clinical data or other clinical or non-clinical results from such programs or any other results under the Current Global Development Program; *provided that* Akebia will [***].

13.4.2 **After Release of Data by Akebia**. Following [***] will review and discuss the plans of the Parties regarding planned publication in the Territory of Study Data or other clinical or non-clinical results relating to the Licensed Compound or the Licensed Products, and coordinate such plans into a single schedule that is [***] by the JDC pursuant to Section 3.2.3(n) (Specific Responsibilities of the JDC) (the "**Joint Publication Plan**") that will be shared with the Parties. With respect to publication in any academic journal, authorship of any publication will be determined based on the accepted standards used in peer-reviewed, academic journals at the time of the proposed publication. Notwithstanding the forgoing, each Party recognizes the interest of both Parties in obtaining valid Patent protection and in protecting business interests and trade secret information. Consequently, except for disclosures permitted pursuant to Section 13.2 (Exceptions), if either Party or its employees or consultants wishes to publish or present to any Third Party results of the Development work, any research results, or any Study Data, or other clinical information in each case, related to the Licensed Compound, the Licensed Products, Co-Packaged Product, or any Combination Product being Developed pursuant to this Agreement, then it will deliver to the other Party a copy of the proposed written publication or an outline of an oral disclosure as soon as practicable prior to submission for publication or presentation. The reviewing Party will notify the other Party promptly after receipt of such proposed publication whether such draft publication contains (a) Confidential Information of the reviewing Party, or (b) information that if published would have an adverse effect on a Patent. The reviewing Party will have the right to (i) propose modifications to the publication or presentation for Patent reasons, trade secret reasons, confidentiality reasons, or business reasons, including reasons relating to the pricing or reimbursement of the Licensed Product, or (ii) request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party requests a delay to protect patentable information, then the publishing Party will delay submission or presentation for a period not to exceed [***] to enable Patent applications protecting each Party's rights in such information to be filed in accordance with the terms of this Agreement. Upon expiration of such [***], the publishing Party will be free to proceed with the publication or presentation. If the reviewing Party reasonably requests modifications to the publication or presentation to prevent disclosure of material trade secret or proprietary business information, then the publishing Party will edit such publication to prevent the disclosure of such information prior to submission of the publication or presentation.

13.5 Injunctive Relief. Each Party acknowledges and agrees that there may be no adequate remedy at law for any breach of its obligations under this Article XIII (Confidentiality), that any such breach may result in irreparable harm to such other Party, and, therefore, that upon any such

breach or any threat thereof, such other Party may seek appropriate equitable relief in addition to whatever remedies it might have at law, without the necessity of showing actual damages.

Article XIV
INDEMNIFICATION

14.1 **Indemnification by Akebia**. Akebia will indemnify, hold harmless, and defend Licensee and its Affiliates and their respective, directors, officers, employees, and agents (the "**Licensee Indemnitees**") from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses, or losses (including reasonable attorneys' fees, court costs, witness fees, damages, judgments, fines, and amounts paid in settlement) ("**Losses**") to the extent that such Losses arise out of (a) a breach of this Agreement by Akebia, (b) [***] of a Licensed Product by or on behalf of Akebia or its Affiliates or licensees (*other than* Licensee), and (c) the negligence or willful misconduct of any Akebia Indemnitee. Notwithstanding the foregoing, Akebia will not have any obligation to indemnify the Licensee Indemnitees to the extent that any Losses arise out of the negligence or willful misconduct of any Licensee Indemnitee or any breach of this Agreement by Licensee.

14.2 **Indemnification by Licensee**. Licensee will indemnify, hold harmless, and defend Akebia and its Affiliates, and their respective directors, officers, employees, and agents (the "**Akebia Indemnitees**") from and against any and all Losses, to the extent that such Losses arise out of (a) a breach of this Agreement by Licensee, (b) [***] of a Licensed Product by or on behalf of Licensee or its Affiliates or sublicensees, (c) [***], and (d) the negligence or willful misconduct of any Licensee Indemnitee. Notwithstanding the foregoing, Licensee will not have any obligation to indemnify the Akebia Indemnitees to the extent that any Losses arise out of the negligence or willful misconduct of any Akebia Indemnitee or any breach of this Agreement by Akebia.

14.3 **Indemnification Procedure**. Each Party, if seeking indemnification under this Article XIV (Indemnification) (the "**Indemnified Party**"), will give written notice of the claim to the other Party (the "**Indemnifying Party**") no later than [***] after becoming aware of the claim; *provided*, *however*, that any failure or delay in providing such notice will not relieve the Indemnifying Party of its indemnification obligation, except to the extent it is actually prejudiced by such failure or delay. Each Party will promptly furnish to the other Party, copies of all papers and official documents received in respect of any Losses. The Indemnifying Party will have the right to assume and control the defense of the indemnification claim at its own expense with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; *provided*, *however*, that an Indemnified Party will have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnifying Party, if representation of such Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual or potential differing interests between the Indemnified Party and any other party represented by such counsel in such proceedings. If the Indemnifying Party does not assume the defense of the indemnification claim as described in this Section 14.3 (Indemnification Procedure), then the Indemnified Party may defend the indemnification claim but will have no obligation to do so. The Indemnified Party will not settle or compromise the indemnification claim without the prior written consent of the Indemnifying Party, and the Indemnifying Party will not settle or compromise the indemnification claim in any manner which would have an adverse effect on the Indemnified Party's interests (including any rights under this Agreement or the scope, validity, or enforceability of any Patents, Confidential Information, or other rights licensed to Licensee by Akebia hereunder), without the prior written consent of the Indemnified Party, which consent, in each case (by the Indemnifying Party or Indemnified Party, as the case may be), will not be

unreasonably withheld. The Indemnified Party will reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense and will make available to the Indemnifying Party all pertinent information under the control of the Indemnified Party, which information will be subject to Article XIII (Confidentiality). The Indemnifying Party will not be liable for any settlement or other disposition of Losses by the Indemnified Party if such settlement is reached without the written consent of the Indemnifying Party pursuant to this Section 14.3 (Indemnification Procedure).

14.4 **Insurance**. Each Party will, at its own expense, obtain and maintain insurance with respect to the Development and Commercialization of the Licensed Compound and the Licensed Products under this Agreement in such amount and subject to such deductibles and other limitations as biopharmaceutical companies customarily maintain with respect to the research, development, and commercialization of similar products in their respective territories. Each Party will provide a copy of such insurance policy to the other Party upon request.

Article XV
TERM AND TERMINATION

15.1 **Term**. The term of this Agreement will begin on the Effective Date and, unless earlier terminated in accordance with the terms of this Article XV (Term and Termination), will expire upon the expiration of the Royalty Term in the last country in the Territory (the "**Term**").

15.2 **Termination for Breach**. Subject to the terms and conditions of this Section 15.2 (Termination for Breach), a Party (the "**Non-Breaching Party**") will have the right, in addition to any other rights and remedies, to terminate this Agreement, in its entirety in the event the other Party (the "**Breaching Party**") is in material breach of its obligations under this Agreement. The Non-Breaching Party will first provide written notice to the Breaching Party, which notice will identify with particularity the alleged breach and state the Non-Breaching Party's intent to terminate this Agreement if such breach is not cured. With respect to material breaches of any payment provision hereunder, the Breaching Party will have a period of [***] after such written notice is provided to cure such breach. With respect to all other breaches, the Breaching Party will have a period of [***] after such written notice is provided to cure such breach; *provided*, *however*, if such breach is not reasonably curable within [***] and if the Breaching Party is making a *bona fide* effort to cure such breach, such termination will be delayed for a time period to be agreed by the Parties in order to permit the Breaching Party a reasonable period of time to cure such breach (but in no event will such time period be more than [***]). Notwithstanding the foregoing, if a Party gives to the other Party a notice pursuant to this Section 15.2 (Termination for Breach) of a material breach by such other Party, and such other Party provides notice during the applicable cure period set forth above that such other Party disputes the basis for termination pursuant to this Section 15.2 (Termination for Breach), then this Agreement will not terminate unless and until an arbitrator issues a final award pursuant to Section 16.2 (Arbitration) upholding such basis for termination. The waiver by either Party of any breach of any term or condition of this Agreement will not be deemed a waiver as to any subsequent or similar breach.

15.3 **Termination by Licensee for Convenience**. At any time after release of the first topline data in the Current Global Development Program (*i.e.*, release of topline data from either the Global Phase 3 NDD-CKD Program or the Global Phase 3 DD-CKD Program, whichever comes first), Licensee may terminate this Agreement in its entirety or for Sub-Territory [***] only, by providing written notice to Akebia thereof, which termination will be effective 12 months following the date of such notice; *provided*, *however*, that such 12-month notice period may be shortened by Akebia in its sole discretion.

15.4 **Termination by Akebia Upon Patent Challenge by Licensee**. Akebia may terminate this Agreement by providing written notice of termination to Licensee if Licensee contests the validity or enforceability of any Patent Controlled by Akebia or any of its Affiliates that Covers a Licensed Product or its manufacture, use, sale, or importation in any court, arbitration proceeding, or other tribunal, including the United States Patent and Trademark Office and the United States International Trade Commission. As used in this definition the term "contest" includes (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patent; (b) filing, or joining in, a petition under 35 U.S.C. § 311 to institute *inter partes* review of any such Patent; (c) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patent or any portion thereof; (d) filing or commencing any opposition, nullity, or similar proceedings challenging the validity of any such Patent in any country, or (e) any foreign equivalent of clauses (a), (b), (c), or (d). Notwithstanding the foregoing, Akebia will not have a right to terminate this Agreement pursuant to this Section 15.4 (Termination by Akebia Upon Patent Challenge by Licensee) with respect to any claim that Akebia first asserts against Licensee or any of its Affiliates where the contest of the validity or enforceability is made by Licensee or its Affiliates in defense of such assertion by Akebia.

15.5 **Termination by Written Agreement**. This Agreement may be terminated in its entirety upon the written agreement of each of Akebia and Licensee.

15.6 **Effects of Expiration**.

15.6.1 **Non-Exclusive License to Licensee; Rights of Reference**. On a country-by-country and Licensed Product-by-Licensed Product basis, all licenses granted to Licensee under this Agreement will become non-exclusive, perpetual, irrevocable, fully paid-up, royalty-free (subject to Section 15.6.3 (Trademark License and Royalty)), and freely sublicenseable, and the rights of reference granted to each Party under Section 5.5 (Rights of Reference; Further Assurance) will survive. In addition, following the technology transfer contemplated pursuant to Section 15.6.2 (Akebia's Supply Obligation), Licensee will have a non-exclusive, perpetual, irrevocable, fully paid-up, royalty-free license under the Akebia Know-How disclosed to Licensee pursuant to such technology transfer to make and have made the Licensed Compound and the Licensed Products inside or outside the Territory, but solely for use in the Commercialization of the Licensed Compound and the Licensed Products in the Field in the Territory.

15.6.2 **Akebia's Supply Obligation**. Following expiration of the Term, Akebia will continue to supply the Licensed Products to Licensee pursuant to the terms of the Supply Agreement and the Quality Agreement during the term of the Supply Agreements set forth in Section 8.5(b) (Term of Supply Agreement and Quality Agreement). On or after expiration of the Term, upon Licensee's written request at any time during the remaining term of the Supply Agreements, Akebia will (a) provide a [***] to Licensee's representatives of information and materials that are necessary or reasonably useful for Licensee or its Affiliate or Third Party subcontractor to [***] and the Licensed Products in each formulation of the Licensed Product, including providing reasonable assistance to Licensee in connection therewith upon request, and (b) [***] of such Licensed Products in the Territory, to the extent that such contract is assignable. If any such contract is not assignable, then Akebia will cooperate with Licensee in all reasonable respects to secure the consent of the applicable Third Party to such assignment or to cause such Third Party to enter into a separate agreement with Licensee on terms substantially similar to those granted to Akebia. [***] for all out-of-pocket costs incurred by or on behalf of [***] in connection with such technology transfer, assignments, and cooperation within [***] of

receiving [***] invoice therefor. Akebia will not be obligated to conduct any negotiation, provide any legal assistance, or make any payments, in connection with any assistance pursuant to this Section 15.6.2 (Akebia's Supply Obligation).

15.6.3 **Trademark License and Royalty**. If Licensee uses any Product Mark or Akebia Housemark in connection with the Commercialization of the Licensed Products in any country in the Territory following the expiration of the Term and during the remaining term of the Supply Agreements, then the licenses granted to Licensee under Section 7.9.5 (Trademark License) to use the Product Marks and Akebia Housemarks will remain non-exclusive as provided in Section 15.6.1 (Non-Exclusive License to Licensee; Rights of Reference) but will bear a royalty of [***]% of Net Sales in each country in the Territory in which Licensee uses the Product Marks or Akebia Housemarks in connection with such Commercialization of the Licensed Products.

15.7 Effects of Termination. In the event of any termination of this Agreement (but not expiration), the following will apply:

15.7.1 **Rights of Reference**. The right of reference granted to [***] pursuant to Section 5.5 (Rights of Reference; Further Assurances) will terminate. The right of reference granted to [***] pursuant to Section 5.5 (Rights of Reference; Further Assurances) will survive.

15.7.2 **Return of Confidential Information**. Licensee will cease using the Akebia Technology and will return to Akebia or destroy all copies of any documents containing any Akebia Know-How. Each Party will return or destroy all Confidential Information of the other Party in its possession upon expiration or termination of this Agreement at the disclosing Party's election and written request. The Recipient will provide a written confirmation of such destruction within [***] of such request; *provided*, *however*, that the foregoing will not apply to any Confidential Information that is necessary to allow such Party to perform its obligations or exercise any of its rights that expressly survive the termination or expiration of this Agreement.

15.7.3 **License Grants to Akebia**. Subject to Section 15.7.6 (Termination by Licensee for Breach), Licensee hereby grants and agrees to grant to Akebia with effect from the effective date of termination, a non-exclusive, fully paid-up, worldwide, perpetual, irrevocable right and license, with the right to grant sublicenses through multiple tiers, under (a) Licensee's interest in Joint Technology, (b) the Retained Licensee Improvement Technology, and (c) any Licensee Contributed Technology, in each case, to research, develop, make, have made, use, import, offer for sale, sell, and otherwise exploit the Licensed Compound and the Licensed Products inside and outside of the Territory. If Licensee is unable to sublicense any Patents or Know-How owned by Third Parties to Akebia pursuant to this Section 15.7.3 (License Grants to Akebia) without the consent of the Third Party, then Licensee undertakes, on request from Akebia, to use reasonable efforts to procure such licenses on behalf of Akebia in as far as it is able to do so, and Akebia will pay such fees and agree to be bound by the terms agreed between Akebia and the Third Party licensor.

15.7.4 **Appointment as Exclusive Distributor**. If any Licensed Products are being Commercialized by Licensee in any country in the Territory as of the effective date of termination, then, at Akebia's election (in its sole discretion) on a country-by-country basis in the Territory, until such time as all Regulatory Approvals with respect to such Licensed Products in such country have been assigned and transferred to Akebia, either

(a) [***] of such Licensed Products in such country and grant [***], to the extent not prohibited by any written agreement between Licensee or any of its Affiliates and a Third Party; *provided that* Akebia will purchase any and all inventory of Licensed Products held by Licensee or its Affiliates as of the effective date of termination at a price equal to [***] to Akebia for such inventory, or (b) [***]; *provided*, *however*, that Licensee's obligations under this Agreement with respect to all such Licensed Product that Licensee sells, including the obligation to remit royalties to Akebia hereunder, will continue in full force and effect during such period.

15.7.5 **Assignment and Disclosure**. Licensee will promptly (and in any event within [***] after the effective date of termination): (a) assign and transfer to Akebia or its designee all of Licensee's rights, title, and interests in and to all Regulatory Submissions, Regulatory Approvals, clinical trial agreements, and distribution agreements (to the extent assignable and not cancelled), confidentiality and other agreements, and Study Data (to the extent in Licensee's Control), in each case, relating to the Licensed Products and that are necessary or reasonably useful for the Development or Commercialization of the Licensed Compound and the Licensed Products, and (b) disclose to Akebia all documents that are controlled by Licensee or that Licensee is able to obtain using reasonable efforts, and that embody the foregoing. In addition, Licensee will promptly assign and transfer to Akebia or its designee, as of the effective date of termination, all of Licensee's rights, title, and interests in and to all domain names associated with the Product Marks (to the extent that they are owned by Licensee or its Affiliates), and will promptly (in any event, within [***] after the effective date of termination) provide to Akebia all login and password information necessary to maintain such domain names. Subject to Section 15.7.6 (Termination by Licensee for Breach), the costs associated with the assignments set forth in this Section 15.7.5 (Assignment and Disclosure) will be borne by [***].

15.7.6 **Termination by Licensee for Breach**. Notwithstanding anything to the contrary in this Section 15.7 (Effects of Termination), in the event of any termination of this Agreement by Licensee for Akebia's material breach pursuant to Section 15.2 (Termination for Breach), (a) the licenses granted to Akebia in Section 2.3 (Grant of Licenses to Akebia) will continue and will bear a royalty of [***]% of Akebia's Net Sales in the Territory, and (b) Akebia will be responsible for [***] associated with the assignments set forth in Section 15.7.5 (Assignment and Disclosure).

