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 March 31, 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 April 30, 2017**
Common Stock, $0.00001 par value	**38,863,238**

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 AKB-6899;
- enrollment in the PRO$_2$TECT and INNO$_2$VATE clinical programs;
- our development program for vadadustat in Japan and Europe;
- our anticipated funding from our collaborations;
- our development plans with respect to vadadustat and our other product candidates;
- the timing or likelihood of regulatory filings and approvals, including any required post-marketing testing or any labeling and 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)

	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 87,250	$ 187,335
Available for sale securities	164,555	73,008
Unbilled receivable	—	33,823
Prepaid expenses and other current assets	3,248	2,155
Total current assets	255,053	296,321
Property and equipment, net	2,904	2,612
Other assets	1,299	1,283
Total assets	$ 259,256	$ 300,216
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 15,083	$ 2,039
Accrued expenses	34,272	30,261
Short-term deferred revenue	84,108	81,968
Total current liabilities	133,463	114,268
Deferred rent	2,835	2,480
Deferred revenue, net of current portion	92,315	115,321
Other non-current liabilities	26	27
Total liabilities	228,639	232,096
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock $0.00001 par value, 25,000,000 shares authorized at March 31, 2017 and December 31, 2016; 0 shares issued and outstanding at March 31, 2017 and December 31, 2016	—	—
Common stock: $0.00001 par value; 175,000,000 shares authorized at March 31, 2017 and December 31, 2016; 38,829,562 and 38,615,709 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	—	—
Additional paid-in capital	372,475	365,298
Accumulated other comprehensive loss	(179)	(42)
Accumulated deficit	(341,679)	(297,136)
Total stockholders' equity	30,617	68,120
Total liabilities and stockholders' equity	$ 259,256	$ 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 March 31,	
	2017	**2016**
Collaboration revenue	$ 20,865	$ —
Operating expenses:		
Research and development	60,049	20,235
General and administrative	5,788	5,811
Total operating expenses	65,837	26,046
Operating loss	(44,972)	(26,046)
Other income (expense):		
Interest income	435	234
Other income	(6)	14
Net loss	$ (44,543)	$ (25,798)
Net loss per share - basic and diluted	$ (1.15)	$ (0.70)
Weighted-average number of common shares - basic and diluted	38,759,221	36,873,594
Comprehensive loss:		
Net loss	$ (44,543)	$ (25,798)
Other comprehensive loss - unrealized loss on securities	(179)	(26)
Comprehensive loss	$ (44,722)	$ (25,824)

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

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

	Three months ended	
	March 31, 2017	**March 31, 2016**
Operating activities:		
Net loss	$ (44,543)	$ (25,798)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	135	32
Amortization of premium/discount on investments	191	144
Stock-based compensation - equity awards	2,016	1,251
Stock-based compensation - warrants	3,413	—
Changes in operating assets and liabilities:		
Unbilled receivable	33,823	—
Prepaid expenses and other current assets	(1,093)	58
Other long-term assets	(1)	—
Accounts payable	13,044	102
Accrued expense	3,998	1,457
Deferred revenue	(20,866)	40,000
Deferred rent	355	188
Net cash provided by operating activities	(9,528)	17,434
Investing activities:		
Purchase of equipment	(427)	(109)
Proceeds from the maturities of available for sale securities	24,490	15,314
Purchase of available for sale securities	(116,366)	(100,160)
Net cash used in investing activities	(92,303)	(84,955)
Financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	1,555	61,166
Proceeds from the sale of stock under employee stock purchase plan	125	—
Proceeds from the exercise of stock options	68	19
Payments on capital lease obligations	(2)	(3)
Net cash provided by financing activities	1,746	61,182
Decrease in cash and cash equivalents	(100,085)	(6,339)
Cash and cash equivalents at beginning of the period	187,335	49,778
Cash and cash equivalents at end of the period	$ 87,250	$ 43,439
Non-cash financing activities		
Unpaid follow-on offering costs	$ 10	$ 20

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, 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 $251.8 million at March 31, 2017, together with the committed funding from its collaboration partners, including $73.0 million received from Otsuka Pharmaceutical Company, Ltd., or Otsuka, in April 2017 (see Note 3 and Note 13), will be sufficient to allow the Company to fund its current operating plan into the first quarter of 2019, and as a result, through at least twelve months from the filing of the Company's 2017 first 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).

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.

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. This ASU simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and

classification on the statement of cash flows. The following summarizes the effects of the adoption on the Company's unaudited condensed consolidated financial statements:

- *Income taxes* - Upon adoption of this standard, all excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payment awards) are recognized as income tax expense or benefit in the income statement. The tax effects of exercised or vested awards are treated as discrete items in the reporting period in which they occur. The Company also recognizes excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. The Company has applied the modified retrospective adoption approach beginning in Fiscal Year 2017 and prior periods have not been adjusted. As a result, the Company will establish a net operating loss deferred tax asset of $0.4 million to account for prior period excess tax benefits through retained earnings, however an offsetting valuation allowance of $0.4 million will also be established through retained earnings because it is not more likely than not that the deferred tax asset will be realized due to historical and expected future losses, such that there is no impact on the Company’s condensed consolidated financial statements.
- *Forfeitures* - 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. As the Company previously estimated forfeitures to determine stock-based compensation expense, this change resulted in a cumulative-effect adjustment as of January 1, 2017 to reduce retained earnings by $0.2 million.
- *Earnings Per Share* - The Company uses the treasury stock method to compute diluted earnings per share, unless the effect would be anti-dilutive. Under this method, the Company will no longer be required to estimate the tax rate and apply it to the dilutive share calculation for determining the dilutive earnings per share. The Company has applied this methodology beginning in Fiscal Year 2017, and prior periods have not been adjusted.

Upon adoption, no other aspects of ASU 2016-09 had a material effect on the Company's unaudited condensed consolidated financial statements or related footnote disclosures.

In January 2017, the FASB issued an ASU 2017-01, *Business Combinations* (Topic 805) Clarifying the Definition of a Business. The amendments in this Update clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Update may be adopted early. The Company adopted the provisions of ASC 2017-01 effective January 1, 2017. Adoption did not have a material impact on the Company's financial position, results of operations, or cash flows.

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. These arrangements contain multiple-elements and have been accounted for pursuant to ASC 605-25. As of March 31, 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 two 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 March 31, 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 March 31, 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 its collaboration arrangement with Otsuka. The terms of this arrangement 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 this arrangement include: (i) up-front fee, (ii) payments for development services and (iii) payments based on the achievement of certain milestones. Also, 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 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 Topic 605-25, *Revenue Recognition Multiple-Element Arrangements* (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 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 March 31, 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 March 31, 2017 and December 31, 2016.

	Useful Life	March 31, 2017	December 31, 2016
		(in thousands)	
Computer equipment and software	3	$ 485	$ 476
Furniture and fixtures	5	769	729
Equipment	7	69	50
Leasehold improvements	Shorter of the useful life or remaining lease term (10 years)	2,123	1,763
Office equipment under capital lease	3	36	36
		3,482	3,054
Less accumulated depreciation		(578)	(442)
Net property and equipment		$ 2,904	$ 2,612

Depreciation expense, including expense associated with assets under capital leases, was approximately $0.1 million and $32,000 for the three months ended March 31, 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 to an additional $60.0 million of development costs (Global Scenario).

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. Alternatively, the Company and MTPC may collectively decide, as provided in the MTPC Agreement, to pursue the Local Scenario prior to such determination by the PMDA.

If Japanese patients are not included in the Phase 3 program (Local Scenario), MTPC will be responsible for the costs of local development in Japan and 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 expects, if under the Local Scenario, to apply the $20.0 million against the Phase 2 costs already incurred, and for MTPC to reimburse the Company for costs in excess of $20.0 million to complete the studies.

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 March 31, 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, 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, unless the Company and MTPC otherwise decide to pursue the Local Scenario prior to such consultation with the PMDA. 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 Company. 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 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 that are necessary through the filing of an NDA, including the ongoing PRO$_2$TECT program and the ongoing INNO$_2$VATE program, as well as other derivative and ancillary 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. The Company retains control over and

responsibility for the manufacturing and supply of vadadustat during development. 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 Agreement are governed by a joint steering committee (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, oversee 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 (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 (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 $106.2 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 with drug development, 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 has 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). Upon Otsuka's exercise of the Royalty Conversion Option, the licenses granted to Otsuka will terminate and the parties will cease joint participation in the collaboration. Effective immediately upon the exercise of the Royalty Conversion Option, the Company will be solely responsible for all future development, manufacturing, medical affairs and commercialization and non-promotional activities. Royalties that would be payable to Otsuka upon the exercise of the Royalty Conversion Option are subject to reduction upon the date on which vadadustat ceases to have exclusivity. Royalties would be due on a product-by-product and country-by-country basis from the date of the first commercial sale of vadadustat in such country until the fifth anniversary of the date on which the licensed product ceases to have exclusivity.

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 if the other party has materially breached its obligations under the agreement and, after receiving written notice identifying such material breach in reasonable detail, the breaching party fails to cure such material breach. 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. If Otsuka exercises the Royalty Conversion Option and the Company subsequently exercises its right to buy-back the royalty obligation, then the Otsuka Agreement will automatically terminate in its entirety. 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, 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 reimbursement to Otsuka.

Revenue Recognition

The Company evaluated the elements of the License 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 R&D Development Services Deliverable), (iii) rights to future intellectual property and (iv) joint committee services.

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 License Agreement does not include a general right of return. Accordingly, each of the other deliverables included in the Otsuka arrangement qualifies as a separate unit of accounting. Therefore, the Company has identified the following three units of accounting in connection with its obligations under the collaboration arrangement with Otsuka as follows:

(i) License and R&D Development Services Combined

The License Deliverable does not have standalone value separate from the R&D 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 R&D Development Services deliverable have standalone value from the Rights to Future Intellectual Property 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.

(iii) Joint Committee Services

The Joint Committee Services has standalone value from the License and R&D Services deliverables 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 Joint Committee Services has standalone value from the Rights to Future Intellectual Property 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 $106.2 million. The cost share payments to be received represent contingent revenue features because the Company's retention of the associated arrangement consideration is dependent upon its future performance of development services. 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 $265.0 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 License 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 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 months ended March 31, 2017, the Company recognized revenue totaling approximately $20.9 million with respect to the License Agreement. The revenue is classified as collaboration revenue in the accompanying consolidated statement of operations. As of March 31, 2017, there is approximately $136.4 million of deferred revenue related to the License Agreement which is classified as current or long-term in the accompanying consolidated balance sheet based on the performance period of the underlying obligations. During the three months ended March 31, 2017, the Company did not incur any costs related to the cost-sharing provisions of the License Agreement.

The Company determined that the medical affairs and commercialization and non-promotional activities elements of the License 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.

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.

4. Available for sale securities

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
March 31, 2017				
Cash and cash equivalents	$ 87,250	$ —	$ —	$ 87,250
Available for sale securities:				
Certificates of deposit	$ 17,797	—	—	$ 17,797
U.S. Government debt securities	101,619	—	(134)	101,485
Corporate debt securities	45,318	2	(47)	45,273
Total available for sale securities	$ 164,734	$ 2	$ (181)	$ 164,555
Total cash, cash equivalents, and available for sale securities	$ 251,984	$ 2	$ (181)	$ 251,805

	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 March 31, 2017, by contractual maturity, is as follows:

Due in one year or less	$ 151,848
Due after one year	12,707
Total available for sale securities	$ 164,555

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 March 31, 2017 and December 31, 2016 are summarized below:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
March 31, 2017				
Assets:				
Cash and cash equivalents	$ 87,250	$ —	$ —	$ 87,250
Certificates of deposit	—	17,797	—	17,797
U.S. Government debt securities	—	101,485	—	101,485
Corporate debt securities	—	45,273	—	45,273
	$ 87,250	$ 164,555	$ —	$ 251,805

	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 March 31, 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:

	March 31, 2017	December 31, 2016
	(in thousands)	
Accrued clinical	$ 29,582	$ 23,643
Accrued bonus	825	2,995
Professional fees	627	539
Accrued vacation	625	513
Accrued payroll	297	596
Other	2,316	1,975
Total accrued expenses	$ 34,272	$ 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 March 31, 2017, the warrant remains outstanding and expires on February 9, 2022.

8. Stockholders' Equity

Authorized and Outstanding Capital Stock

As of March 31, 2017, the authorized capital stock of the Company included 175,000,000 shares of common stock, par value $0.00001 per share, of which 38,829,562 and 38,615,709 shares are issued and outstanding at March 31, 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 March 31, 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, stock units, 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 three months of 2017, the Company granted 781,400 stock options to employees, of which 62,000 were granted under the Inducement Award program, 434,900 RSUs to employees and no 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:

	March 31, 2017	December 31, 2016
Common stock options and RSU's outstanding	4,719,995	3,579,694
Shares available for issuance under the 2014 Plan (1)	966,420	885,328
Warrant to purchase common stock	509,611	—
Shares available for issuance under the ESPP (2)	677,762	803,105
Total	6,873,788	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 $1.6 million of stock-based compensation expense related to stock options during the three months ended March 31, 2017.

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 $8,000 of stock-based compensation expense related to restricted stock during the three months ended March 31, 2017 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 $0.4 million of stock-based compensation expense related to the RSUs during the three months ended March 31, 2017.

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 of stock-based compensation expense related to ESPP during the three months ended March 31, 2017.

Compensation Expense Summary

The Company has recognized the following compensation cost related to share-based awards:

	Three months ended	
	March 31, 2017	March 31, 2016
	(in thousands)	
Research and development	$ 4,174	$ 392
General and administrative	1,255	859
Total	$ 5,429	$ 1,251

Compensation expense by type of award:

	Three months ended	
	March 31, 2017	March 31, 2016
	(in thousands)	
Stock options	$ 1,575	$ 1,128
Restricted stock	8	(14)
Restricted stock units	391	106
Employee stock purchase plan	42	31
Warrant	3,413	—
Total	$ 5,429	$ 1,251

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 March 31, 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 $256,765 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 March 31, 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 March 31, 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 March 31, 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	$ 2,659	$ 257	$ 2,402	$ 6	$ 2,408
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	$ 31,470	$ 514	$ 30,956	11	$ 30,967
Less amount representing interest				—	
Present value of minimum lease payments at March 31, 2017				$ 11	

The Company recorded approximately $0.8 million and $0.4 million in rent expense for the three months ended March 31, 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_2TECT and $INNO_2$VATE programs, the total remaining contract costs as of March 31, 2017 were approximately $367.2 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 $20.6 million and $24.9 million at March 31, 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.

In September 2015, a purported securities class action lawsuit was filed against the Company, including its Chief Executive Officer, its Chief Financial Officer, and members of the Company's Board of Directors, in the Business Litigation Section of the Suffolk County Superior Court of Massachusetts. The complaint is brought on behalf of an alleged class of those who purchased common stock of the Company pursuant or traceable to the Company's initial public offering, and purports to allege claims arising under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended. The complaint generally alleges that the defendants violated the federal securities laws by, among other things, making material misstatements or omissions concerning the Phase 2b clinical study of vadadustat. The complaint seeks, among other relief, unspecified compensatory damages, rescission of certain stock purchases, attorneys' fees, and costs. In October 2015, the Company removed the case to the United States District Court for the District of Massachusetts, and the plaintiff filed a motion to remand the case back to the Business Litigation Section of the Suffolk County Superior Court of Massachusetts. The plaintiff's motion to remand was granted in April 2016. The plaintiff filed an amended complaint in the Suffolk County Superior Court on August 15, 2016, and the Company served a memorandum in support of its motion to dismiss the amended complaint on October 14, 2016. The motion to dismiss hearing was held on January 31, 2017. The Court granted the Company's motion to dismiss and dismissed the case with prejudice on February 21, 2017. The plaintiff did not appeal the decision.

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.

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. 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. 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. While, for the reasons set forth in our oppositions, the Company believes that the '153 patent and the '155 patent should be revoked in their entirety, the ultimate outcomes of the oppositions remains uncertain. If the European Patent Office decides not to revoke the '153 patent or the '155 patent in their entirety, or only certain claims of those patents, and any surviving claims are determined to encompass the Company's intended use of the Company's lead product candidate, the Company may not be able to commercialize the Company's lead product candidate in the European Union for its intended use, which could materially adversely affect the Company's business, operating results and financial condition.

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 $0.1 million were made during the three months ended March 31, 2017 and 2016.

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	
	March 31, 2017	March 31, 2016
Warrants	509,611	—
Outstanding stock options	3,857,607	2,706,718
Unvested restricted stock	43,041	189,273
Unvested restricted stock units	862,388	405,363
Total	5,272,647	3,301,354

13. Subsequent Event

In April 2017, the Company entered into a Collaboration and License Agreement with Otsuka, the Otsuka EU Agreement, pursuant to which the Company granted Otsuka an exclusive license for the development and commercialization of vadadustat. The territory covered by the Agreement includes the European Union, Russia, China, Australia, Canada, the Middle East and certain other countries, but excludes Latin America and other previously licensed countries. Under the Agreement, Otsuka will be responsible for certain development activities and commercializing vadadustat in the territory, while the Company will continue to lead the ongoing global Phase 3 development program. Otsuka will fund a significant percentage of the costs of such global development program regardless of the total actual costs ultimately incurred. This Agreement follows the previously announced Otsuka U.S. Agreement.

Under the terms of the Agreement, Akebia expects Otsuka to pay the Company at least $208.0 million, comprised of $73.0 million upon execution of the Agreement and at least $135.0 million of development funding. In addition, the Company is eligible to receive from Otsuka up to an aggregate of $657.0 million in development and commercial milestones. Otsuka also agreed to make tiered, escalating royalty payments ranging from low double digits up to thirty percent of net sales of vadadustat within the territory. In limited circumstances, upper tier royalties may be subject to reduction if the supply price charged by the Company to Otsuka for vadadustat exceeds certain agreed upon thresholds. Otsuka may elect to conduct additional studies of vadadustat in the European Union, 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 collaboration will be governed by joint committees and operational teams, leveraging the governance structure established in the Otsuka U.S. Agreement. The Company will retain final decision making authority with respect to the manufacture and supply of vadadustat in the Territory, the global Phase 3 development program, and the global brand strategy for vadadustat. Otsuka will have final decision making authority with respect to certain territory-specific development activities and commercialization matters in the territory.

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, 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 approximately 5,700 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 have recently instituted a cap on enrollment in the PRO$_2$TECT program which could bring the full MACE program enrollment to 6,300. We expect the cost of the Phase 3 program to be in the range of $80,000 to $85,000 per patient, aggregating in the range of $504.0 million to $535.5 million in external CRO costs for the total program. We plan to initiate a Phase 3 study 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. We currently anticipate submitting marketing applications for the treatment of anemia associated with CKD in the United States and Europe in 2019.

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 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 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, such as AKB-6899, as well as in-licensed product candidates, such as AKB-5169. AKB-6899 has demonstrated a robust hemoglobin response in early preclinical studies, and we plan to further investigate its potential in multiple preclinical models of anemia and assess next steps based on these data. In February 2017, we signed an agreement with Janssen Pharmaceutica NV, or Janssen, 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 (IBD) and we intend to complete further preclinical development with the goal of an Investigational New Drug application with 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 $44.5 million and $25.8 million for the three months ended March 31, 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;
- 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 future 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 March 2017 we have raised approximately $255.7 million of net proceeds including $230.0 million from three underwritten public offerings, including $61.0 million of net proceeds raised in January 2016 whereby we sold 7,250,000 shares of common stock at a price of $9.00 per share and $25.7 million of net proceeds in an at-the-market offering, or ATM, pursuant to a Sales Agreement with Cantor Fitzgerald & Co.

Financial Overview

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 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, collaboration revenue in the current period is generated exclusively from our collaboration arrangement with Otsuka. The terms of this arrangement 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 R&D Services Deliverable), (iii) rights to future intellectual property and (iv) joint committee services. We have identified three units of accounting in connection with our obligations under the collaboration agreement with Otsuka as follows: (i) License Unit of Accounting, which combines the License Deliverable and the R&D 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, 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-6899, 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-6899, 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 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 March 31, 2017, we have incurred $291.9 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-6899 and 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 two 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 $5.4 million and $1.3 million for the three months ended March 31, 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 March 31, 2017 and 2016

	Three months ended		Increase
	March 31, 2017	March 31, 2016	(Decrease)
	(In Thousands)		
Collaboration revenue	$ 20,865	$ —	$ 20,865
Operating expenses:			
Research and development	60,049	20,235	39,814
General and administrative	5,788	5,811	(23)
Total operating expenses	65,837	26,046	39,791
Loss from operations	(44,972)	(26,046)	18,926
Other income, net	429	248	181
Net loss	$ (44,543)	$ (25,798)	$ 18,745

Collaboration Revenue. Collaboration revenue was $20.9 million for the three months ended March 31, 2017 under our agreement with Otsuka. We did not recognize any collaboration revenue in the three month period ended March 31, 2016.

Research and Development Expenses. Research and development expenses were $60.0 million for the three months ended March 31, 2017, compared to $20.2 million for the three months ended March 31, 2016, an increase of $39.8 million. The increase was primarily due to the following:

	(in millions)
Vadadustat development	$ 32,434
Regulatory activities and other clinical and non-clinical	1,097
Manufacture of drug substance	(561)
Total increase related to the continued development of vadadustat	32,970
Fair value of warrant issued in connection with Janssen Agreement	3,413
Headcount, consulting and facilities	1,802
License fee in connection with Janssen Agreement	1,000
Other	629
Total net increase	$ 39,814

The increase in the costs related to the development of vadadustat is primarily attributable to external costs related to the PRO_2TECT and $INNO_2VATE$ Phase 3 program. The increase in headcount, consulting and facility related costs is primarily due to additional headcount and consulting costs to support the Phase 3 programs as well as rent associated with our leasing of additional office and lab space to support our additional headcount. 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 $5.8 million for the three months ended March 31, 2017 and March 31, 2016. General and administrative expenses are materially consistent period over period. 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 $0.4 million for the three months ended March 31, 2017 and $0.2 million for the three months ended March 31, 2016. Other income, net for the three months ended March 31, 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 March 31, 2017, we had an accumulated deficit of $341.7 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 equity offerings and payments received from our collaboration partners. As of March 31, 2017, we had cash and cash equivalents and available for sale securities of approximately $251.8 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:

	Three months ended	
	March 31, 2017	**March 31, 2016**
	(In Thousands)	
Net cash provided by (used in):		
Operating activities	$ (9,528)	$ 17,434
Investing activities	(92,303)	(84,955)
Financing activities	1,746	61,182
Net increase in cash and cash equivalents	$ (100,085)	$ (6,339)

Operating Activities. The net cash used in operating activities was $9.5 million for the three months ended March 31, 2017 consisted primarily of a net loss of $44.5 million adjusted for non-cash items, including stock-based compensation expense of $5.4 million, amortization of premium/discount on investments of $0.2 million, depreciation and amortization of $0.1 million and a net increase in operating assets and liabilities of $29.3 million. The significant items in the change in operating assets and liabilities include an increase 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 $17.0 million and an increase of $0.4 million in deferred rent partially offset by a decrease of approximately $20.9 million in deferred revenue and $1.1 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 provided by operating activities was $17.4 million for the three months ended March 31, 2016 and consisted primarily of a net loss of $25.8 million adjusted for non-cash items, including stock-based compensation expense of $1.3 million and amortization of premium/discount on investments of $0.1 million and a net increase in operating assets and liabilities of $41.8 million. The significant items in the change in operating assets and liabilities include an increase in deferred revenue of $40.0 million and an increase in accounts payable, accrued expenses and other liabilities of approximately $1.7 million. The increase in accounts payable, accrued expenses and other liabilities is primarily driven by accrued clinical and non-clinical study costs associated with vadadustat and AKB-6899.

