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, 2015

☐ **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: 001-36721

Coherus BioSciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**27-3615821**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

201 Redwood Shores Parkway, Suite 200
Redwood City, California 94065
(650) 649-3530

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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 Data 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 the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a small reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated Filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

As of April 30, 2015, 37,841,347 shares of the registrant's common stock were outstanding.

COHERUS BIOSCIENCES, INC.
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2015
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. 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 "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "positioned," "potential," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the timing and the success of the design of the clinical trials and planned clinical trials of CHS-0214 (our etanercept (Enbrel) biosimilar candidate), CHS-1420 (our adalimumab (Humira) biosimilar candidate) and CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate);
- whether the results of our trials will be sufficient to support domestic or global regulatory approvals for CHS-0214, CHS-1420 and CHS-1701;
- our ability to obtain and maintain regulatory approval of CHS-0214, CHS-1420 and CHS-1701 or our future product candidates;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our expectation that our existing capital resources together with funding we expect to receive under our license agreements with Daiichi Sankyo Company, Limited and Baxter International, Inc. will be sufficient to fund our operations for at least the next 12 months;
- the implementation of our business model and strategic plans for our business and product candidates;
- the initiation, timing, progress and results of future preclinical and clinical studies and our research and development programs;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- our expectations regarding the scope or enforceability of third party intellectual property rights, or the applicability of such rights to our product candidates;
- our ability to maintain and establish collaborations or obtain additional funding;
- our reliance on third-party contract manufacturers to manufacture and supply our product candidates for us;
- our reliance on third-party contract research organizations to conduct clinical trials of our product candidates for us;
- the benefits of the use of CHS-0214, CHS-1420 and CHS-1701;
- the rate and degree of market acceptance of CHS-0214, CHS-1420 and CHS-1701 or any future product candidates;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to manufacture CHS-0214, CHS-1420 and CHS-1701 in conformity with regulatory requirements and to scale up manufacturing capacity of these products for commercial supply;
- our ability to compete with companies currently producing the reference products, including Enbrel, Humira and Neulasta;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012;
- our financial performance; and
- developments and projections relating to our competitors and our industry.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and 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 discussed 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, even if new information becomes available in the future.

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 uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. 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.

PART I. FINANCIAL INFORMATION

ITEM I. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Coherus BioSciences, Inc.

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

	March 31, 2015 (unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 115,136	$ 150,392
Restricted cash	60	60
Receivables from collaboration and license agreement	2,015	2,417
Notes receivable	1,837	1,815
Prepaid assets	20,114	20,485
Other assets	3,044	2,276
Other assets - related party	1,691	1,691
Total current assets	143,897	179,136
Property and equipment, net	5,104	4,472
Intangible assets	2,620	2,620
Goodwill	943	943
Other assets, non-current	589	50
Total assets	$ 153,153	$ 187,221
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,871	$ 8,778
Accounts payable - related parties	3,723	2,020
Accrued liabilities	13,271	11,231
Advance payments under license agreement	1,192	1,192
Deferred revenue	22,800	22,800
Contingent consideration	—	5,710
Other liabilities	56	52
Total current liabilities	51,913	51,783
Deferred revenue, non-current	34,403	39,899
Contingent liability to collaborator	27,650	27,650
Contingent consideration, non-current	860	785
Other liabilities, non-current	334	347
Total liabilities	115,160	120,464
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; Shares authorized: 5,000,000 at March 31, 2015; Shares issued and outstanding: no shares at March 31, 2015 and December 31, 2014	—	—
Common stock, $0.0001 par value; Shares authorized: 300,000,000 at March 31, 2015; Shares issued and outstanding: 33,701,017 and 33,257,978 at March 31, 2015 and December 31, 2014, respectively	3	3
Additional paid-in capital	266,246	254,048
Accumulated other comprehensive loss	(648)	(525)
Accumulated deficit	(227,450)	(186,725)
Total Coherus stockholders' equity	38,151	66,801
Non-controlling interest	(158)	(44)
Total stockholders' equity	37,993	66,757
Total liabilities and stockholders' equity	$ 153,153	$ 187,221

See accompanying notes to condensed consolidated financial statements.

Coherus BioSciences, Inc.

Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenue:		
Collaboration and license revenue	$ 5,810	$ 3,090
Collaboration and license revenue - related party (1)	—	506
Total revenue	5,810	3,596
Operating expenses:		
Research and development (includes related party of $11,481 and $4,265 for the three months ended March 31, 2015 and 2014, respectively)	36,467	13,936
General and administrative (includes related party of $66 and $0 for the three months ended March 31, 2015 and 2014, respectively)	6,091	3,421
Total operating expenses	42,558	17,357
Loss from operations	(36,748)	(13,761)
Interest expense (includes related party of $0 and $1,889 for the three months the ended March 31, 2015 and 2014, respectively)	—	(2,741)
Other expense, net	(4,091)	(8,668)
Net loss	(40,839)	(25,170)
Net loss attributable to non-controlling interest	114	—
Net loss attributable to Coherus	$ (40,725)	$ (25,170)
Net loss per share attributable to Coherus, basic and diluted	$ (1.22)	$ (6.03)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	33,377,298	4,177,230

(1) Represents revenue from Daiichi Sankyo Company, a holder of more than 10% of our common stock until the closing of our initial public offering ("IPO") on November 12, 2014.