15.7.7 **Termination for Sub-Territory [***]**. Without limiting any other legal or equitable remedies that either Party may have, if this Agreement is terminated only for Sub-Territory [***] pursuant to Section 15.3 (Termination by Licensee for Convenience), then as of the effective date of such termination in Sub-Territory [***] (a) Licensee will be responsible for [***]% of all Current Global Development Costs and Akebia will be responsible for the remaining [***]% of all Current Global Development Costs, and accordingly the definition of Licensee R&D Cost Share will be automatically amended to be defined as "[***]% of all Current Global Development Costs" and this Agreement will continue to survive in all respects with respect to all countries and jurisdictions in the Territory other than Sub-Territory [***], and (b) except as expressly set forth therein, the effects of termination set forth in Section 15.7.1 (Rights of Reference) through Section 15.7.5 (Assignment and Disclosure) will apply solely with respect to Sub-Territory [***].

15.8 Survival; Accrued Rights. The following Articles and Sections of this Agreement will survive expiration or early termination for any reason: Article I (Definitions); Section 2.3 (Grant of

Licenses to Akebia); Section 2.4 (Rights of Akebia to Grant Sublicenses); Section 9.3.5 (Royalty Payments and Reports) (but only with respect to Net Sales made during the Term); Section 9.4 (Accounting; Audit) (but only with respect to payment obligations accruing during the Term and only for a period of [***] after expiration or termination); Section 9.8 (Late Payment; Disputed Payment) (but only with respect to payment obligations accruing during the Term); Section 10.1 (Akebia Intellectual Property); Section 10.2 (Licensee Intellectual Property); Section 10.3 (Joint Technology); Section 10.5 (Prosecution of Joint Patents); Section 12.6 (Limitation of Liability); Article XIII (Confidentiality); Article XIV (Indemnification) (excluding Section 14.4 (Insurance)); Section 15.6 (Effects of Expiration); Section 15.7 (Effects of Termination); Section 15.8 (Survival; Accrued Rights); Article XVI (Dispute Resolution; Governing Law); Section 17.1 (Assignment); Section 17.7 (Entire Agreement); Section 17.8 (Severability); Section 17.9 (Notices); Section 17.13 (Agency); Section 17.14 (No Waiver); Section 17.15 (No Strict Construction); and Section 17.16 (Cumulative Remedies). In addition, Section 5.5.2 (Rights Granted to Akebia) and Section 5.5.3 (Further Assurances) will survive the expiration (but not termination) of this Agreement. In any event, expiration or termination of this Agreement will not relieve the Parties of any liability that accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

Article XVI
DISPUTE RESOLUTION; GOVERNING LAW

16.1 **Executive Officers; Disputes**. Each Party will ensure that an Executive Officer is designated for such Party at all times during the Term for dispute resolution purposes, and will promptly notify the other Party of any change in its designated Executive Officer. Except as expressly set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties, the Parties will refer such dispute to their respective Executive Officer, and such Executive Officers or designees will attempt in good faith to resolve such dispute. If the dispute is an Akebia Reserved Dispute, then the Executive Officer of Akebia will determine the final outcome of such dispute. If the dispute is a Licensee Reserved Dispute, then the Executive Officer of Licensee will determine the final outcome of such dispute.

16.2 **Arbitration**. If the Parties are unable to resolve a given dispute within [***] of referring such dispute to the designated Executive Officers pursuant to Section 16.1 (Executive Officers; Disputes), then, other than an Akebia Reserved Dispute, a Licensee Reserved Dispute, an Expert Reserved Matter, or a dispute with respect to the validity, scope, enforceability, or ownership of any Patent or other intellectual property rights under this Agreement (unless otherwise agreed by the Parties), either Party may have such dispute settled by binding arbitration in the manner described below:

16.2.1 **Arbitration Request**. If a Party intends to begin an arbitration proceeding to resolve a dispute arising under this Agreement (*other than* an Akebia Reserved Dispute or a Licensee Reserved Dispute), then such Party will provide written notice (the "**Arbitration Request**") to the other Party of such intention and the issues for resolution. From the date of the Arbitration Request and until such time as the dispute has become finally settled, the running of the time periods within which a Party must cure a breach of this Agreement will be suspended with respect to the subject matter of the dispute.

16.2.2 **Additional Issues**. Within [***] after the receipt of the Arbitration Request, the other Party may, by written notice, add additional issues for resolution.

16.2.3 **Arbitration Procedure**. Except as expressly provided in this Agreement, any dispute, controversy, or claim arising out of or in connection with this Agreement, including any question regarding its existence, validity, or termination, will be referred to and finally resolved by binding arbitration administered by the American Arbitration Association ("**AAA**") in accordance with its International Arbitration Rules as then in effect, which rules are deemed to be incorporated by reference into this Section 16.2.3 (Arbitration Procedure). There will be one arbitrator, and such arbitrator will be chosen pursuant to the AAA Rules. The seat, or legal place, of arbitration will be New York, New York, or such other venue as the Parties agree. The language to be used in the arbitral proceedings will be English. THE PARTIES UNDERSTAND AND ACKNOWLEDGE THAT UNDER THIS SECTION 16.2.3 (ARBITRATION PROCEDURE) EACH PARTY WAIVES THE RIGHT TO A TRIAL BY JURY IN CONNECTION WITH ANY ARBITRABLE CONTROVERSY OR CLAIM. The Parties hereby agree that the arbitrator has authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator deems reasonable and necessary with or without petition therefor by the Parties as well as the final ruling and judgment. All rulings by the arbitrator will be final. Judgment on the award granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets. Nothing in this Agreement will prevent either Party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, proprietary information, trade secrets, Know-How, or any other proprietary right or otherwise to avoid irreparable harm. If the issues in dispute involve scientific or technical matters, then any arbitrator chosen hereunder will have educational training or experience sufficient to demonstrate a reasonable level of knowledge in the field of biotechnology and pharmaceuticals. The Parties agree that arbitration of any dispute will be confidential, and all claims, proceedings, and evidence provided in the arbitration and all decisions of the arbitrators will be considered the Confidential Information of both Parties under this Agreement.

16.3 Intellectual Property Disputes. Notwithstanding Section 16.2 (Arbitration), if a dispute arises with respect to the validity, scope, enforceability, or ownership of any Patent or other intellectual property rights, and such dispute is not resolved in accordance with Section 16.1 (Executive Officers; Disputes), then such dispute will not be submitted to an arbitration proceeding in accordance with Section 16.2 (Arbitration), unless otherwise agreed by the Parties in writing, and instead, either Party may initiate litigation in a court of competent jurisdiction in any country in which such rights apply.

16.4 Baseball Arbitration for Expert Reserved Matters. If the Parties, following escalation through the JSC and the Executive Officers, cannot reach agreement regarding an Expert Reserved Matter, then the matter will be determined through binding "baseball" arbitration as follows:

16.4.1 **Proposals**. Each Party will (a) [***], and (b) submit its [***] to the other Party. Within [***] of such submissions, the Parties will meet to determine whether they agree to adopt either Party's [***], or a modified version thereof, [***].

16.4.2 **Submission to Expert**. If the Parties are unable to agree on a [***] within the [***] period set forth in Section 16.4.1 (Proposals), then the Parties will appoint an agreed upon expert with relevant experience and expertise. If the Parties are unable to agree upon an expert within [***], then Akebia and Licensee will each select an expert and the Parties' two selected experts will, within [***], jointly select a third expert who will be

the appointed expert. Within [***] after the appointment of such expert, each Party will submit its proposed resolution to the expert. The expert will be instructed to select one Party's [***] within [***] following the receipt of both such [***] and to select the [***] that he or she determines is the most fair and reasonable to the Parties under the circumstances and is best suited to [***], taking into account all relevant factors. The expert will be limited to selecting only one or the other of the [***] submitted by the Parties without modification. The selection by the expert of one [***] will be binding and conclusive upon both Parties.

16.4.3 **Costs of Baseball Arbitration**. The (a) fees of the expert and (b) costs and expenses of the baseball arbitration will, in each case ((a) and (b)), be borne by the Party whose [***] is not selected by the expert.

16.5 **Choice of Law; English Language**. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the Parties hereunder, will be construed under and governed by the laws of the state of New York, United States, exclusive of its conflicts of laws principles. This Agreement has been prepared in the English language and the English language will control its interpretation. All consents, notices, reports, and other written documents to be delivered or provided by a Party under this Agreement will be in the English language, and in the event of any conflict between the provisions of any document and the English language translation thereof, the terms of the English language translation will control.

Article XVII
MISCELLANEOUS

17.1 **Assignment**. Neither Party may assign this Agreement and the licenses herein granted without the other Party's prior written consent *unless* such assignment is to (a) a Third Party successor or purchaser of all or substantially all of the assets or businesses to which this Agreement relates whether pursuant to a sale of assets, merger, or other transaction, in which case the assigning Party will provide prior written notice to the other Party and need not obtain the other Party's consent, (b) an Affiliate of such Party, in which case the assigning Party will provide prior written notice to the other Party and need not obtain the other Party's consent; *provided that* the assigning Party remains fully liable for the performance of its obligations hereunder by such assignee. In addition, and notwithstanding the foregoing, Akebia may assign its right to receive payments under this Agreement as part of a royalty factoring transaction undertaken for *bona fide* financing purposes. Any other assignment of this Agreement by a Party requires the prior written consent of the other Party. Any assignment in violation of this Section 17.1 (Assignment) will be null, void, and of no legal effect. This Agreement will be binding on and will inure to the benefit of the permitted successors and assigns of the Parties.

17.2 **Standstill**. Licensee will not, without the written consent of Akebia, acquire directly or indirectly, in a public or private transaction, including by purchase in the open market, any common stock of Akebia if Licensee's beneficial ownership of the common stock of Akebia would thereafter exceed [***]%. In addition, unless approved in advance in writing by Akebia, Licensee will not, directly or indirectly:

(a) Make any statement or proposal to Akebia, other than a non-public statement or proposal delivered directly to the chief executive officer or chairman of the board of directors, or to any of Akebia's stockholders regarding, or make any public announcement, proposal or offer (including a "solicitation" of "proxies" as such terms are defined or used in Regulation 14A of the Exchange Act) with respect to, or otherwise solicit, seek, or offer

to effect (including, for the avoidance of doubt, indirectly by means of communication with the press or media) (i) any business combination, merger, tender offer, exchange offer, or similar transaction in Akebia, (ii) any restructuring, recapitalization, liquidation, or similar transaction involving Akebia, (iii) any acquisition of any of Akebia's equity securities or assets or rights or options to acquire equity securities or assets, (iv) any proposal to seek representation on the board of directors of Akebia or otherwise seek to control or influence the management, board of directors, or policies of Akebia, or (v) any proposal, arrangement, or other statement that is inconsistent with this Section 17.2 (Standstill);

(b) Instigate, encourage, or assist any Third Party (including forming a "group" with any such Third Party) to do, or enter into any discussions or agreements with any Third Party with respect to, any of the actions set forth in this Section 17.2 (Standstill); or

(c) Take any action which would reasonably be expected to require Akebia or any of its Affiliates to make a public announcement regarding any of the actions set forth in this Section 17.2 (Standstill).

Notwithstanding the foregoing provisions, the restrictions set forth in this Section 17.2 (Standstill) will terminate and be of no further force and effect (i) if [***], *provided that* the provisions of this Section 17.2 (Standstill) will be revived if [***]; or (ii) upon the termination of this Agreement. For the avoidance of doubt, nothing in this Section 17.2 (Standstill) will prohibit Licensee from acquiring beneficial ownership of the common stock of Akebia to the extent such ownership remains less than [***]% of Akebia's total outstanding common stock. "**Sale Transaction**" means a transaction between Akebia and a Third Party (A) involving the direct or indirect acquisition by such Third Party of [***]% or more of Akebia's outstanding shares of common stock or consolidated assets (including assets held by subsidiaries), or (B) involving the sale of substantially all of the Akebia's rights with respect to vadadustat.

17.3 **Exclusivity**. Except as provided in this Section 17.3 (Exclusivity), until the date that is [***] prior to the anticipated expiration of the Royalty Term in a country in the Territory, neither Party nor its Affiliates will [***] (or authorize any Third Party to [***]) [***] in such country in the Territory.

17.3.1 **Exception for Acquisition by a Third Party**. Notwithstanding the foregoing, if a Party, as a result of a merger, acquisition, change of control, or similar transaction, is acquired by an entity that, as of the time of such transaction, directly or through an affiliate, is (a) [***], or (b) [***], then such Party, such acquiror, and their respective affiliates (collectively, the "**Acquiror**") will not be in breach of this Section 17.3 (Exclusivity) and may [***] in the Territory (including any [***]) so long as the Acquiror [***] in the Territory following such acquisition (and, if the [***]), unless otherwise agreed by the non-acquired Party through the JSC. In addition, in such event, if the Acquiror does not [***] within [***] of the closing of such acquisition transaction, then (i) the Acquiror will be required to continue to [***] in the Territory (and, if the [***]), unless otherwise agreed by the non-acquired Party through the JSC, and (ii) the restrictions set forth in this Section 17.3 (Exclusivity) will otherwise cease to bind either Party. In addition, in such event if Akebia is the acquired Party, then, unless the Acquiror gives Licensee written notice within [***] of the closing of such acquisition transaction that it [***]:

[***].

17.3.2 **Divestiture**. If a Party or any of its Affiliates, either as a result of a merger, acquisition, change of control, or similar transaction, acquires an entity that is [***] in the Territory, then such Party or its Affiliates will not be in breach of this Section 17.3 (Exclusivity) if such Party or such Affiliate divests its rights to such [***] in the Territory or discontinues [***] such [***] in the Territory within [***] of the closing of such acquisition transaction.

17.3.3 **Discussion of Competing Products**. On a case-by-case basis, either Party may propose to [***] from the definition of Competing Product. If the Parties agree to [***] from the definition of Competing Product, then the terms of this Section 17.3 (Exclusivity) will not apply with respect to such [***], and each Party will be free to promote, market, and sell such [***] in the Territory.

17.4 **[***]**. If either Party Controls Patents, Know-How, or other intellectual property rights with respect to a [***] during the Term, then it will promptly notify the other Party of such product. In such event, upon the other Party's request, the Parties, [***], will discuss whether or not to [***] with respect to such [***] pursuant to Section 3.1.5(u) (Specific Responsibilities of the JSC).

17.5 **[***]**. If Akebia's board of directors elects to engage in negotiations with respect to a [***] with a Third Party that is clinically Developing or Commercializing a Competing Product, then Akebia will [***].

17.6 **Force Majeure**. If either Party will be delayed, interrupted in, or prevented from the performance of any obligation hereunder by reason of any cause beyond its reasonable control, including an act of God, fire, flood, earthquake, war (declared or undeclared), public disaster, act of terrorism, strike, or labor differences, then such Party will not be liable to the other Party therefor; and the time for performance of such obligation will be extended for a period equal to the duration of the force majeure that occasioned the delay, interruption, or prevention. The Party invoking the force majeure rights set forth in this Section 17.6 (Force Majeure) must notify the other Party by courier or overnight dispatch (*e.g.*, Federal Express) no later than [***] after both the first and last day of the force majeure, unless the force majeure renders such notification impossible, in which case notification will be made as soon as possible. If the delay resulting from the force majeure exceeds [***].

17.7 **Entire Agreement; Amendment**. This Agreement, together with all exhibits and schedules attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter hereof (including that certain Confidential Disclosure Agreement between the Parties dated [***], as amended by Amendment #1 dated [***] ("**Confidential Disclosure Agreement**")); *provided that* all information shared by the Parties pursuant to the Confidential Disclosure Agreement will be Confidential Information under this Agreement, and the use and disclosure thereof will be governed by Article XIII (Confidentiality). This Agreement will not be modified, or amended, except by another agreement in writing executed by the Parties. Nothing in this Agreement supersedes, replaces, or amends any provision of the U.S. Collaboration and License Agreement, and this Agreement and the U.S. Collaboration and License Agreement are intended to be interpreted independently. To the extent there is any conflict between this Agreement and the U.S. Collaboration and License Agreement, this Agreement will govern with respect to matters relating to the Territory, and the U.S. Collaboration and License Agreement will govern with respect to matters relating to the U.S.

17.8 **Severability**. If any provision of this Agreement is declared invalid by a court of last resort or by any court or other governmental body from the decision of which an appeal is not taken within the time provided by law, then and in such event, this Agreement will be deemed to have been terminated only as to the portion thereof that relates to the provision invalidated by that decision and only in the relevant jurisdiction, but this Agreement will remain in force, in all other respects and all other jurisdictions; *provided, however*, that if the provision so invalidated is essential to the Agreement as a whole, then the Parties will negotiate in good faith to amend the terms hereof as nearly as practical to carry out the original intent of the Parties, and, failing such amendment, either Party may submit the matter for resolution pursuant to Article XVI (Dispute Resolution; Governing Law).