Investing Activities. Net cash used in investing activities for the three months ended March 31, 2017 was $92.3 million and was comprised primarily of purchases of available for sale securities of $116.4 million and purchases of equipment of $0.4 million, offset by proceeds from the maturities of available for sale securities of $24.5 million.

Net cash used in investing activities for the three months ended March 31, 2016 was $85.0 million and was comprised primarily of purchases of available for sale securities of $100.2 million and purchases of equipment of $0.1 million, offset by proceeds from the maturities of available for sale securities of $15.3 million.

Financing Activities. Net cash provided by financing activities for the three months ended March 31, 2017 was $1.7 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 three months ended March 31, 2016 was $61.2 million and consisted primarily of net proceeds from the issuance of common stock in connection with our follow-on public offering.

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 first quarter of 2017 with cash, cash equivalents and available for sale securities of $251.8 million. The Company is also entitled to receive $373.0 million or more in committed capital from collaborators, which is expected to be received over the course of the global development program for vadadustat, of which $73.0 million was received in April 2017 in connection with the expanded collaboration with Otsuka. Based on the timing of payments from collaborators, the Company expects its existing and committed cash resources to fund the Company's current operating plan into the first quarter of 2019. However the remaining committed research and development funding will continue to be received from Otsuka on a prepaid, quarterly basis up to an estimated aggregate of $60.0 million.

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 March 31, 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 March 31, 2017 and December 31, 2016, we had cash and cash equivalents and available-for-sale securities of $251.8 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 March 31, 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. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of March 31, 2017, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended March 31, 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

Item 1. Legal Proceedings

Shareholder Litigation

In September 2015, a purported securities class action lawsuit was filed against us, including our Chief Executive Officer, our Chief Financial Officer, and members of our Board of Directors, in the Business Litigation Section of the Suffolk County Superior Court of Massachusetts. The complaint is brought on behalf of an alleged class of those who purchased our common stock pursuant or traceable to our initial public offering, and purports to allege claims arising under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended. The complaint generally alleges that the defendants violated the federal securities laws by, among other things, making material misstatements or omissions concerning the Phase 2b clinical study of vadadustat. The complaint seeks, among other relief, unspecified compensatory damages, rescission of certain stock purchases, attorneys' fees, and costs. In October 2015, we removed the case to the United States District Court for the District of Massachusetts, and the plaintiff filed a motion to remand the case back to the Business Litigation Section of the Suffolk County Superior Court of Massachusetts. The plaintiff's motion to remand was granted in April 2016. The plaintiff filed an amended complaint in the Suffolk County Superior Court on August 15, 2016, and we served our memorandum in support of our motion to dismiss the amended complaint on October 14, 2016. The motion to dismiss hearing was held on January 31, 2017. The Court granted our motion to dismiss and dismissed the case with prejudice on February 21, 2017. The plaintiff did not appeal.

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.

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. 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. 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. While, for the reasons set forth in our oppositions, we believe that the '153 patent and the '155 patent should be revoked in their entirety, the ultimate outcomes of the oppositions remains uncertain. If the European Patent Office decides not to revoke the '153 patent or the '155 patent in their entirety, or only certain claims of those patents, and any surviving claims are determined to encompass our intended use of our lead product candidate, we may not be able to commercialize our lead product candidate in the European Union for its intended use, which could materially adversely affect our business, operating results and financial condition.

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 $44.5 million for the three months ended March 31, 2017, and $25.8 million for the three months ended March 31, 2016. As of March 31, 2017, we had an accumulated deficit of $341.7 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 Phase 3 development program of vadadustat for the treatment of anemia secondary to CKD, including the PRO_2TECT and $INNO_2VATE$ programs;
- develop plans for the preclinical and clinical development of AKB-5169 and AKB-6899;
- 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-6899, 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 March 31, 2017, our cash and cash equivalents and available for sale securities were $251.8 million. We believe that we will continue to expend substantial resources for the foreseeable future developing vadadustat, AKB-6899, 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 cost of the Phase 3 program to be in the range of $80,000 to $85,000 per patient and the PRO_2TECT and $INNO_2$VATE Phase 3 programs are designed to enroll up to approximately 6,300 CKD patients, aggregating in the range of $504.0 million to $535.5 million in external CRO costs for the total program; 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;
- if Japanese subjects are not included in either $INNO_2$VATE or PRO_2TECT, the amount of development funding received from our collaboration partner, Mitsubishi Tanabe Pharma Corporation, or MTPC, could differ materially;
- 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-6899, 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-6899, AKB-5169 and other product candidates that we may develop or acquire, if clinical studies are successful;
- 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 first quarter of 2017 with cash, cash equivalents and available for sale securities of $251.8 million. We are also entitled to receive $373.0 million or more in committed capital from collaborators, which is expected to be received over the course of the global development program for vadadustat, of which $73.0 million was received in April 2017 in connection with the expanded collaboration with Otsuka. Based on the timing of payments from collaborators, the company expects existing and committed cash resources to fund the company's current operating plan into the first quarter of 2019. However, the remaining committed research and development funding will continue to be received from Otsuka on a prepaid, quarterly basis up to an estimated aggregate of $60.0 million. 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-6899, 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 good clinical practice, or GCP, or good manufacturing practice, or GMP, 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 will be responsible for the costs of the local Phase 3 study in Japan and 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 expects, if under the Local Scenario, to apply the $20.0 million against the Phase 2 costs already incurred, and for MTPC to 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 Data Safety Monitoring Board, or DSMB, 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 REMS 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 $INNO_2$VATE 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 expect to 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$_2$TECT clinical program. 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. Also, if we choose to engage a second source for the manufacture of drug product, we may 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.

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 contractual 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 if, for example, development or approval of a product is delayed or sales of an approved product are disappointing.

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 will likely negotiate 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-6899, 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 products 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 DaVita, Fresenius or other operators of 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.

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 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. The U.K. Bribery Act similarly prohibits bribery but applies to well being of private citizens as well;
- 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 (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 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 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 has been filed against us. 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 March 31, 2017, in connection with the Janssen Agreement, we issued a warrant to purchase 509,611 shares of common stock pursuant to Rule 506 promulgated under the Securities Act. We did not receive cash proceeds in connection with the warrant issuance.

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 May 9, 2017, Akebia announced its financial results for the quarter ended March 31, 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#	Common Stock Purchase Warrant between Akebia Therapeutics, Inc. and Janssen Pharmaceutica NV, dated February 9, 2017.
10.1#	Research and License Agreement between Akebia Therapeutics, Inc. and Janssen Pharmaceutica NV, dated February 9, 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 May 9, 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: May 9, 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: May 9, 2017

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

Date: May 9, 2017

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

CONFIDENTIAL

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS.

COMMON STOCK PURCHASE WARRANT
AKEBIA THERAPEUTICS, INC.

Warrant Shares: 509,611

Initial Issuance Date: February 9, 2017

THIS COMMON STOCK PURCHASE WARRANT (this "**Warrant**") certifies that Johnson & Johnson Innovation -- JJDC, Inc. or its assigns (the "**Holder**") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "**Initial Issuance Date**") and on or prior to the close of business on the fifth anniversary of the Initial Issuance Date (the "**Termination Date**") but not thereafter, to subscribe for and purchase from Akebia Therapeutics, Inc., a Delaware corporation (the "**Company**"), up to 509,611 shares (as subject to adjustment hereunder, the "**Warrant Shares**") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). The Company and the Holder are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

Section 1. **Definitions**. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"**Affiliate**" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"**Board of Directors**" means the board of directors of the Company.

"**Business Day**" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the Commonwealth of Massachusetts are authorized or required by law or other governmental action to close.

"**Commission**" means the United States Securities and Exchange Commission.

"**Common Stock**" means (i) the Company's shares of Common Stock, par value $0.00001 per share, and (ii) any share capital into which such Common Stock shall have been changed or any share capital resulting from a reclassification of such Common Stock.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

[***] 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.

"**Executive Officer**" means, with respect to the Holder, its President and, with respect to the Company, any of its Chief Executive Officer, Chief Financial Officer, Chief Business Officer or General Counsel.

"**Person**" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"**Trading Day**" means a day on which the Common Stock is traded on a Trading Market.

"**Trading Market**" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE MKT, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

"**Transfer Agent**" means American Stock Transfer & Trust Company, LLC, the current transfer agent of the Company, with a mailing address of 6201 15th Avenue, Brooklyn, NY 11219, and any successor transfer agent of the Company.

Section 2. **Exercise**.

(a) Exercise. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Issuance Date and on or before the Termination Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of the Notice of Exercise in the form annexed hereto. Within [***] following the date on which the Holder delivers a Notice of Exercise to the Company, the Holder shall deliver to the Company an amount equal to the product of (x) the Exercise Price multiplied by (y) the number of Warrant Shares specified in the applicable Notice of Exercise for such Warrant Shares by wire transfer to the account specified by the Company unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and this Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within [***] Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within [***] of receipt of such notice. **The Holder and any assignee, by its acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

(b) Exercise Price. The exercise price per share of the Common Stock under this Warrant shall be $9.81, subject to adjustment hereunder (the "Exercise Price").

(c) Cashless Exercise. This Warrant may also be exercised, in whole or in part, at any time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = the last VWAP immediately preceding the time of delivery of the Notice of Exercise giving rise to the applicable "cashless exercise", as set forth in the applicable Notice of Exercise (to clarify, the "last VWAP" will be the last VWAP as calculated over an entire Trading Day such that, in the event that this Warrant is exercised at a time that the Trading Market is open, the prior Trading Day's VWAP shall be used in this calculation);

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

"**VWAP**" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is then listed or quoted for trading and neither OTCQB nor OTCQX is a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX, as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

Notwithstanding anything herein to the contrary, on the Termination Date, if the VWAP is greater than the Exercise Price, this Warrant shall be automatically exercised with respect to any and all outstanding Warrant Shares via cashless exercise pursuant to this Section 2(c).

(d) Mechanics of Exercise.

(i) Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("**DWAC**") if the Company is then a participant in such system and there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder, and otherwise by book entry form, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is [***] Trading Days after the later of (i) the delivery to the Company of the Notice of

Exercise or (ii) payment to the Company of the aggregate exercise price (other than in the case of a cashless exercise) (such date, the "**Warrant Share Delivery Date**"). Upon (a) delivery of the Notice of Exercise and (b) payment to the Company of the aggregate Exercise Price (other than in the case of a cashless exercise), the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable.

(ii) Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical to this Warrant, except for the number of unpurchased Warrant Shares remaining available under the new Warrant.

(iii) No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole Warrant Share.

(iv) Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. For the avoidance of doubt, the Holder will be responsible for its own income tax, if any, that may become due upon the exercise of the Warrant. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

(v) Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

Section 3. **Certain Adjustments**.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the

numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after (x) the record date for the determination of stockholders entitled to receive such dividend or distribution or (y) the effective date in the case of a subdivision, combination or re-classification.

(b) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person following which the holders of 50% or more of the outstanding Common Stock immediately prior to such transaction own less than a majority of the outstanding stock of the surviving entity, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and such offer has been accepted by the holders of at least 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "**Fundamental Transaction**"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, the cash or property it would have been entitled to receive as a result of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of a share of Common Stock immediately prior to such Fundamental Transaction (the "**Alternate Consideration**"). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction.

The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "**Successor Entity**") to assume all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(b) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder prior to such Fundamental Transaction (such approval not to be unreasonably withheld, delayed or conditioned) and shall, at the

option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "**Company**" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

(c) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(d) Notice to Holder.

(i) Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

(ii) Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered at least [***] calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the

delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. **Restrictions on Transfer of Warrant**.

(a) Restricted Securities. This Warrant and the Warrant Shares purchasable hereunder constitute "restricted securities" under federal and state securities laws inasmach as they are, or will be, acquired from the Company in transactions not involving a public offering and accordingly may not, under such laws and applicable regulations, be resold or transferred without registration under the Securities Act, or an applicable exemption from such registration; provided, however, that, for the sake of clarity, the Holder shall have the right to transfer this Warrant, in whole or in part, to an Affiliate of the Holder pursuant to a transfer in which the Holder receives no consideration. A securities legend to the foregoing effect shall be placed on any Warrant Shares issued to the Holder upon exercise of this Warrant, which legend shall be removed by the Company if such Warrant Shares are registered under the Securities Act.

(b) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "**Warrant Register**"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. **Compliance with the Securities Act**.

(a) Agreement to Comply with the Securities Act. The Holder, by acceptance of this Warrant, agrees to comply in all respects with the provisions of this Section 5 and the restrictive legend requirements set forth on the face of this Warrant and further agrees not to offer, sell or otherwise dispose of this Warrant or any Warrant Shares to be issued upon exercise hereof except under circumstances that will not result in a violation of the Securities Act.

(b) Representations of the Holder. In connection with the issuance of this Warrant, the Holder represents, as of the date hereof, to the Company by acceptance of this Warrant as follows:

(i) The Holder is an "accredited investor" as defined in Rule 501(a) of Regulation D promulgated under the Securities Act. The Holder is acquiring this Warrant and the Warrant Shares to be issued upon exercise thereof for investment for its own account and not with a view towards, or for resale in connection with, the public sale or distribution of this Warrant or the Warrant Shares, except pursuant to sales registered or exempted under the Securities Act.

(ii) The Holder understands and acknowledges that this Warrant and the Warrant Shares to be issued upon exercise thereof are "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 and applicable regulations, such securities may be resold without registration under the Securities Act on in certain limited circumstances. In addition, the Holder represents that it is familiar with Rule 144 under the Securities Act, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act.

(iii) The Holder acknowledges that it can bear the economic and financial risk of its investment for an indefinite period, and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in this Warrant and the Warrant Shares. The Holder has had the opportunity to ask questions and receive answers from the Company regarding the terms and conditions of this Warrant and the business, properties, prospects and financial condition of the Company.

Section 6. **Miscellaneous**.

(a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i).

(b) Loss, Theft, Destruction or Mutilation. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which shall not include the posting of any bond), and upon surrender and cancellation of such Warrant, if mutilated, the Company will make and deliver a new Warrant of like tenor and dated as of such cancellation, in lieu of such Warrant.

(c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

(d) Authorized Shares.

The Company covenants that, during the period this Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of executing stock certificates to execute and issue the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to

such increase in par value, (ii) take all such action as may be necessary in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(e) Dispute Resolution.

(i) Disputes. If a dispute arises between the Parties relating to either Party's rights or obligations hereunder, including the interpretation, alleged breach, enforcement, termination or validity of this Warrant (a "**Dispute**"), then either Party shall have the right to refer such Dispute to the Executive Officers for attempted resolution by good faith negotiations during a period of [***] Business Days.

(ii) Mediation. If a Dispute remains unresolved after the end of the [***] Business Day negotiation period provided for in subsection (i) (Disputes), then either Party may, by notice to the other Party submit the dispute to non-binding mediation in accordance with the CPR Mediation Procedure for Business Disputes then in effect of the CPR, except where that procedure conflicts with these provisions, in which case these provisions shall prevail. The mediation shall be conducted in New York, New York and shall be attended by a senior executive with authority to resolve the dispute from each Party. The mediator shall confer with the Parties to design procedures to conclude the mediation within no more than [***] days after initiation. Under no circumstances may the commencement of arbitration be delayed more than [***] days by the mediation process specified herein except by mutual agreement of the Parties. No statements made by either Party during the mediation may be used by the other or referred to during any subsequent proceedings.

(iii) Arbitration. Any Dispute that cannot be resolved pursuant to subsection (ii) (Mediation) by mediation may be referred to and finally resolved by binding arbitration in accordance with this subsection (iii) (Arbitration) by one Party providing written notice to the other Party (an "**Arbitration Notice**"). Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three experts with relevant industry experience (the "**Arbitrators**"). Each of the Holder and Company shall promptly select one Arbitrator each, which selections shall in no event be made later than [***] days after the notice of initiation of arbitration. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by the Holder and the Arbitrator chosen by Company, but in no event later than [***] days after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery; *provided that* the Arbitrators shall permit such discovery as they deem necessary to permit an equitable resolution of the dispute. The arbitration shall be administered by the AAA in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Warrant. The arbitration shall be held in New York, New York, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The

Arbitrators shall, within [***] days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with applicable law in any court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Warrant.

(iv) Additional Terms Applicable to Dispute Resolution Procedures. Each Party shall bear its own counsel fees, costs and disbursements arising out of the dispute resolution procedures described herein, and shall pay an equal share of the fees and costs of the mediator and Arbitrators, as applicable, and all other general fees related to any mediation or arbitration described herein, as applicable. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is pending under this Warrant, the Parties shall continue to comply with all those terms and provisions of this Warrant that are not the subject of such pending arbitration proceeding. Nothing contained in this Warrant shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding.

(f) Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Warrant to the substantive law of another jurisdiction.

(g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of the Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

(h) Notices. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Warrant shall be in writing, shall refer specifically to this Warrant and shall be deemed given only if delivered by hand or sent by email or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Company or the Holder at their respective addresses specified below or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this subsection. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by email if an email address is set forth below or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by email shall be confirmed by a hard copy delivered as soon as practicable thereafter.

If to the Company, to:
Akebia Therapeutics, Inc.
245 First Street
14th Floor
Cambridge, MA 02142

[***] 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.

Attention: [***]
Email: [***]

With a copy to (which will not constitute notice):

Ropes & Gray LLP
800 Boylston Street; Prudential Tower
Boston, MA 02199
Attention: [***]
Email: [***]

If to the Holder, to:

Johnson & Johnson Innovation – JJDC, Inc.
410 George Street
New Brunswick, NJ 08901
Attention: [***]

With a copy to (which will not constitute notice):

Johnson & Johnson Law Department
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Attention: [***]

(i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

(j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

(k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of the Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

(l) Amendment and Waiver. Except as otherwise provided herein, the provisions of this Warrant may be amended or waived and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written

consent of the Holder. Any such amendment or waiver shall apply to all Warrants and be binding upon all registered holders of such Warrants.

(m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

(n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

AKEBIA THERAPEUTICS, INC.

By: /s/ Jason A. Amello
Name: Jason A. Amello
Title Senior Vice President and Chief Financial Officer

Agreed and Accepted

JOHNSON & JOHNSON INNOVATION – JJDC, INC.

By: /s/ Asish K. Xavier
Name: Asish K. Xavier
Title VP, Venture Investments

[Signature Page to Common Stock Purchase Warrant]

[***] 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.

NOTICE OF EXERCISE

TO: Akebia Therapeutics, Inc.

(1) The undersigned hereby elects to purchase Warrant Shares of the Company pursuant to the terms of the Warrant, and will tender payment of the exercise price in full together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

Cash Payment: [ ] in lawful money of the United States; or

Cashless Exercise: [ ] the cancellation of such number of Warrant Shares purchased pursuant to this Notice of Exercise as is necessary, in accordance with the formula set forth in subsection 2(c) of the Warrant, to exercise the Warrant pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares, and in the case of a Cashless Exercise net of the number of shares cancelled, in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number (if applicable):

[SIGNATURE OF HOLDER]

Name of Investing Entity:

Signature of Authorized Signatory of Investing Entity:

Name of Authorized Signatory:

Title of Authorized Signatory:

Date:

[***] 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.

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name:
(Please Print)
Address:
(Please Print)

Dated: ,

Holder's Signature:

Holder's Address:

[***] 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

RESEARCH AND LICENSE AGREEMENT

between

AKEBIA THERAPEUTICS, INC.

and

JANSSEN PHARMACEUTICA NV

Dated as of February 9, 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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SCHEDULES

RESEARCH AND LICENSE AGREEMENT

This RESEARCH AND LICENSE AGREEMENT (the "**Agreement**") is made and entered into effective as of February 9, 2017 (the "**Effective Date**"), by and between Akebia Therapeutics, Inc., a company organized and existing under the laws of the State of Delaware having a business address at 245 First Street, Suite 1100, Cambridge, MA 02142 ("**Licensee**"), and Janssen Pharmaceutica NV, a company organized and existing under the laws of Belgium having a business address at Turnhoutseweg 30, 2340 Beerse, Belgium ("**Janssen**"). Janssen and Licensee are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

Recitals

WHEREAS, Janssen owns and Controls certain intellectual property rights with respect to the Portfolio Compounds in the Territory; and

WHEREAS, Janssen wishes to grant a license to Licensee, and Licensee wishes to take, a license under such intellectual property rights to conduct research with respect to Portfolio Compounds and to develop and commercialize Licensed Compounds and Licensed Products in the Territory, in each case, in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1. "**AAA**" means the American Arbitration Association or its successor entity.

1.2. "**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" (and, with correlative meanings, the terms "controlled by" and "under common control with") means: (i) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise; or (ii) the ownership, directly or indirectly, of at least 50% of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.3. "**Agreement**" has the meaning set forth in the preamble hereto.

1.4. "**Anti-Corruption Laws**" means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

1.5. "**Applicable Law**" means applicable laws, rules and regulations, including any rules, regulations, guidelines, principles of common law, or other requirements of the Regulatory Authorities that may be in effect from time to time.

1.6. "**Arbitration Notice**" has the meaning set forth in Section 12.5.3 (Arbitration).

1.7. "**Arbitrators**" has the meaning set forth in Section 12.5.3 (Arbitration).

1.8. "**Auditor**" has the meaning set forth in Section 6.10 (Audit Dispute).

1.9. "**Back-Up Compound**" means a Designated Compound designated by Licensee as a Back-Up Compound pursuant to Section 3.5.2 (Back-Up Compounds).

1.10. "**Bundled Product**" means a Licensed Product sold in combination with one or more separate products, each in finished form, by Licensee, its Affiliates or its Sublicensees where a Third Party customer receives a discount for such "bundling" of products. A Bundled Product will not include any fixed combination of two or more active ingredients in a single finished package.

1.11. "**Business Day**" means a day other than a Saturday or Sunday or a day on which banking institutions in New York, New York are permitted or required to be closed.

1.12. "**Calendar Quarter**" means each period of three consecutive calendar months ending on March 31, June 30, September 30 or December 31.

1.13. "**Calendar Year**" means each period of 12 consecutive months commencing on January 1 and ending on December 31.

1.14. "**CDA**" has the meaning set forth in Section 12.9 (Entire Agreement; Amendments).