See accompanying notes to condensed consolidated financial statements.

Coherus BioSciences, Inc.

Condensed Consolidated Statements of Comprehensive Loss
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Net loss	$ (40,839)	$ (25,170)
Other comprehensive loss:		
Foreign currency translation adjustments, net of tax	(123)	(64)
Comprehensive loss	(40,962)	(25,234)
Comprehensive loss attributable to non-controlling interest	114	—
Comprehensive loss attributable to Coherus	$ (40,848)	$ (25,234)

See accompanying notes to condensed consolidated financial statements.

Coherus BioSciences, Inc.

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

	Three Months Ended March 31,	
	2015	2014
Operating activities		
Net loss	$ (40,839)	$ (25,170)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	232	116
Remeasurement of contingent consideration	4,214	—
Remeasurement of convertible preferred stock warrants	—	8,655
Preferred stock issued in exchange for services	—	10
Non-cash interest (income) expense and amortization of (receivable) debt discount	(22)	2,740
Stock-based compensation expense	2,182	3,291
Changes in operating assets and liabilities:		
Receivables from collaboration and license agreement	402	—
Receivables from related party	—	17
Notes receivable from related parties	—	(1)
Prepaid assets	—	(1,449)
Other current assets	389	—
Other assets	(768)	—
Other assets - non-current	(1)	—
Accounts payable	3,027	3,902
Accounts payable - related parties	1,703	1,905
Accrued and other liabilities	1,944	(2,493)
Deferred revenue	(5,512)	9,387
Advance payments under license agreements with related party	—	1,192
Contingent liability to collaborator	—	12,650
Other liabilities, non-current	(13)	(7)
Net cash (used in) provided by operating activities	(33,062)	14,745
Investing activities		
Net cash acquired from acquisition of InteKrin Therapeutics, Inc.	—	2,334
Purchases of property and equipment	(1,313)	(260)
Net cash (used in) provided by investing activities	(1,313)	2,074
Financing activities		
Proceeds from issuances of common stock upon exercise of stock options	168	10
Repurchase of restricted common stock	—	(2)
Payments of initial public offering costs	(855)	
Payments of follow-on offering costs	(42)	—
Net cash (used in) provided by financing activities	(729)	8
Effect of exchange rate changes in cash and cash equivalents	(152)	(64)
Net (decrease) increase in cash and cash equivalents	(35,256)	16,763
Cash and cash equivalents at beginning of period	150,392	39,554
Cash and cash equivalents at end of period	$ 115,136	$ 56,317

See accompanying notes to condensed consolidated financial statements.

1. Organization and Operations

Description of the Business

Coherus BioSciences, Inc. (the "Company", "Coherus", "we", "our" or "us") was incorporated in the state of Delaware as BioGenerics, Inc. in September 2010 and changed its name to Coherus BioSciences, Inc. in April 2012. The Company is a late-stage clinical biologics platform company, focused on the global biosimilar market. The Company's headquarters and laboratories are located in Redwood City, California and in Camarillo, California, respectively. The Company operates in one segment.

The Company's clinical stage pipeline consists of a long-acting form of granulocyte colony-stimulating factor ("G-CSF"), and two anti-inflammatory agents targeting tumor necrosis factor ("TNF"):

- The Company's long-acting G-CSF product candidate, CHS-1701, is being developed as a pegfilgrastim (Neulasta) biosimilar. The Company has initiated a pivotal pharmacokinetic (PK) and pharmacodynamics (PD) study for CHS-1701 in the United States (U.S.), which, if positive, the Company believes will support the planned filing of a biologics license application ("BLA") in the U.S. An additional immunogenicity study is planned in healthy volunteers pursuant to this BLA and is projected to be concluded in 2015.
- The Company's most clinically advanced anti-TNF product candidate, CHS-0214, is being developed as an etanercept (Enbrel) biosimilar that the Company has partnered with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively "Baxter") and Daiichi Sankyo Company, Limited ("Daiichi Sankyo") to develop and commercialize in key markets outside of the U.S. The Company is currently enrolling two Phase 3 clinical trials in rheumatoid arthritis and psoriasis. The Company expects that results of these trials, if positive, combined with data from our Phase 1 studies, will support the expected filing of a marketing application in Europe and Japan in 2016. The Company has retained the development and commercial rights in the U.S. However, the therapeutic protein in etanercept is subject to certain originator-controlled U.S. patents expiring in 2028 and 2029. Assuming these patents are valid and enforceable, and that the Company would be unable to obtain a license to them, the Company does not expect to commercialize CHS-0214 in the U.S. prior to their expiration. On April 14, 2015, the Company obtained positive results of a repeat Phase 1 PK bioequivalence study for CHS-0214. This study was initiated due to the change in the manufacturing location from the U.S. to the European Union (E.U.) of CHS-0214, and compared the E.U. produced CHS-0214 to a lot of Enbrel manufactured in Europe. In May 2015, the Company completed the enrollment of the Phase 3 studies, as such received $35.0 million of the milestone payment from Baxter.
- The Company's second anti-TNF product candidate, CHS-1420, is being developed as an adalimumab (Humira) biosimilar. This product successfully completed a pivotal Phase 1 PK study in August 2014 by meeting the primary study endpoint. The Company plans to initiate a Phase 3 study in psoriasis in mid-2015 to support the planned filing of a marketing application in the U.S. in 2016 and the E.U. in 2017.