17.9 **Notices**. Except as expressly provided otherwise in this Agreement, any notice or report required or permitted to be given under this Agreement will be in writing and will be mailed by internationally recognized express delivery service, or sent by email or facsimile and confirmed by mailing, as follows:

If to Akebia:

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142
Attention: Chief Executive Officer
Facsimile: [***]
Email: [***]

With a copy to (which will not constitute notice for purposes of this Agreement):

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142
Attention: General Counsel
Facsimile: [***]
Email: [***]

and

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attention: [***]
Facsimile: [***]
Email: [***]

If to Licensee:

Otsuka Pharmaceutical Co., Ltd.
Shinagawa Grand Central Tower,
2-16-4 Konan, Minato-ku,
Tokyo, 108-8242 Japan,
Attention: [***]

Tel: [***]
Facsimile: [***]

With a copy to (which will not constitute notice for purposes of this Agreement):

Otsuka Pharmaceutical Co., Ltd.
Shinagawa Grand Central Tower,
2-16-4 Konan, Minato-ku,
Tokyo, 108-8242 Japan,
Attention: [***]
Email: [***]
Tel: [***]

Otsuka Pharmaceutical Co., Ltd.
Shinagawa Grand Central Tower
2-16-4 Konan, Minato-ku
Tokyo, 108-8242 Japan
Attn: [***]
Email: [***]
Tel: [***]

Otsuka Pharmaceutical Europe, Ltd.
Gallions, Wexham Springs, Framewood Road.
Wexham SL3 6PJ, United Kingdom
Attn: [***]
Email: [***]
Tel: [***]

Otsuka Pharmaceutical Co., Ltd.
OIAA division, Osaka Headquarters
3-2-27 Otedori, Chuo-ku,
Osaka 540-0021, Japan
Attn: [***]
Email: [***]
Tel: [***]

17.10 **Further Assurances**. The Parties agree to reasonably cooperate with each other in connection with any actions required to be taken as part of their respective obligations under this Agreement, and will (a) furnish to each other such further information; (b) execute and deliver to each other such other documents; and (c) do such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

17.11 **Performance by Affiliates**. Notwithstanding anything to the contrary set forth herein, either Party will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Affiliate. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

17.12 **Exit of the United Kingdom from E.U.** At either Party's request, the Parties will discuss and agree upon such amendments to this Agreement as may be necessary to fairly and reasonably

adjust the terms of this Agreement in light of the United Kingdom's exit from the E.U. Any such amendment should preserve the basic economic and legal terms of this Agreement insofar as possible in light of the change in circumstances caused by the United Kingdom's exit from the E.U.

17.13 **Agency**. Neither Party is, nor will be deemed to be an employee, agent, or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party will have the authority to speak for, represent, or obligate the other Party in any way without prior written authority from the other Party.

17.14 **No Waiver**. Any omission or delay by either Party at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants, or provisions hereof, by the other Party, will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement. Any waiver by a Party of a particular breach or default by the other Party will not operate or be construed as a waiver of any subsequent breach or default by the other Party.

17.15 **No Strict Construction**. This Agreement has been prepared jointly by the Parties and will not be strictly construed against either Party.

17.16 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

17.17 **Counterparts**. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Each Party may execute this Agreement in Adobe™ Portable Document Format (PDF) sent by electronic mail. PDF signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Remainder of page intentionally left blank; Signature page follows.]

IN WITNESS WHEREOF, the Parties have executed this Agreement through their duly authorized representatives to be effective as of the Effective Date.

AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler
Name: John P. Butler
Title: CEO

AKEBIA THERAPEUTICS, INC.

By: /s/ Jason A. Amello
Name: Jason A. Amello
Title: SVP, Chief Financial Officer

OTSUKA PHARMACEUTICAL CO. LTD.

By: /s/ Tatsuo Higuchi
Name: Tatsuo Higuchi
Title: President and Representative Director

OTSUKA PHARMACEUTICAL CO. LTD.

By: /s/ Susumu Tamai
Name: Susumu Tamai
Title: Executive Deputy President

OTSUKA PHARMACEUTICAL CO. LTD.

By: /s/ Tetsuya Tachikawa
Name: Tetsuya Tachikawa
Title: Senior Vice President

Schedule 1.10

Akebia Patents

[***]

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

Schedule 1.44

Current Global Development Program Studies

PRO2TECT program (Global Phase 3 NDD-CKD Program)
INNO2VATE program (Global Phase 3 DD-CKD Program)
Three times weekly dosing study
Hyporesponder study
[***]

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

Schedule 1.183

Sub-Territory B Countries

[***]

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

Schedule 12.2

Exceptions to Akebia Warranties

[***]

CONFIDENTIAL

LICENSE AGREEMENT

BY AND BETWEEN

AKEBIA THERAPEUTICS, INC.

AND

VIFOR (INTERNATIONAL) LTD.

Dated May 12, 2017

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

TABLE OF CONTENTS

LICENSE AGREEMENT

THIS **LICENSE AGREEMENT** (this "**Agreement**") is made and entered into as of May 12, 2017 (the "**Execution Date**") between Akebia Therapeutics, Inc., a company organized and existing under the laws of the State of Delaware, United States of America with its principal offices at 245 First Street, Cambridge, MA 02142 ("**Akebia**"), and Vifor (International) Ltd., a corporation established in accordance with Swiss laws and registered in the commercial registry under CH-107.360.718, with its premises at Rechenstrasse 37, 9014 St. Gallen, Switzerland ("**Licensee**").

Akebia and Licensee may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Akebia is the owner of, or otherwise controls, the Akebia Technology, the Licensed Compound, and the Licensed Products in the Territory;

WHEREAS, as of the Execution Date, the Licensed Product is an investigational agent in Phase 3 clinical trials for the treatment of anemia secondary to chronic kidney disease for which the safety and effectiveness has not yet been established, and, as of such date, the Licensed Product has not yet received Regulatory Approval;

WHEREAS, Licensee has commercial capabilities in the Territory, and is interested in obtaining an exclusive license to sell Licensed Products in the Field in the Territory;

WHEREAS, as of the Execution Date, Galenica Ltd., the ultimate parent company of Licensee, and Fresenius Medical Care AG & Co KGaA, the parent company of FMCNA, are joint venture partners of Vifor Fresenius Medical Care Renal Pharma ("**VFMCRP**"), with Galenica Ltd. owning a controlling interest of VFMCRP;

WHEREAS, Licensee and its Affiliates (including VFMCRP) are strategic partners of Fresenius Kidney Care Group LLC, a Delaware limited liability company ("**FKC**"), which is an Affiliate of FMCNA, and Licensee (either itself or through one of its Affiliates) intends to enter into a supply agreement with FKC;

WHEREAS, pursuant to such supply agreement with FKC, FKC will distribute such Licensed Products only to Authorized Dialysis Centers either itself or through [***] distributors;

WHEREAS, Akebia wishes to grant Licensee an exclusive license to sell Licensed Products to FKC in the Field in the Territory, upon the terms set forth herein; and

WHEREAS, Licensee acknowledges that Akebia has entered into as of the Execution Date, and may during the Term enter into, other agreements with Third Parties with respect to the Licensed Product in the Territory, including granting such Third Parties rights and licenses to Promote or otherwise commercialize such Licensed Products in the Territory, and Licensee agrees that this Agreement is subject to and will be consistent with such agreements.

NOW THEREFORE, the Parties agree as follows:

Article 1

DEFINITIONS

1.1 "**Accounting Standards**" means (a) International Financial Reporting Standards, as adopted in Switzerland, (b) U.S. GAAP, or (c) the applicable accounting standards to which the entity making the Net Sales is subject.

1.2 "**Affiliate**" means, with respect to an entity, any corporation, or other business entity controlled by, controlling, or under common control with the first entity, with "control" meaning direct or indirect beneficial ownership of at least 50% of the voting stock of, or at least a 50% interest in the income of, the applicable entity. For clarity, as of the Execution Date, Licensee is not an Affiliate of FMC or any member of the FMC Group.

1.3 "**Agreement**" has the meaning set forth in the Preamble.

1.4 "**Akebia**" has the meaning set forth in the Preamble.

1.5 "**Akebia Indemnitees**" has the meaning set forth in Section 15.2 (Indemnification by Licensee).

1.6 "**Akebia Know-How**" means all Know-How that is both (a) Controlled as of the Execution Date or during the Term by Akebia or any of its Affiliates, and (b) is either (i) disclosed to Licensee or any of its Affiliates pursuant to this Agreement, or (ii) reasonably necessary for the sale of a Licensed Product.

1.7 "**Akebia Patents**" means all Patents that both (a) are Controlled as of the Execution Date or during the Term by Akebia or any of its Affiliates in the Territory; and (b) [***]. All Akebia Patents as of the Execution Date are, and as of the Effective Date will be, set forth on Schedule 1.7.

1.8 "**Akebia Technology**" means Akebia Know-How and Akebia Patents.

1.9 "**Akebia Trademarks**" means one or more trademarks selected by Akebia or its Affiliates or licensees under which Akebia or its Affiliates or licensees [***], as well as the Akebia company name and logo, and all trademark registrations and applications therefor, and all goodwill associated therewith. All Akebia Trademarks as of the Execution Date are, and as of the Effective Date will be, set forth on Schedule 1.9.

1.10 "**API**" means active pharmaceutical ingredient, which is also commonly referred to as drug substance. For the avoidance of doubt, API will include any prodrug form.

1.11 "**Applicable Law**" means any applicable law (including common law), statute, rule, regulation, order, judgment, or ordinance of any Governmental Authority (including the FDA), including those concerning environmental, health, regulatory, privacy, and safety matters.

1.12 "**Authorized Dialysis Center**" means Majority Owned Clinics and Formulary Clinics, and home dialysis programs administered through Majority Owned Clinics or Formulary Clinics.

1.13 "**Breaching Party**" has the meaning set forth in Section 16.2 (Termination for Breach).

1.14 "**Business Day**" means any day (other than a Saturday or Sunday) on which the banks in both Cambridge, Massachusetts and Zurich, Switzerland are open for business.

1.15 "**CMS**" means the Centers for Medicare & Medicaid Services.

1.16 "**Combination Product**" means any Licensed Product that is comprised of two or more APIs, at least one of which is the Licensed Compound.

1.17 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party with respect to any objective under this Agreement, those efforts and resources that a company within the biopharmaceutical industry of comparable size and resources would typically devote to accomplishing such similar objective under similar circumstances, in each case, with respect to Akebia's efforts, taking into account the Relevant Factors in effect at the time such efforts are expended.

1.18 "**Competing Product**" means any product or product candidate that is not a Licensed Product and that (a) [***] and is approved for the DD-CKD Indication or the NDD-CKD Indication, or (b) is based on [***]. For the avoidance of doubt, the Parties acknowledge and agree that [***].

1.19 "**Confidential Information**" means Know-How and any technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other information that may be disclosed by one Party to the other Party pursuant to this Agreement (including information disclosed prior to the Execution Date pursuant to a Confidential Disclosure Agreement between the Parties dated [***], as amended by Amendment No. 1 dated [***]), regardless of whether such information is specifically designated as confidential and regardless of whether such information is in written, oral, electronic, or other form.

1.20 "**Controlled**" means, with respect to a Party or its Affiliate, any Know-How, Patents, or other intellectual property right that such Party or Affiliate, as the case may be, owns or has a license to and has the ability to grant to the other Party a license or sublicense to, or a right of access with respect to, such Know-How, Patent, or other intellectual property right without violating the terms of any agreement or other arrangements with any Third Party or incurring any additional payments obligations to a Third Party.

1.21 "**Coordination Committee**" has the meaning set forth in Section 2.1 (Formation and Purpose of the Coordination Committee).

1.22 "**Co-Packaged Product**" means a product that contains a Licensed Product and one or more Other Components and that is either (a) packaged together for sale or shipment as a single unit or sold at a single price, or (b) marketed or sold collectively as a single product.

1.23 "**Cost of Goods Sold**" or "**COGS**" means, with respect to any Licensed Product in [***] (a) for products and services acquired from or performed by Third Parties, the [***] actual amounts [***] such Third Parties to the extent [***]; and (b) to the extent manufacturing services are performed by [***] or its Affiliates, the fully-burdened cost of all direct materials and labor and fully allocated manufacturing overhead directly attributable to the manufacture, storage, packaging, and shipping of a Licensed Product [***], calculated in accordance with the Accounting Standards *provided that* for the Licensed Product manufactured by Akebia, [***] will be excluded from the calculation of COGS. In each case ((a) or (b)), COGS includes all [***], Licensed Product testing and yield loss costs, quality control, quality assurance, or other testing of Licensed Products, together with all reasonably allocated indirect costs and overhead

applicable to the manufacturing of each Licensed Product, quality control, or technical operations functions, less costs of goods returned in accordance with Akebia's, or its suppliers', return policy.

1.24 "**Cover**" means with respect to a particular subject matter at issue and a relevant Patent, that the manufacture, use, sale, offer for sale, or importation of the subject matter would fall within the scope of a claim in such Patent.

1.25 "**DD-CKD Indication**" means the treatment of anemia in dialysis patients with chronic kidney disease.

1.26 "**Dollars**" or "**$**" means the legal tender of the U.S.

1.27 "**Effective Date**" has the meaning set forth in Section 3.2 (Effectiveness).

1.28 "**ESA**" means erythropoiesis stimulating agent.

1.29 "**Execution Date**" has the meaning set forth in the Preamble.

1.30 "**FDA**" means the U.S. Food and Drug Administration or any successor agency thereto.

1.31 "**Field**" means the treatment of FMCNA Dialysis Patients solely at Authorized Dialysis Centers with a Licensed Product (a) for which Akebia receives Regulatory Approval in the DD-CKD Indication in the Territory, (b) that is determined by CMS to be in a Medicare Bundled Dialysis Treatment, and (c) that is actually reimbursed under the End-Stage Renal Disease Prospective Payment System.

1.32 "**Finished Form**" means a Licensed Product containing the Licensed Compound as its sole API in the [***] form in any dosage strength that receives Regulatory Approval in the Territory in the DD-CKD Indication, with all applicable packaging and labeling.

1.33 "**First Commercial Sale**" means, for each Licensed Product in the Territory, the first sale for end use or consumption to a Third Party of such Licensed Product in the Territory by Licensee or its Affiliates after the granting of Regulatory Approval in the DD-CKD Indication in the Territory for such Licensed Product by the FDA.

1.34 "**FKC**" has the meaning set forth in the Recitals.

1.35 "**Flash Reports**" has the meaning set forth in Section 11.3.1 (Flash Reports).

1.36 "**FMC Group**" means FMCNA, FMCNA's Affiliates (including FKC), Majority Owned Clinics, and Formulary Clinics.

1.37 "**FMCNA**" or "**Fresenius Medical Care North America**" means Fresenius Medical Care Holdings, Inc., and any successor entity of all or substantially all of Fresenius Medical Care Holdings, Inc.'s dialysis clinic business in the Territory (by operation of law or by sale, merger, restructuring, or other transfer of direct or indirect ownership of dialysis clinics).

1.38 "**FMCNA Dialysis Patients**" means those patients who receive treatment with the Licensed Product in the DD-CKD Indication through an Authorized Dialysis Center, and for which one of the following is true: (a) the treatment is reimbursed as a Medicare Bundled Dialysis Treatment,

(b) the treatment is reimbursed through any similar state program or commercial insurance plan, in each case, on a bundled payment basis for a defined set of services and medications, or (c) the Parties agree to include such patients as FMCNA Dialysis Patients for purposes of this Agreement in accordance with Section 2.3.3 (Specific Responsibilities of the Coordination Committee).

1.39 "**Formulary Clinics**" means all dialysis clinics (including home dialysis programs) in the Territory that [***].

1.40 "**Global Phase 3 DD-CKD Program**" means the Phase 3 global clinical studies for the DD-CKD Indication, known informally as the INNO2VATE studies, consisting of a conversion study and a correction study, and known formally as the "Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Maintenance Treatment of Anemia in Subjects with Dialysis-Dependent Chronic Kidney Disease (INNO2VATE – Conversion)" (AKB-6548-CI-0017) and the "Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Correction of Anemia in Subjects with Incident Dialysis-Dependent Chronic Kidney Disease (INNO2VATE – Correction)" (AKB-6548-CI-0016).

1.41 "**Governmental Authority**" means any court, agency, department, authority, or other instrumentality of any national, state, county, city, or other political subdivision.

1.42 "**HIF**" means hypoxia-inducible factor.

1.43 "**Indemnified Party**" has the meaning set forth in Section 15.3 (Indemnification Procedure).

1.44 "**Indemnifying Party**" has the meaning set forth in Section 15.3 (Indemnification Procedure).

1.45 "**Know-How**" means inventions, discoveries, trade secrets, information, experience, data, formulas, procedures, technology and results (whether or not patentable), including practices, knowledge, know-how, experience and test data (including physical, chemical, biological, toxicological, pharmacological, clinical and veterinary data), dosage regimens, control assays, product specifications, analytical and quality control data, marketing, pricing, distribution cost and sales data or descriptions.

1.46 "**Knowledge**" means the actual knowledge of each Party's [***], in each case, without any inquiry or investigation.

1.47 "**License**" has the meaning set forth in Section 3.1 (Grant of License to Licensee).

1.48 "**Licensed Compound**" means vadadustat, formerly known as AKB-6548, and any salt or crystal form thereof. Licensed Compound includes any prodrug form of vadadustat.

1.49 "**Licensed Product**" means any pharmaceutical product, drug product, preparation, formulation, or dosage form thereof that has the Licensed Compound as at least one API.

1.50 "**Licensee**" has the meaning set forth in the Preamble.

1.51 "**Licensee Indemnitees**" has the meaning set forth in Section 15.1 (Indemnification by Akebia).

1.52 "**Licensee-FKC Supply Agreement**" has the meaning set forth in Section 5.1 (Licensee-FKC Supply Agreement).

1.53 "**Losses**" has the meaning set forth in Section 15.1 (Indemnification by Akebia).

1.54 "**MACE**" means any major adverse cardiovascular event, specifically, [***].

1.55 "**MACE Endpoint**" means a [***].

1.56 "**Majority Owned Clinics**" means all dialysis clinics and home dialysis programs in the Territory that are Affiliates of FMCNA.