1.15. "**Change of Control**" means, with respect to a Person, (i) any other Person or group of Persons within the meaning of § 13(d)(3) of the Exchange Act becoming the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act), directly or indirectly, of 50% or more of the outstanding Equity Interests of such Person; or (ii) the consummation of a reorganization, merger, share exchange, consolidation or sale or disposition of all or substantially all of the assets of such Person or any parent company of such Person or any merger of any direct or indirect subsidiary of such Person unless, in any case, the beneficial owners of the Equity Interests of such Person immediately before such transaction beneficially own, directly or indirectly, immediately after such transaction, all or substantially all of the Equity Interests of such Person or any other corporation or other entity resulting from or surviving the transaction in substantially the same proportion as their respective ownership of the Equity Interests of such Person immediately before that transaction. For purposes of this definition "**Equity Interests**" means, with respect to a Person, the common equity of such Person or the voting securities of such Person entitled to vote generally in an election of directors (or similar governing persons) of such Person.

1.16. "**Combination Product**" means a Licensed Product that contains at least one Licensed Compound as an active ingredient together with one or more Other Component(s) and that is sold either as a fixed dose or as separate doses in a single package.

1.17. "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of or sale of a product, including Manufacturing in support thereof and activities related to marketing, Promoting, distributing and importing such product and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization and "**Commercialized**" has a corresponding meaning.

1.18. "**Commercially Reasonable Efforts**" means, with respect to the performance of activities by Licensee under this Agreement, the carrying out of such activities using efforts and resources comparable to the efforts and resources that a biopharmaceutical company would typically devote to the performance of similar activities or the accomplishment of similar objectives, it being understood that with respect to the research, Development or Commercialization of a Portfolio Compound or Licensed Product, such efforts and resources shall be comparable to those efforts and resources that a biopharmaceutical company would typically devote to a compound or product of similar market potential, profit potential and strategic value and at a comparable stage in development or product life to such Portfolio Compound or Licensed Product, based on conditions then prevailing and taking into account issues of safety and efficacy, product profile, difficulty in developing such Portfolio Compound or Licensed Product, competitiveness of alternative Third Party products in the marketplace, the patent or other proprietary position of such Portfolio Compound or Licensed Product, the regulatory structure involved, payments to be made under the Agreement and the potential profitability of the Licensed Product marketed or to be marketed.

1.19. "**Competing Infringement**" has the meaning set forth in Section 7.3.1 (Notification).

1.20. "**Competing Infringement Notice**" has the meaning set forth in Section 7.3.1 (Notification).

1.21. "**Compound Forms**" means, with respect to a particular compound, any pharmaceutically acceptable salt forms, free acids or bases, hydrates, anhydrides, solvates, racemates, isomers, positional isomers, radioisomers, stereoisomers, polymorphs, prodrugs, or metabolites of such compound.

1.22. "**Confidential Candidate Information**" has the meaning set forth in Section 8.1.2 (Confidential Candidate Information).

1.23. "**Confidential Information**" has the meaning set forth in Section 8.1.1 (Confidential Information).

1.24. "**Contact Person**" has the meaning set forth in Section 5.2 (Contact Persons).

1.25. "**Control**" means, with respect to any item of Information, Regulatory Documentation, Material, Patent or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the license and other grants in this Agreement), to grant a license, sublicense, option or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, Material, Patent or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.

1.26. "**Cover**," "**Covers**," or "**Covered**" means, with respect to a particular subject matter at issue and the relevant Patent, that, but for ownership of such Patent or the grant of a license in or to such Patent, the Manufacture, use, sale, offer for sale or importation of the subject matter at issue would infringe a claim of such Patent or, in the case of a Patent that is a patent application, would infringe a claim in such patent application if it were to issue as a patent, in a particular country or countries, in each case, without taking into account the validity or enforceability of any such Patent.

1.27. "**Data Package**" means, with respect to a Licensed Compound (and any Licensed Product containing such Licensed Compound), a package containing (i) [***] with respect to such Licensed Compound (or any Licensed Product containing such Licensed Compound), (ii) [***] for such Licensed

Compound (or any Licensed Product containing such Licensed Compound), (iii) [***] with respect to such Licensed Compound (or any Licensed Product containing such Licensed Compound), (iv) [***] of such Licensed Compound (or any Licensed Product containing such Licensed Compound) and (v) a schedule identifying all Patents owned or otherwise Controlled by Licensee, its Affiliates or any of its Sublicensees that claim such Licensed Compound (or any Licensed Product containing such Licensed Compound), including Patents that claim the composition of matter of or any method of using such Licensed Compound (or any Licensed Product containing such Licensed Compound).

1.28. "**Declined Compound**" means (i) any Development Candidate that is not designated as a Designated Compound by the end of the Research Term in accordance with Section 3.5 (Selection of Designated Compounds); and (ii) any Derivative made by Licensee during the Research Term that Licensee does not designate as a Designated Compound in accordance with Section 3.5 (Selection of Designated Compounds).

1.29. "**Derivative**" means a compound that Licensee (or any of its Affiliates or its Sublicensees) makes from, derives from, or bases upon any Portfolio Compound(s).

1.30. "**Designated Compound**" means (i) each [***], (ii) each other [***] that is designated by Licensee in accordance with Section 3.5 (Selection of Designated Compounds) and (iii) each [***] designated by Licensee during the Research Term in accordance with Section 3.5 (Selection of Designated Compounds).

1.31. "**Designation Criteria**" has the meaning ascribed thereto in Section 3.5.1 (Notice; Fee).

1.32. "**Designation Fee**" means the amount of [***] ($[***]).

1.33. "**Designation Notice**" has the meaning set forth in Section 3.5.1 (Notice; Fee).

1.34. "**Development**" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. When used as a verb, "**Develop**" means to engage in Development.

1.35. "**Development Candidate**" means a [***] other than a [***] (or Compound Form thereof).

1.36. "**Development Plan**" means, (i) with respect to [***], the [***] Development Plan that is attached as Schedule 3.7.1 ([***] Development Plan) and (ii) with respect to each Licensed Compound other than [***], the written plan describing (a) the [***] to be conducted by Licensee with respect thereto and (b) a [***] of such activities, as each such plan may be adopted pursuant to Section 3.5 (Selection of Designated Compounds) or Section 3.7.1 (Initial Adoption of Lead Compound Development Plans), and in each case ((i) and (ii)) as such plan may be amended or updated from time-to-time pursuant to Section 3.7.3 (Updates to Development Plans).

1.37. "**Disclosed Know-How**" has the meaning set forth in Section 4.1.1 (In General).

1.38. "**Dispute**" has the meaning set forth in Section 12.5.1 (Disputes).

1.39. "**Dollars**" or "**$**" means United States Dollars.

1.40. "**Drug Approval Application**" means a New Drug Application as defined in the FFDCA or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval.

1.41. "**Effective Date**" has the meaning set forth in the preamble hereto.

1.42. "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.43. "**European Union**" means the economic, scientific and political organization of member states as it may be constituted from time-to-time.

1.44. "**Executive Officer**" means, with respect to Janssen, either its [***] (as may be designated by Janssen from time-to-time) and with respect to Licensee, its [***].

1.45. "**Exploit**" means to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, Promote, market or have sold or otherwise dispose of.

1.46. "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.47. "**FFDCA**" means the United States 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).

1.48. "**Field**" means the treatment, prevention and diagnosis of any and all diseases and conditions in humans and animals.

1.49. "**First Commercial Sale**" means, with respect to a Licensed Product and a country, the first sale for monetary value for use or consumption by the end user of such Licensed Product in such country to a Third Party by or on behalf of Licensee or its Affiliate or any Sublicensee in such country after Regulatory Approval for such Licensed Product has been obtained in such country.

1.50. "**First Extension Fee**" has the meaning set forth in Section 3.6 (Research Term).

1.51. "**GAAP**" means United States generally accepted accounting principles ("**U.S. GAAP**"), International Financial Reporting Standards or such other similar national standards applied on a consistent basis.

1.52. "**Generic Product**" means, with respect to a Licensed Product, any pharmaceutical product that (i) [***]; (ii) [***]; and (iii) [***]. A Licensed Product licensed or produced by Licensee or any of its Affiliates or its Sublicensees (*i.e.*, an authorized generic product) will not constitute a Generic Product.

1.53. "**HIF-PH**" means hypoxia-inducible factor prolyl hydroxylase.

1.54. "**IBD**" means inflammatory bowel disease and [***].

1.55. "**IND**" means (i) an Investigational New Drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other countries or regulatory jurisdictions and (ii) all supplements and amendments that may be filed with respect to the foregoing.

1.56. "**Indemnification Claim Notice**" has the meaning set forth in Section 10.3.1 (Notice of Claim).

1.57. "**Indemnified Party**" has the meaning set forth in Section 10.3.1 (Notice of Claim).

1.58. "**Information**" means all scientific or technical information, know-how and data, including screens, assays, models, methods, test data (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information), study designs and protocols, manufacturing procedures, processes, designs, drawings, methods (including testing methods), formulas, specifications and other data related to Materials.

1.59. "**Infringement Action**" has the meaning set forth in Section 7.3.2 (Infringement Actions).

1.60. "**Initiating Party**" has the meaning set forth in Section 7.3.3 (Cooperation).

1.61. "**Initiation**" means, with respect to a clinical study, the first dosing of the first human subject in such clinical study.

1.62. "**Invented**" means invented, developed, generated, discovered, conceived, reduced to practice, created or otherwise made (with a correlative meaning for "**Invent**" and "**Invention**").

1.63. "**Janssen**" has the meaning set forth in the preamble hereto.

1.64. "**Janssen Designated Compound Confirmation**" has the meaning set forth in Section 3.5.1 (Notice; Fee).

1.65. "**Janssen Know-How**" means (i) all Information and Materials Controlled by Janssen or any of its Affiliates as of the Effective Date that are reasonably necessary or useful for (a) conducting research with respect to any [***] in accordance with this Agreement and (b) Exploiting any [***] in the Field in the Territory, but in each case ((a) and (b)), excluding any and all Information and Materials Controlled by Janssen or any of its Affiliates that was not obtained, generated or used by Janssen or any of its Affiliates with respect to the [***] prior to the Effective Date and (ii) all other (1) Information provided and (2) Materials transferred, in each case ((1) or (2)) by or on behalf of Janssen and its Affiliates to Licensee related to any [***] or [***] (or any Compound Form thereof).

1.66. "**Janssen Patents**" means (i) the Patents set forth on Schedule 1.66 (Janssen Patents) and (ii) all Patents Controlled by Janssen that Cover a Licensed Compound that directly or indirectly claim priority to any Patent set forth on Schedule 1.66 (Janssen Patents) or share common priority therewith whether filed before or after the Effective Date. For clarity, Product Patents are a subset of Janssen Patents.

1.67. **"Janssen Patent Prosecution Period"** has the meaning set forth in Section 7.2.1(i) (Janssen Rights).

1.68. "**Janssen Technology**" means the Janssen Patents and the Janssen Know-How.

1.69. "**JNJ5169**" means the compound having the structure set forth on Schedule 1.69 (JNJ5169).

1.70. "**[***] Development Plan**" means the Development Plan for [***] that is attached as Schedule 3.7.1 ([***] Development Plan) as the same may be amended or updated from time to time pursuant to Section 3.7.3 (Updates to Development Plans).

1.71. "**JNJ7414**" means the compound having the structure set forth on Schedule 1.71 (JNJ7414).

1.72. "**Joint Know-How**" means Information and Materials that are conceived, discovered, invented, created, made or reduced to practice or tangible medium jointly by at least one employee or contractor of each of the Parties or their Affiliates in the conduct of activities under this Agreement.

1.73. "**Joint Patents**" means any Patents (i) that claim Joint Know-How and (ii) naming at least one inventor with an obligation to assign such Patents to Licensee (or a Licensee Affiliate) and at least one inventor with an obligation to assign such Patent to Janssen (or a Janssen Affiliate), with inventorship determined according to U.S. patent laws.

1.74. "**Joint Review Committee**" or "**JRC**" has the meaning set forth in Section 5.1.1 (Establishment of Joint Review Committee).

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

1.76. "**Knowledge**" means the actual knowledge of Janssen personnel with knowledge of the Portfolio Compounds, with no duty of inquiry (including any duty to conduct freedom to operate analysis on any Portfolio Compound).

1.77. "**Lead Compound**" means either (i) JNJ5169 or (ii) [***], and "**Lead Compounds**" means, collectively, JNJ5169 and [***].

1.78. "**Lead Product**" has the meaning set forth in Section 6.2.3 (Lead Products).

1.79. "**Licensed Compounds**" means, individually and collectively, any Designated Compounds and Compound Forms thereof.

1.80. "**Licensed Materials**" has the meaning set forth in Section 4.1.1 (In General).

1.81. "**Licensed Product**" means any product that contains one or more [***], alone or in a [***], in any and all forms, presentations, dosages and formulations. For purposes of the sales milestone and royalty provisions of this Agreement, two or more products shall be considered the same Licensed Product if each contains or consists of the same [***] (or in the case of a [***], if such product contains the same combination of [***]), even if such products have different formulations, dosage strengths, forms or presentations.

1.82. "**Licensee**" has the meaning set forth in the preamble hereto.

1.83. "**Licensee Background Know-How**" means all Information that is owned or Controlled by Licensee or any of its Affiliates as of the Effective Date or Controlled by Licensee, or any of its Affiliates or its Sublicensees, during the Term that is reasonably necessary or useful to Exploit any Portfolio Compound, Licensed Compound or Licensed Product.

1.84. "**Licensee Background Patents**" means Patents owned or Controlled by Licensee, or any of its Affiliates as of the Effective Date or Controlled by Licensee, or any of its Affiliates or its Sublicensees, during the Term that claim Licensee Background Know-How or that is reasonably necessary or useful to Exploit any Portfolio Compound, Licensed Compound or Licensed Product.

1.85. "**Licensee Foreground Know-How**" means all Information that is necessary or useful to Exploit any Declined Compound and is Invented by Licensee or any of its Affiliates or its Sublicensees (or by Third Parties working on behalf of Licensee or its Affiliates or its Sublicensees) under or in connection with this Agreement; *provided that* in the case of Information Invented by any Sublicensee under or in connection with this Agreement, such Information shall constitute Licensee Foreground Know-How only to the extent Controlled by Licensee or any of its Affiliates; *provided*, *however*, that Licensee Foreground Know-How shall exclude Licensee Background Know-How.

1.86. "**Licensee Foreground Patents**" means all of the Patents Controlled by Licensee or any of its Affiliates or any Sublicensee that claim Licensee Foreground Know-How; *provided that* in the case of any Patent owned by any Sublicensee, such Patent shall constitute a Licensee Foreground Patent only to the extent Controlled by Licensee or any of its Affiliates; *provided*, *however*, that Licensee Foreground Patents shall exclude Licensee Background Patents.

1.87. "**Licensee Know-How**" means the Licensee Background Know-How and the Licensee Foreground Know-How.

1.88. "**Licensee Patents**" means the Licensee Background Patents and the Licensee Foreground Patents.

1.89. "**Licensee Regulatory Documentation**" has the meaning set forth in Section 3.12.1(ii) (Licensee Regulatory Documentation).

1.90. "**Licensee Technology**" means the Licensee Patents and Licensee Know-How.

1.91. "**Losses**" has the meaning set forth in Section 10.1 (Indemnification of Janssen).

1.92. "**Major Market**" means each of the [***].

1.93. "**Manufacture**" and "**Manufacturing**" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of any compound or product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.

1.94. "**Materials**" means chemical, biological or other tangible materials.

1.95. "**Mono Product**" means a Licensed Product containing as its sole active ingredient a Licensed Compound that is also contained in a Combination Product.

1.96. "**Net Sales**" means the gross amounts invoiced on sales of a Licensed Product by Licensee or any of its Affiliates or its Sublicensees (other than a Third Party Distributor) to a Third Party purchaser in an arms-length transaction (for clarity, including to a Third Party Distributor), less the following deductions, determined in accordance with U.S. GAAP and its internal policies, procedures and accounting standards, to the extent allocable to such Licensed Product under U.S. GAAP and actually taken, paid, accrued, allowed, included or allocated based on good-faith estimates in the gross sales price with respect to such sales:

1.96.1. normal and customary trade, cash and quantity discounts, allowances, deductions, fees and credits, in the form of deductions actually allowed with respect to sales of such Licensed Product (to the extent not already reflected in the amount invoiced), excluding commissions for commercialization;

1.96.2. excise taxes, use taxes, tariffs, sales taxes and customs duties and other government charges imposed on the sale of such Licensed Product to the extent separately itemized on the invoice (but specifically excluding any income taxes assessed against the income arising from such sale);

1.96.3. outbound freight, shipment and insurance costs and distribution fees paid to Third Parties that are associated with physical distribution and handling of product. For clarity, such fees exclude fees paid to such Third Parties for sales and marketing activities;

1.96.4. compulsory payments and cash rebates related to the sales of such Licensed Product paid to a governmental authority (or agent thereof) pursuant to governmental regulations, including government levied fees as a result of healthcare reform policies;

1.96.5. retroactive price reductions, credits or allowances for rejections or returns of such Licensed Product including for recalls, damaged goods and billing errors;

1.96.6. invoiced amounts from a prior period that have not been collected and have been written off by Licensee, its Affiliates or its Sublicensees (other than Third Party Distributors), including bad debts, to the extent such amounts have not been previously deducted and do not exceed, in the aggregate, 1% of Net Sales in the applicable period; *provided that* any such amounts that are written off will be added back in a subsequent period to the extent later collected; and

1.96.7. rebates, chargebacks and discounts (or the equivalent thereof) to managed health care organizations, pharmacy benefit managers (or the equivalent thereof), federal, state, provincial, local or other governments, or their agencies or purchasers, reimbursers or trade customers.

The foregoing deductions shall be based on Licensee's sales reporting system to the extent the same complies with Applicable Law. All such discounts, allowances, credits, rebates and other deductions shall be fairly and equitably allocated between such Licensed Product and other products of Licensee and its Affiliates and its Sublicensees (other than Third Party Distributors) such that such Licensed Product does not bear a disproportionate portion of such deductions. Sales of a Licensed Product by and between Licensee and its Affiliates and its Sublicensees (other than Third Party Distributors) are not sales to Third Parties and shall be excluded from Net Sales calculations for all purposes; *provided that* (i) any resale by such Affiliate or Sublicensee to a Third Party Distributor or to a Third Party for end use, shall be included in Net Sales even if such Third Party Distributor is granted a sublicense and (ii) the resale of Licensed Products by a Third Party Distributor shall be excluded from Net Sales even if such Third Party Distributor is a Sublicensee. Compassionate use, "named patient sales", sales made in connection with clinical trials and product donations shall be excluded from Net Sales calculations for all purposes.

If a Bundled Product is sold by Licensee, its Affiliates or its Sublicensees (other than Third Party Distributors), then the Net Sales of such Licensed Product, for the purposes of determining royalty and sales-based milestone payments, shall be determined on a country by country basis by multiplying the Net Sales of the Bundled Product in such country by the fraction, A/(A+B) where A is the sales-volume-weighted average sale price in that country of such Licensed Product in the previous Calendar Year when sold separately and B is the sales-volume-weighted average sale price in that country in the previous Calendar Year of the other product sold separately. In the event that such average sale price cannot be determined for either such Licensed Product or the other product in the Bundled Product, then, for purposes of determining the royalty payments due in respect of such Licensed Product, the adjustment to Net Sales shall be determined by the Parties in good faith to reasonably reflect the fair market value of the contribution of such Licensed Product in the Bundled Product to the total fair market value of such Bundled Product.

In the event a Licensed Product is a Combination Product, the Net Sales for such Combination Product shall be calculated as follows:

If Licensee, its Affiliates or its Sublicensees (other than Third Party Distributors) separately sells in such country, (a) a Mono Product and (b) products containing as their sole active ingredient the Other Component in such Combination Product, then the Net Sales attributable to such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B) where: A is Licensee's (or its Affiliate's or its Sublicensee's) average Net Sales price during the period to which the Net Sales calculation applies for the Mono Product in such country and B is Licensee's (or its Affiliate's or its Sublicensee's, as applicable) average Net Sales price during the period to which the Net Sales calculation applies in such country, for products that contain as their sole active ingredient the Other Component in such Combination Product.

If Licensee, its Affiliate or its Sublicensee (other than Third Party Distributors) separately sells in such country the Mono Product but does not separately sell in such country products containing as their sole active ingredient the Other Component in such Combination Product, then the Net Sales attributable to such Combination Product shall be calculated by multiplying the Net Sales of such Combination Product by the fraction A/C where: A is Licensee's (or its Affiliate's or its Sublicensee's) average Net Sales price during the period to which the Net Sales calculation applies for the Mono Product in such country and C is Licensee's (or its Affiliate's or its Sublicensee's) average Net Sales price in such country during the period to which the Net Sales calculation applies for such Combination Product.

If Licensee, its Affiliates and its Sublicensees (other than Third Party Distributors) do not separately sell in such country the Mono Product but do separately sell products containing as their sole active ingredient the Other Component in such Combination Product, then the Net Sales attributable to such Combination Product shall be calculated by multiplying the Net Sales of such Combination Product by the fraction (D-E)/D where: D is the average Net Sales price during the period to which the Net Sales calculation applies for such Combination Product in such country and E is the average Net Sales price during the period to which the Net Sales calculation applies for products that contain as their sole active ingredient the Other Component in such Combination Product.

If Licensee, its Affiliates and its Sublicensees (other than Third Party Distributors) do not separately sell in such country either the Mono Product or any product containing as its sole active ingredient the Other Component in such Combination Product, then the Net Sales attributable to such Combination Product shall be determined by the Parties in good faith based on the relative fair market value of such Mono Product and such Other Components.

1.97. "**Non-Initiating Party**" has the meaning set forth in Section 7.3.3 (Cooperation).

1.98. "**Non-Lead Product**" has the meaning set forth in Section 6.2.2 (Non-Lead Products).

1.99. "**Other Components**" means any other active ingredients in a Combination Product besides the Licensed Compound.

1.100. "**Party**" and "**Parties**" have the meaning set forth in the preamble hereto.

1.101. "**Patents**" means: (i) all national, regional and international patents and patent applications, including provisional patent applications; (ii) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents, innovation patents and design patents and certificates of invention; and (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((i), (ii) and (iii)).

1.102. "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.103. "**Phase 1 Clinical Trial**" means a human clinical trial for pharmacological effect of a product or that would otherwise satisfy the requirements of §21 C.F.R. 312.21(a), or an equivalent clinical trial in a country other than the United States.

1.104. "**Phase 2 Clinical Trial**" means a human clinical trial for which the primary endpoints include a determination of dose ranges or an indication of efficacy of a product in patients being studied or that otherwise is described in 21 C.F.R. §312.21(b), or an equivalent clinical trial in a country other than the United States.

1.105. "**Phase 3 Clinical Trial**" means a human clinical trial that is intended to gather the additional information about whether a product is safe and effective that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling as described in 21 C.F.R. §312.21(c), or an equivalent clinical trial in a country other than the United States.

1.106. "**POC Trial**" means the first proof of concept [***] that meets the POC Trial Criteria.