1.57 "**Medicare Bundled Dialysis Treatment**" means a treatment protocol for which CMS has either (a) issued a final ruling to include a Licensed Product in the bundled payment under the End-Stage Renal Disease Prospective Payment System for renal dialysis services, or (b) provided written confirmation that CMS considers the Licensed Product to be included as part of the bundled payment under such End-Stage Renal Disease Prospective Payment System.

1.58 "**NDA**" means a New Drug Application or its equivalent for submission to the FDA.

1.59 "**NDD-CKD Indication**" means the treatment of anemia in non-dialysis patients with chronic kidney disease.

1.60 "**Net Sales**" means the gross amounts invoiced by Licensee or its Affiliates for the sales of a Licensed Product to FKC in the Territory, to the extent recognized and allowed in accordance with the Accounting Standards, as applicable and consistently applied, less the following deductions:

1.60.1 inventory management fees paid to distributors and reasonably allocated to such Licensed Product, not to exceed [***]% of aggregate Net Sales in the applicable period;

1.60.2 tariffs, duties, excises, value added tax, and other sales taxes, and other taxes imposed upon and paid with respect to the sale, transportation, delivery, use, exportation, or importation of such Licensed Product (which taxes do not include income taxes);

1.60.3 amounts actually repaid or credited upon returns, rejections, defects, recalls (due to spoilage, damage, or expiration of useful life), price adjustments, billing errors, or trial prescriptions;

1.60.4 freight, shipping, and insurance expenses specific to such Licensed Product and allocated accordingly;

1.60.5 allowances or credits actually paid or given to customers on account of price reductions affecting such Licensed Product; and

1.60.6 discounts actually paid under state-legislated or Licensee-sponsored discount prescription drug programs or reductions or coupon and voucher programs.

Net Sales will be determined from books and records of Licensee or its applicable Affiliate, maintained in accordance with the Accounting Standards, as consistently applied, with respect to sales of any Licensed Product.

The sale of Licensed Products among Licensee or Licensee's Affiliates that are [***], but in such cases Net Sales will [***] of such Licensed Products to a person or entity who is not an Affiliate.

Net Sales will not include Licensed Products transferred for use in connection with promotional use (including samples).

If Licensee or any of its Affiliates receives [***] for a Licensed Product, then the Net Sales amount for such Licensed Product will be [***].

In the event that a Licensed Product is sold as part of a Combination Product or a Co-Packaged Product, the Net Sales from the Combination Product or Co-Packaged Product, for the purposes of determining payments hereunder based on Net Sales, will be determined by multiplying the Net Sales of the Combination Product or Co-Packaged Product (as applicable), during the applicable reporting period, by the fraction, A/(A+B), where A is the average sale price of a Licensed Product when sold separately in Finished Form and B is either (a) the average sale price of the other APIs included in the Combination Product when sold separately in finished form (in the case of a Combination Product), or (b) the average sale price of the Other Components included in the Co-Packaged Product when sold separately (in the case of a Co-Packaged Product), in each case, during the applicable reporting period or, if sales of both the Licensed Product and the other APIs did not occur in such period, then in the most recent reporting period in which sales of both occurred. In the event that such average sale price cannot be determined for both the Licensed Product and all other APIs included in such Combination Product or all Other Components included in such Co-Packaged Product (as applicable), then Net Sales for the purposes of determining payments to Akebia hereunder will be calculated by multiplying the Net Sales of the Combination Product or Co-Packaged Product (as applicable) during the applicable reporting period by the fraction of C/(C+D) where C is the fair market value of a Licensed Product and D is either (i) the fair market value of all other APIs included in the Combination Product (in the case of a Combination Product), or (ii) the average sales price of the Other Components included in such Co-Packaged Product when sold separately (in the case of a Co-Packaged Product). In such event, Licensee will in good faith make a determination of the respective fair market values of the Licensed Product and all other APIs or Other Components, as applicable, included in the Combination Product or Co-Packaged Product (as applicable).

If a Licensed Product is sold as part of a Co-Packaged Product, then Licensee or its applicable Affiliate [***].

1.61 "**Non-Breaching Party**" has the meaning set forth in Section 16.2 (Termination for Breach).

1.62 "**Other Component**" means one or more other devices or components.

1.63 "**Party**" and collectively "**Parties**" has the meaning set forth in the Preamble.

1.64 "**Patents**" means (a) all patents and patent applications in any country or jurisdiction in the Territory, and (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates, and the like.

1.65 "**Product Materials**" means any and all promotional materials, training materials, medical education materials, packaging and labeling, and all other literature or other information related to a Licensed Product.

1.66 "**Profit**" means, with respect to a Licensed Product in the Territory, the Net Sales or other revenue received in the Territory for such Licensed Product in a given period *minus* (a) the Supply Price paid by Licensee for such Licensed Product, *minus* (b) an amount equal to [***], and *minus* (c) [***].

1.67 "**Promote**," "**Promotion**," or "**Promoting**" means to market, detail, advertise, or otherwise promote the Licensed Product, but does not include the sale of such Licensed Product.

1.68 "**Quarterly Report**" has the meaning set forth in Section 11.3.2 (Quarterly Reports).

1.69 "**Recipient**" has the meaning set forth in Section 14.2 (Exceptions).

1.70 "**Regulatory Approval**" means any NDA approval by the FDA.

1.71 "**Regulatory Filings**" means all applications, filings, dossiers, and other documents submitted to the FDA in support of research or development of the Licensed Compound and the Licensed Products, including for the purpose of obtaining Regulatory Approval from the FDA. Regulatory Filings will include all INDs and NDAs.

1.72 "**Relevant Factors**" means the following factors that may affect the research, development, Regulatory Approval, manufacturing, or commercialization of a Licensed Product (without taking into account any other product or products that Akebia or its Affiliates may be developing, manufacturing, or commercializing): actual issues of safety, efficacy, or stability; product profile (including product modality, category and mechanism of action); stage of development or life cycle status; actual and projected research, development, Regulatory Approval, manufacturing, and commercialization costs; issues regarding the ability to manufacture or have manufactured any Licensed Product; the likelihood of obtaining Regulatory Approvals for any Licensed Product in the Territory and the timing of such Regulatory Approvals; the labeling and anticipated labeling of such Licensed Product; past performance of such Licensed Product or similar products; present and future market potential of such Licensed Product; existing or projected pricing, sales, reimbursement, and profitability of such Licensed Product; pricing or reimbursement changes in relevant countries in the Territory; and proprietary position, strength, and duration of patent protection and anticipated exclusivity of such Licensed Product; and other relevant scientific, technical, operational, and commercial factors.

1.73 "**Safety Data**" has the meaning set forth in Section 12.2 (Adverse Drug Events).

1.74 "**Sale Transaction**" has the meaning set forth in Section 18.2 (Standstill).

1.75 "**Statistically Significant**" means a p-value less than [***].

1.76 "**Sub-Distributor**" has the meaning set forth in Section 5.2.1 (Terms of the Licensee-FKC Supply Agreement).

1.77 "**Supply Agreement**" has the meaning set forth in Section 10.2 (Commercial Supply Agreement).

1.78 "**Supply Price**" has the meaning set forth in Section 10.2 (Commercial Supply Agreement).

1.79 "**Term**" has the meaning set forth in Section 16.1 (Term).

1.80 "**Territory**" means the United States of America and its possessions, including Puerto Rico.

1.81 "**Third Party**" means any person or entity other than a Party or its Affiliates.

1.82 "**U.S.**" means the United States of America and its territories and possessions, including Puerto Rico.

1.83 "**Valid Claim**" means (a) a claim in any issued and unexpired Akebia Patent in the Territory, which claim has not been held invalid or unenforceable by a non-appealed or un-appealable decision of a court or Governmental Authority or other appropriate body of competent jurisdiction and has not been admitted invalid or unenforceable through reissue, reexamination, or disclaimer, or has not been made unenforceable due to failure to pay maintenance fees; or (b) a claim in any pending Akebia Patent in the Territory that has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application; *provided that* such claim has not been pending more than seven years from the priority date of such application (but if such pending claim with a pendency of seven years or longer subsequently issues it will be considered a Valid Claim upon issuance). "Valid Claim" does not include any claim in any issued and unexpired Akebia Patent in the Territory Covering an alternative manufacturing process to produce the Licensed Compound or the Licensed Product, including its components (*i.e.*, a manufacturing process other than the manufacturing process used to produce the Licensed Compound or the Licensed Product as of the Effective Date).

1.84 "**VFMCRP**" has the meaning set forth in the Recitals.

Article 2

GOVERNANCE

2.1. **Formation and Purpose of Coordination Committee**. Licensee and Akebia will establish the coordination committee ("**Coordination Committee**"), which committee will coordinate and oversee the Parties' activities hereunder and have the additional responsibilities provided for herein. The Coordination Committee will dissolve upon the expiration of the Term. Each Party will designate up to three representatives with appropriate knowledge and expertise to serve as members of the Coordination Committee. Each Party may replace its Coordination Committee representatives at any time upon written notice to the other Party.

2.2. **Meetings**. The Coordination Committee will hold meetings at such times as it elects to do so, but in no event will such meetings be held less frequently than [***] per calendar year, and such meetings may be held by audio or video teleconference. Other employees of each Party involved in activities under this Agreement may attend meetings of the Coordination Committee as participants, and, with the consent of each Party, consultants, representatives, or advisors involved in the same activities may attend meetings of the Coordination Committee as observers; *provided*, *however*, that such Third Party participants and observers are under legally binding obligations of confidentiality and non-use applicable to the Confidential Information of each Party that are at least as stringent as those set forth in Article 14 (Confidentiality).

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

2.3. **Specific Responsibilities of the Coordination Committee**. The Coordination Committee will:

2.3.1 coordinate the activities of the Parties hereunder;

2.3.2 [***] a Party's indication of interest in having [***], as described in [***];

2.3.3 [***] whether to add or remove any patient populations from the definition of FMCNA Dialysis Patients, as described in Section 4.5 (FMCNA Dialysis Patients);

2.3.4 [***] supply of the Licensed Products in the Territory; and

2.3.5 perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.

Article 3

LICENSE GRANT

3.1. **Grant of License to Licensee**. Subject to the terms and conditions of this Agreement (including Section 3.2 (Effectiveness), Section 3.3 (No Implied Rights), and Section 7.1 (Akebia Restrictions)), Akebia hereby grants to Licensee an exclusive (even as to Akebia), non-sublicensable, non-transferrable, license under the Akebia Technology to sell the Licensed Products solely to FKC in the Territory in the Field during the Term (the "**License**").

3.2. **Effectiveness**. The License granted in Section 3.1 (Grant of License to Licensee) will only become effective and exercisable by Licensee if (a) the FDA has granted Regulatory Approval for a Licensed Product in the DD-CKD Indication in the Territory, (b) CMS has determined such Licensed Product to be in a Medicare Bundled Dialysis Treatment, and (c) Licensee has paid to Akebia the $20,000,000 milestone payment in accordance with Section 11.2 (Milestone Payment) (the date on which (a), (b), and (c) have occurred, the "**Effective Date**").

3.3. **No Implied Rights**. Licensee will not practice the Akebia Technology or exploit the Licensed Compound or any Licensed Product other than as expressly licensed and permitted under this Agreement. Nothing in this Agreement will be interpreted to grant Licensee or any of its Affiliates any rights under any intellectual property rights owned or Controlled by Akebia or its Affiliates (including Akebia Technology) that are not expressly granted herein, whether by implication, estoppel, or otherwise. Any rights not expressly granted to Licensee by Akebia under this Agreement are hereby retained by Akebia. Without limiting the generality of the foregoing, Akebia retains the exclusive right to sell Licensed Products to any Third Party outside of the Field.

Article 4

SALES OF LICENSED PRODUCTS

4.1. **No Unauthorized Sales**. Licensee will not import, offer for sale, sell, or distribute the Licensed Compound or any Licensed Product (a) other than as expressly set forth in this Agreement in the Field in the Territory, (b) outside of the Territory, or (c) to any person or entity who uses or who Licensee reasonably expects will use the Licensed Product outside of the Field in the Territory. Licensee will promptly report to Akebia any unauthorized use, distribution, or transfer of the Licensed Compound or any Licensed Product in the Territory by or on behalf of Licensee or its

Affiliates, FKC, the Sub-Distributor, or any Authorized Dialysis Center. Licensee will use Commercially Reasonable Efforts to stop any such unauthorized use, distribution, or transfer of such Licensed Compound or Licensed Product. In addition, if there is any unauthorized use, distribution, or transfer of any Licensed Product by FKC, its Sub-Distributor, or any Authorized Dialysis Center or any of their Affiliates to or by a Third Party that is not an FMCNA Dialysis Patient or Authorized Dialysis Center, then, if Licensee does not cause such unauthorized use, distribution, or transfer to cease or terminate the rights of the offending Sub-Distributor, Authorized Dialysis Center or any of their Affiliates, in each case, within [***] of the date on which Licensee knows or should have known about such unauthorized use, distribution, or transfer, then the Parties will discuss in good faith an agreeable resolution for a period of [***]. If the Parties do not reach such a resolution during such [***] period, then Akebia may terminate this Agreement pursuant to Section 16.4 (Termination by Akebia for Unauthorized Sales).

4.2. **Codes, Marks, and Packaging**. Unless otherwise agreed by the Parties, the Licensed Products sold by Licensee to FKC under this Agreement will not be resold or distributed under a different labeler code, product code, trade name, trademark, or packaging than units sold by Akebia outside of this Agreement or supplied by Akebia under this Agreement. Licensee will not change any such code, trade name, trademark, or packaging of the Licensed Product supplied to it under the Supply Agreement and will not affix any label or sticker on any Licensed Product without Akebia's prior written consent.

4.3. **Promotion and Detailing**. Akebia retains for itself and on behalf of its Affiliates and licensees (other than Licensee) the sole right to Promote the Licensed Products, and Licensee and its Affiliates will not, and Licensee will ensure that the entities in the FMC Group do not, Promote any Licensed Product. If either Party desires [***], then such Party will provide such [***] to the other Party in writing as soon as possible after [***] for a Licensed Product in the DD-CKD Indication in the Territory, and the Parties will [***] such [***] in the Territory through the Coordination Committee pursuant to Section 2.3.2 (Specific Responsibilities of the Coordination Committee). In any event, Licensee will provide written notification to Akebia of [***] no later than [***] after (a) the [***] in the DD-CKD Indication in the Territory, and (b) [***] to be in a Medicare Bundled Dialysis Treatment, and following such notice the Parties will [***]. Nothing in this Agreement will prohibit FKC or any entity in the FMC Group from including references to any Licensed Product or otherwise engaging in customary and routine clinical communications with their respective patient care staff regarding any Licensed Product or dosing regimens that include any Licensed Product. Licensee and its Affiliates will only use Product Materials that are prepared by Akebia, or otherwise approved in advance in writing by Akebia, in each case, in connection with its sale of the Licensed Products under this Agreement or any [***] that may be [***] in accordance with this Section 4.3 (Promotion and Detailing). In addition, Licensee will ensure that the entities in the FMC Group only use Product Materials that are consistent with those Product Materials prepared and provided by Akebia. For the avoidance of doubt, unless otherwise agreed in writing by the Parties pursuant to this Section 4.3 (Promotion and Detailing), nothing in this Agreement will prevent Akebia or its Affiliates or licensees (other than Licensee) from Promoting any Licensed Product at any Authorized Dialysis Center.

4.4. **Use by the FMC Group**.

4.4.1 **Medicaid or 340B Programs**. Licensee will, will cause its Affiliates to, and will require the FMC Group to, use and sell (as applicable) each Licensed Product solely in the Field in the Territory. To the fullest extent permitted by Applicable Law, Licensee will not, and will not knowingly permit its Affiliates or the FMC Group to, use or sell (as applicable) the Licensed Product in any manner that [***]. In addition, to the fullest extent permitted

by Applicable Law, in a written agreement with each of its Affiliates or the FMC Group, Licensee will cause and require such Affiliates or members of the FMC Group not to use or sell (as applicable) the Licensed Product in any manner that [***]. Licensee will provide prompt written notice to Akebia if Licensee or any of its Affiliates or member of the FMC Group uses or sells, or plans to use or sell, in each case, the Licensed Product in any manner that [***].

4.4.2 **Licensed Product Prices**. To the fullest extent permitted by Applicable Law, Licensee will not, and will not knowingly permit its Affiliates or the FMC Group to, use or sell (as applicable) the Licensed Product in any manner that would result in [***]. In addition, to the fullest extent permitted by Applicable Law, in a written agreement with each of its Affiliates or any member of the FMC Group that receives the Licensed Product, Licensee will cause and require such Affiliates or member of the FMC Group not to use or sell (as applicable) the Licensed Product in any manner that would result in [***].

4.5. **FMCNA Dialysis Patients**. Without limiting the generality of Section 6.2 (Intention Regarding Impacts on Pricing), it is the intention of the Parties that no patient will receive the Licensed Product supplied under this Agreement if the supply of the Licensed Product to such patient [***]. The Coordination Committee will [***] of any patient populations from the definition of FMCNA Dialysis Patients, and following such recommendation by the Coordination Committee the Parties may agree in writing whether to [***] (as applicable) such patient populations in or from the definition of FMCNA Dialysis Patients; *provided that* no patient will be included in the definition of FMCNA Dialysis Patient if the supply of the Licensed Product to such patient would violate the intention statement set forth in the first sentence of Section 4.5 (FMCNA Dialysis Patients), and any such patient will be removed from such definition.

Article 5

SUPPLY AGREEMENTS

5.1. **Licensee-FKC Supply Agreement**. Licensee will enter into a single supply agreement with FKC pursuant to which, after the FDA has granted Regulatory Approval for a Licensed Product in the DD-CKD Indication, each Licensed Product will be sold by Licensee or its Affiliates to FKC in an arms-length transaction for use in Authorized Dialysis Centers (the "**Licensee-FKC Supply Agreement**").

5.1.1 No later than [***] after the Execution Date, Licensee and FKC will enter into the Licensee-FKC Supply Agreement, which supply agreement will satisfy the requirements of Section 5.2 (Terms of the Licensee-FKC Supply Agreement), but will not include any terms related to [***] of the Licensed Product. If Licensee and FKC do not enter into such agreement during such [***] period, or if the Licensee-FKC Supply Agreement is terminated or expires, then Akebia may terminate this Agreement pursuant to Section 16.6 (Termination by Akebia for Failure to Enter into or Amend the Licensee-FKC Supply Agreement). Licensee will provide notice to Akebia that the Licensee-FKC Supply Agreement has been executed and delivered by Licensee and FKC no later than [***] after entering into such agreement.

5.1.2 No later than [***] after (a) the FDA has granted Regulatory Approval for a Licensed Product in the DD-CKD Indication in the Territory, and (b) CMS has determined such Licensed Product to be in a Medicare Bundled Dialysis Treatment, Licensee and FKC will amend the Licensee-FKC Supply Agreement to finalize such agreement in order to

include all applicable terms and otherwise satisfy all requirements of Section 5.2 (Terms of the Licensee-FKC Supply Agreement). If Licensee and FKC do not enter into an amendment of such Licensee-FKC Supply Agreement during such [***] period, then (i) Licensee or FKC may terminate such agreement if Licensee and FKC are unable to agree to such an amendment to memorialize their agreement regarding [***] of the Licensed Product in accordance with this Section 5.1.2, or (ii) Akebia may terminate this Agreement pursuant to Section 16.6 (Termination by Akebia for Failure to Enter into or Amend the Licensee-FKC Supply Agreement**)**. Licensee will provide notice to Akebia that the amendment described herein has been executed and delivered by the parties thereto no later than [***] after entering into such agreement.

5.2. Terms of the Licensee-FKC Supply Agreement. The Licensee-FKC Supply Agreement will:

5.2.1 require that FKC either (a) use [***] distributors (each, a "**Sub-Distributor**") to distribute the Licensed Products to the Authorized Dialysis Centers (which distributor will not own or take title to any Licensed Product), or (b) itself directly distribute such Licensed Products to Authorized Dialysis Centers;

5.2.2 prohibit FKC from distributing or transferring Licensed Products to any person or entity other than the Sub-Distributors or Authorized Dialysis Centers;

5.2.3 require that FKC report any unauthorized use, distribution, or transfer of any Licensed Product promptly to Licensee;

5.2.4 name Akebia as an intended third party beneficiary of such Licensee-FKC Supply Agreement with respect to relevant and appropriate provisions of such agreement;

5.2.5 (a) prohibit FKC and the FMC Group from [***], except as required by Applicable Law, and (b) [***]; and

5.2.6 require FKC to cause each Authorized Dialysis Center to (a) not distribute or transfer any Licensed Product to any person or entity other than an FMCNA Dialysis Patient or another Authorized Dialysis Center, (b) use each Licensed Product, and implement reasonable measures to ensure that each Licensed Product is used, only for (i) the treatment of FMCNA Dialysis Patients in the DD-CKD Indication, and (ii) delivering clinical treatment consistent with the requirements of Section 4.4 (Use by the FMC Group) and to FMCNA Dialysis Patients; (c) report any unauthorized use, distribution, or transfer of any Licensed Product promptly to FKC; and (d) [***], except as required by Applicable Law and to promptly inform Licensee, FKC, and Akebia if the Authorized Dialysis Center believes that it is required by Applicable Law [***]; and

5.2.7 contain such additional provisions as may be necessary to ensure Licensee's compliance with the terms set forth in this Agreement.

5.3. Akebia's Right to Review Agreements. Upon request, Licensee further agrees to permit an independent auditor or law firm selected by Akebia and approved by Licensee, which approval will not be unreasonably withheld or delayed, to examine the Licensee-FKC Distribution Agreement, or other agreement between Licensee and FKC or any member of the FMC Group regarding the Licensed Product, in each case, solely to ensure that such agreements are consistent with the terms set forth in this Agreement. Such auditor or law firm will be bound by a legal agreement obligating it to maintain the confidentiality of such information and not to share such

information with Akebia or any other person. Such auditor or law firm will summarize its findings solely by stating whether or not such agreements are consistent with Licensee's obligations hereunder, and if such agreements are inconsistent with Licensee's obligations, identify such inconsistencies to Akebia. Such examination will not be performed more than once per calendar year. Akebia will be responsible for the expenses incurred in connection with such examination, except in the event that the results of any examination reveal that such agreements are materially inconsistent with the terms set forth in this Agreement, in which case reasonable fees for such examination will be paid by Licensee.

5.4. **FMC Group**. As of the Effective Date, the companies listed on Schedule 5.4 are all of the Authorized Dialysis Centers (including each Formulary Clinic and Majority Owned Clinic, which are each listed under separate headings). Licensee will provide to the Coordination Committee an updated Schedule 5.4 on an annual basis on or before January 31st of each calendar year, and on the Effective Date.

Article 6

PRICING AND PRICE REPORTING

6.1. **Pricing**. Other than with respect to the FMC Group's customary dialysis clinic cost reporting to CMS and any other Governmental Authority, Licensee will not, will cause its Affiliates not to, and will require the FMC Group not to, disclose [***], and in each case, such information will be Confidential Information subject to the terms of Article 14 (Confidentiality).

6.2. **Intention Regarding Impacts on Pricing**. Akebia intends, and enters into this Agreement in reliance upon, the Agreement and the supply of Licensed Product by Akebia to Licensee under the Supply Agreement not giving rise to, or otherwise affecting, [***].

6.3. **Impacts on Pricing**. If, at any time, (a) there has been a breach of Section 6.1 (Pricing), (b) through the actions by or on behalf of Licensee or any of its Affiliates or members of the FMC Group ([***], and even if such actions do not constitute a breach by Licensee under Section 4.4.2 (Licensed Product Prices)), [***], or (c) [***], then, in each case, without limiting Akebia's other rights and remedies under this Agreement, the Parties will [***] an agreeable resolution for a period of [***]. If the Parties do not reach such a resolution during such [***] period, then Akebia may terminate this Agreement pursuant to Section 16.7 (Termination by Akebia for Impacts on Pricing).

Article 7

EXCLUSIVITY

7.1. **Akebia Restrictions**. During the Term, Akebia will not, and will cause its Affiliates and licensees to not, sell any Licensed Product directly to any member of the FMC Group for any use in the Field; *provided*, *however*, that Akebia will not be required to prohibit any Third Party wholesaler or distributor from selling any Licensed Product to the FMC Group. Commencing on the [***] of First Commercial Sale of the Licensed Product in the Territory, if the aggregate Net Sales of all Licensed Products during any [***] period is less than or equal to [***]% of the FMC Group's total spending (amounts paid to manufacturers or wholesalers) for [***] period, then Akebia may terminate this Agreement in accordance with Section 16.8 (Termination by Akebia for Net Sales Levels).

7.2. **Licensee Restrictions**. Without the prior written consent of Akebia, neither Licensee nor any of its Affiliates will directly or indirectly Promote, sell, or have sold, or enter into any agreement to Promote, sell, or have sold, any Competing Product in the Territory to FKC, any entity in or member of the FMC Group, or any Authorized Dialysis Center. Notwithstanding the foregoing, if [***].

Article 8

REGULATORY

Akebia will use Commercially Reasonable Efforts to (a) prepare the NDA in the Territory for each Licensed Product based on its global development plan for such Licensed Product, and (b) obtain and maintain Regulatory Approval in the DD-CKD Indication in the Territory for each Licensed Product. Akebia will be responsible for preparing, filing, and submitting, directly or through its Affiliates or licensees, all Regulatory Filings and correspondence with Regulatory Authorities for each Licensed Product at its sole cost and expense.

Article 9

TRADEMARKS; NAMES

9.1. **Trademark Responsibility**. Akebia will be responsible for (a) registering, prosecuting, maintaining, and enforcing the Akebia Trademarks in the Territory, (b) preparing any guidelines applicable to the use of the Akebia Trademarks, and (c) investigating and defending any infringement or threatened infringement relating to any of the foregoing, in each case, at its sole cost and expense. Licensee will cooperate and assist Akebia with any of the foregoing activities with respect to all Akebia Trademarks, including, if requested by Akebia, providing any specifications, affidavits, declarations, or other documents necessary for Akebia to submit to appropriate Governmental Authorities in order to register and prosecute the Akebia Trademarks. Akebia will own and be responsible for securing any domain names associated with the Akebia Trademarks, and will be responsible for the costs associated with protecting such domain names. Neither Licensee nor any of its Affiliates will obtain or hold any such domain name in its own name.

9.2. **Trademark License**. Subject to the terms and conditions of this Agreement, effective as of the Effective Date, Akebia hereby grants and will grant to Licensee and its Affiliates a non-exclusive non-sublicensable, non-transferrable, royalty-free license to use the Akebia Trademarks solely in connection with the sale, and, [***], of the Licensed Products in the Field in the Territory in accordance with this Agreement. Licensee will maintain the quality of the Licensed Products in accordance with this Agreement and the Supply Agreement. Licensee additionally will assure at all times that the Licensed Products are sold in accordance with Applicable Law.

9.3. **Trademark Ownership and Cooperation**. Each Party acknowledges that Akebia has sole and exclusive ownership of all rights, title, and interests in and to the Akebia Trademarks. Licensee will not, and will cause its Affiliates and the entities in the FMC Group not to, register in their own name any trademark, corporate name, domain name, social media account, or other source identifier containing any trademark owned by Akebia or any word or mark that is confusingly similar to any such trademark. All use of any Akebia Trademark and all goodwill and benefit arising from such use will inure to the sole and exclusive benefit of Akebia. Licensee will place and display the Akebia Trademarks on and in connection with the Licensed Products only in such form and manner as specified in the guidelines adopted from time-to-time by Akebia and

provided to Licensee. Except as otherwise expressly provided in this Agreement, Licensee is not granted any license under, and will not use, any trademarks of Akebia in connection with any Licensed Product.

9.4. Defense of Third Party Infringement Claims.

9.4.1 Notice; Akebia Initiation. Licensee will immediately provide written notice to Akebia if a Third Party asserts that a Patent or other right controlled by such Third Party is or will be infringed by Licensee's activities under this Agreement or Licensee becomes aware of a Patent or other right that might form the basis for such a claim, which notice will include all facts related to such claim in reasonable detail. [***].

9.4.2 Right to Defend. If, during the Term of the Agreement, a Third Party asserts that a Patent or other right controlled by such Third Party is infringed or will be infringed in the Territory by Licensee's exercise of the rights granted to it under this Agreement, then:

(a) [***] in the Territory, [***] will defend [***] against any such claim at its own expense using the counsel of its own choosing, so long as [***] is in breach of any of its obligations under this Agreement. [***] will be responsible for [***]% of the amounts owed to any Third Party directly related to such claim, whether by settlement or judgment; and

(b) [***] in the Territory, [***] will have the right, but not the obligation, to defend any such claim at its own expense using the counsel of its own choosing. If [***] exercises such right to defend, then it will be responsible for [***]% of the amounts owed to any Third Party directly related to such claim, whether by settlement or judgment.

In addition, with respect to any such claim by a Third Party that a Patent or other right controlled by such Third Party is infringed or will be infringed as a result of Licensee's activities under this Agreement in the Territory (whether or not [***]), the Parties will reasonably assist each other and cooperate and share information related to any such claim.

9.4.3 Responsibility for Third Party Licenses. If at any time during the Term, Akebia believes that it is necessary or advisable to seek to acquire or obtain a license from any Third Party in order to avoid infringement of Patents owned or controlled by such Third Party as a result of Licensee's activities under this Agreement, whether or not such Third Party has instituted an infringement claim, then Akebia will have the sole right, but not the obligation, [***] under such Patents from such Third Party. [***]. This Section 9.4.3 (Responsibility for Third Party Licenses) will not be interpreted as placing on either Party a duty of inquiry regarding Third Party intellectual property rights.

Article 10

MANUFACTURING AND SUPPLY

10.1. Commercial Supply. Subject to the terms and conditions of this Agreement and the Supply Agreement, Licensee will purchase from Akebia all of Licensee's requirements of the Licensed Products in Finished Form for sale in the Territory.

10.2. **Commercial Supply Agreement**. No later than [***] after the Execution Date, the Parties will discuss and use good faith efforts to agree on the material terms to be included in the Supply Agreement. No later than [***] after the filing of the NDA, the Parties will enter into a supply agreement for the commercial supply to Licensee of the Licensed Products in Finished Form that contains standard and customary terms for commercial supply arrangements (the "**Supply Agreement**"), which Supply Agreement will include those material terms on which the Parties have agreed pursuant to this Article 10 (Manufacturing and Supply). The supply price for the Licensed Products supplied by Akebia to Licensee pursuant to the Supply Agreement will be equal to [***] *plus* [***] (the "**Supply Price**") and the term of the Supply Agreement will be conterminous with the Term of this Agreement.

Article 11

PAYMENTS

11.1. **Profit Share**. Subject to the provisions of this Agreement, as partial consideration for the License, Licensee will pay to Akebia [***]% of the Profit accrued by Licensee or its Affiliates with respect to the sale of Licensed Products in each [***]; *provided that* if [***] then, in lieu of the foregoing [***]% profit share, Licensee will pay to Akebia [***]% of the Profit accrued by Licensee or its Affiliates with respect to the sale of Licensed Products in each [***]. Licensee will make each such payment to Akebia [***].

11.2. **Milestone Payment**. Subject to the provisions of this Agreement, as further consideration for the License, Licensee will pay to Akebia a non-creditable, nonrefundable payment of $20,000,000 no later than [***] following the date on which the following two conditions are satisfied: (a) the FDA has granted Regulatory Approval for a Licensed Product in the DD-CKD Indication in the Territory, and (b) such Licensed Product is determined by CMS to be in a Medicare Bundled Dialysis Treatment.

11.3. **Sales Reports**.

11.3.1 **Flash Reports**. Within [***] after the end of each calendar quarter in which Licensee or its Affiliates sell a Licensed Product, Licensee will provide to Akebia a "flash" report. Each such flash report will set forth (a) for the first and second month of such calendar quarter: (i) the actual gross sales of all Licensed Products sold by Licensee or its Affiliates in the Territory in such months; and (ii) the actual total aggregate Net Sales of the Licensed Products sold by Licensee or its Affiliates in the Territory in such months, and (b) for the third month of such calendar quarter, Licensee's good faith estimate of the amounts set forth in the foregoing clauses (a)(i) and (a)(ii) of this Section 11.3.1 (Flash Reports). All amounts for the third month of each calendar quarter included in each Flash Report will be prepared as good faith estimates and will be updated with definitive numbers in the applicable Quarterly Report.

11.3.2 **Quarterly Reports**. In addition to the flash reports to be provided in accordance with Section 11.3.1 (Flash Reports), within [***] after the end of each calendar quarter in which Licensee or its Affiliate sells any Licensed Product, Licensee will provide to Akebia a detailed written sales report (each, a "**Quarterly Report**") that sets forth (a) the units of each Licensed Product purchased by FKC, (b) the number of units of each Licensed Product held in inventory at all centralized warehouses of FKC, (c) the number of FMCNA Dialysis Patients treated with a Licensed Product through an Authorized Dialysis Center for the preceding 12-month period, (d) the number of units of Licensed

Products dispensed to FMCNA Dialysis Patients, (e) the number of units of Licensed Products supplied to Authorized Dialysis Centers in such calendar quarter, (f) Net Sales of Licensed Products sold to FKC during such calendar quarter and the Profit in such calendar quarter from such sales, together with all calculations used to determine such Net Sales and Profit, and (g) a certification of an Executive Officer of FKC stating whether or not the [***]% threshold set forth in Section 16.8 (Termination by Akebia for Net Sales Levels) has been achieved for the previous calendar quarter which, in the case of ((a) through (f)), will be broken down on a monthly and quarterly basis. In addition, on an annual basis, Licensee will provide to Akebia the annual Net Sales and Profit forecasts for each Licensed Product to be sold by Licensee under the License in the upcoming calendar year. The Parties will seek to resolve any questions or issues related to a Quarterly Report within [***] following receipt by Akebia of such Quarterly Report.

11.4. **Accounting**. Licensee agrees to keep full, clear, and accurate records in accordance with the Accounting Standards consistently applied for a period of at least three years after the relevant payment is owed pursuant to this Agreement in sufficient detail to enable compensation payable to Akebia hereunder to be determined. Licensee further agrees to permit its books and records to be examined by an independent accounting firm selected by Akebia and approved by Licensee, which approval will not be unreasonably withheld or delayed, to verify the reports provided in Section 11.3 (Sales Reports), including the FMC Group's [***] during the applicable period. Such auditor will be bound by a legal agreement obligating it to maintain the confidentiality of such information and to not share it with Akebia. The auditor's report will be provided simultaneously to both Licensee and Akebia, will be limited to a disclosure of the extent of any underpayment or overpayment by Licensee in sufficient detail to allow Akebia and Licensee to understand the source of any error. Such audit will not be performed more frequently than once per calendar year. Such examination is to be made at the expense of Akebia, except in the event that the results of the audit reveal an underpayment by Licensee of [***]% or more during the period being audited, in which case reasonable audit fees for such examination will be paid by Licensee.