1.107. "**POC Trial Criteria**" means the criteria for the POC Trial developed by [***] and provided to the JRC for [***] pursuant to Section 3.7.2 (POC Trial Criteria Review).

1.108. "**Portfolio Compounds**" means (i) the [***], (ii) [***] or identified on Schedule 1.108 (Specified Compounds) and (iii) [***].

1.109. "**Preliminary Data Package**" means, with respect to a Licensed Compound (or any Licensed Product containing such Licensed Compound), a package containing, to the extent available based on the stage of development, [***].

1.110. "**Primary Designated Compound**" has the meaning set forth in Section 3.5.2 (Back-Up Compounds).

1.111. "**Product Patent**" means a Janssen Patent that Covers a Designated Compound, a Licensed Compound or a Licensed Product.

1.112. "**Product-Specific Third Party Agreements**" means, with respect to a Licensed Compound or Licensed Product, any agreement entered into by and between Licensee or any of its Affiliates, on the one hand, and one or more Third Parties, on the other hand, that is related to Exploiting such Licensed Compound or Licensed Product in the Field in the Territory, including (i) any agreement pursuant to which Licensee or its Affiliates receives any license or other rights to Exploit such Licensed Compound or Licensed Product, (ii) supply agreements pursuant to which Licensee or its Affiliates obtain or may obtain quantities of such Licensed Compound or Licensed Product, (iii) clinical trial agreements, (iv) contract research organization agreements and (v) other service agreements.

1.113. "**Promotion**" means the conduct of activities ordinarily undertaken by a pharmaceutical company's field sales representatives in the Territory aimed at encouraging the approved use of a pharmaceutical product. When used as a verb, "**Promoting**" means to engage in any of the foregoing activities.

1.114. "**Reduction Floor**" has the meaning set forth in Section 6.3.4 (Maximum Amount of Royalty Reduction).

1.115. "**Regulatory Approval**" means, with respect to a country in the Territory, any and all approvals (including Drug Approval Applications), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Product in such country, including, where applicable, (i) pricing or reimbursement approval in such country, (ii) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (iii) labeling approval.

1.116. "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to Development, Manufacturing, marketing, commercialization, reimbursement or pricing of a Licensed Product in the Territory, including the FDA in the United States and the EMA in the European Union.

1.117. "**Regulatory Documentation**" means: all (i) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals); (ii) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files; and (iii) clinical and other data contained or relied upon in any of the foregoing; in each case ((i), (ii) and (iii)) relating to Development Candidates, Licensed Compounds or Licensed Products.

1.118. "**Regulatory Exclusivity Period**" means, with respect to each Licensed Product in any country in the Territory, a period of exclusivity (other than Patent exclusivity) granted or afforded by Applicable Law or by a Regulatory Authority in such country that confers exclusive marketing rights with respect to such Licensed Product in such country, such as new chemical entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, non-patent related pediatric exclusivity or any other applicable marketing or data exclusivity, including any such periods listed in the FDA's Orange Book or any such periods under national implementations in the EU of Article 10 of

Directive 2001/83/ED, Article 14(11) of Parliament and Council Regulation (EC) No. 726/2004, Parliament and Council Regulation (ED) No. 141/2000 on orphan medicines, Parliament and Council Regulation (ED) No. 1901/2006 on medicinal products for pediatric use and all international equivalents of any of the foregoing.

1.119. "**Research Plan**" means the written plan describing the [***] to be conducted by Licensee with respect to [***] as described in Section 3.2 (Research Performance).

1.120. "**Research Term**" means the period commencing on the Effective Date and, unless the Agreement is earlier terminated by a Party pursuant to Article 11 (Term and Termination), ending on the later to occur of (i) the date that is three years after the Effective Date and (ii) the date that is established under Section 3.6 (Research Term) below as the end of the applicable extension period.

1.121. "**Responsible Party**" has the meaning set forth in Section 7.2.3 (Information and Cooperation).

1.122. "[***]" has the meaning set forth in Section 2.7.1 ([***] Compounds and [***] Products).

1.123. "[***] **Agreement**" has the meaning set forth in Section 2.7.4 ([***] Agreement).

1.124. "[***] **Compound**" has the meaning set forth in Section 2.7.1 ([***] Compounds and [***] Products).

1.125. "[***] **Election Notice**" has the meaning set forth in Section 2.7.3 ([***] Exercise).

1.126. "[***] **Exercise Period**" has the meaning set forth in Section 2.7.3 ([***] Exercise).

1.127. "[***] **Negotiation Period**" has the meaning set forth in Section 2.7.4 ([***] Agreement).

1.128. "[***] **Notice**" has the meaning set forth in Section 2.7.2 (Delivery of [***] Notice).

1.129. "[***] **Product**" has the meaning set forth in Section 2.7.1 ([***] Compounds and [***] Products).

1.130. "[***] **Term**" has the meaning set forth in Section 2.7.1 ([***] Compounds and [***] Products).

1.131. "**Royalty Term**" means, with respect to each Licensed Product and each country in the Territory, the period beginning on the date of the First Commercial Sale of such Licensed Product in such country and ending on the latest to occur of: (i) there ceasing to be a Valid Claim of a Janssen Patent in such country that Covers a Licensed Product or a Licensed Compound contained in such Licensed Product as a composition of matter or as a method of treatment included in the label of such Licensed Product; (ii) the expiration of Regulatory Exclusivity Period in such country for such Licensed Product; and (iii) the 10th anniversary of the First Commercial Sale of such Licensed Product in such country.

1.132. "**Second Extension Fee**" has the meaning set forth in Section 3.6 (Research Term).

1.133. "**Sublicensee**" means a Person, other than an Affiliate, that is, directly or indirectly, granted a sublicense under any of the licenses or other rights granted to Licensee in Section 2.1 (Grants to Licensee), as provided in Section 2.4 (Sublicenses).

1.134. "**Term**" has the meaning set forth in Section 11.1 (Term and Expiration).

1.135. "**Territory**" means the entire world.

1.136. "**Third Party**" means any Person other than Janssen, Licensee and their respective Affiliates.

1.137. "**Third Party Claims**" has the meaning set forth in Section 10.1 (Indemnification of Janssen).

1.138. "**Third Party Distributor**" means any Third Party appointed by Licensee or any of its Affiliates or Sublicensees to distribute, market and sell any Licensed Product, with or without packaging rights, in one or more countries in the Territory, in circumstances where such Third Party purchases its requirements of, and takes title to, Licensed Product from Licensee or its Affiliates or Sublicensees for resale but does not make any royalty or profit share payment to Licensee or its Affiliates or Sublicensees with respect to its resale of such Licensed Product.

1.139. "**Third Party License**" has the meaning set forth in Section 6.3.3 (Reductions).

1.140. "**Trademark**" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.141. "**United States**" or "**U.S.**" means the United States of America and its territories and possessions.

1.142. "**Unspecified Compounds**" means all compounds targeting [***] that are generically encompassed by the claims of, and are Covered by, the [***], but that are not (i) the [***] or (ii) [***] or identified on [***] (Specified Compounds).

1.143. "**UPC**" has the meaning set forth in Section 7.6 (EU Unitary Patent System).

1.144. "**Valid Claim**" means (i) a claim of any issued and unexpired Patent whose validity, enforceability or patentability has not been affected by (a) irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer or (b) a holding, finding or decision of invalidity, unenforceability or non-patentability by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal or (ii) a claim of a pending Patent application that was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application; *provided that* under this clause (ii) such claim has not been pending for more than five (5) years from the start of priority date, and *provided*, *further*,

if such pending claim with a pendency period of five years or longer subsequently issues, then it will be considered a Valid Claim upon issuance.

ARTICLE 2
GRANT OF RIGHTS

2.1 **Grants to Licensee**.

2.1.1 Research Term License. Subject to the terms and conditions of this Agreement, Janssen hereby grants to Licensee for the duration of the Research Term only (i) [***] license (even as to Janssen, but subject to Section 2.5 (Retention of Rights; No Other Rights Granted) and Section 2.7 ([***])) under the [***] and (ii) [***] license under the other [***], in each case ((i) and (ii)), with a right to grant sublicenses in accordance with Section 2.4 (Sublicenses), solely for Licensee to [***], and [***] in the Field in the Territory.

2.1.2 Derivatives License. Subject to the terms and conditions of this Agreement, Janssen hereby grants to Licensee for the duration of the Research Term (i) [***] license (even as to Janssen, but subject to Section 2.5 (Retention of Rights; No Other Rights Granted) and Section 2.7 ([***])) under the [***] and [***] and (ii) [***] license under the other [***], in each case ((i) and (ii)), with a right to grant sublicenses in accordance with Section 2.4 (Sublicenses), [***] and to [***] pursuant to Section 3.5 (Selection of Designated Compounds) in accordance with Section 3.4 (Derivatives).

2.1.3 Licensed Compound License. Subject to the terms and conditions of this Agreement, Janssen hereby grants to Licensee, (i) for the duration of the Term, [***] license (even as to Janssen, but subject to Section 2.5 (Retention of Rights; No Other Rights Granted) and Section 2.7 ([***])) under the [***] and (ii) [***] license under the other [***], in each case ((i) and (ii)), with a right to grant sublicenses in accordance with Section 2.4 (Sublicenses), to Exploit Licensed Compounds and Licensed Products in the Field in the Territory.

2.1.4 Declined Compound License. Subject to the terms and conditions of this Agreement, Janssen hereby grants to Licensee [***] license, without the right to grant sublicenses except to contract research organizations conducting research on behalf of Licensee, under the Janssen Technology, to use any [***] (or Compound Form thereof) solely: (i) in the [***] of the Licensed Compounds and Licensed Products; (ii) to perform its obligations under this Agreement; and (iii) [***] (including the right to use contract research organizations to conduct research on its behalf).

2.2 **Limitations to License Grant**. The licenses granted in Section 2.1 (Grants to Licensee) are subject to the following limitations:

2.2.1 in the case of any Licensed Product that is a [***], the license in Section 2.1.3 (Licensed Compound License) [***] to the extent that it Covers (in the case of Patents) or is directed to (in the case of other Janssen Technology) [***], but includes a license under any [***] to the extent that it Covers (in the case of Patents) or is directed to (in the case of other Janssen Technology) [***]

2.2.2 notwithstanding the exclusivity provided for in Section 2.1 (Grants to Licensee), the licenses granted in Section 2.1 (Grants to Licensee) shall be [***] in the business of Janssen and its Affiliates and that is not [***] any Licensed Compound, Licensed Product or Combination Product.

2.3 **Grant to Janssen**. Subject to the terms and conditions of this Agreement, Licensee hereby grants to Janssen and its Affiliates, after expiration of the Research Term, [***] (subject to Licensee's rights under Section 2.1.4 (Declined Compound License)), royalty-free, fully paid-up license,

with the right to grant sublicenses (through multiple tiers), under the [***] and any Compound Forms thereof and products containing any such [***].

2.4 **Sublicenses**. Subject to Section 2.7 ([***]), Licensee shall have the right to grant sublicenses (through multiple tiers) (i) under the licenses granted in Section 2.1.1 (Research Term License) and Section 2.1.2 (Derivatives License) during the Research Term to subcontractors; *provided that* such sublicenses are entered into in accordance with Section 2.6 (Subcontracting) and (ii) under the license granted in Section 2.1.3 (Licensed Compound License) with respect to Licensed Compounds and Licensed Products. Any sublicense granted by Licensee under this Section 2.4 (Sublicenses) shall be consistent with, and expressly made subject to, the terms and conditions of this Agreement including Section 2.7 ([***]). Licensee hereby guarantees the performance of its Affiliates and permitted Sublicensees and the grant of any such sublicense shall not relieve Licensee of its obligations under this Agreement, except to the extent they are satisfactorily performed by such Sublicensee. Licensee shall provide to Janssen a copy of any sublicense agreement executed by Licensee or any of its Affiliates that includes [***] within [***] days after its execution; *provided that* such sublicense agreement may [***]. If the licenses granted to Licensee under Section 2.1.1 (Research Term License), Section 2.1.2 (Derivatives License), or Section 2.1.3 (Licensed Compound License) are terminated pursuant to Article 11 (Term and Termination), then, at the written request of any Sublicensee (other than a [***]), [***] that is sublicensed to such Sublicensee of the [***] as set forth in such sublicense agreement between Licensee and such Sublicensee; *provided*, *however*, that (a) such Sublicensee undertakes to perform in all respects its obligations under the applicable sublicense agreement, (b) such direct license agreement would not impose on Janssen [***] under this Agreement, and (c) the direct license agreement would require such Sublicensee to [***] as a result of such Sublicensee's performance under the sublicense agreement.

2.5 **Retention of Rights; No Other Rights Granted**.

2.5.1 Retained Rights of Janssen. Notwithstanding anything to the contrary in this Agreement and without limitation of any rights granted to or reserved by Janssen pursuant to any other term or condition of this Agreement, Janssen hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its licensors, (sub)licensees and contractors) rights in and to the Janssen Technology, in each case, (i) to perform its obligations under this Agreement; (ii) to conduct [***] with respect to any [***] other than a Licensed Compound; and (iii) to conduct [***].

2.5.2 Retained Rights of Licensee. Notwithstanding anything to the contrary in this Agreement and without limitation of any rights granted to or reserved by Licensee pursuant to any other term or condition of this Agreement, Licensee hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its licensors, (sub)licensees and contractors) rights in and to the Licensee Foreground Know-How and Licensee Foreground Patents, in each case, to use [***] and Compound Forms thereof (i) in the [***] of Licensed Compounds and Licensed Products; (ii) to perform its obligations under this Agreement; and (iii) to conduct [***].

2.5.3 No Other Rights Granted. Except as expressly provided in this Agreement (including in Section 2.7 ([***])), and without limitation of Section 2.5.1 (Retained Rights of Janssen) or Section 2.5.2 (Retained Rights of Licensee), each Party specifically reserves all rights not expressly granted to the other Party and grants no other right or license not expressly granted herein.

2.6 **Subcontracting**. Licensee may subcontract with a Third Party to perform services in connection with its performance of its obligations and exercise of its rights under this Agreement (including contract research organizations, contract manufacturers and academic collaborators); *provided that* (i) no such permitted subcontracting shall relieve Licensee of obligations hereunder (except to the extent satisfactorily performed by such subcontractor) or any liability and (ii) the agreement pursuant to

which Licensee engages any Third Party subcontractor must (a) be consistent in all material respects with this Agreement and (b) obligate such subcontractor to comply with terms substantially similar to the confidentiality, intellectual property and other relevant provisions of this Agreement.

2.7 [***].

2.7.1 [***] Compounds and [***] Products. Subject to Section 2.7.6 ([***] Limitations), with respect to each Licensed Compound Developed by or on behalf of Licensee, its Affiliates or Sublicensees for [***] (any such Licensed Compound, a "[***] **Compound**" and any Licensed Product containing such [***] Compound (or Compound Form thereof), a "[***] **Product**"), during the period beginning on the Effective Date and continuing until the date that is [***] days following [***] for the applicable [***] Product in a Major Market (such period, the "[***] **Term**"), Janssen shall have [***] with Licensee to (i) [***] from Licensee [***] (ii) [***] from Licensee [***], in each case ((i) and (ii)), to [***] such [***] (and Compound Forms thereof) and [***] in the Field in the Territory, before Licensee [***], any such [***] (and Compound Forms thereof) or [***] in the Field in the Territory as set forth in this Section 2.7 [***] (such right with respect to each [***].

2.7.2 Delivery of [***] Notice. Subject to Section 2.7.6 ([***] Limitations), if [***], any [***] (or any [***] containing such [***]) during the [***], then, in each case, Licensee shall so notify Janssen in writing and provide Janssen [***] with respect to such [***] (and any [***] Products containing such [***]) (such notice and the Preliminary Data Package, a "[***] **Notice**").

2.7.3 [***] Exercise. Janssen may exercise a [***] with respect to a [***] Compound (and any [***] containing such [***]) by providing written notice to Licensee (a "[***] **Election Notice**") at any time during the period commencing on the first date on which Janssen has received the [***] and ending [***] days thereafter (the "[***] **Exercise Period**") with respect to such [***] opportunity.

2.7.4 [***] Agreement. If Janssen exercises a [***] with respect to a [***] (and [***] containing such [***]) during the [***], then (i) within [***] days of Licensee's receipt of the [***], Licensee will provide to Janssen a [***] with respect to such [***] (and any [***] containing such [***]) and will certify to Janssen that it has provided to Janssen the [***] and (ii) during the period [***] that Licensee certifies to Janssen that Licensee has provided the [***] to Janssen and ending [***] days thereafter (or such later date as may be mutually agreed by the Parties) (the "[***] **Negotiation Period**"), the Parties shall [***] in good faith the terms and conditions of an agreement pursuant to which Janssen or an Affiliate of Janssen would obtain the [***] such [***] (and any [***] containing such [***]) in the Field in the Territory (a "[***] **Agreement**").

2.7.5 Janssen Failure to Exercise. Subject to Section 2.7.7 ([***]), if (i) Janssen does not deliver a [***] to Licensee with respect to any [***] during the applicable [***] or (ii) Licensee and Janssen cannot agree on the terms of a [***] with respect to the applicable [***] (and [***] containing such [***]) during the applicable [***], then, in either case ((i) or (ii)), Licensee or its Affiliate, as applicable, shall be [***]; *provided that*, in the case of (ii) above, [***].

2.7.6 [***] Limitations. The [***] granted to Janssen in this Section 2.7 ([***]) shall not be triggered by any [***] in circumstances in which [***]. In addition, the [***] granted to Janssen in this Section 2.7 ([***]) will not be triggered in the event of [***]; *provided that* in the event of any such [***], the [***] granted to Janssen in this Section 2.7 ([***]) shall survive for the benefit of Janssen.

2.7.7 [***]. It is the intention of the Parties that in the event that Licensee [***] (or a Back-Up Compound thereto) (or [***] (or Back-Up Compound thereto)), [***] would be [***].

Accordingly, notwithstanding the terms of Section 2.7.2 (Delivery of [***]) or Section 2.7.5 (Janssen's Failure to Exercise), (i) Licensee may not deliver a [***] to Janssen with respect to [***] (or a Back-Up Compound thereto) or [***] (or Back-Up Compound thereto) prior to [***] (or a Back-Up Compound thereto) or [***] (or Back-Up Compound thereto) and (ii) if Janssen delivers a [***] to Licensee with respect [***] (or Back-Up Compound thereto) during the applicable [***], but Licensee and Janssen do not agree on [***] (or Back-Up Compound thereto) ([***] (or Back-Up Compound thereto)) during the applicable [***], then during any period that Licensee is engaged in [***] (or Back-Up Compound thereto) (or any [***] (or Back-Up Compound thereto)), at Janssen's request, Licensee will continue to engage on a [***] with Janssen with respect to such [***]. During any such [***], Licensee shall promptly update the [***] delivered pursuant to Section 2.7.4 ([***]) to include [***] to the [***] that are generally [***].

2.8 **Janssen Exclusivity**.

2.8.1 Research Term. During the Research Term, Janssen shall not, directly or indirectly, Exploit (or license, authorize, appoint, engage or otherwise enable any Affiliate or Third Party to Exploit) any Portfolio Compound or any Derivative of any Portfolio Compound in the Field in the Territory other than (i) to perform its obligations under this Agreement; (ii) to [***] with respect to any [***] or [***] other than a Licensed Compound; and (iii) [***].

2.8.2 Licensed Compounds. During the Term, Janssen shall not, directly or indirectly, Exploit, or license, authorize, appoint, engage or otherwise enable any Affiliate or Third Party to Exploit, Licensed Compounds or Licensed Products in each case, in the Field in the Territory.

2.9 **Licensee Exclusivity**. After the Research Term, Licensee shall not, directly or indirectly, [***] any [***], and Compound Forms thereof, other than (i) in the [***] Licensed Compounds and Licensed Products; (ii) to perform its obligations under this Agreement; and (iii) to conduct [***].

ARTICLE 3
DEVELOPMENT, REGULATORY AND COMMERCIALIZATION ACTIVITIES

3.1 **Research and Development Program; Overview**. The principal goal of the program of research and Development under this Agreement is to identify, Develop and Commercialize Licensed Products as set forth below. Janssen shall have no responsibility for conducting any activities in the Research Plan or Development Plans.

3.2 **Research Performance**. The Research Plan shall consist solely of [***] activities directed to the identification of Development Candidates for designation as Designated Compounds as described below. Within [***] days of the Effective Date, Licensee shall develop and adopt the Research Plan and shall provide such plan to Janssen, whereupon such plan shall be appended by the Parties to this Agreement as Schedule 3.2 (Research Plan); *provided that* activities under the Research Plan will be consistent with the terms of this Agreement. Licensee shall be responsible for all costs and expenses in connection with the conduct of such research activities.

3.3 **Research Reports**. On a semi-annual basis in each Calendar Year during the Research Term, Licensee shall provide to Janssen [***] reports of the research activities with respect to the Portfolio Compounds that it has performed, or caused to be performed, since the preceding report, which reports shall be in the same format as Licensee produces in the ordinary course of business for similar programs conducted by Licensee.

3.4 **Derivatives**. During the Research Term, subject to the terms and conditions of this Agreement, Licensee may make Derivatives of any Portfolio Compound for the purpose of identifying

potential compounds for designation as Designated Compounds pursuant to Section 3.5.1 (Notice; Fee) and for the purpose of Developing Licensed Compounds and Licensed Products.

3.5 **Selection of Designated Compounds**.

3.5.1 Notice; Fee. During the Research Term, Licensee shall have the right to designate [***] in accordance with the terms of this Section 3.5.1 (Notice; Fee). Licensee may designate any [***] by providing a written notice to Janssen (each such notice, a "**Designation Notice**") that sets forth [***] and [***] with respect to such [***]; *provided that*, in the case of an [***], Licensee shall include in the applicable Designation Notice the [***] and the [***] demonstrating that such [***] meets the [***] each as set forth in Schedule 3.5.1 (the "**Designation Criteria**"). In addition, notwithstanding its failure to meet the Designation Criteria, Janssen [***], following Licensee's request for such designation, confirm that Licensee may designate as a Designated Compound any [***] (each a "**Janssen Designated Compound Confirmation**"). Upon receipt by Janssen of (i) a Designation Notice and the Designation Fee for any [***] (which notice, for any [***], will include the applicable [***]), and (ii) the Designation Fee for any [***], but that Janssen has confirmed in a Janssen Designated Compound Confirmation that such [***] for purposes of this Agreement, and in each case ((i) and (ii)), the applicable compound shall become a "Designated Compound" under this Agreement; *provided that* the Designation Fee will not be payable with respect to the [***], but will be payable with respect to any other [***], whether such compound is a [***]. Subject to Section 3.5.2 (Back-Up Compounds) and Section 3.7.1 (Initial Adoption of Lead Compound Development Plans), within [***] months following designation of a [***] as a Designated Compound, Licensee shall develop and adopt a [***].