11.5. **Methods of Payment**. All payments due to Akebia under this Agreement will be made in U.S. Dollars by wire transfer to a bank account of Akebia designated from time-to-time in writing by Akebia.

11.6. **Late Payments**. Any amount owed by Licensee to Akebia under this Agreement that is not paid within the applicable time period set forth herein will accrue interest at the lesser of (a) the London Interbank Offered Rate *plus* [***]%, or (b) the highest rate permitted under Applicable Law. If a Party disputes an invoice or other payment obligation under this Agreement, then such Party will timely pay the undisputed amount of the invoice or other payment obligation, and the Parties will resolve such dispute in accordance with Article 17 (Dispute Resolution; Governing Law).

Article 12

INFORMATION AND ADVERSE DRUG EVENTS AND REPORTS

12.1. **Data Security**. During the Term of this Agreement, Licensee will maintain and, as applicable, cause its Affiliates to maintain, environmental, safety, and facility procedures, data security procedures and other safeguards against the disclosure, destruction, loss, or alteration of any clinical data, post-marketing data, commercialization information, or any other information concerning the Licensed Compound or the Licensed Products known by Licensee or any of its

Affiliates at any time during the Term that are no less rigorous than those maintained by Licensee (or any of its Affiliates) for its own information of a similar nature.

12.2. **Adverse Drug Events**. Licensee will provide to Akebia any information that it becomes aware of in the Territory concerning any adverse event relating to the Licensed Compound or any Licensed Product, whether or not determined to be attributable to the Licensed Compound or any Licensed Product, including any such information received by either Party from a Third Party (subject to receipt of any required consents from such Third Party) (such information, the "**Safety Data**") no later than [***] after becoming aware of any such Safety Data. Akebia will own all of the Safety Data, and the global safety database associated with the Licensed Products will be owned and maintained by Akebia. [***] will have the sole right and responsibility to administer and otherwise make decisions with respect to recalls and withdrawals of a Licensed Product, and [***] will, [***], provide assistance and cooperation reasonably requested by [***] in connection with any such recall or withdrawal.

Article 13

REPRESENTATIONS, WARRANTIES, AND COVENANTS

13.1. **Mutual Representations and Warranties**. Each of Licensee and Akebia hereby represents and warrants to the other Party as of the Execution Date that:

13.1.1 (a) It is a corporation or entity duly organized and validly existing under the laws of the state, municipality, provinces, administrative division, or other jurisdiction of its incorporation or formation, and (b) it has full power and authority and the legal right to own and operate property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.

13.1.2 The execution, delivery and performance of this Agreement by it has been duly authorized by all requisite corporate action.

13.1.3 This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, and binding obligation of such Party and is enforceable against such Party in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity.

13.1.4 It has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and such performance does not conflict with or constitute a breach of any of its agreements with Third Parties.

13.1.5 It has obtained all necessary consents, approvals, and authorizations of all Regulatory Authorities and other Third Parties required to be obtained in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder.

13.1.6 The execution and delivery of this Agreement and the performance of its obligations hereunder (a) do not conflict with or violate any requirement of Applicable Law or any provision of its articles of incorporation, bylaws, limited partnership agreement, or any similar instrument, as applicable, and (b) do not conflict with, violate, or breach or

constitute a default or require any consent under, any Applicable Law or any contractual obligation or court or administrative order by which it is bound.

13.1.7 It has the right to grant the rights and licenses described in this Agreement.

13.2. Additional Mutual Representations and Warranties. Each of Licensee and Akebia represents and warrants as of the Execution Date that it has not been debarred by the FDA, is not the subject of a conviction described in Section 306 of the FD&C Act, and is not subject to any similar sanction of other Governmental Authorities outside of the Territory, and neither it nor any of its Affiliates has used, in any capacity, any person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act, or is subject to any such similar sanction.

13.3. Additional Akebia Representations and Warranties. Akebia hereby represents and warrants as of the Execution Date that:

13.3.1 The Akebia Patents and the Akebia Trademarks have been duly filed in the Territory.

13.3.2 All applicable filing, maintenance, and other fees have been timely paid for all of the Akebia Patents set forth on Schedule 1.7 and the Akebia Trademarks set forth on Schedule 1.9, and, to Akebia's Knowledge, all of the Akebia Patents set forth on Schedule 1.7 that are issued patents and the Akebia Trademarks set forth on Schedule 1.9 that are registered trademarks, in each case, are in full force and effect.

13.3.3 There is no pending or, to Akebia's Knowledge, threatened (in writing) re-examination, opposition, interference, *inter partes* review, or claim challenging the inventorship, ownership, validity, enforceability, or patentability of the Akebia Patents or other litigation or proceeding in the Territory relating to any of the Akebia Patents.

13.3.4 The sale of the Licensed Products does not and will not infringe any valid Patent or other intellectual property rights of any Third Party in the Territory.

13.3.5 Akebia has received no written notice of any claim that a patent or trade secret owned or controlled by a Third Party is or would be infringed or misappropriated by the sale of the Licensed Products in the Territory.

13.3.6 To Akebia's Knowledge, there is no use, infringement, or misappropriation of the Akebia Technology in the Territory in derogation of the rights granted to Licensee in this Agreement.

13.3.7 There are no investigations, inquiries, actions, or other proceedings pending before or to Akebia's Knowledge threatened by the FDA or other Governmental Authority in the Territory with respect to the Licensed Products arising from any default by Akebia or a Third Party acting on behalf Akebia in the research or development of the Licensed Compound, and Akebia has not received written notice threatening any such investigation, inquiry, action or other proceeding.

13.3.8 Akebia owns or has licensed the rights, title, and interests in and to the Akebia Technology granted to Licensee pursuant the License.

13.3.9 The research, development, and manufacture of the Licensed Product conducted by Akebia or its Affiliates has been conducted in compliance with Applicable Law and, to Akebia's Knowledge, the research, development, and manufacture of the Licensed Product conducted by Akebia's Third Party contractors has been conducted in compliance with Applicable Law.

13.4. Additional Licensee Representations and Warranties. Licensee hereby represents and warrants as of the Execution Date that:

13.4.1 Galenica Ltd. and Fresenius Medical Care AG & Co KGaA are the joint venture partners of VFMCRP, with Galenica Ltd. owning a controlling interest of VFMCRP and Fresenius Medical Care AG & Co KGaA owning the remaining interest.

13.4.2 FKC is an Affiliate of FMCNA and a strategic partner of Licensee.

13.4.3 Licensee is not an Affiliate of FMC or any member of the FMC Group.

13.4.4 Licensee is a drug manufacturer that is not engaged in the wholesale distribution of prescription drugs to "retail community pharmacies" (as that term is defined in 42 U.S.C. § 1396r-8(k)(10)).

13.4.5 The transmission of all information required to be included in each Quarterly Report pursuant to this Agreement is consistent with Applicable Law and Licensee's contractual obligations with Third Parties.

13.5. Additional Covenants.

13.5.1 Each Party covenants that it will not will engage, in any capacity in connection with this Agreement or any ancillary agreements, any person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act, or is subject to any such similar sanction. Each Party will inform the other Party in writing promptly if it or any person engaged by it or any of its Affiliates who is performing services under this Agreement, or any ancillary agreements, is debarred or is the subject of a conviction described in Section 306 of the FD&C Act, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or, to each Party's knowledge, is threatened, relating to the debarment or conviction of a Party, any of its Affiliates, or any such person performing services hereunder or thereunder.

13.5.2 Each Party covenants that it will comply with all Applicable Laws in performing its activities hereunder.

13.5.3 If either Party determines, based on reasonable advice of counsel, that its compliance with this Agreement will violate Applicable Law, then the Parties will negotiate to amend this Agreement as necessary to ensure that the terms hereof to permit such Party to comply with Applicable Law and this Agreement during the Term.

13.5.4 Licensee covenants that throughout the Term it will not, and will cause each of its Affiliates that are involved in the supply or distribution of any Licensed Product to not, engage in the wholesale distribution of prescription drugs to "retail community pharmacies" (as that term is defined in 42 U.S.C. § 1396r-8(k)(10)) in the Territory.

13.5.5 Licensee covenants that throughout the Term it will provide prompt written notice to Akebia in the event that any of its Affiliates intends to engage, or has engaged, in the wholesale distribution of prescription drugs to "retail community pharmacies" (as that term is defined in 42 U.S.C. § 1396r-8(k)(10)) in the Territory.

13.5.6 On the Effective Date, Akebia will provide to Licensee an updated Schedule 1.7 that includes all Akebia Patents as of the Effective Date, and an updated Schedule 1.9 that includes all Akebia Trademarks as of the Effective Date.

13.6. **Disclaimer**. EXCEPT AS EXPRESSLY SET FORTH HEREIN, INCLUDING THE WARRANTIES SET FORTH IN SECTION 13.3 (ADDITIONAL AKEBIA REPRESENTATIONS AND WARRANTIES), THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY AKEBIA ARE PROVIDED "AS IS" AND WITHOUT WARRANTY. EXCEPT AS EXPRESSLY SET FORTH HEREIN, INCLUDING THE WARRANTIES SET FORTH IN SECTION 13.3 (ADDITIONAL AKEBIA REPRESENTATIONS AND WARRANTIES), AKEBIA EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR ENFORCEABILITY OF ITS RESPECTIVE INTELLECTUAL PROPERTY RIGHTS, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, ARISING FROM A COURSE OF DEALING, USAGE, OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO.

13.7. **Limitation of Liability**. NEITHER OF THE PARTIES WILL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, INDIRECT, CONSEQUENTIAL, OR PUNITIVE DAMAGES OR DAMAGES FOR LOSS OF PROFIT OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT, ITS PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER, EXCEPT TO THE EXTENT THE DAMAGES RESULT FROM A PARTY'S WILLFUL MISCONDUCT, OR INTENTIONAL BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT, A BREACH OF THE OBLIGATIONS OF A PARTY UNDER [***], A VIOLATION BY A PARTY OR ITS AFFILIATES OF [***].

Article 14

CONFIDENTIALITY

14.1. **Generally**. During the Term and for a period of seven years following the early termination of this Agreement, each Party (a) will maintain in confidence all Confidential Information of the other Party; (b) will not use such Confidential Information for any purpose except in connection with the activities contemplated by this Agreement or in order to further the purpose of this Agreement; and (c) will not disclose such Confidential Information, except that each Party may disclose such Confidential Information to its Affiliates, investors, prospective investors, lenders, prospective lenders, financing sources, prospective financing sources (including, in each case, in connection with any royalty factoring or similar transaction), prospective acquirers, licensees, sublicensees, prospective sublicensees, employees, consultants, financial or legal advisors, agents, or subcontractors who are bound by obligations of nondisclosure and non-use no less stringent than those set forth in this Article 14 (Confidentiality) and to whom such disclosure is reasonably necessary or advisable in connection with such Party's activities as contemplated in this Agreement or in connection with financing or acquisition activities (including its right to assign its rights hereunder pursuant to Section 18.1 (Assignment) as part of a royalty factoring or

other similar transaction). Each Party will ensure that its Affiliates, investors, prospective investors, lenders, prospective lenders, acquirors, licensees, sublicensees, prospective acquirors, licensees, sublicensees, prospective sublicensees, employees, consultants, agents, consultants, and subcontractors comply with these obligations. Each Party will notify the other Party promptly on discovery of any unauthorized use or disclosure of the other Party's Confidential Information, including the other Party's trade secrets or proprietary information. Licensee acknowledges that all (i) Safety Data, (ii) Akebia Know-How, and (iii) other information related to Akebia's and its Affiliates', licensees', and sublicensees' development and commercialization of the Licensed Compound and the Licensed Products constitutes Confidential Information of Akebia. The terms of this Agreement will be the Confidential Information of each Party.

14.2. **Exceptions**. The obligations of confidentiality, non-disclosure, and non-use set forth in Section 14.1 (Generally) will not apply to the extent the receiving Party (the "**Recipient**") can demonstrate that the disclosed information (a) was in the public domain at the time of disclosure to the Recipient by the other Party, or thereafter entered the public domain, in each case, other than as a result of actions of the Recipient, its Affiliates, employees, licensees, agents, or subcontractors, in breach of this Agreement; (b) was rightfully known by the Recipient or its Affiliates (as shown by its written records) prior to the date of disclosure to the Recipient by the other Party; (c) was received by the Recipient or its Affiliates on an unrestricted basis from a Third Party rightfully in possession of such information and not under a duty of confidentiality to the other Party; or (d) was independently developed by or for the Recipient or its Affiliates without reference to or reliance on the Confidential Information of the other Party (as demonstrated by written records). Notwithstanding any other provision of this Agreement, the Recipient's disclosure of Confidential Information will not be prohibited if such disclosure: (i) is in response to a valid order of a court or other Governmental Authority; or (ii) is otherwise required by Applicable Law or regulation or rules of a nationally recognized securities exchange. Further notwithstanding any other provision of this Agreement, Akebia may disclose Licensee's Confidential Information to the extent disclosure is required in connection with the filing or prosecuting patent applications, prosecuting, or defending litigation, responding to an investigation by a Governmental Authority, or otherwise establishing rights or enforcing obligations under this Agreement, making Regulatory Filings with respect to the Licensed Products, or conducting research, development, or clinical studies with respect to the Licensed Products. If a Recipient is required to disclose Confidential Information pursuant to this Section 14.2 (Exceptions), then prior to any disclosure the Recipient will provide the other Party with prior written notice of such disclosure in order to permit the other Party to seek a protective order or other confidential treatment of such Confidential Information.

14.3. **Publicity**. The Parties recognize that each Party may from time-to-time desire to issue press releases and make other public statements or disclosures regarding the terms of this Agreement. In such event, the Party desiring to issue a press release or make a public statement or disclosure will provide the other Party with a copy of the proposed press release, statement, or disclosure for review and approval as soon as practicable prior to publication, which advance approval will not be unreasonably withheld or delayed. No other public statement or disclosure of, or concerning, the terms of this Agreement will be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party. Once any public statement or disclosure has been approved in accordance with this Section 14.3 (Publicity), then either Party may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding the foregoing provisions of this Article 14 (Confidentiality), a Party may disclose the terms of this Agreement where required, as reasonably determined by the disclosing Party, by Applicable Law, regulation or legal process, or by applicable stock exchange rule (with prompt notice of any such legally required disclosure to the other Party and, to the extent

practicable, sufficient opportunity for the other Party to review and comment on such required disclosure and request confidential treatment thereof or a protective order therefor).

14.4. **Publications**. If, [***], Licensee, its Affiliates, FMCNA, the FMC Group, or any healthcare professional having an investigator initiated trial agreement in place with any of the previously listed entities desires to publish any clinical data or other clinic results from the administration of the Licensed Compound or any Licensed Product, then Licensee will, will cause its Affiliates to, and will cause FMCNA, the FMC Group, and such healthcare professionals to, in each case, [***]. If Akebia determines that any such proposed publication contains patentable subject matter requiring protection, then Akebia may require the delay of such publication for a period of time not to exceed an additional [***] to pursue such protection or negotiate with such healthcare professional. If Akebia determines that the proposed publication contains Confidential Information, then Akebia may require such Confidential Information to be deleted from the Publication. If, [***], Licensee, its Affiliates, FMCNA, or the FMC Group desires to publish any preclinical or non-clinical results from the research and development of the Licensed Compound or any Licensed Product, then Licensee will, will cause its Affiliates to, and will cause FMCNA and the FMC Group to, in each case, [***].

Article 15

INDEMNIFICATION

15.1. **Indemnification by Akebia**. Unless otherwise provided herein, Akebia will indemnify, hold harmless, and defend Licensee and its Affiliates and their respective, directors, officers, employees, and agents (the "**Licensee Indemnitees**") from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses, or losses (including reasonable attorneys' fees, court costs, witness fees, damages, judgments, fines, and amounts paid in settlement) ("**Losses**") to the extent that such Losses arise out of (a) a breach of this Agreement by Akebia, (b) [***] of a Licensed Product by or on behalf of Akebia or its Affiliates or licensees (other than Licensee, the Sub-Distributor, or a member of the FMC Group), or (c) the negligence or willful misconduct of any Akebia Indemnitee (as defined in Section 15.2 (Indemnification by Licensee)). Notwithstanding the foregoing, Akebia will not have any obligation to indemnify the Licensee Indemnitees to the extent that any Losses arise out of the negligence or willful misconduct of any Licensee Indemnitee or any breach of this Agreement by Licensee.

15.2. **Indemnification by Licensee**. Unless otherwise provided herein, Licensee will indemnify, hold harmless, and defend Akebia and its Affiliates and their respective directors, officers, employees, and agents (the "**Akebia Indemnitees**") from and against any and all Losses, to the extent that such Losses arise out of (a) a breach of this Agreement by Licensee, (b) [***], in each case, of a Licensed Product by or on behalf of Licensee, the Sub-Distributor, or the FMC Group (including any communications regarding the Licensed Product by Licensee, the Sub-Distributor, or the FMC Group), or (c) the negligence or willful misconduct of any Licensee Indemnitee. Notwithstanding the foregoing, Licensee will not have any obligation to indemnify the Akebia Indemnitees (i) to the extent that any Losses arise out of the negligence or willful misconduct of any Akebia Indemnitee or any breach of this Agreement by Akebia, or (ii) for any [***] of any Licensed Product, other than any [***] of any Licensed Product by or on behalf of Licensee, the Sub-Distributor, or the FMC Group.