3.5.2 Back-Up Compounds. Licensee may, in its discretion, at any time during the Research Term, designate in accordance with Section 3.5.1 (Notice; Fee) [***] Designated Compounds as Back-Up Compounds with respect to any other Designated Compound (such Designated Compound, a "**Primary Designated Compound**"). If, at any time during the Term Licensee reasonably determines in good faith that the Development of a [***] has not yielded sufficient progress and that Development activities with respect to such Primary Designated Compound should be discontinued, then Licensee shall use Commercially Reasonable Efforts to designate one of the [***], and such [***] will thereafter be considered a [***]; *provided that* [***]. If the Parties agree upon a Development Plan for a Back-Up Compound for [***], then all provisions of this Agreement that relate specifically to [***], including Section 3.7 (Development Plans and Performance) and Section 11.2.3 (Termination without Cause by Licensee), will thereafter relate to such [***]. In each case, following substitution of a given [***] for the corresponding [***], the discontinued [***] will thereafter be considered to be a [***] for such new [***]. The Development diligence obligations set forth in Section 3.8 (Development Diligence) and the Commercialization diligence obligations set forth in Section 3.13.1 (Commercialization Diligence) will not apply to any [***] unless and until Licensee designates a particular [***] as a [***], and Licensee will not be required to [***] with respect to any [***] until such time.

3.5.3 Conclusion of Research Term; Declined Compounds. Any [***] or [***] not designated by Licensee as a Designated Compound (either as a [***] or as a [***]) by the end of the Research Term and any Compound Form of such [***] or [***] shall automatically become a "Declined Compound." Other than with respect to any Back-Up Compound, Licensee's rights to designate any Development Candidate as a Designated Compound shall automatically expire upon the expiration of the [***]. Without limitation to other reporting obligations set forth in this Article 3 (Development, Regulatory and Commercialization Activities), at the end of the Research Term, Licensee shall provide to Janssen a [***] that it identified, discovered, researched or otherwise Developed during the Research Term, but did not designate as a Designated Compound. In addition, Licensee shall use reasonable efforts deliver to Janssen any [***] in its possession with respect to such [***] within [***] months of the completion of the Research Term.

3.6 **Research Term**. If Licensee has used Commercially Reasonable Efforts to perform research activities with respect to the [***] during the Research Term but [***], then Licensee may elect, on a year-by-year basis, by providing written notice thereof to Janssen, to extend the Research Term for a total of up to two additional years as follows. For the first year that the Research Term is extended pursuant to the preceding sentence (i.e., the Research Term is extended through the date that is the fourth anniversary of the Effective Date), Licensee shall make a non-refundable payment to Janssen of [***] (the "**First Extension Fee**"). For the second year that the Research Term is extended pursuant to the first sentence of this Section 3.6 (Research Term) (*i.e.*, the Research Term is extended through the date that is the fifth anniversary of the Effective Date), Licensee shall make a non-refundable payment to Janssen of [***] paid by Licensee to Janssen with respect to designations made subsequent to payment of the First Extension Fee (the "**Second Extension Fee**"). Any election to extend the Research Term must be made prior to the end of the then-current Research Term. The First Extension Fee and the Second Extension Fee shall each be paid in the manner specified in Section 6.5 (Mode of Payment) no later than [***] Business Days after Licensee provides its written notice of extension to Janssen.

3.7 **Development Plans and Performance**.

3.7.1 Initial Adoption of Lead Compound Development Plans. The [***] Development Plan is set forth on Schedule 3.7.1 ([***] Development Plan). Within [***] months after the Effective Date, [***] shall develop a Development Plan for [***] and shall adopt such plan upon written notice and provision thereof to [***].

3.7.2 POC Trial Criteria Review. No later than [***] days prior to the filing of the first IND for a Licensed Product containing [***] or any Compound Form thereof, Licensee will develop the POC Trial Criteria for such Licensed Product, present such criteria to the JRC for its [***] in accordance with Section 5.1.2 (JRC Responsibilities) and [***]. Licensee shall be solely responsible for [***] the POC Trial in a manner consistent with the POC Trial Criteria last presented to the JRC.

3.7.3 Updates to Development Plans. Licensee shall have the right to update or amend any Development Plan upon [***]; *provided that* Licensee will provide to the JRC for its [***] drafts of any updates or amendments to the [***] Development Plan and will consider such comments in good faith. Notwithstanding the foregoing, in no event may Licensee amend or update any Development Plan in a manner that imposes obligations on Janssen or is inconsistent with Licensee's obligations under Section 3.8 (Development Diligence).

3.7.4 Performance. For each Designated Compound, Licensee shall use Commercially Reasonable Efforts to perform or cause to be performed the activities provided for in the Development Plan for such Designated Compound.

3.8 **Development Diligence**. Subject to Section 3.5.2 (Back-Up Compounds), Licensee shall use Commercially Reasonable Efforts to (i) [***] and (ii) [***].

3.9 **Development Costs**. Licensee shall be responsible for all costs and expenses incurred in connection with the Development of, and obtaining and maintaining Regulatory Approvals for, the Licensed Products.

3.10 **Development Reports**. On a semi-annual basis in each Calendar Year during which Licensee or its Affiliate or Sublicensee is performing Development activities with respect to any Licensed Compound or Licensed Product under any Development Plan, Licensee shall, or shall cause such Affiliate or Sublicensee to, provide to Janssen [***] reports of such Development activities it has performed, or caused to be performed, since the preceding report (including all regulatory activities), which

reports shall be in the same format as Licensee or such Affiliate or Sublicensee produces in the ordinary course of business for similar programs conducted by Licensee or such Affiliate or Sublicensee. Each such report shall contain sufficient detail to enable Janssen to assess Licensee's compliance with its obligations set forth in Section 3.8 (Development Diligence).

3.11 **Records**. Licensee shall, and shall cause its Affiliates and its Sublicensees to, maintain, in good scientific manner, complete and accurate books and records pertaining to the conduct of activities under the Research Plan and the Development of Licensed Compounds and Licensed Products hereunder. Such books and records shall (i) be appropriate for patent and regulatory purposes, (ii) be in compliance with Applicable Law, (iii) properly reflect all work done and results achieved in the performance of such activities hereunder and (iv) be retained by Licensee for at least [***] years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law.

3.12 **Regulatory Activities**.

3.12.1 Regulatory Approvals.

(i) *Drug Approval Applications.* As between the Parties and except as otherwise set forth in this Agreement, Licensee shall have the sole right to prepare, obtain and maintain Drug Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals and other submissions and to conduct communications with the Regulatory Authorities, for Licensed Products in the Territory (which shall include filings of or with respect to INDs and other filings or communications with the Regulatory Authorities).

(ii) *Licensee Regulatory Documentation*. Subject to the terms and conditions of this Agreement, Janssen shall and hereby does transfer and assign to Licensee, and Licensee hereby receives and assumes from Janssen, all of Janssen's rights, title and interests in and to the [***]. Janssen will promptly submit all filings, letters and other documentation to the applicable Regulatory Authority necessary to effect such assignment and transfer of the [***]. Except to the extent prohibited by Applicable Law, or as provided in Section 11.4 (Consequences of Termination), all Regulatory Documentation (including all Regulatory Approvals) for the Licensed Compounds or Licensed Products with respect to the Territory developed or generated by or granted to Licensee, its Affiliates or its Sublicensees or granted to Licensee, its Affiliates or its Sublicensees after the Effective Date shall be owned by and shall be the sole property and held in the name of, Licensee or its designated Affiliate or Sublicensee (together with the IND for JNJ7414 assigned by Janssen to Licensee, the "**Licensee Regulatory Documentation**").

3.13 **Commercialization**.

3.13.1 Commercialization Diligence. Licensee shall be solely responsible for Commercialization of the Licensed Products throughout the Territory at Licensee's own cost and expense. For each Licensed Product that obtains Regulatory Approval in any Major Market, Licensee shall use Commercially Reasonable Efforts to Commercialize such Licensed Product in such Major Market.

3.13.2 Commercialization Reports. On a [***] basis in each Calendar Year during which Licensee or its Affiliate or Sublicensee is performing Commercialization activities with respect to any Licensed Compound or Licensed Product, Licensee shall provide, or shall cause such Affiliate or Sublicensee, as applicable, to provide to Janssen [***] reports of such Commercialization activities it has performed, or caused to be performed, since the preceding report, which reports shall be in the same format as Licensee or such Affiliate or Sublicensee produces in the ordinary course of business

for similar programs conducted by Licensee or such Affiliate or Sublicensee. Each such report shall contain sufficient detail to enable Janssen to assess Licensee's compliance with its obligations set forth in Section 3.13.1 (Commercialization Diligence).

ARTICLE 4
TECHNOLOGY DISCLOSURE AND TRANSFER; SUPPLY

4.1 **Technology Disclosure and Transfer**.

4.1.1 In General.

(i) *Disclosed Know-How*. Within [***] days of the Effective Date, Janssen shall disclose and make available to Licensee [***] of each Portfolio Compound set forth on Schedule 1.108 (Specified Compounds); and certain specified data available for certain Portfolio Compounds set forth in Schedule 4.1.1(i) (Disclosed Know-How) ([***] and data disclosed by Janssen to Licensee hereunder, the "**Disclosed Know-How**"). Janssen shall make such Disclosed Know-How available to Licensee substantially in the form maintained by Janssen or in such other form as the Parties shall agree.

(ii) *Licensed Materials*. Within [***] days of the Effective Date, Janssen shall transfer to Licensee the Materials in the quantities set forth on Schedule 4.1.1(ii) (Licensed Materials) (such Materials, together with any additional Materials disclosed or transferred by Janssen to Licensee hereunder, the "**Licensed Materials**"). Janssen shall make such Licensed Materials available to Licensee substantially in the form maintained by Janssen or in such other form as the Parties shall agree.

(iii) *Further Know-How*. Within [***] of the Effective Date, Janssen and Licensee will cooperate as provided for in Section 4.1.3 (Related Cooperation) and Janssen will disclose and make available to Licensee during such [***] period [***] the data for the Portfolio Compounds set forth on Schedule 4.1.1(iii) (Further Know-How). In addition, until the [***] anniversary of the Effective Date, if Licensee reasonably determines that there is material Information within the Janssen Know-How with respect to any Portfolio Compound set forth on Schedule 1.108 (Specified Compounds) in Janssen's possession that has not been provided pursuant to Schedule 4.1.1(i) (Disclosed Know-How) or Schedule 4.1.1(iii) (Further Know-How) that is necessary or useful for Licensee to Exploit such Portfolio Compound in accordance with this Agreement, then Licensee may notify Janssen, and Janssen will use reasonable commercial efforts to promptly disclose and make available to Licensee such Information in substantially the form such Information is maintained (*e.g.*, as reports or raw data as applicable) by Janssen; *provided that* Janssen is under no obligation to provide any such requested Information that cannot be located after using reasonable efforts. Any Information that is provided under this Section 4.1.1(iii) (Further Know-How) shall thereafter be considered "Disclosed Know-How" for purposes of this Agreement.

4.1.2 Licensed Materials Disclaimer. Licensee acknowledges that compounds, reagents and other materials supplied by Janssen hereunder are experimental in nature and provided as is, without any warranties as to merchantability or fitness for a particular purpose, including [***] (Licensed Materials). Licensee further acknowledges that all of such materials' properties or characteristics are not known, and agrees that it shall use such materials with reasonable care and shall assume responsibility for any losses or injuries incurred by it or its Affiliates or subcontractors or Sublicensees through use of such materials.

4.1.3 Related Cooperation. Representatives from each Party's scientific organizations will reasonably cooperate with each other to facilitate the transfer of Disclosed Know-How and Licensed Materials as set forth in Section 4.1.1 (In General). Without limiting the generality of the

foregoing, during the [***] period referred to in Section 4.1.1(iii) (Further Know-How) and for a [***] day period thereafter, and for no more than a cumulative total of [***], at no cost to Licensee, Janssen shall provide reasonable assistance requested by Licensee to facilitate its understanding of the Disclosed Know-How by making appropriate personnel of Janssen reasonably available for meetings at applicable Janssen facilities or teleconferences and e-mail communications regarding the Disclosed Know-How and the Licensed Materials. Licensee acknowledges that such cooperation shall not require Janssen to conduct any research or development activities or generate any information or materials. Each Party shall designate an employee to serve as the primary point of contact between the Parties in relation to any questions raised by Licensee pursuant to this Section 4.1.3 (Related Cooperation).

4.1.4 Return of Janssen Know-How and Licensed Materials. Upon expiration of the Research Term, Licensee shall return to Janssen (or destroy and confirm such destruction in writing) all Janssen Know-How in its possession or Control that is reasonably necessary or useful for the Development of any Portfolio Compound, other than Janssen Know-How that pertains specifically to or is reasonably necessary or useful for the Exploitation of any Licensed Compounds and Licensed Products.

4.2 **Manufacture and Supply**. Following the Effective Date, Licensee shall be solely responsible, itself and through its Affiliates and Sublicensees at their own expense, for Manufacturing or having Manufactured Development Candidates, Licensed Compounds and Licensed Products.

ARTICLE 5
JOINT REVIEW COMMITTEE

5.1 **Joint Review Committee**.

5.1.1 Establishment of Joint Review Committee. Promptly after the Effective Date, the Parties shall establish a joint committee (the "**Joint Review Committee**" or "**JRC**"), which shall consist of two representatives from each of the Parties. From time-to-time, each Party may substitute one or more of its representatives to the JRC upon written notice to the other Party. Licensee shall select from its representatives the chairperson for the JRC, which chairperson may be changed from time-to-time upon written notice to Janssen. The chairperson shall perform administrative tasks required to facilitate efficient operation of the JRC.

5.1.2 JRC Responsibilities. The JRC shall [***]. The purpose of the JRC shall be to [***] Licensee's conduct of activities in relation to the Research Plan and Development activities with respect to Licensed Compounds, including progress under the Research Plan, Development Plans and this Agreement. Without limiting the generality of the foregoing, the JRC shall [***] (i) the [***]; (ii) the [***]; and (iii) updates and amendments to the [***]; *provided that* Licensee [***]. In addition, the JRC will provide [***] contained in the research reports provided by Licensee pursuant to Section 3.3 (Research Reports) and Development reports provided by Licensee pursuant to Section 3.10 (Development Reports), to the extent the research and Development activities contained in such reports pertain to Portfolio Compounds, Licensed Compounds or Licensed Products (as applicable).

5.1.3 Meetings. The JRC shall meet two times per Calendar Year or as otherwise agreed to by the Parties. Representatives of the Parties on the JRC may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by and be heard by, the other participants. The chairperson of the JRC shall be responsible for calling meetings on no less than 20 Business Days' notice unless exigent circumstances require shorter notice. The chairperson shall set agendas for such meetings, taking account of any inputs or proposals made by Janssen with respect to such agendas. Each Contact Person or other employees or consultants of a Party who are not representatives of the Parties on the JRC may attend meetings of the JRC; *provided, however*, that such

attendees are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 8 (Confidentiality and Non-Disclosure).

5.1.4 Expenses. Each Party shall bear all its own costs, including expenses incurred by its JRC members or by any additional non-member participants of such Party in connection with their attendance at JRC meetings and other activities related to the JRC.

5.1.5 No Authority to Modify Agreement. The JRC shall have no authority to modify any provision set forth in the body or in any Schedule of this Agreement, including any payment conditions or terms, periods for performance, or obligations of the Parties as set forth in this Agreement, which may be modified only by written agreement of the Parties.

5.1.6 Discontinuation; Disbandment; Annual Reports. The JRC shall continue to exist until the first to occur of: (i) the Parties mutually agreeing to disband the JRC; or (ii) Janssen providing to Licensee written notice of its intention to disband the JRC. Upon the occurrence of any of the foregoing, (a) the JRC shall disband, have no further responsibilities or authority under this Agreement and will be considered dissolved by the Parties and (b) any requirement of a Party to provide Information or other materials to the JRC shall be deemed a requirement to provide such Information or other materials to the other Party.

5.2 **Contact Persons**. Each Party shall appoint a person who shall oversee contact between the Parties for all matters relating to this Agreement (each, a "**Contact Person**"), which person may be replaced at any time upon written notice to the other Party. Each Contact Person shall work together to manage and facilitate the communication between the Parties under this Agreement. The Contact Persons shall not have decision-making authority with respect to any matter under this Agreement.

ARTICLE 6
PAYMENTS AND RECORDS

6.1 **Upfront Payment**. In partial consideration of the rights granted by Janssen to Licensee hereunder, Licensee shall pay Janssen the amount of $1,000,000 within 30 days following the Effective Date.

6.2 **Milestones**. In partial consideration of the rights granted by Janssen to Licensee hereunder, Licensee shall pay to Janssen the following nonrefundable and noncreditable milestone payments, at the time and in the manner specified in Section 6.2.6 (Determination that Milestones Have Occurred and Timing of Payments).

6.2.1 First Licensed Product. Upon the [***], Licensee shall pay to Janssen a one-time milestone payment of $[***]. Such milestone payment will be made in addition to the applicable milestone payment to be made by Licensee to Janssen upon the [***] pursuant to Section 6.2.2(i) (Non-Lead Products; Milestones) or a [***] pursuant to Section 6.2.3(i) (Lead Products; Milestones). For example, if such Licensed Product is a [***], then Licensee would pay to Janssen a total of $[***] upon [***], and if such Licensed Product is a [***], then Licensee would pay to Janssen a total of $[***] upon such [***].

6.2.2 Non-Lead Products.

(i) *Milestones*. On a Non-Lead Product by Non-Lead Product basis, Licensee shall pay to Janssen a milestone payment upon the achievement of each of the following milestone events for the first Licensed Product to achieve the applicable milestone that contains a particular Licensed

Compound other than a Lead Compound (or any Compound Form thereof) or any Back-Up Compound (or any Compound Form thereof) with respect to which such Lead Compound is the Primary Designated Compound (each a "**Non-Lead Product**").

TABLE 6.2.2(i) – Non-Lead Products		
	EVENT	**PAYMENT AMOUNT**
(1)	[***]	$[***]
(2)	[***]	$[***]
(3)	[***]	$[***]
(4)	[***]	$[***]
(5)	[***]	$[***]
(6)	[***]	$[***]

(ii) *Product-by-Product Payment*. Subject to Section 6.2.2(iii) (One Payment per Compound) and Section 6.2.2(iv) (Subsequent Non-Lead Products), each milestone payment in Section 6.2.2(i) (Milestones) shall be payable on a Non-Lead Product-by-Non-Lead Product basis based on the first achievement of such milestone for each applicable Non-Lead Product.

(iii) *One Payment per Compound*. The Parties recognize that different Non-Lead Products may contain the same Licensed Compound. Notwithstanding anything to the contrary in Section 6.2.2(i) (Milestones) or 6.2.2(ii) (Product-by-Product Payment), the Parties agree that the milestones in Section 6.2.2(i) (Milestones) ((1) through (6), inclusive) shall be payable only once with respect to each distinct Licensed Compound (or Compound Form thereof) regardless of the number of Non-Lead Products containing such Licensed Compound (or Compound Form thereof).

(iv) [***]. Notwithstanding anything to the contrary in Section 6.2.2(i) (Milestones), Section 6.2.2(ii) (Product-by-Product Payment), and Section 6.2.2(iii) (One Payment per Compound), Milestone (1) ([***]) and Milestone (2) ([***]) set forth in Table 6.2.2(i) will not be owed with respect to Non-Lead Products containing a second or any subsequent Licensed Compound unless, at the time of designation of the applicable second or subsequent Licensed Compound pursuant to Section 3.5 (Selection of Designated Compounds), there is at least [***] remaining on any Janssen Patent Covering the composition of matter of such second or subsequent Licensed Compound, not taking into account the availability of any [***].

6.2.3 Lead Products.

(i) *Milestones.* On a Lead Product-by-Lead Product basis, Licensee shall pay to Janssen a milestone payment upon the achievement of certain milestone events for the first

Licensed Product to achieve the applicable milestone that contains each Lead Compound (or any Compound Form thereof) (*i.e.*, each of (a) [***] and Compound Forms thereof and (b) [***] and Compound Forms thereof) or, in each case ((a) and (b)), any Back-Up Compound (or any Compound Form thereof) with respect to which such Lead Compound is the Primary Designated Compound (each a "**Lead Product**"). Licensee shall pay to Janssen the milestone payments set forth in Table 6.2.3(i) upon Licensee's achievement of the applicable events set forth in such table for the applicable Lead Product.

TABLE 6.2.3(i) – Lead Products		
	EVENT	**PAYMENT AMOUNT**
(1)	[***]	$[***]
(2)(a)	[***]	$[***]
(2)(b)	[***]	$[***]
(3)(a)	[***]	$[***]
(3)(b)	[***]	$[***]
(4)	[***]	$[***]
(5)	[***]	$[***]
(6)	[***]	$[***]

(ii) *Product-by-Product Payment*. Subject to Section 6.2.3(iii) (One Payment per Compound), each milestone payment in Section 6.2.3(i) (Milestones) shall be payable on a Lead Product-by-Lead Product basis based on the first achievement of such milestone for each applicable Lead Product.

(iii) *One Payment per Compound*. The Parties recognize that different Lead Products may contain the same Lead Compound. Notwithstanding anything to the contrary in Section 6.2.3(i) (Milestones) and Section 6.2.3(ii) (Product-by-Product Payment), the Parties agree that the milestones in Section 6.2.3(i) (Milestones) ((1) through (6), inclusive) shall be payable only once with respect to each distinct Lead Compound (or Compound Form thereof) (*i.e.*, each of (a) [***] and Compound Forms thereof and (b) [***] and Compound Forms thereof) or, in each case ((a) and (b)), any Back-Up Compound (or Compound Form thereof) with respect to which such Lead Compound is the Primary Designated Compound, regardless of the number of Lead Products containing such Lead Compound (or Compound Form thereof) or Back-Up Compound (or Compound Form thereof).

6.2.4 Sales Milestones. In partial consideration of the license rights granted by Janssen to Licensee hereunder, Licensee shall pay to Janssen sales milestone payments with respect to each Licensed Product, as follows:

(i) in the event that the aggregate of all Net Sales of a Licensed Product in a given Calendar Year during the Royalty Term exceeds [***] ($[***]), then Licensee shall pay to Janssen [***] ($[***]);

(ii) in the event that the aggregate of all Net Sales of a Licensed Product in a given Calendar Year during the Royalty Term exceeds [***] ($[***]), then Licensee shall pay to Janssen [***] ($[***]); and

(iii) in the event that the aggregate of all Net Sales of a Licensed Product in a given Calendar Year during the Royalty Term exceeds [***] ($[***]), then Licensee shall pay to Janssen [***] ($[***]).

6.2.5 Milestone Payment Terms. In the event that in a given Calendar Year more than one of the foregoing thresholds set forth in clauses (i) through (iii) of this Section 6.2.4 (Sales Milestones) is exceeded with respect to a Licensed Product, then Licensee shall pay to Janssen a separate milestone payment with respect to each such threshold that is exceeded in such Calendar Year with respect to such Licensed Product. Each milestone payment in this Section 6.2.4 (Sales Milestones) shall be payable only once for a given Licensed Product upon the first achievement of such milestone in a given Calendar Year and no amounts shall be due for subsequent or repeated achievements of such milestone with respect to such Licensed Product in subsequent Calendar Years.