15.3. **Indemnification Procedure**. Each Party, if seeking indemnification under this Article 15 (Indemnification) (the "**Indemnified Party**"), will give [***] written notice of the claim to the other Party (the "**Indemnifying Party**"); *provided*, *however*, that any failure or delay in

providing such notice will not relieve the Indemnifying Party of its indemnification obligation, except to the extent it is actually prejudiced by such failure or delay. Each Party will promptly furnish to the other Party copies of all papers and official documents received in respect of any Losses. The Indemnifying Party will have the right, exercisable by written notice to the Indemnified Party, to assume and control the defense of the indemnification claim at its own expense with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; *provided*, *however*, that an Indemnified Party will have the right to retain its own counsel, at its own expense, except that the fees and expenses of the Indemnified Party's counsel will be paid by the Indemnifying Party if representation of such Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual or potential differing interests between the Indemnified Party and any other party represented by such counsel in such proceedings. If the Indemnifying Party does not assume the defense of the indemnification claim as described in this Section 15.3 (Indemnification Procedure), then the Indemnified Party may defend the indemnification claim but will have no obligation to do so. The Indemnified Party will not settle or compromise the indemnification claim without the prior written consent of the Indemnifying Party, and the Indemnifying Party will not settle or compromise the indemnification claim in any manner that would have an adverse effect on the Indemnified Party's interests (including any rights under this Agreement or the scope or enforceability of any Patents, Confidential Information, or other rights licensed to Licensee by Akebia hereunder), without the prior written consent of the Indemnified Party, which consent, in each case (by the Indemnifying Party or Indemnified Party, as the case may be), will not be unreasonably withheld or delayed. The Indemnified Party will reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense and will make available to the Indemnifying Party all pertinent information under the control of the Indemnified Party, which information will be subject to Article 14 (Confidentiality). The Indemnifying Party will provide periodic updates to the Indemnified Party (and its counsel, if applicable) regarding its defense of the action with immediate notice regarding any material developments. The Indemnifying Party will not be liable for any settlement or other disposition of Losses by the Indemnified Party if such settlement is reached without the written consent of the Indemnifying Party pursuant to this Section 15.3 (Indemnification Procedure).

15.4. **Insurance**. Akebia and Licensee will each, at their own expense, obtain and maintain insurance with respect to the use and sale of the Licensed Products under this Agreement in such amount and subject to such deductibles and other limitations as biopharmaceutical companies in the Territory customarily maintain with respect to the use and sale of similar products. Each Party will provide a copy of such insurance policy to the other Party upon request.

Article 16

TERM AND TERMINATION

16.1. **Term**. The term of this Agreement will begin on the Effective Date and, unless earlier terminated in accordance with the terms of this Article 16 (Term and Termination), will extend until the later of (a) expiration of the last-to-expire Valid Claim [***] that would, but for the licenses granted hereunder, be infringed by the making, using, selling, or importing of such Licensed Product in the Territory, or (b) expiration of marketing or regulatory exclusivity in the Territory (the "**Term**").

16.2. **Termination for Breach**. Subject to the terms and conditions of this Section 16.2 (Termination for Breach), a Party (the "**Non-Breaching Party**") will have the right, in addition to any other rights and remedies, to terminate this Agreement in its entirety in the event the other Party (the

"**Breaching Party**") is in material breach of any of its obligations under this Agreement. The Non-Breaching Party will first provide written notice to the Breaching Party, which notice will identify with particularity the alleged breach and state the Non-Breaching Party's intent to terminate this Agreement if such breach is not cured. With respect to material breaches of any payment provision hereunder, the Breaching Party will have a period of [***] after such written notice is provided to cure such breach. With respect to all other breaches, the Breaching Party will have a period of [***] after the Non-Breaching Party provides written notice to cure such breach. Notwithstanding the foregoing, if a Non-Breaching Party provides notice to the Breaching Party pursuant to this Section 16.2 (Termination for Breach) of an alleged material breach by such Breaching Party, and such Non-Breaching Party provides notice during the applicable cure period set forth above that such Non-Breaching Party disputes the basis for termination pursuant to this Section 16.2 (Termination for Breach) and initiates the dispute resolution procedure set forth in Article 17 (Dispute Resolution; Governing Law) during the applicable cure period, then the cure periods set forth in this Section 16.2 (Termination for Breach) for the alleged material breach will run from the date that such written notice is first provided to the Breaching Party through the resolution of such dispute pursuant to Article 17 (Dispute Resolution; Governing Law) and it is understood and acknowledged that, during the pendency of a dispute pursuant this Section 16.2 (Termination for Breach), all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement. The waiver by either Party of any breach of any term or condition of this Agreement will not be deemed a waiver as to any subsequent or similar breach.

16.3. **Termination for Bankruptcy**. Subject to the terms and conditions of this Agreement, either Party may terminate this Agreement upon notice to the other Party should the other Party: (a) consent to the appointment of a receiver or a general assignment for the benefit of creditors of the other Party that is not discharged within [***], or (b) file a petition under any bankruptcy or insolvency law or have any such petition filed against it that has not been stayed within [***] of such filing.

16.4. **Termination by Akebia for Unauthorized Sales**. If the Parties do not reach a resolution of the applicable matter during the [***] period as set forth under Section 4.1 (No Unauthorized Sales), or Licensee does not (a) [***] any unauthorized use, distribution, or transfer of the Licensed Compound or any Licensed Product by Licensee, FKC, its Sub-Distributor, or any Authorized Dialysis Center to or by a Third Party that is not an FMCNA Dialysis Patient or Authorized Dialysis Center, or (b) [***] of any Sub-Distributor or Authorized Dialysis Center that is using, distributing, or transferring the Licensed Compound or any Licensed Product other than as expressly permitted under this Agreement, in each case ((a) and (b)), then Akebia may terminate this Agreement with immediate effect upon written notice to Licensee.

16.5. **Termination by Akebia Upon Occurrence of Certain Events**. If any of the following events occur, then, Akebia may terminate this Agreement with immediate effect upon written notice to Licensee:

16.5.1 Licensee or its Affiliate involved in the supply or distribution of any Licensed Product becomes an Affiliate of FMC or any member of the FMC Group; or

16.5.2 There is no affiliation or other strategic relationship between Licensee or its Affiliate involved in the supply or distribution of any Licensed Product and FMC.

16.6. **Termination by Akebia for Failure to Enter into or Amend the Licensee-FMC Distribution Agreement**. Akebia may terminate this Agreement with immediate effect upon written notice to

Licensee if (a) Licensee does not enter into the Licensee-FKC Supply Agreement with FKC in accordance with Section 5.1.1 (Licensee-FKC Supply Agreement) within [***] after the Execution Date, (b) Licensee does not enter into an amendment of the Licensee-FKC Supply Agreement with FKC in accordance with Section 5.1.2 (Licensee-FKC Supply Agreement) within [***] after (i) the FDA has granted Regulatory Approval for a Licensed Product in the DD-CKD Indication in the Territory, and (ii) such Licensed Product is determined by CMS to be in a Medicare Bundled Dialysis Treatment, or (c) the Licensee-FKC Supply Agreement is terminated or expires.

16.7. **Termination by Akebia for Impacts on Pricing**. If (a) there has been a breach of Section 6.1 (Pricing), (b) through the actions by or on behalf of Licensee or any of its Affiliates or members of the FMC Group (even if pursuant to FMC Group's customary dialysis clinic cost reporting to CMS or any other Governmental Authority, and even if such actions do not constitute a breach by Licensee under Section 4.4.2 (Licensed Product Prices)), any Third Party purchaser or potential purchaser (other than each Party's Affiliates or any member of the FMC Group) becomes aware of the price at which Licensee or any of its Affiliates or members of the FMC Group acquired any Licensed Product, or the price at which such entity sells any Licensed Product to any purchaser (even if pursuant to FMC Group's customary dialysis clinic cost reporting to CMS or any other Governmental Authority), (c) [***], or (d) Licensee or any of its Affiliates or any member of the FMC Group sells, or plans to sell, in each case, any Licensed Product in any manner that [***], and, in each case ((a) through (d)), the Parties do not reach an agreeable resolution within [***] after Akebia notifies Licensee of its intent to terminate based on such condition, then, in either case, Akebia may terminate this Agreement with immediate effect upon written notice to Licensee.

16.8. **Termination by Akebia for Net Sales Levels**. Commencing on the [***] of First Commercial Sale of a Licensed Product in the Territory, Akebia may terminate this Agreement with immediate effect upon written notice to Licensee within the time period stated herein if the aggregate Net Sales of all Licensed Products during any [***] period is less than or equal to [***]% of the FMC Group's [***] during the preceding [***] period. To exercise the foregoing termination right, Akebia must provide such notice of termination to Licensee no later than [***] after Akebia's receipt of the Quarterly Report that documents that the aggregate Net Sales of all Licensed Products in the preceding [***] is less than or equal to [***]% of the FMC Group's total spending (amounts paid to manufacturers or wholesalers) for all [***] during such [***] period and, absent such timely notice, [***].

16.9. **Termination by Akebia for Patent Challenge**. Akebia may terminate this Agreement with immediate effect upon written notice to Licensee if Licensee or any of its Affiliates contests the validity or enforceability of any Patent Controlled by Akebia or any of its Affiliates that Covers a Licensed Product or its manufacture, use, sale, or importation, in any court, arbitration proceeding, or other tribunal, including the United States Patent and Trademark Office and the United States International Trade Commission. As used in this definition, the term "contest" includes (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patent; (b) filing, or joining in, a petition under 35 U.S.C. § 311 to institute *inter partes* review of any such Patent; (c) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patent or any portion thereof; (d) filing or commencing any opposition, nullity, or similar proceedings challenging the validity of any such Patent in any country, or (e) any foreign equivalent of clauses (a), (b), (c), or (d).

16.10. **Termination by Licensee for Convenience**. At any time after release of the topline data from the Global Phase 3 DD-CKD Program, Licensee may terminate this Agreement in its entirety by

providing written notice to Akebia thereof, which termination will be effective 12 months following the date of such notice; *provided*, *however*, that such 12-month notice period may be shortened by written agreement of both Akebia and Licensee.

16.11. Termination Based on Written Agreement of the Parties. This Agreement may be terminated in its entirety upon the written agreement of both Akebia and Licensee.

16.12. Effects of Termination. In the event of any expiration or termination of this Agreement, the following will apply:

16.12.1 Termination of Licenses. Except as expressly set forth in this Section 16.12 (Effects of Termination), and subject to Section 16.14 (Survival; Accrued Rights), all rights and licenses granted to Licensee under this Agreement will automatically terminate.

16.12.2 Return of Confidential Information. Licensee will cease using the Akebia Technology and will return to Akebia all copies of any documents containing any Akebia Know-How. Each Party will return or destroy all Confidential Information of the other Party in its possession upon expiration or termination of this Agreement at the disclosing Party's election and written request. The Recipient will provide a written confirmation of such destruction within [***] of such request; *provided*, *however*, that the foregoing will not apply to any Confidential Information that is necessary to allow such Party to perform its obligations or exercise any of its rights that expressly survive the termination or expiration of this Agreement, *provided*, *further*, that [***].

16.12.1 Cessation of Sales. Except for sales made in accordance with Section 16.12.2(a)(i) (Termination Other than for Cause by Akebia), Licensee will cease all sales of Licensed Product in the Territory.

16.12.2 Sell-Off or Buy-Back.

(a) Termination Other than for Cause by Akebia. If this Agreement is terminated by Licensee pursuant to Section 16.3 (Termination for Bankruptcy), or Section 16.11 (Termination Based on Written Agreement of the Parties), then, after the effective date of such termination: (i) Licensee and FKC may continue to sell the Licensed Product for a period of [***] after the effective date of such termination in order to fill existing binding orders and commitments, and (ii) following such [***] period, at Akebia's option and in its sole discretion, [***] for such Licensed Products by Licensee or its Affiliates. Licensee will destroy, or cause to be destroyed, all Licensed Products remaining in inventory that [***] following such [***] period, at Licensee's cost and expense.

(b) Termination for Cause by Akebia. If this Agreement is terminated by Akebia pursuant to Section 16.2 (Termination for Breach), Section 16.4 (Termination by Akebia for Unauthorized Sales), Section 16.5 (Termination by Akebia Upon Occurrence of Certain Events), Section 16.6 (Termination by Akebia for Failure to Enter into or Amend the Licensee-FKC Distribution Agreement), Section 16.7 (Termination by Akebia for Impacts on Pricing), Section 16.8 (Termination by Akebia for Net Sales Levels), Section 16.9 (Termination by Akebia for Patent Challenge), or Section 16.10 (Termination by Licensee for Convenience), then, after the effective date of such termination, at Akebia's option in its sole discretion, [***] for such Licensed Products by Licensee or its Affiliates.

Licensee will destroy, or cause to be destroyed, all Licensed Products remaining in inventory as of the effective date of termination that [***], at Licensee's cost and expense.

16.13. **Additional Effect of Termination for Net Sales Levels**. If Akebia terminates this Agreement pursuant to Section 16.8 (Termination by Akebia for Net Sales Levels), then, in addition to the effects of termination set forth in Section 16.12 (Effects of Termination), upon Akebia's request (in its sole discretion) Akebia [***] effective upon the date of such termination.

16.14. **Survival; Accrued Rights**. The following Articles and Sections of this Agreement will survive expiration or early termination for any reason: Section 9.1 (Trademark Responsibility), Section 9.3 (Trademark Ownership and cooperation), Section 11.3 (Sales Reports), but only with respect to Net Sales made during the Term, Section 11.4 (Accounting), Section 11.5 (Method of Payment), Section 11.6 (Late Payments), Section 13.7 (Limitation of Liability), Section 14 (Confidentiality), Section 15 (Indemnification), other than Section 15.4 (Insurance), Section 16.12 (Effects of Termination), Section 16.13 (Additional Effects of Termination for Net Sales Levels), Section 16.14 (Survival; Accrued Rights), Section 17 (Dispute Resolution; Governing Law), and Section 18 (Miscellaneous). In any event, expiration or termination of this Agreement will not relieve the Parties of any liability that accrued hereunder prior to the effective date of such termination (including Licensee's obligation to pay Akebia pursuant to Article 11 (Payments) with respect to sales made prior to termination or expiration), nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

Article 17

DISPUTE RESOLUTION; GOVERNING LAW

17.1. **Executive Officers**. Unless otherwise set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties, the Parties will refer such dispute to their respective chief executive officers, and such chief executive officers will attempt in good faith to resolve such dispute.

17.2. **Litigation**. Any unresolved dispute which was subject to Section 17.1 (Executive Officers) must be brought exclusively in a court of competent jurisdiction, federal or state, located in the State of New York, and in no other jurisdiction. Each Party hereby consents to personal jurisdiction and venue in, and agrees to service of process issued or authorized by, such court.

17.3. **Jurisdiction**. Each Party to this Agreement, by its execution hereof, (a) hereby irrevocably submits to the exclusive jurisdiction of the United States District Court for the Southern District of New York and state courts located in New York, New York for the purpose of any and all unresolved disputes which were subject to Section 17.1 (Executive Officers), (b) hereby waives to the extent not prohibited by Applicable Law, and agrees not to assert, by way of motion, as a defense or otherwise, in any such action, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that any such action brought in one of the above-named courts in such jurisdiction should be dismissed on grounds of *forum non conveniens*, should be transferred to any court other than one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such court, and (c) hereby agrees not to

commence any such action other than before one of the above-named courts nor to make any motion or take any other action seeking or intending to cause the transfer or removal of any such action to any court other than one of the above-named courts whether on the grounds of inconvenient forum or otherwise. Notwithstanding the foregoing, application may be made to any court of competent jurisdiction with respect to the enforcement of any judgment or award.

17.4. **Governing Law**. This Agreement will be governed by and construed in accordance with the laws of the State of New York, without reference to conflict of law principles.

17.5. **Injunctive Relief**. Notwithstanding the foregoing, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance, or other injunctive relief) in any court or other forum, without first submitting to the dispute resolution procedures set forth in Section 17.1 (Executive Officers).

Article 18

MISCELLANEOUS

18.1. **Assignment**. Neither Party may assign this Agreement and the licenses herein granted without the other Party's prior written consent unless such assignment is in writing to (a) a Third Party successor or purchaser of all or substantially all of the assets or businesses to which this Agreement relates whether pursuant to a sale of assets, merger, or other transaction, in which case the assigning Party will provide prior written notice to the other Party and need not obtain the other Party's consent, or (b) an Affiliate of such Party; *provided that* the permitted assignee must assume all obligations of the assigning Party under the Agreement in writing and the assigning Party will remain fully liable for the performance of its obligations hereunder by such permitted assignee. In addition, and notwithstanding the foregoing, Akebia may assign its right to receive payments under this Agreement as part of a royalty factoring or other similar transaction undertaken for *bona fide* financing purposes. Any other assignment of this Agreement by a Party requires the prior written consent of the other Party. Any assignment in violation of this Section 18.1 (Assignment) will be null, void, and of no legal effect. This Agreement will be binding on and will inure to the benefit of the permitted successors and assigns of the Parties.