6.2.6 Determination that Milestones Have Occurred and Timing of Payments. Licensee shall notify Janssen in writing within [***] days following the achievement of each milestone in Section 6.2.1 (First Licensed Product), Section 6.2.2 (Non-Lead Products) and Section 6.2.3 (Lead Products), and shall make the applicable milestone payment within [***] days after the achievement of such milestone. In the case of each milestone in Section 6.2.4 (Sales Milestones), Licensee shall notify Janssen in writing within, and each such milestone payment shall be due within, [***] days of the end of the Calendar Quarter in which such milestone was achieved. In the event that, notwithstanding the fact that Licensee has not provided Janssen a required milestone notice, Janssen believes that any such milestone has been achieved, it shall so notify Licensee in writing and the Parties shall promptly meet and discuss in good faith whether such milestone has been achieved. Any dispute under this Section 6.2.6 (Determination that Milestones Have Occurred and Timing of Payments) regarding whether or not such a milestone has been achieved shall be subject to resolution in accordance with Section 12.5 (Dispute Resolution).

6.3 **Royalties**.

6.3.1 Royalty Rates. As further consideration for the rights granted to Licensee hereunder, commencing upon the First Commercial Sale of a Licensed Product in the Territory, Licensee shall pay to Janssen a royalty on Net Sales (to the extent made during the Royalty Term applicable in each country in the Territory) by Licensee, its Affiliates and Sublicensees on a Licensed Product-by-Licensed Product basis during each Calendar Year at the following rates:

(i) for that portion of aggregate Net Sales of a Licensed Product in the Territory during a Calendar Year equal to or less than [***] ($[***]), a royalty rate of [***]%;

(ii) for that portion of aggregate Net Sales of a Licensed Product in the Territory during a Calendar Year greater than [***] ($[***]) but less than or equal to [***] ($[***]), a royalty rate of [***]%; and

(iii) for that portion of aggregate Net Sales of a Licensed Product in the Territory during a Calendar Year greater than [***] ($[***]), a royalty rate of [***]%;

provided that, for any Non-Lead Product containing a second or any subsequent Designated Compound (or Compound Form thereof) for which Milestone (1) ([***]), and Milestone (2) ([***]) in Section 6.2.2(i) (Milestones) was not paid pursuant to Section 6.2.2(iv) ([***]), the royalty rates set forth above shall be increased by [***]% at each tier.

An example of the calculation of the amount of royalty to be paid hereunder is shown on Schedule 6.3.1 (Example Royalty Calculation); *provided*, *however*, that the calculation of the actual amount of royalties to be paid hereunder shall be made using the actual Net Sales figures.

6.3.2 Royalty Term. Licensee shall have no obligation to pay any royalty with respect to Net Sales of any Licensed Product in any country after the Royalty Term for such Licensed Product in such country has ended. Following the end of the Royalty Term for a Licensed Product in a country, the license grants in Section 2.1 (Grants to Licensee) shall become fully-paid, royalty-free and irrevocable for such Licensed Product in such country.

6.3.3 Reductions.

(i) *Expiration of Valid Claims*. Subject to Section 6.3.4 (Maximum Amount of Royalty Reduction), from and after the date on which a Licensed Product is sold in a country and is not claimed by an issued and unexpired Valid Claim of a Janssen Patent or Licensee Foreground Patent that claims (a) [***] of such Licensed Product or any Licensed Compound contained in such Licensed Product or (b) [***] of such Licensed Product in such country, the applicable royalty rate set forth in Section 6.3.1 (Royalty Rates) with respect to Net Sales in such country shall be reduced by [***]%.

(ii) *Generic Product Entry*. In any country in the Territory during the Royalty Term for a Licensed Product, a Generic Product is launched in such country by a Third Party in a given Calendar Quarter, then the royalties to be paid by Licensee on Net Sales of such Licensed Product in such country thereafter shall be reduced to [***]% of the royalties otherwise due to Janssen with respect to such Licensed Product in such country.

(iii) *Third Party License Adjustments*. If Licensee reasonably determines that it is necessary for Licensee to license or acquire one or more Patents from one or more Third Parties in order to Exploit any Licensed Compound or Licensed Product in any country in the Territory, then Licensee will have the sole right to, and may, in its sole discretion, negotiate and obtain a license or acquire rights under such Patents (each such Third Party license, a "**Third Party License**"). Licensee may, on a Licensed Product-by-Licensed Product basis, offset and deduct from the royalties otherwise payable to Janssen pursuant to Section 6.3 (Royalties), an amount equal to [***]% of any amounts paid by Licensee to such Third Party pursuant to the applicable Third Party License with respect to the Exploitation of Licensed Products; *provided that* no reduction taken pursuant to this Section 6.3.3(iii) (Third Party License Adjustments) may reduce the royalty rate payable by Licensee to a royalty rate of less than [***]%.

6.3.4 Maximum Amount of Royalty Reduction. Any reductions set forth in Section 6.3.3 (Reductions) shall be applied to the royalty rate payable to Janssen under Section 6.3.1 (Royalty Rates) in the order in which the event triggering such reduction occurs. In no event shall the adjustments under Section 6.3.3(i) (Expiration of Valid Claims), Section 6.3.3(ii) (Generic Product Entry), and Section 6.3.3(iii) (Third Party License Adjustments) taken together reduce the royalties due to Janssen in any Calendar Quarter with respect to a Licensed Product by more than [***]% of the royalty amount that would have been due in such Calendar Quarter but for the application of the reductions in Section 6.3.3 (Reductions) (the "**Reduction Floor**"); *provided that* to the extent that any such amount cannot be offset or deducted against any royalty payment due with respect to such Licensed Product for any given period

due to the Reduction Floor or the proviso in Section 6.3.3(iii) (Third Party License Adjustments), then the [***] (subject always to the Reduction Floor for any such payment).

6.4 **Royalty Payments and Reports**. Licensee shall calculate all amounts payable to Janssen pursuant to Section 6.3 (Royalties) at the end of each Calendar Quarter, which amounts shall be converted to Dollars, in accordance with Section 6.5 (Mode of Payment). Licensee shall pay to Janssen the royalty amounts due with respect to a given Calendar Quarter within [***] days after the end of such Calendar Quarter. Each payment of royalties due to Janssen shall be accompanied by a statement of the amount of gross sales and Net Sales of each Licensed Product in each country in the Territory during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter. Without limiting the generality of the foregoing, Licensee shall require its Affiliates and Sublicensees to account for Net Sales and to provide such reports with respect thereto as if such sales were made by Licensee.

6.5 **Mode of Payment**. All payments to either Party under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as the Payee Party may from time-to-time designate by notice to the paying Party. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate's or Sublicensee's standard conversion methodology consistent with GAAP.

6.6 **Taxes**.

6.6.1 Deductions and Withholdings. Licensee will make all payments to Janssen under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by Applicable Law in effect at the time of payment.

6.6.2 Required Withholdings. Any tax required to be withheld on amounts payable under this Agreement will promptly be transferred by Licensee on behalf of Janssen to the appropriate governmental authority, and Licensee will furnish Janssen with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by Janssen.

6.6.3 Failure to Withhold. If Licensee had a duty to withhold taxes in connection with any payment it made to Janssen under this Agreement but Licensee failed to withhold, and such taxes were assessed against and paid by Licensee, then Janssen will indemnify and hold harmless Licensee from and against the assessment and enforcement of such taxes (including interest). If Licensee makes a claim under this Section 6.6.3 (Failure to Withhold), and Janssen provides it with the requisite payment, Licensee will comply with the obligations imposed by Section 6.6.2 (Required Withholdings) as it would have had Licensee withheld taxes from a payment to Janssen.

6.6.4 Cooperation. Janssen and Licensee will cooperate with respect to all documentation required by any taxing authority or reasonably requested by each other to request a reduction in the rate of applicable withholding taxes.

6.7 **Interest on Late Payments**. If any undisputed payment due to either Party under this Agreement is not paid when due, then the paying Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of [***]% above the then-current prime rate quoted by Citibank in New York City, New York (but in no event in excess of the maximum

rate permissible under Applicable Law), such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

6.8 **Financial Records**. Licensee shall and shall cause its Affiliates and its Sublicensees to, keep complete and accurate financial books and records pertaining to the Net Sales of Licensed Products, in sufficient detail to calculate and verify all amounts payable hereunder. Licensee shall, and shall cause its Affiliates and its Sublicensees to, retain such books and records until the later of (i) [***] years after the end of the period to which such books and records pertain or (ii) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

6.9 **Audit**. During the Term and for a period of [***] years thereafter, at the request of Janssen, Licensee shall and shall cause its Sublicensees that are Commercializing a Licensed Product (other than Third Party Distributors) and its Affiliates to, permit an independent auditor designated by Janssen and reasonably acceptable to Licensee, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant Section 3.11 (Records) and Section 6.8 (Financial Records) to ensure the accuracy of all reports and payments made hereunder. Janssen will cause the accounting firm to enter into a commercially reasonable written confidentiality agreement and to limit its audit report to Janssen solely to that information set forth in the preceding sentence. The accounting firm will be instructed to provide its audit report first to Licensee, and then will be further instructed to redact any proprietary information of Licensee not relevant to verifying the accuracy of the applicable reports prior to providing that audit report to Janssen. Except as provided below, the cost of this audit shall be borne by Janssen, unless the audit reveals a variance of more than [***]% from the reported amounts, in which case Licensee shall bear the cost of the audit. Unless disputed pursuant to Section 6.10 (Audit Dispute), if such audit concludes that (i) additional amounts were owed by Licensee, Licensee shall pay the additional amounts, with interest from the date originally due as provided in Section 6.7 (Interest on Late Payments) or (ii) excess payments were made by Licensee, then Janssen shall reimburse such excess payments, in either case ((i) or (ii)), within [***] days after the date on which such audit is completed.

6.10 **Audit Dispute**. In the event of a dispute with respect to any audit under Section 6.9 (Audit), Janssen and Licensee shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [***] days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party or to such other Person as the Parties shall mutually agree (the "**Auditor**"). The decision of the Auditor shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than [***] days after such decision and in accordance with such decision, the owing Party shall pay the additional amounts as provided in Section 6.9 (Audit).

ARTICLE 7
INTELLECTUAL PROPERTY

7.1 **Ownership of Intellectual Property**.

7.1.1 Ownership of Information and Patents. As between the Parties, each Party shall own and retain all rights, title and interests in and to any and all Information and Inventions that are Invented by or on behalf of such Party (or its Affiliates or its (sub)licensees (or Sublicensee(s)), as applicable) under or in connection with this Agreement, whether or not patented or patentable, and any and

all Patents and other intellectual property rights with respect thereto, except that the Parties shall jointly own an equal and undivided interest in all Joint Technology.

7.1.2 United States Law. The determination of whether Information or other Inventions are Invented by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States irrespective of where such conception, discovery, development or making occurs.

7.1.3 Exploitation of Joint Technology. Subject to the rights and licenses granted to, and the obligations of each Party, in this Agreement, either Party is entitled to practice the Joint Patents and Joint Know-How for all purposes on a worldwide basis and license the Joint Patents and Joint Know-How without the consent of and without a duty of accounting to the other Party. Each Party will grant and hereby does grant all permissions, consents and waivers with respect to, and all licenses under, the Joint Patents and Joint Know-How, throughout the world, necessary to provide the other Party with such rights of use and Exploitation of the Joint Patents and Joint Know-How, and will execute documents as necessary to accomplish the foregoing.

7.1.4 Assignment Obligation. In order to ensure that Janssen receives the full benefit of the rights and licenses afforded to it, including in Section 2.2 (Limitations to License Grant) and Article 11 (Term and Termination), Licensee shall cause all Persons who perform Development activities, Manufacturing activities, regulatory activities or any other activities under or in connection with this Agreement or who Invent any Information or inventions on behalf of Licensee, its Affiliates or Sublicensees in connection with this Agreement to be under an obligation to assign (or, if Licensee is unable to cause any such Person to agree to such assignment obligation despite such Party's using commercially reasonable efforts to negotiate such assignment obligation, provide a license under) their rights in any Information and inventions resulting therefrom to Licensee, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions bound by U.S. statutory requirements against such an assignment (in which case a suitable license or right to obtain such a license shall be obtained).

7.2 **Filing, Prosecution and Maintenance of Patents**.

7.2.1 Janssen Patents, Product Patents and Licensee Patents.

(i) [***] *Rights.* Subject to Section 7.2.2 (Joint Patents) and Section 7.2.3 (Information and Cooperation), upon execution of this Agreement, [***] will select an independent outside patent counsel acceptable to Licensee to prepare, file, prosecute and maintain the Janssen Patents during the period commencing on the Effective Date and extending through the Research Term, *provided*, *however*, that for each Product Patent, such period shall end upon [***] by Licensee for a Licensed Product or Licensed Compound Covered by such Product Patent (such period, the **"**[***] **Patent Prosecution Period"**). [***] will direct independent outside patent counsel in matters relating to preparation, filing, prosecution and maintenance of Janssen Patents that require direction but will provide Licensee with an opportunity to review and comment on such matters and will give such comments due consideration. All costs and expenses for preparation, filing, prosecution and maintenance of the Janssen Patents will be borne by [***] during the applicable [***] Patent Prosecution Period.

(ii) [***] *Rights*. Upon [***] by Licensee with respect to a Licensed Product, [***] will direct such independent outside patent counsel in matters relating to preparation, filing, prosecution and maintenance throughout the world of any Product Patent Covering such Licensed Product or Licensed Compound that requires direction, but will provide [***] with an opportunity to review and

comment on such matters and will give such comments due consideration. All costs and expenses for preparation, filing, prosecution and maintenance of such Janssen Patents will be borne by [***].

(iii) *Abandonment by* [***]. If during the Research Term for a Janssen Patent that is not a Product Patent or during the [***] Patent Prosecution Period for a Product Patent, [***] elects not to prosecute or maintain such Janssen Patent or Product Patent in a country, then [***] will provide [***] with written notice after any such election to allow [***] a reasonable period of time to determine, in its sole discretion, its interest in such Janssen Patent or Product Patent (which notice by [***] will be given no later than [***] days prior to the final deadline for any pending action or response that may be due with respect to such Patent with the applicable patent authority). If [***] provides written notice to [***] expressing its interest in maintaining such Janssen Patent or Product Patent, then, with respect to such Janssen Patent or Product Patent (a) [***] will no longer be responsible for [***] relating to prosecuting and maintaining (as applicable) such Janssen Patent; (b) [***] may, in its sole discretion [***], prosecute and maintain such Janssen Patent or Product Patent; (c) upon [***]'s request [***],[***] will promptly provide all files related to filing, prosecuting and maintaining such Janssen Patent or Product Patent to [***] or counsel designated by [***]; and (d) such Janssen Patent or Product Patent will cease to be [***] in such country.

(iv) *Abandonment by* [***]. In the event [***] elects not to prosecute or maintain any Product Patent that is being prosecuted or maintained by [***], then [***] will provide [***] with written notice after any such election to allow [***] a reasonable period of time to determine, in its sole discretion, its interest in such Product Patent (which notice by [***] will be given no later than [***] days prior to the final deadline for any pending action or response that may be due with respect to such Product Patent with the applicable patent authority). If [***] provides written notice to [***] expressing its interest in maintaining such Product Patent, then, with respect to such Product Patent (a) [***] will no longer be responsible for [***] relating to prosecuting and maintaining (as applicable) such Product Patent; (b) [***] may, in its sole discretion [***], prosecute and maintain such Product Patent; and (c) upon [***]'s request [***], [***] will promptly provide all files related to filing, prosecuting and maintaining such Product Patent to [***] or counsel designated by [***].

7.2.2 Joint Patents. If the Parties make any Joint Know-How, then the Parties will promptly meet to discuss and determine whether to seek Joint Patents thereon.

(i) [***]'s *Rights*. If either Party decides to seek any Joint Patents, then Licensee will have the first right, but not the obligation, to prepare, file, prosecute and maintain throughout the world, at its expense, any Joint Patents.

(ii) [***]'s *Rights*. If [***] elects not to prepare, file, prosecute or maintain any Joint Patent, then [***] will have the second right, but not the obligation, to prepare, file, prosecute and maintain throughout the world, [***], such Joint Patent, in which case, [***] will be responsible for, and will have final decision-making authority with respect to, the preparation, filing, prosecution and maintenance of such Joint Patent.

(iii) Prosecution Upon Termination. Following the expiration of the Janssen Patent Prosecution Period, if this Agreement is terminated in its entirety for any reason or as to a particular Licensed Compound or Licensed Product by Licensee pursuant to Section 11.2.3 (Termination Without Cause by Licensee) or a Janssen Patent otherwise ceases to be a Product Patent (because such Janssen Patent does not Cover or ceases to Cover any Designated Compound, Licensed Compound, Licensed Product), then [***]'s right to prepare, file, prosecute and maintain such former Product Patent will revert to [***], and thereafter [***] will be solely responsible at its discretion for the preparation, filing,

prosecution and maintenance of such reverted Product Patents [***], and will have all decision-making authority associated therewith.

7.2.3 Information and Cooperation. The Parties hereby agree to cooperate fully with each other in all matters related to the filing, prosecution and maintenance of Janssen Patents, Product Patents and Joint Patents under this Section 7.2 (Filing, Prosecution and Maintenance of Patents) and to perform such filing, prosecution and maintenance in accordance with this Section 7.2 (Filing, Prosecution and Maintenance of Patents) and Section 7.3 (Enforcement and Defense of Patents). Such cooperation will include the Party who is responsible for patent prosecution with respect to a Patent pursuant to Section 7.2.1 (Janssen Patents, Product Patents and Licensee Patents) and Section 7.2.2 (Joint Patents) (the "**Responsible Party**") (i) reasonably consulting with the other Party as to the preparation, filing, foreign filing, prosecution, correction of defects and maintenance of all Janssen Patents, Product Patents and Joint Patents for which the Responsible Party is responsible reasonably prior to any deadline for action in any patent office in which such Janssen Patents, Product Patents and Joint Patents are filed or pending; (ii) furnishing the other Party with copies of all material filings to be made with respect to such Janssen Patents, Product Patents and Joint Patents reasonably in advance of consultation thereon; and (iii) reasonably discussing in good faith all comments and suggestions made by the other Party in the course of such consultation to the extent such comments are reasonable and made by other Party in a timely manner. Each Party and its Affiliates hereby agree to promptly supply or execute all papers and instruments, or require their respective employees to supply or execute such papers and instruments, as may be necessary and appropriate for purposes of preparing, filing, prosecuting and maintaining the Janssen Patents, Product Patents and Joint Patents and promptly inform the prosecuting Party of matters that may be expected to reasonably affect the preparation, filing, prosecution, maintenance, validity and enforceability of any of the Janssen Patents or Joint Patents.

7.3 **Enforcement and Defense of Patents**.

7.3.1 Notification. If either Party (i) becomes aware of any suspected infringement or misappropriation of any Janssen Technology, Licensee Technology or Joint Technology anywhere in the Territory that (in the case of Patents) Cover (or in the case of Information, is used in) the Exploitation of (a) Portfolio Compound during the Research Term or (b) a Licensed Compound or a Licensed Product during the Term or (ii) receives any application, submission or notice under 21 U.S.C. §355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) or a certification that is, or is comparable to, a Paragraph IV Patent Certification by a Third Party filing an Abbreviated New Drug Application or filing an application under §505(b)(2), or other similar patent certification by a Third Party, in each case that comprises, incorporates, or otherwise competes with any Licensed Product (each (i) and (ii), a "**Competing Infringement**"), that Party will promptly notify the other Party (in all instances, such timeframe to be sufficiently prompt to provide the other Party the opportunity to respond to such proceedings) and provide it with all details of such Competing Infringement of which it is aware (each, a "**Competing Infringement Notice**").

7.3.2 Infringement Actions. [***] will have the first right, but not the obligation, to initiate an infringement, misappropriation or other appropriate suit anywhere in the world against any Third Party as to any Competing Infringement (an **"Infringement Action"**). If within [***] days of receiving a Competing Infringement Notice from [***] (or at least [***] days before the expiration of any time limit set forth in an Applicable Law, including the time limits set forth under 21 U.S.C. §355), [***] does not notify [***] of its intent to initiate an Infringement Action with respect to such Competing Infringement, then [***] will have the second right, but not the obligation, to initiate such Infringement Action.

7.3.3 Cooperation. In either case, the Party not initiating an Infringement Action (the **"Non-Initiating Party"**) will provide reasonable cooperation to the Party initiating such Infringement Action (the **"Initiating Party"**) in connection therewith, including by promptly supplying or executing all papers and instruments, or requiring its employees to supply or execute such papers and instruments, as may be necessary for purposes of initiating and pursuing such Infringement Action. Neither Party will incur any liability to the other Party as a consequence of any such Infringement Action or any unfavorable decision resulting therefrom, including any decision holding any claim of the Janssen Patents or the Joint Patents invalid, not infringed or unenforceable. Neither Party will take any position with respect to, or compromise or settle, such dispute in any way that will be reasonably likely to adversely affect the scope, validity or enforceability of the Janssen Patents or the Joint Patents, in each case, without the prior written consent of the other Party, not to be unreasonably withheld or delayed.

7.3.4 Procedures; Assistance; Expenses. The Initiating Party will have the sole and exclusive right to select counsel for and control the conduct of any such Infringement Action and will pay all expenses of such Infringement Action, including attorneys' fees and court costs and reimbursement of the Non-Initiating Party's reasonable out-of-pocket costs in rendering assistance requested by the Initiating Party. If requested by the Initiating Party, the Non-Initiating Party will join as a party to such Infringement Action and will execute, and cause its Affiliates to execute, all documents necessary for the Initiating Party to initiate litigation to prosecute and maintain such Infringement Action. In addition, at the Initiating Party's request, the Non-Initiating Party will provide reasonable assistance to the Initiating Party in connection with an Infringement Action at no charge to the Initiating Party except for reimbursement by the Initiating Party of reasonable out-of-pocket costs incurred in rendering such assistance. The Non-Initiating Party will have the right to participate and be represented in any such Infringement Action by its own counsel at its own expense.

7.3.5 Recoveries. Any recoveries obtained by the Initiating Party as a result of any proceeding in connection with the enforcement of Janssen Patents and Joint Patents against a Competing Infringement will be allocated as follows:

(i) first, such recovery will be used to reimburse the Parties for all out-of-pocket litigation costs in connection with such litigation; and

(ii) second, with respect to any remaining portion of such recovery, [***]% will be paid to [***] and [***]% will be paid to [***].

7.3.6 Licensee Technology. Licensee will have the exclusive right, but not the obligation, to initiate an infringement, misappropriation or other appropriate suit anywhere in the world against any Third Party with respect to the Licensee Technology at its sole cost and expense and to retain all recoveries obtained as a result thereof.

7.4 **Potential Infringement of Third Party Rights**.

7.4.1 Notice. If any action, suit or proceeding is brought against either Party or any Affiliate of either Party or any Sublicensee or distributor of Licensee alleging the infringement of the technology or Patents of a Third Party by reason of or the Exploitation of any Licensed Product by or on behalf of Licensee, its Affiliates, Sublicensees or distributors, such Party will notify the other Party as promptly as possible following the receipt of service of process in such action, suit or proceeding, or the date such Party becomes aware that such action, suit or proceeding has been instituted.

7.4.2 Defense. Unless otherwise mutually agreed to by the Parties, and subject to Article 10 (Indemnity), (i) [***] will have the right, but not the obligation, to defend such action, suit or

proceeding at its sole expense; (ii) if [***] exercises such right with respect to an action, suit, or proceeding brought against [***], then [***] or any of its Affiliates will have the right to separate counsel at its own expense in any such action, suit or proceeding; and (iii) the Parties will cooperate with each other in all reasonable respects in any such action, suit or proceeding. Each Party will promptly furnish the other Party with a copy of each communication relating to the alleged infringement that is received by such Party including all documents filed in any litigation. If [***] exercises its right to defend an action, suit or proceeding brought against [***], in no event will [***] settle or otherwise resolve any such action, suit or proceeding without [***] prior written consent, not to be unreasonably withheld or delayed.

7.5 **Patent Term Extensions; Patent Listings.**

7.5.1 Extensions. The Parties agree to cooperate in an effort to avoid loss of any Product Patents, Joint Patents, Licensee Patents or Janssen Patents which may otherwise be available to the Parties under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 or comparable U.S. or foreign laws, including by executing any documents as may be reasonably required. In particular, the Parties shall cooperate with each other in obtaining patent term extension or supplemental protection certificates or their equivalents in any country and region where applicable to the relevant Patents.

7.5.2 Listings. [***] shall make decisions regarding and shall have the right to make filings with Regulatory Authorities in the Territory with respect to the Licensed Products as required or allowed (i) in the United States, in the FDA's Orange Book and (ii) in the European Union, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents; *provided that* [***] shall consult with [***] to determine the course of action with respect to such filings.

7.6 **EU Unitary Patent System**. Without limiting [***] rights under Section 7.3 (Enforcement and Defense of Patents), [***] will have the exclusive right to opt-in and opt-out any Product Patent or Joint Patent from the jurisdiction of the EU Unified Patent Court, in accordance with the terms of Unified Patent Court Regulation (EU) No 1257/2012 and its applicable Annexes and Rules of Procedure, as amended from time-to-time and in effect (the "**UPC**"). Unless [***] has expressly opted-in to the EU Unitary Patent System with respect to a given Product Patent or Joint Patent, [***] will not initiate any action to enforce any such Product Patent or Joint Patent under the EU Unitary Patent System without Licensee's prior written approval.

ARTICLE 8
CONFIDENTIALITY AND NON-DISCLOSURE

8.1 **Confidentiality Obligations**.

8.1.1 Confidential Information. At all times during the Term and for a period of [***] following termination or expiration hereof in its entirety, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly licensed or otherwise permitted by the terms of this Agreement. "**Confidential Information**" means any technical, business or other information provided by or on behalf of one Party to the other Party, including information relating to the terms of this Agreement (subject to Section 8.6 (Public Announcements)), information relating to the Portfolio Compounds or any Licensed Product (including the Regulatory Documentation), any research of the Portfolio Compounds or the Development or Commercialization of the Licensed Compounds or Licensed Products, any know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including Licensee Know-How) or the

scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, Information that is jointly-owned by the Parties pursuant to Section 7.1.1 (Ownership of Information and Patents) and the terms of this Agreement shall be deemed to be the Confidential Information of both Parties and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto.

8.1.2 Confidential Candidate Information. During the Research Term all Information generated or developed hereunder by or on behalf of Licensee, its Affiliates or its Sublicensees pertaining to Portfolio Compounds and Derivatives (other than Designated Compounds) ("**Confidential Candidate Information**") shall be the Confidential Information of Licensee; *provided that* Licensee may not disclose such Confidential Candidate Information without Janssen's written consent except pursuant to Section 8.2 (Permitted Disclosures). After the conclusion of the Research Term, any and all Confidential Candidate Information pertaining to any Licensed Compound or Licensed Product shall remain the Confidential Information of Licensee. Upon the conclusion of the Research Term (or at such earlier time as a compound becomes a Declined Compound prior to the conclusion of the Research Term pursuant to Section 3.5.1 (Notice; Fee)), Confidential Candidate Information pertaining to any Declined Compound (and any Compound Form thereof) shall become the Confidential Information of Janssen, and Licensee may not disclose such Information without Janssen's written consent except pursuant to Section 8.2 (Permitted Disclosures).

8.1.3 Exceptions to Confidentiality Obligations. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 8.1 (Confidentiality Obligations) with respect to any Confidential Information shall not include any information that:

(i) is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no breach of this Agreement by the receiving Party;

(ii) can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information; *provided that* the foregoing exception shall not operate to relieve either Party of its obligations under this Article 8 (Confidentiality and Non-Disclosure) with respect to any Confidential Candidate Information;

(iii) is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information;

(iv) has been published by a Third Party or otherwise enters the public domain through no fault of the receiving Party in breach of this Agreement; or

(v) can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference or access to the disclosing Party's Confidential Information; *provided that* the foregoing exception shall not operate to relieve either Party of its obligations under this Article 8 (Confidentiality and Non-Disclosure) with respect to any Confidential Candidate Information.

8.1.4 Public Domain. Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving

Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

8.2 **Permitted Disclosures.** Each Party may disclose Confidential Information to the extent that such disclosure is:

8.2.1 made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by law, including by reason of filing with securities regulators; *provided*, *however*, that the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided*, *further*, that the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

8.2.2 made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval made by or on behalf of a Party or any of its Affiliates or sublicenses (including Sublicensees) consistent with the terms and conditions of this Agreement (which filing, application or request by or on behalf of Licensee, its Affiliates or Sublicensees shall be solely to a Regulatory Authority in the Territory); *provided*, *however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

8.2.3 subject to Section 7.3 (Enforcement and Defense of Patents), made by or on behalf of the receiving Party to a patent authority as may be reasonably necessary or useful for purposes of obtaining or enforcing a Patent in a manner consistent with the terms of this Agreement; *provided*, *however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;

8.2.4 made by or on behalf of the receiving Party to (i) actual or *bona fide* potential investors or acquirers or other Third Party transactional parties (and to each of their respective bankers, lawyers, accountants and agents), as may be necessary in connection with their evaluation of such potential or actual investment or acquisition, or (ii) its actual or *bona fide* potential (sub)licensees, subcontractors, contract research organizations, academic collaborators or other similar Third Parties (and to each of their respective bankers, lawyers, accountants and agents) as may be necessary in connection with the exercise of such Party's rights hereunder; *provided*, *however*, that such Third Parties shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 8.2 (Permitted Disclosures) (with a duration of confidentiality and non-use obligations as appropriate that is no less than five years from the date of disclosure); or

8.2.5 made by or on behalf of the receiving Party in accordance with Section 8.7 (Scientific Publications).

8.3 **Joint Know-How**. Any and all Joint Know-How generated or developed during the Term shall be the Confidential Information of both Parties.

8.4 **Secrecy of Janssen Know-How and Confidential Candidate Information**. Without prejudice to the disclosures permitted pursuant to Section 8.2 (Permitted Disclosures), Janssen will protect, and will cause its Affiliates and Sublicensees and its and their respective officers, directors, employees and agents to protect, the secrecy and confidentiality of the Janssen Know-How using not less than the same degree of care as it uses to prevent the disclosure of its other confidential information of like importance. Without prejudice to the disclosures permitted pursuant to Section 8.2 (Permitted Disclosures), Licensee will protect, and will cause its Affiliates and Sublicensees and its and their respective officers, directors, employees and agents to protect, the secrecy and confidentiality of the Confidential Candidate Information using not less than the same degree of care as it uses to prevent the disclosure of its other confidential information of like importance.

8.5 **Use of Name**. Nothing contained in this Agreement shall be construed as conferring any right to a Party to use in advertising, publicity or other promotional activities any name, trade name, trademark or other designation of the other Party or any of its Affiliates, except as provided in Section 8.6 (Public Announcements).

8.6 **Public Announcements**. The Parties will agree upon the content of a press release to be released promptly upon execution of this Agreement in a manner agreed to by the Parties. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed. In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 8.6 (Public Announcements); *provided that* such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable.

8.7 **Scientific Publications**.

8.7.1 [***]'s Rights. [***] may make oral or written scientific publications (such as any abstracts, manuscripts, posters, slide presentations or other materials) of any activities or results relating to Licensed Compounds and Licensed Products without the written consent of [***], except as expressly provided in this Section 8.7 (Scientific Publications).

8.7.2 Right to Review. On a Licensed Product-by-Licensed Product basis, [***] with respect to any Licensed Product, [***] shall deliver a complete copy of the proposed written publication or the proposed written abstract and slides or any other materials for the proposed oral presentation for [***] review at least [***] days prior to submitting the paper to a publication or making the presentation. [***] shall review any such paper and give its comments to [***] within [***] days after the delivery of such publications or other materials to [***]. [***] shall comply with [***] reasonable requests to make modifications to any such proposed publication material prior to its submission or release to protect confidential or proprietary information. [***] also may request a reasonable delay in publication or oral presentation in order to protect patentable information. In such case, if [***] is the Responsible Party for such subject matter in accordance with Article 7 (Intellectual Property), [***] shall use Commercially Reasonable Efforts to file any patent applications necessary to protect the rights and interests of [***] under this Agreement.

8.7.3 Development Candidate, Derivative and Declined Compound Restrictions. During the Research Term, until such time as any Development Candidate or Derivative becomes a Designated Compound in accordance with the terms of Section 3.5.1 (Notice; Fee), [***] shall not make any [***] with respect to any such [***] (or any Compound Form of either of them) without [***] consent, not to be unreasonably withheld or delayed. After the Research Term, [***] shall not make any [***] with respect to any [***] (or any Compound Form thereof) without [***] consent, not to be unreasonably withheld or delayed. [***] shall be free to make [***] (and any Compound Form thereof).

8.7.4 Licensed Compound Restrictions. [***] shall not make any oral or written publications with respect to any Licensed Compounds (or any Compound Form thereof) without [***]'s consent, not to be unreasonably withheld or delayed.

8.7.5 Patent Filings. For clarity, this Section 8.7 (Scientific Publications) is not intended to cover Patent filings which are addressed in Section 7.2 (Filing, Prosecution and Maintenance of Patents).

8.8 **Required Publication Regarding Clinical Trials**. Regardless of any obligation of confidentiality hereunder, a Party may publically disclose and register information relating to clinical studies of Licensed Products as required by Applicable Law (*e.g.*, listing with www.clinicaltrials.gov when required by United States law).

8.9 **Return of Confidential Information**. Upon the effective date of the termination (but not expiration) of this Agreement for any reason, either Party may request in writing and the non-requesting Party shall either, with respect to Confidential Information to which such non-requesting Party does not retain rights under the surviving provisions of this Agreement: (i) promptly destroy all copies of such Confidential Information in the possession or control of the non-requesting Party and confirm such destruction in writing to the requesting Party; or (ii) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the non-requesting Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted to (a) retain such Confidential Information to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder and, in any event, copies of such Confidential Information for archival purposes and (b) retain any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 8.1 (Confidentiality Obligations).

ARTICLE 9
REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 **Mutual Representations and Warranties**. Janssen and Licensee each represents and warrants to the other, as of the Effective Date, that:

9.1.1 Organization. It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement.

9.1.2 Authorization. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (i) such Party's charter documents, bylaws or other organizational

documents; (ii) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound; (iii) any requirement of any Applicable Law; or (iv) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party.

9.1.3 Binding Obligation. This Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity).

9.1.4 No Inconsistent Obligations. It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

9.1.5 Debarment. Except with regard to Janssen as reflected by, and subject to the terms of, the Corporate Integrity Agreement between The Office of Inspector General of the Department of Health and Human Services and Johnson & Johnson dated October 31, 2013 (publicly available at https://www.janssenbiotech.com/company/pharmaceutical-affiliate-corporate-intergrity-agreement), as of the Effective Date, neither Party nor any of its Affiliates has been debarred or is subject to debarment.

9.2 **Additional Representations and Warranties of Janssen**. Except as set forth in the Disclosure Schedule attached hereto as Schedule 9.2, Janssen further represents and warrants to Licensee, as of the Effective Date, that:

9.2.1 Ownership or Control. Except as provided in Schedule 9.2.1 (Disclosure Schedule), Janssen (i) Controls the Janssen Know-How set forth on Schedule 4.1.1(i) (Disclosed Know-How) and (ii) is the sole and exclusive owner of the Janssen Patents set forth on Schedule 1.66 (Janssen Patents), and no other Person has any claim of ownership with respect to such Janssen Patents. Janssen has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in or to the Janssen Technology in any manner inconsistent with the license rights granted to Licensee under this Agreement. Schedule 1.66 (Janssen Patents) sets forth all Patents Controlled by Janssen that Cover any Portfolio Compound or the Manufacture or use thereof.

9.2.2 No Claims. (i) There are no claims, judgments or settlements against Janssen pending or, to the Knowledge of Janssen, threatened, that [***], (ii) there is no [***] pending in any jurisdiction outside of the United States that [***] in that jurisdiction, (iii) there is no litigation pending against Janssen or any Affiliate of Janssen that alleges that [***] (nor has it received any written communication threatening such litigation) and (iv) except as Janssen has disclosed to Licensee in writing, Janssen has not received [***].

9.2.3 Knowledge of Infringement, Validity. To the Knowledge of Janssen, (i) Janssen is not aware of any Third Party Patent that [***], and (ii) [***].

9.2.4 License Agreements. Janssen is not party to any agreement with any Third Party pursuant to which Janssen has received a license under any Patents or Information included in the Janssen Technology. Janssen is not party to any agreement with any Third Party pursuant to which Janssen has granted a license under any Janssen Patents.

9.2.5 Completeness of Janssen Schedules. Other than the Janssen Patents set forth on Schedule 1.66 (Janssen Patents), Janssen does not Control any Patent that Covers any Portfolio

Compound or any Compound Form thereof. The Janssen Know-How identified on Schedule 4.1.1(i) (Disclosed Know-How) includes all material Information Controlled by Janssen that is necessary or useful to Exploit the Portfolio Compounds. To the Knowledge of Janssen, Schedule 1.108 (Specified Compounds) lists all compounds that are Covered by the Janssen Patents that were generated and used by Janssen or any of its Affiliates in the course of [***] conducted by Janssen prior to the Effective Date.

9.2.6 Diligent Prosecution and Maintenance. The Janssen Patents have been diligently prosecuted with the respective patent offices in accordance with Applicable Law, and all fees necessary to maintain the Janssen Patents set forth on Schedule 1.66 (Janssen Patents) have been paid on or before the due date for such payment.

9.2.7 Invention Assignments. Each individual who is an inventor of, or otherwise contributed in a material manner to the creation or development of, any Janssen Patents in existence as of the Effective Date and identified as being owned by Janssen on Schedule 1.66 (Janssen Patents) has assigned to Janssen all of his or her interest therein.

9.3 **Covenants of Both Parties.**

9.3.1 Debarment. Neither Party nor any of its Affiliates will use in any capacity, in connection with its activities under this Agreement, any person who has been debarred pursuant to Section 306 of the FFDCA, or who is the subject of a conviction described in such section. Each Party agrees to inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder.

9.3.2 Compliance with Law. Each Party, its officers, directors and employees and its Affiliates, agents, representatives, consultants, Sublicensees, distributors and subcontractors shall comply with Applicable Law in connection with this Agreement and the transactions contemplated hereunder, including the Anti-Corruption Laws, and shall not take any action that will, or would reasonably be expected to, cause the other Party or any of its Affiliates to be in violation of any such Applicable Law.

9.3.3 No Inconsistent Obligations. During the Term, neither Party will enter into any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

9.4 **Additional Covenants of Licensee**. Licensee covenants to Janssen that other than in connection with an assignment or other transfer of this Agreement as permitted under Section 12.3 (Assignment), Licensee shall not assign, transfer, convey or otherwise encumber (including through attachment of a lien) its rights to the Licensee Foreground Patents and the Licensee Foreground Know-How for as long as Janssen retains any license, option or other rights therein by virtue of this Agreement without the prior written consent of Janssen, such consent not to be unreasonably withheld or delayed.

9.5 **Additional Covenants of Janssen**. Other than in connection with an assignment or other transfer of this Agreement as permitted under Section 12.3 (Assignment), Janssen shall not assign, transfer, convey or otherwise encumber (including through attachment of a lien) its rights to the Janssen Technology set forth on Schedule 1.66 (Janssen Patents) and Schedule 4.1.1(i) (Disclosed Know-How) in any manner inconsistent with the license rights granted to Licensee under this Agreement without the prior written consent of Licensee, such consent not to be unreasonably withheld or delayed.

9.6 **DISCLAIMER OF WARRANTIES**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 10
INDEMNITY

10.1 **Indemnification of Janssen.** Licensee shall indemnify Janssen, its Affiliates and its and their respective directors, officers, employees and agents and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") to the extent arising from or occurring as a result of: (i) the breach by Licensee of this Agreement; (ii) the negligence or willful misconduct on the part of Licensee, its Affiliates or its Sublicensees in performing its or their obligations under this Agreement; and (iii) the Exploitation by Licensee, its Affiliates or its Sublicensees of any Licensed Compounds or Licensed Products, except, in each case ((i), (ii) and (iii)), to the extent such Losses arise from or occur as a result of the breach by Janssen of this Agreement or the negligence or willful misconduct on the part of Janssen, its Affiliates or its or their respective directors, officers, employees or agents.

10.2 **Indemnification of Licensee**. Janssen shall indemnify Licensee, its Affiliates and their respective directors, officers, employees and agents and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims to the extent arising from or occurring as a result of: (i) the breach by Janssen of this Agreement; (ii) the negligence or willful misconduct on the part of Janssen in performing its obligations under this Agreement; (iii) the Exploitation by Janssen, its Affiliates or (sub)licensees of Declined Compounds or any Licensed Compounds or Licensed Products following termination of this Agreement with respect to such Licensed Compound or Licensed Product; (iv) studies conducted by Licensee on Janssen's behalf pursuant to Section 11.4.1(iv) (Transfer of Clinical Studies Upon Termination); and (v) [***] based on Janssen's activities in connection with [***], except, in each case ((i), (ii), (iii), (iv) and (v)), to the extent such Losses arise from or occur as a result of the breach by Licensee of this Agreement or the negligence or willful misconduct on the part of Licensee, its Affiliates or its Sublicensees or its or their respective directors, officers, employees or agents.

10.3 **Indemnification Procedures**.

10.3.1 Notice of Claim. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents shall be made solely by the applicable Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party written notice within [***] days (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 10 (Indemnity), but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

10.3.2 Control of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 10.3.3 (Right to Participate in Defense), the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in its defense of the Third Party Claim.

10.3.3 Right to Participate in Defense. Any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to engage counsel of its choice for such purpose; *provided*, *however*, that such engagement shall be at the Indemnified Party's sole cost and expense unless (i) the engagement thereof has been specifically authorized in writing by the indemnifying Party, or (ii) the indemnifying Party has failed to assume the defense in accordance with Section 10.3.2 (Control of Defense) (in which case the Indemnified Party shall control the defense).

10.3.4 Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the applicable indemnitee becoming subject to injunctive or other relief and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the applicable indemnitee hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Losses, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 10.3.2 (Control of Defense), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; *provided that* it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim.

10.3.5 Cooperation. Regardless of whether the indemnifying Party chooses to defend any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and

explanation of any material provided hereunder and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket expenses in connection therewith.

10.3.6 Expenses. Except as provided above, the costs and expenses, including permissible fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

10.4 **SPECIAL, INDIRECT AND OTHER LOSSES**. EXCEPT WITH RESPECT TO (A) [***] OR [***], (B) A BREACH OF THE OBLIGATIONS OF A PARTY UNDER [***] OR, (C) DAMAGES REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 10 (INDEMNITY), NEITHER PARTY NOR ANY OF ITS AFFILIATES OR (SUB)LICENSEES SHALL BE LIABLE IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS (EVEN IF DEEMED DIRECT DAMAGES) SUFFERED BY THE OTHER PARTY ARISING OUT OF THIS AGREEMENT; *PROVIDED THAT* WITH RESPECT TO (A) AND (B) ABOVE, THE MAXIMUM AGGREGATE AMOUNT OF ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOST PROFITS (EVEN IF DEEMED DIRECT DAMAGES) THAT MAY BE RECOVERED BY A PARTY FROM THE OTHER PARTY SHALL BE [***] ($[***]).

10.5 **Insurance**. Each Party, at its own expense, shall maintain liability insurance in an amount consistent with industry standards during the Term, but in no event shall such insurance be in an amount less than [***] ($[***]) per occurrence and annual aggregate during the Term. In addition, during the term of Commercialization of any Licensed Product by Licensee or its Affiliates and for a period of at least [***] years thereafter, Licensee shall maintain product liability insurance coverage in an amount not less than [***] ($[***]) per occurrence and annual aggregate. Further, during the term of Commercialization of any product containing a Licensed Compound or Declined Compound by Janssen or its Affiliates and for a period of at least [***] years thereafter, Janssen shall maintain product liability insurance in an amount not less than [***] ($[***]) per occurrence and annual aggregate. A Party responsible for conducting any clinical studies hereunder shall maintain clinical trial insurance in compliance with all Applicable Law pertaining to the jurisdictions in which such clinical studies are conducted. Each Party shall provide a certificate of insurance evidencing such coverage to the other Party upon its written request. Each Party shall notify the other Party [***] days in advance of cancelation of any such insurance. Janssen shall be permitted to satisfy its obligations hereunder through a program of self-insurance.

ARTICLE 11
TERM AND TERMINATION

11.1 **Term and Expiration**. This Agreement shall commence on the Effective Date and shall continue in force and effect until the last to expire Royalty Term, unless earlier terminated in accordance with this Article 11 (Term and Termination) (such period, the "**Term**").

11.2 **Termination**.

11.2.1 By Either Party for the Other Party's Material Breach. Upon and subject to the terms and conditions of this Section 11.2.1 (By Either Party for the Other Party's Material Breach),

this Agreement may be terminated by a Party upon written notice to the other Party, if such other Party commits a material breach of this Agreement including in the case of Licensee, a material breach of this Agreement based on its failing to satisfy its obligations to use Commercially Reasonable Efforts pursuant to Section 3.8 (Development Diligence) or Section 3.13.1 (Commercialization Diligence) *provided*, *however*, that if a material breach by Licensee relates only to one or more Licensed Compounds or Licensed Products (but not all Licensed Compounds or Licensed Products), then Janssen shall have the right to terminate this Agreement only with respect to the particular Licensed Compounds or Licensed Products to which such material breach relates. Such notice of termination shall be effective [***] days after the date such notice is given unless the breaching Party shall have cured such breach within such [***] day period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such [***] day period, such longer period not to exceed [***] days so long as the breaching party is using diligent efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such [***] day period or such time as the breaching party ceases to use diligent efforts to cure such breach); *provided that* if either Party initiates a dispute resolution procedure under Section 12.5 (Dispute Resolution) to resolve a Dispute regarding the material breach for which termination is being sought and is diligently pursuing such procedure, then the cure period set forth in this Section 11.2.1 (By Either Party for the Other Party's Material Breach) will be tolled during the pendency of such dispute resolution procedures.