18.2. **Standstill**. Except in connection with the acquisition of shares by Licensee pursuant to the terms of the Investment Agreement dated as of the Effective Date by and between the Parties, Licensee will not, without the written consent of Akebia, acquire directly or indirectly, in a public or private transaction, including by purchase in the open market, any common stock of Akebia if the Licensee's beneficial ownership of the common stock of Akebia would thereafter exceed [***]%. In addition, unless approved in advance in writing by Akebia, Licensee will not, directly or indirectly:

(a) Make any statement or proposal to Akebia, other than a non-public statement or proposal delivered directly to the chief executive officer or chairman of the board of directors, or to any of Akebia's stockholders regarding, or make any public announcement, proposal, or offer (including a "solicitation" of "proxies" as such terms are defined or used in Regulation 14A of the Exchange Act) with respect to, or otherwise solicit, seek, or offer to effect (including, for the avoidance of doubt, indirectly by means of communication with the press or media) (i) any business combination, merger, tender offer, exchange offer, or similar transaction involving Akebia, (ii) any restructuring, recapitalization, liquidation, or similar transaction involving Akebia, (iii) any acquisition of any of Akebia's equity

securities or assets or rights or options to acquire equity securities or assets, (iv) any proposal to seek representation on the board of directors of Akebia or otherwise seek to control or influence the management, board of directors, or policies of Akebia, or (v) any proposal, arrangement, or other statement that is inconsistent with this Section 18.2 (Standstill);

(b) Instigate, encourage, or assist any Third Party (including forming a "group" with any such Third Party) to do, or enter into any discussions or agreements with any Third Party with respect to, any of the actions set forth in Section 18.2 (Standstill); or

(c) Take any action that would reasonably be expected to require Akebia or any of its Affiliates to make a public announcement regarding any of the actions set forth in Section 18.2 (Standstill).

Notwithstanding the foregoing provisions, the restrictions set forth in this Section 18.2 (Standstill) will terminate and be of no further force and effect (a) [***], *provided that* the provisions of this Section 18.2 (Standstill) will be revived if such [***]; or (b) upon the expiration or termination of this Agreement. For the avoidance of doubt, nothing in this Section 18.2 (Standstill) will prohibit Licensee from acquiring beneficial ownership of the common stock of Akebia to the extent such ownership remains less than [***]% of Akebia's total outstanding common stock. For purposes of this Section 18.2 (Standstill), "**Sale Transaction**" means a transaction between Akebia and a Third Party (i) involving the direct or indirect acquisition by such Third Party of [***]% or more of Akebia's outstanding shares of common stock or consolidated assets (including assets held by subsidiaries), *excluding* a transaction in which (A) [***], or (B) [***], or (ii) involving the sale of substantially all of Akebia's rights with respect to the Licensed Product.

18.3. **Force Majeure**. If either Party will be delayed, interrupted in, or prevented from the performance of any obligation hereunder by reason of any cause beyond its reasonable control, including an act of God, fire, flood, earthquake, war (declared or undeclared), public disaster, act of terrorism, or strikes (other than strikes of a Party's own employees), then such Party will not be liable to the other therefor; and the time for performance of such obligation will be extended for a period equal to the duration of the force majeure that occasioned the delay, interruption, or prevention. The Party invoking such force majeure rights of this Section 18.3 (Force Majeure) must notify the other Party by courier or overnight dispatch (*e.g.*, Federal Express) no later than 30 days after each of the first and last day of the force majeure unless the force majeure renders such notification impossible, in which case notification will be made as soon as possible. If the delay resulting from the force majeure exceeds three months, then the Party not affected by the force majeure will have the right to terminate this Agreement forthwith pursuant to Section 16.2 (Termination for Breach) with the consequences set out in Section 16.12 (Effects of Termination), as if the Party affected by the force majeure were in material breach of this Agreement.

18.4. **Entire Agreement**. This Agreement, together with exhibits and schedules attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter hereof (including that certain Confidential Disclosure Agreement between the Parties dated [***], as amended by Amendment No. 1 dated [***]) and will not be modified, amended, or terminated, except as herein provided or except by another agreement in writing executed by the Parties.

18.5. **Severability**. If any provision of this Agreement is declared invalid by a court of last resort or by any court or other governmental body from the decision of which an appeal is not taken within the time provided by law, then and in such event, this Agreement will be deemed to have been terminated only as to the portion thereof that relates to the provision invalidated by that decision and only in the relevant jurisdiction, but this Agreement, in all other respects and all other jurisdictions, will remain in force; *provided*, *however*, that if the provision so invalidated is essential to the Agreement as a whole, then the Parties will negotiate in good faith to amend the terms hereof as nearly as practical to carry out the original intent of the Parties, and, failing to agree to such amendment, then either Party may submit the matter for resolution pursuant to Article 17 (Dispute Resolution; Governing Law).

18.6. **Notices**. Any notice or report required or permitted to be given under this Agreement will be in writing and will be mailed by internationally recognized express delivery service, or sent by email or facsimile and confirmed by mailing, as follows:

If to Akebia:

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142
Attention: Chief Executive Officer
Facsimile: [***]
Email: [***]

With copies to (which will not constitute notice for purposes of this Agreement):

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142
Attention: General Counsel
Facsimile: [***]
Email: [***]

and

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attention: [***]
Facsimile: [***]
Email: [***]

If to Licensee:

Vifor Pharma Ltd.
Flughofstrasse 61, 8152 Glattbrugg, Switzerland
Attention: [***]
Facsimile: [***]
Email: [***]

With a copy to (which will not constitute notice for purposes of this Agreement):

Vifor Pharma
Flughofstrasse 61, 8152 Glattbrugg, Switzerland
Facsimile: [***]
Attention: [***]
Email: [***]

18.7. **Further Assurances**. The Parties agree to reasonably cooperate with each other in connection with any actions required to be taken as part of their respective obligations under this Agreement, and will (a) furnish to each other such further information; (b) execute and deliver to each other such other documents; and (c) do such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

18.8. **Agency**. Neither Party is, nor will be deemed to be an employee, agent, or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party will have the authority to speak for, represent, or obligate the other Party in any way without prior written authorization from the other Party.

18.9. **No Waiver**. Any omission or delay by either Party at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants, or provisions hereof, by the other Party, will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement. Any waiver by a Party of a particular breach or default by the other Party will not operate or be construed as a waiver of any subsequent breach or default by the other Party.

18.10. **Interpretation**. (a) Whenever any provision of this Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" and "including but not limited to" (or "includes without limitations" and "includes but is not limited to") regardless of whether the words "without limitation" or "but not limited to" actually follow the term "including" (or "includes"); (b) "herein," "hereby," "hereunder," "hereof," and other equivalent words will refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used; (c) all definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural; (d) wherever used herein, any pronoun or pronouns will be deemed to include both the singular and plural and to cover all genders; (e) the recitals set forth at the start of this Agreement, along with the schedules and exhibits to this Agreement, and the terms and conditions incorporated in such recitals and schedules and exhibits will be deemed integral parts of this Agreement and all references in this Agreement to this Agreement will encompass such recitals and schedules and exhibits and the terms and conditions incorporated in such recitals and schedules and exhibits; *provided that* in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions set forth in the recitals, schedules, or exhibits, the terms of this Agreement will control; (f) in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement, or otherwise, the terms and conditions of this Agreement will govern; (g) this Agreement will be construed as if both Parties drafted it jointly, and will not be construed against either Party as principal drafter; (h) unless otherwise provided, all references to Sections, Articles, and Schedules in this Agreement are to Sections, Articles, and Schedules of and to this Agreement; (i) any reference to any federal, national, state, local, or foreign statute or law will be deemed to also refer to all rules and regulations promulgated thereunder, unless the context

requires otherwise; (j) wherever used, the word "shall" and the word "will" are each understood to be imperative or mandatory in nature and are interchangeable with one another; (k) the word "or" will not be exclusive; (l) references to a particular person include such person's successors and assigns to the extent not prohibited by this Agreement; and (m) the section headings and captions used herein are inserted for convenience of reference only and will not be construed to create obligations, benefits, or limitations.

18.11. **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

18.12. **Counterparts**. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. This Agreement may be executed by facsimile, .pdf, or other electronically transmitted signatures and such signatures will be deemed to bind each Party hereto as if they were the original signatures.

[Remainder of page intentionally left blank, signature page follows.]

IN WITNESS WHEREOF, the Parties have executed this Agreement through their duly authorized representatives to be effective as of the Execution Date.

AKEBIA THERAPEUTICS, INC.	VIFOR (INTERNATIONAL) LTD.
By: /s/ John P. Butler	By: /s/ Christoph Springer
Name: John P. Butler	Name: Dr. Christoph Springer
Title: President & Chief Executive Officer	Title: Global Head of Business Development
AKEBIA THERAPEUTICS, INC.	VIFOR (INTERNATIONAL) LTD.
By: /s/ Jason A. Amello	By: /s/ Dr. Oliver P. Kronenberg
Name: Jason A. Amello	Name: Dr. Oliver P. Kronenberg
Title: SVP, Chief Financial Officer	Title: Group General Counsel

Schedule 1.7

Akebia Patents

[***]

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

Schedule 1.9

Akebia Trademarks

[***]

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

Schedule 1.46

Executive Leadership Teams

Akebia

[***]

Licensee

[***]

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

Schedule 5.4

Authorized Dialysis Centers

[***]

[***] **Portions of this exhibit have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John P. Butler, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akebia Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2017

By: /s/ John P. Butler
John P. Butler
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jason A. Amello, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akebia Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2017

By: /s/ Jason A. Amello
Jason A. Amello
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. Section 1350

In connection with the accompanying Quarterly Report of Akebia Therapeutics, Inc. (the Company) on Form 10-Q for the fiscal quarter ended June 30, 2017 (the Report), I, John P. Butler, as Chief Executive Officer and President of the Company, and I, Jason A. Amello, as Senior Vice President, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2017

By: /s/ John P. Butler
John P. Butler
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 8, 2017

By: /s/ Jason A. Amello
Jason A. Amello
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 99.1

Akebia Therapeutics, Inc.
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www.akebia.com

Akebia Announces Second Quarter 2017 Financial Results

CAMBRIDGE, MA, August 8, 2017 -- Akebia Therapeutics, Inc. (NASDAQ:AKBA), a biopharmaceutical company focused on delivering innovative therapies to patients with kidney disease through the biology of hypoxia-inducible factor (HIF), today announced financial results for the second quarter ended June 30, 2017.

"Akebia continues to maximize the potential of vadadustat through value-enhancing deals and executing on our clinical development program," said John P. Butler, President and Chief Executive Officer of Akebia. "Our agreement with Vifor Pharma establishes vadadustat as its exclusive HIF product for distribution to Fresenius Medical Care, the largest kidney dialysis provider in the U.S., following FDA approval. In addition, we initiated our Phase 2 FO2RWARD study in patients with renal anemia who are hyporesponsive to erythropoiesis-stimulating agents, and plan to start our Phase 3 TRILO2GY trial in the second half of the year to confirm previous positive results of vadadustat administered on a three-times-weekly basis. Topline data from both of these studies are expected by the end of 2018, followed by results from our global Phase 3 program for vadadustat."

Mr. Butler added, "Substantial financial commitments from our collaborators, together with our existing cash, position Akebia well in advance of multiple value-creating events anticipated over the next 12-18 months, including filing an IND for AKB-5169, our HIF product candidate for inflammatory bowel disease, in the first half of next year."

Second Quarter 2017 and Recent Corporate Highlights

- Entered into an exclusive license agreement with Vifor Pharma to sell vadadustat as its only HIF product for distribution to Fresenius Medical Care in the U.S., a kidney dialysis provider serving approximately 40% of dialysis patients, following approval of vadadustat by the U.S. Food and Drug Administration (FDA). The profit-sharing arrangement is based on inclusion of vadadustat in a bundled reimbursement model, which will generate a $20 million payment to Akebia from Vifor Pharma. Separately, Vifor Pharma made a $50 million equity investment in Akebia;

- Dosed the first patient in the randomized, open-label Phase 2 FO2RWARD study of vadadustat in dialysis-dependent chronic kidney disease patients who are hyporesponsive to erythropoiesis-stimulating agents (ESAs). Akebia expects to report data from FO2RWARD by the end of 2018;

- Prevailed in two additional European Patent disputes in which the Opposition Division of the European Patent Office revoked another FibroGen, Inc. HIF-related patent in Europe, and

another of their patents was significantly narrowed to cover only an indication for which Akebia is not intending to develop vadadustat;

- Appointed Rita Jain, M.D. as Senior Vice President and Chief Medical Officer to lead the global development program for vadadustat and the clinical development of Akebia's growing HIF pipeline;

- Raised approximately $67 million through an underwritten public offering of common stock and full exercise of the underwriters' option to purchase additional shares; and

- Otsuka Pharmaceutical Co. Ltd. waived its option, in advance of its expiration, to convert its U.S. arrangement with Akebia from a profit share to a right to receive royalties.

Financial Results
Akebia reported a net loss of ($21.5) million, or ($0.53) per share, for the second quarter of 2017 as compared to a net loss for the second quarter of 2016 of ($35.8) million or ($0.95) per share.

Collaboration revenue was $28.5 million for the second quarter of 2017, which related to the Company's agreements with Otsuka. Collaboration revenue in connection with Akebia's agreement with Mitsubishi Tanabe Pharma Corporation is expected to commence in the second half of 2017.

Research and development expenses were $43.8 million for the second quarter of 2017 compared to $30.9 million for the second quarter of 2016. The increase is primarily attributable to external costs related to the global PRO2TECT and INNO2VATE Phase 3 programs, as well as the FO2RWARD and TRILO2GY studies. Research and development expenses were further increased by headcount and compensation-related costs.

General and administrative expenses were $6.9 million for the second quarter of 2017 compared to $5.3 million for the second quarter of 2016. The increase is primarily attributable to an increase in costs to support the Company's research and development programs, including headcount and compensation-related costs and associated facility costs.

Akebia ended the second quarter of 2017 with cash, cash equivalents and marketable securities of $321.2 million, which included a $50.0 million equity investment from Vifor Pharma. In July 2017, the Company raised approximately $67.0 million from a follow-on offering. The Company's collaborators have committed up to $373.0 million or more in license and cost-share funding, which Akebia continues to receive on a quarterly prepaid basis. Akebia expects existing cash resources, including net proceeds from the July 2017 follow-on offering and the timing of committed research and development funding from its collaborators to fund the Company's current operating plan into the second quarter of 2019. Thereafter, committed research and development funding will continue to be received from Otsuka on a prepaid, quarterly basis.

About Akebia Therapeutics
Akebia Therapeutics, Inc. is a biopharmaceutical company headquartered in Cambridge, Massachusetts, focused on delivering innovative therapies to patients with kidney disease through hypoxia-inducible factor biology. Akebia's lead product candidate, vadadustat, is an oral, investigational therapy in development for the treatment of anemia related to chronic kidney disease in both non-dialysis and dialysis patients. Akebia's global Phase 3 program for vadadustat, which includes the PRO2TECT studies for non-dialysis patients with anemia secondary to chronic kidney

disease and the INNO2VATE studies for dialysis-dependent patients, is currently ongoing. In addition, the Company has initiated the Phase 2 FO2RWARD study of vadadustat in dialysis-dependent chronic kidney disease patients who are hyporesponsive to erythropoiesis-stimulating agents (ESAs), and expects to commence the Phase 3 TRILO2GY study to further evaluate a three-times-weekly dosing regimen for vadadustat. For more information, please visit our website at www.akebia.com.

Forward-Looking Statements

This press release includes forward-looking statements. Such forward-looking statements include those about Akebia's strategy, future plans and prospects, including statements regarding the potential commercialization of vadadustat if approved by regulatory authorities, the potential indications and benefits of vadadustat and Akebia's other product candidates, the expected timing of clinical studies, the timing of the potential submission of an IND for AKB-5169, anticipated financial contributions from Otsuka and Mitsubishi Tanabe Pharma Corporation under Akebia's collaboration agreements, and the expected timing and use of Akebia's existing cash resources. The words "anticipate," "appear," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the actual funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the actual costs incurred in the clinical studies of vadadustat and the availability of financing to cover such costs; early termination of Akebia's collaboration or license agreements; Akebia's ability to satisfy its obligations under its collaboration or license agreements; the timing and content of decisions made by the FDA and other regulatory authorities; the timing of any additional studies initiated by Akebia or its collaborators for vadadustat; the rate of enrollment in clinical studies of vadadustat; the actual time it takes to initiate and complete research and clinical studies; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for vadadustat and its other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-Q for quarter ended June 30, 2017, and other filings that Akebia may make with the Securities and Exchange Commission in the future. Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

Akebia contact:
Theresa McNeely
SVP, Corporate Communications and Investor Relations
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Tables Follow

AKEBIA THERAPEUTICS, INC
Consolidated Statements of Operations
(in thousands except share and per share data)
(unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Collaboration revenue	$ 28,520	$ —	$ 49,385	$ —
Operating expenses:				
Research and development	43,751	30,877	103,800	51,112
General and administrative	6,905	5,311	12,693	11,122
Total operating expenses	50,656	36,188	116,493	62,234
Operating loss	(22,136)	(36,188)	(67,108)	(62,234)
Other income, net	618	409	1,048	657
Net loss	$ (21,518)	$ (35,779)	$ (66,060)	$ (61,577)
Net loss per share - basic and diluted	$ (0.53)	$ (0.95)	$ (1.66)	$ (1.65)
Weighted-average number of common shares - basic and diluted	40,819,957	37,811,056	39,795,282	37,342,324

AKEBIA THERAPEUTICS, INC.
Selected Balance Sheet Data
(in thousands)
(unaudited)

	June 30, 2017	December 31, 2016
Cash, cash equivalents and available for sale securities	$ 321,215	$ 260,343
Working capital	150,798	182,053
Total assets	336,822	300,216
Total stockholders' equity	56,998	68,120

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