11.2.2 Termination by Janssen.

(i) *For Patent Challenges*. In the event that Licensee or any of its Affiliates or Sublicensees, anywhere in the Territory, institutes, prosecutes or otherwise participates in (or Licensee or its Affiliates in any way aids any Third Party in instituting, prosecuting or participating in), at law or in equity or before any administrative or regulatory body, including the U.S. Patent and Trademark Office or its foreign counterparts, any claim, demand, action or cause of action for declaratory relief, damages or any other remedy or for an enjoinment, injunction or any other equitable remedy, including any interference, re-examination, opposition or any similar proceeding, alleging that any claim in a Janssen Patent (or in the case of such a claim, demand or cause of action instituted, prosecuted or participated in by a Sublicensee, those Janssen Patents sublicensed to such Sublicensee) is invalid, unenforceable or otherwise not patentable or would not be infringed by Licensee's activities absent the rights and licenses granted hereunder, then Janssen may, in its sole discretion either (i) exclude such Janssen Patent from the scope of the Janssen Technology licensed to Licensee under Section 2.1 (Grants to Licensee) or (ii) immediately terminate this Agreement (a) with respect to the Licensed Compounds or Licensed Products Covered by such Patent in the country in which Licensee or its Affiliate challenges such Patent, or (b) in its entirety if such Licensed Compound is [***] (or a Back-Up Compound that has been designated as a Primary Designated Compound [***]), upon written notice to Licensee where such proceeding is instituted prior to the termination of this Agreement with respect to [***].

(ii) [***]. This Agreement may be terminated in its entirety by Janssen upon written notice to Licensee, if Licensee breaches its obligations set forth under [***]. Such termination shall be effective [***] days after the date such notice is given unless Licensee shall have cured such breach within such [***] day period; *provided that* if Licensee initiates a dispute resolution procedure under Section 12.5 (Dispute Resolution) to resolve a Dispute regarding whether or not Licensee is in breach of its obligations under [***] and is diligently pursuing such procedure, then the cure period set forth in this Section 11.2.2(ii) ([***]) will be tolled during the pendency of such dispute resolution procedures.

11.2.3 Termination without Cause by Licensee. Licensee may terminate this Agreement either in its entirety or with respect to a particular Licensed Compound or Licensed Product upon 180 days' prior written notice to Janssen; *provided*, *however*, that in the event of termination of this Agreement by Licensee with respect to [***].

11.2.4 Termination for Insolvency. In the event that either Party (i) files for protection under bankruptcy or insolvency laws, (ii) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within 90 days after such filing, (iii) is a party to any dissolution or liquidation or (iv) files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within 60 days of the filing thereof, then, in each case, ((i) – (iv)), the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

11.3 **Rights in Bankruptcy**. All rights, options and licenses granted under or pursuant to this Agreement by Licensee or Janssen are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party. The Parties stipulate and agree that all payments by Licensee and Janssen under this Agreement, other than royalty payments pursuant to Section 6.3 (Royalties) and sales milestone payments pursuant to Section 6.2.4 (Sales Milestones), do not constitute "royalties" within the meaning of Section 365(n) of the U.S. Bankruptcy Code.

11.4 **Consequences of Termination**.

11.4.1 Termination in its Entirety. In the event of a termination of this Agreement in its entirety by either Party for any reason:

(i) *Termination of Rights.* All rights and licenses granted by Janssen hereunder shall immediately terminate, including any sublicense granted by Licensee pursuant to Section 2.4 (Sublicenses).

(ii) *Assignment of Regulatory Documents and Trademarks.* At Janssen's written request, Licensee shall and hereby does, and shall cause its Affiliates and its Sublicensees to, effective as of the effective date of termination, assign to Janssen all of its right, title and interest in and to (a) all Regulatory Documentation (including any Regulatory Approvals) applicable to the Licensed Compounds or Licensed Products then owned or Controlled by Licensee or any of its Affiliates or its Sublicensees and (b) each Trademark exclusively associated with marketed Licensed Products.

(iii) *Right of Reference and Grant Back License*. In the event of a termination of this Agreement by either Party for any reason other than termination by Licensee due to Janssen's material breach, at Janssen's written request, Licensee shall and hereby does, and shall cause its Affiliates and its Sublicensees to, effective as of the effective date of termination, grant to Janssen a license and right of reference, with the right to grant sublicenses, in and to any and all (a) Regulatory Documentation (including any Regulatory Approvals) then owned or Controlled by Licensee, its Affiliates or its Sublicensees that are not assigned to Janssen pursuant to Section 11.4.1(ii) (Assignment of Regulatory

Documents and Trademarks) and (b) Licensee Foreground Know-How and Licensee Foreground Patents, in each case ((a) and (b)), solely to Exploit in the Territory any Licensed Compounds or Licensed Products and any subsequent improvements to such Licensed Compounds and Licensed Products. Such license shall be, at [***] election, either (1) [***] or (2) [***] shall pay to [***]% except that if a [***], then [***] shall pay to [***]%, in each case on Net Sales of Licensed Products by [***], its Affiliates or Sublicensees for a period of [***] years from First Commercial Sale of the Licensed Product in the Territory, and the provisions of Section 6.3.3 (Reductions) shall apply *mutatis mutandis.*

(iv) *Transfer of Clinical Studies Upon Termination.* In the event of a termination of this Agreement by either Party for any reason other than termination by Licensee due to Janssen's material breach, unless expressly prohibited by any Regulatory Authority, at Janssen's written request, Licensee shall use Commercially Reasonable Efforts to, and shall cause its Affiliates and its Sublicensees to use Commercially Reasonable Efforts to, transfer control to Janssen of all clinical studies involving Licensed Compounds or Licensed Products being conducted by or on behalf of Licensee, an Affiliate or a Sublicensee as of the effective date of termination and continue to conduct such clinical studies, at Janssen's cost, to enable such transfer to be completed without interruption of any such clinical study; *provided that* Janssen shall not have any obligation to continue any clinical study unless required by Applicable Law.

(v) *Product-Specific Third Party Agreements*. In the event of a termination of this Agreement by either Party for any reason other than termination by Licensee due to Janssen's material breach, at Janssen's written request, Licensee shall, and cause its Affiliates and its Sublicensees to, assign to Janssen all Product-Specific Third Party Agreements, unless, with respect to any such Product-Specific Third Party Agreement, (a) such Product-Specific Third Party Agreement expressly prohibits such assignment or otherwise requires one or more Third Parties to consent to such assignment and such Third Party will not provide such consent after reasonable efforts by Janssen to secure such consent of the Third Party, or (b) such Product-Specific Third Party Agreement applies to any compound or product other than the Licensed Compounds and Licensed Products subject to termination. Licensee (or such Affiliate or Sublicensee, as applicable) shall cooperate with Janssen in all reasonable respects to secure the consent of the applicable Third Party to such assignment. If the consent of a Third Party is not obtained pursuant to subsection (a) or subsection (b) applies, then Licensee shall, and cause its Affiliates and its Sublicensees to, make reasonable efforts for a period of [***] months to effect an orderly transition of the activities being performed by such Third Party under such Product-Specific Third Party Agreement.

(vi) *Product Supply*. In the event of a termination of this Agreement by either Party for any reason other than termination by Licensee due to Janssen's material breach, to the extent that the Licensed Compounds and Licensed Products are not supplied by a Third Party pursuant to a Product-Specific Third Party Agreement that is assigned to Janssen pursuant to Section 11.4.1(v) (Product-Specific Third Party Agreements), at Janssen's written request, Licensee shall supply to Janssen, pursuant to a supply agreement to be negotiated promptly and in good faith and entered into by the Parties containing standard and customary terms, such quantities of the Licensed Compounds and Licensed Products as Janssen indicates in written forecasts and orders therefor from time-to-time at Licensee's actual, fully-loaded cost to Manufacture such Licensed Compounds and Licensed Products until the [***] of (a) such time as [***] for the Licensed Compound and Licensed Products and Janssen is [***] and (b) the [***] of the effective date of termination of this Agreement.

11.4.2 Termination with respect to a Licensed Compound or Licensed Product. If this Agreement is terminated with respect to a Licensed Compound or Licensed Product (but not in its entirety), then the provisions set forth above in Section 11.4.1 (Termination in its Entirety) shall apply solely to such terminated Licensed Compound or Licensed Product.

11.5 **Remedies**. Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to one or more products) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

11.6 **Accrued Rights; Surviving Obligations**. Termination or expiration of this Agreement (either in its entirety or with respect to one or more products) for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Sections 2.4 (Sublicenses), 2.5 (Retention of Rights; No Other Rights Granted), 3.5.3 (Conclusion of Research Term; Declined Compounds), 3.11 (Records), 4.1.4 (Return of Janssen Know-How and Materials), 6.3.2 (Royalty Term), 6.7 (Interest on Late Payments), 6.8 (Financial Records), 6.9 (Audit) and 6.10 (Audit Dispute) and Article 7 (Intellectual Property), Article 8 (Confidentiality and Non-Disclosure), Article 10 (Indemnity), Article 11 (Term and Termination) and Article 12 (Miscellaneous) shall survive the termination or expiration of this Agreement for any reason.

ARTICLE 12
MISCELLANEOUS

12.1 **Force Majeure.** Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within [***] days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use Commercially Reasonable Efforts to remedy its inability to perform.

12.2 **Export Control**. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time-to-time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

12.3 **Assignment**. Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that (i) either Party may assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of any other Party; *provided that* the Party assigning to an Affiliate any part of this Agreement shall remain liable and responsible to the non-assigning Party for the performance and observance of all such duties and obligations by such Affiliate; and (ii) either Party may assign this Agreement in its entirety to a successor to all or substantially all of its business relating to Licensed Compounds and Licensed Products, whether by merger, sale of stock, sale of assets or otherwise. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and

be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 12.3 (Assignment) shall be void and of no effect.

12.4 **Severability**. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (i) such provision shall be fully severable, (ii) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (iii) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (iv) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect.

12.5 **Dispute Resolution**.

12.5.1 Disputes. Except as provided in Section 6.10 (Audit Dispute) or Section 12.6 (Intellectual Property Disputes), if a dispute arises between the Parties relating to either Party's rights or obligations hereunder, including the interpretation, alleged breach, enforcement, termination or validity of this Agreement (a "**Dispute**"), then either Party shall have the right to refer such Dispute to the Executive Officers for attempted resolution by good faith negotiations during a period of [***] Business Days.

12.5.2 Mediation. If a Dispute remains unresolved after the end of the [***] Business Day negotiation period provided for in Section 12.5.1 (Disputes), then either Party may, by notice to the other Party submit the dispute to non-binding mediation in accordance with the CPR Mediation Procedure for Business Disputes then in effect, except where that procedure conflicts with these provisions, in which case these provisions shall prevail. The mediation shall be conducted in New York, New York and shall be attended by a senior executive with authority to resolve the dispute from each Party. The mediator shall confer with the Parties to design procedures to conclude the mediation within no more than [***] after initiation. Under no circumstances may the commencement of arbitration be delayed more than [***] by the mediation process specified herein except by mutual agreement of the Parties. No statements made by either Party during the mediation may be used by the other or referred to during any subsequent proceedings.

12.5.3 Arbitration. Any Dispute that cannot be resolved pursuant to Section 12.5.2 (Mediation) by mediation may be referred to and finally resolved by binding arbitration in accordance with this Section 12.5.3 (Arbitration) by one Party providing written notice to the other Party (an "**Arbitration Notice**"). Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three experts with relevant industry experience (the "**Arbitrators**"). Each of Licensee and Janssen shall promptly select one Arbitrator each, which selections shall in no event be made later than [***] after the notice of initiation of arbitration. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Licensee and the Arbitrator chosen by Janssen, but in no event later than [***] after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery; *provided that* the Arbitrators shall permit such discovery as they deem necessary to permit an equitable resolution of the dispute. The arbitration shall be administered by the AAA in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Agreement. The arbitration shall be held in New York, New York, and the Parties shall use reasonable

efforts to expedite the arbitration if requested by either Party. The Arbitrators shall, within [***] after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with Applicable Law in any court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.

12.5.4 Additional Terms Applicable to Dispute Resolution Procedures. Each Party shall bear its own counsel fees, costs and disbursements arising out of the dispute resolution procedures described in this Section 12.5 (Dispute Resolution), and shall pay an equal share of the fees and costs of the mediator and Arbitrators, as applicable, and all other general fees related to any mediation or arbitration described in Section 12.5.2 (Mediation), or Section 12.5.3 (Arbitration), as applicable. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Section 12.5.3 (Arbitration) is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of such pending arbitration proceeding. Nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding. All arbitration proceedings and decisions of the Arbitrators, under this Section 12.5 (Dispute Resolution) shall be deemed the Confidential Information of both Parties under Article 8 (Confidentiality and Non-Disclosure).

12.6 **Intellectual Property Disputes**. Notwithstanding Section 12.5 (Dispute Resolution) to the contrary, in the event that a Dispute arises with respect to the validity, scope, enforceability, inventorship or ownership of any Information or any Patent or other intellectual property rights hereunder, then such Dispute [***] of the relevant jurisdiction to be resolved under Applicable Law in such jurisdiction.

12.7 **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

12.8 **Notices**.

12.8.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by email or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 12.8.2 (Address for Notice) or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 12.8.1 (Notice Requirements). Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by email if an email address is set forth below or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by email shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 12.8.1 (Notice Requirements) is not intended to govern the day-to-day business

communications necessary between the Parties in performing their obligations under the terms of this Agreement.

12.8.2 Address for Notice.

If to Licensee, to:
Akebia Therapeutics, Inc.
245 First Street
14th Floor
Cambridge, MA 02142
Attention: [***]
Email: [***]

With a copy to (which will not constitute notice):

Ropes & Gray LLP
800 Boylston Street; Prudential Tower
Boston, MA 02199
Attention: [***]
Email: [***]

If to Janssen, to:

Janssen Pharmaceutica NV
Turnhoutseweg 30, B-2340
Beerse, Belgium
Attention: [***]

With a copy to (which will not constitute notice):

Office of the Chief Intellectual Property Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Attention: [***]

12.9 **Entire Agreement; Amendments**. This Agreement, together with the Schedules and any other attachments attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto (including that certain Confidential Disclosure Agreement between the Parties dated as of [***] (the "**CDA**")) are superseded hereby; *provided*, *however*, that the Information (as defined in the CDA) disclosed by Janssen to Licensee or by Licensee to Janssen under the CDA shall be deemed and treated as Confidential Information disclosed by Janssen to Licensee, or by Licensee to Janssen, respectively, under this Agreement. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

12.10 **Waiver and Non-Exclusion of Remedies**. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

12.11 **No Benefit to Third Parties**. Except as provided in Article 10 (Indemnity), the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons.

12.12 **Further Assurance**. Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

12.13 **Relationship of the Parties; Recourse**. It is expressly agreed that Janssen, on the one hand and Licensee, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Janssen, on the one hand, nor Licensee, on the other hand, shall have the authority to make any statements, representations or commitments of any kind or to take any action that will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party. No past, present or future director, officer, employee, agent or attorney of either Party hereto, or any of their successors or permitted assigns, shall have any liability for any obligations or liabilities of a Party hereto under this Agreement (including with respect to any representation or y made in or in connection with this Agreement) or for any claim, action, suit or other legal proceeding (whether in contract, in tort, in equity, or otherwise) based on, in respect of or by reason of the transaction contemplated herein.

12.14 **References**. Unless otherwise specified, (i) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (ii) references in any Section to any clause are references to such clause of such Section and (iii) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time-to-time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto.

12.15 **Construction**. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. Whenever the words “include”, “includes” or “including” are used in this Agreement, they shall be deemed to be followed by the words “without limitation”, whether or not they are in fact followed by those words or words of like import. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties

and no rule of strict construction shall be applied against either Party hereto. References to the terms "Section," or "Schedule" are to a Section or Schedule of this Agreement unless otherwise specified. The terms "hereof," "hereby," "hereto," and derivative or similar words refer to this entire Agreement. The word "or" will not be exclusive. References to "written" or "in writing" include in electronic form. The word "will" will be construed to have the same meaning and effect as the word "shall." A reference to any Person includes such Person's successors and permitted assigns.

12.16 **Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

JANSSEN PHARMACEUTICA NV

By: /s/ Tom Aelbrecht

Name: Tom Aelbrecht

Title: Head Janssen Campus Office Member of the Management Board Janssen Pharmaceutica NV

By: /s/Chris Vaes

Name: Chris Vaes

Title: Board Member

AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

By: /s/ Jason A. Amello

Name: Jason A. Amello

Title: Senior Vice President and Chief Financial Officer

Schedule 1.66

Janssen Patents

[***].

Schedule 1.69

JNJ5169

[***].

Schedule 1.71

JNJ7414

[***].

Schedule 1.108

Specified Compounds

[***].

Schedule 3.2

Research Plan

[***].

Schedule 3.5.1

Designation Criteria

[***].

Schedule 3.7.1

[***] Development Plan

[***].

Schedule 4.1.1(i)

Disclosed Know-How

[***].

Schedule 4.1.1(ii)

Licensed Materials

[***].

Schedule 4.1.1(iii)

Further Know-How

[***].

Schedule 6.3.1

Example Royalty Calculation

[***].

Schedule 9.2.1

Disclosure Schedule

[***].

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: May 9, 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: May 9, 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 March 31, 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: May 9, 2017

By: /s/ John P. Butler
John P. Butler
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 9, 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.
245 First Street, Suite 1100
Cambridge, MA 02142
T: +1 617.871.2098 F: +1 617.871.2099
www.akebia.com

Akebia Announces First Quarter 2017 Financial Results

– Recent Collaboration Agreements Position Vadadustat Global Phase 3 Development Program for Success, Offer Strong Financial and Commercial Support, and Drive Significant Value Creation –

CAMBRIDGE, MA, May 9, 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 first quarter ended March 31, 2017.

"Our team at Akebia continues to execute on our goals in 2017, as we advance the Phase 3 program for vadadustat and expand our pipeline," said John P. Butler, President and Chief Executive Officer of Akebia. "We established two major collaborations with Otsuka Pharmaceutical in the last four months that support our global development program for vadadustat and drive long-term value for Akebia. The Otsuka agreements, coupled with an earlier collaboration with Mitsubishi Tanabe, provide for $573 million or more in committed capital and a total potential deal value of $2.2 billion plus royalties ranging from mid-single digit to tiered double digit. We believe that the strength of our collaborations is a testament to the potential of vadadustat to change the standard of care for patients with anemia associated with chronic kidney disease. With cash plus committed development funding of over $600 million, Akebia is in a very strong financial position."

First Quarter 2017 and Recent Corporate Highlights

- Expanded relationship with Otsuka for vadadustat from a profit share agreement in the U.S. to include a collaboration and license agreement for Europe, China and other territories, excluding Latin America. This agreement provides for committed capital and potential milestone payments from Otsuka of up to $865 million, including $208 million or more in upfront and development funding and up to $657 million in milestone payments;

- Signed an exclusive agreement with Johnson & Johnson Innovation to in-license HIF product candidates and access an extensive library of HIF compounds, including AKB-5169, a differentiated, oral, non-absorbed preclinical compound for the treatment of inflammatory bowel disease, which is poised for IND submission in the second half of 2018;

- Published positive Phase 2a study results in the *American Journal of Nephrology,* demonstrating that vadadustat increased hemoglobin levels in a dose-dependent manner and improved iron mobilization in non-dialysis chronic kidney disease (CKD) patients; and

- The Independent Data Monitoring Committee for Akebia's global Phase 3 PRO2TECT and INNO2VATE programs met and recommended continuing the studies without modification.

Financial Results
The company reported a net loss of ($44.5) million, or ($1.15) per share, for the first quarter of 2017 as compared to a net loss for the first quarter of 2016 of ($25.8) million or ($0.70) per share.

Collaboration revenue was $20.9 million for the first quarter of 2017, which related to our agreement with Otsuka. Collaboration revenue in connection with our agreement with Mitsubishi Tanabe Pharma Corporation is expected to commence in the second half of 2017.

Research and development expenses were $60.0 million for the first quarter of 2017 compared to $20.2 million for the first quarter of 2016. The increase is primarily attributable to external costs related to the global PRO2TECT and INNO2VATE Phase 3 programs. Research and development expenses were further increased by headcount and compensation-related costs.

General and administrative expenses were $5.8 million for both the first quarters of 2017 and 2016 due to offsetting increases and decreases in associated costs.

The company ended the first quarter of 2017 with cash, cash equivalents and marketable securities of $251.8 million. The company is also entitled to receive $373.0 million or more in committed capital from collaborators, which is expected to be received over the course of the global development program for vadadustat, of which $73.0 million was received in April 2017 in connection with the expanded collaboration with Otsuka. Based on the timing of payments from collaborators, Akebia expects existing and committed cash resources to fund the company's current operating plan into the first quarter of 2019. However, the remaining committed research and development funding will continue to be received from Otsuka on a prepaid, quarterly basis up to an estimated aggregate of $60.0 million.

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 associated with chronic kidney disease and the INNO2VATE studies for dialysis-dependent patients, is currently ongoing. 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, anticipated financial contributions from Otsuka Pharmaceutical and Mitsubishi Tanabe under Akebia's collaboration agreements, and the timing of the potential filing of an IND for AKB-5169. 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 funding required to develop Akebia's product candidates and operate the company, and the actual

expenses associated therewith; the actual costs incurred in the Phase 3 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 and license agreements; the timing and content of decisions made by the FDA and other regulatory authorities; the actual time it takes to initiate and complete research and development; 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 March 31, 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
Theresa McNeely
SVP, Corporate Communications and
Investor Relations
617-844-6113
tmcneely@akebia.com

Tables Follow

AKEBIA THERAPEUTICS, INC
Consolidated Statements of Operations
(in thousands except share and per share data)
(unaudited)

	Three Months Ended	
	March 31, 2017	March 31, 2016
Collaboration revenue	$ 20,865	$ —
Operating expenses:		
Research and development	60,049	20,235
General and administrative	5,788	5,811
Total operating expenses	65,837	26,046
Operating loss	(44,972)	(26,046)
Other income, net	429	248
Net loss	$ (44,543)	$ (25,798)
Net loss per share - basic and diluted	$ (1.15)	$ (0.70)
Weighted-average number of common shares - basic and diluted	38,759,221	36,873,594

AKEBIA THERAPEUTICS, INC.
Selected Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2017	December 31, 2016
Cash, cash equivalents and available for sale securities	$ 251,805	$ 260,343
Working capital	121,590	182,053
Total assets	259,256	300,216
Total stockholders' equity	30,617	68,120

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