In March 2015, the Company's registration statement on Form S-1 (File No. 333-202936) relating to its follow-on public offering ("Follow-on Offering") of its common stock was declared effective by the Securities and Exchange Commission ("SEC"). The price of the shares sold in the Follow-on Offering was $29.00 per share. The Follow-on Offering closed on April 7, 2015, pursuant to which the Company sold 4,137,931 shares of common stock. The Company granted the underwriters the option to purchase up to an additional 620,689 shares of common stock at the public offering price less underwriting discounts and commissions, which expired on April 30, 2015. The Company received total gross proceeds from the offering of $120.0 million. After deducting underwriting discounts and commissions of $7.2 million and offering expenses of approximately $0.6 million, the net proceeds were approximately $112.2 million.

Need to Raise Additional Capital

As of March 31, 2015, the Company had an accumulated deficit of $227.5 million and cash and cash equivalents of $115.1 million. In April 2015, the Company completed its Follow-on Offering and raised net proceeds of approximately $112.2 million, after deducting underwriting discounts and commissions and offering expenses. The Company believes that its current available cash and cash equivalents together with the cash received from the Follow-on Offering will be sufficient to fund its planned expenditures and meet the Company's obligations through at least the next twelve months. However, if the anticipated operating results are not achieved in future periods, the planned expenditures may need to be reduced in order to extend the time period over which the then-available resources would be able to fund the operations. The Company will need to raise additional funds in the future, however there

can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable.

2. Basis of Presentation and Summary of Significant Accounting Policies

Unaudited Condensed Consolidated Financial Statements

The accompanying condensed consolidated financial statements include the accounts of Coherus and its wholly owned subsidiaries as of March 31, 2015: Coherus Intermediate Corp, InteKrin Therapeutics, Inc. ("InteKrin"), and Intekrin's 82.5% majority owned subsidiary of InteKrin Russia. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the Securities Act of 1933, as amended (Securities Act). Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring accruals that the Company believes are necessary to fairly state the financial position and the results of the Company's operations and cash flows for interim periods in accordance with U.S. GAAP. Interim-period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period.

The accompanying condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K filed with the SEC on March 23, 2015.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to its common stock valuation and related stock-based compensation, the valuations of the convertible preferred stock warrant liability and embedded derivative instruments, valuation of deferred tax assets, impairment of goodwill and long-lived assets, the valuation of acquired intangible assets, clinical trial accruals, revenue recognition period, as well as certain accrued liabilities. Management bases its estimates on historical experience and on various other assumptions 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 could differ from those estimates.

Foreign Currency

The functional currency of InteKrin Russia, which the Company acquired in February 2014, is the Russian Ruble. Accordingly, the financial statements of this subsidiary are translated into U.S. dollars using appropriate exchange rates. Unrealized gains or losses on translation are recognized in accumulated other comprehensive loss in the condensed consolidated balance sheet.

For the three months ended March 31, 2015 and 2014, the foreign exchange gains and losses recorded in other expense, net in the condensed consolidated statements of operations was a $91,000 gain and a $15,000 loss, respectively.

Segment Reporting

The Company operates and manages its business as one reportable and operating segment, which is the business of developing and commercializing biosimilar products, and small molecules as part of the InteKrin acquisition. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. Long-lived assets are primarily maintained in the United States of America.

The following table summarizes revenue by geographic region (in thousands):

	Three Months Ended March 31,	
	2015	2014
United States	$ 5,313	$ 3,090
Rest of World	497	506
Total Revenue	$ 5,810	$ 3,596

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct incremental legal and accounting fees relating to the Follow-on Offering, are capitalized. The deferred offering costs were recorded in additional paid-in capital upon the closing of the Follow-on offering on April 7, 2015. As of March 31, 2015, $0.5 million of deferred offering costs were capitalized in other assets – noncurrent on the condensed consolidated balance sheet. No deferred offering costs were capitalized as of December 31, 2014.

Derivative Liability

The Company has a derivative liability related to the contingent consideration associated with the acquisition of InteKrin. There were two contingent payments: (i) the completion of the first dosing of a human subject in the first Phase 2 clinical trial for InteKrin, ("Earn-Out Payment") and (ii) upon the execution of any license, sublicense, development, collaboration, joint venture, partnering or similar agreement between the Company and the third party ("Compound Transaction Payment"). The derivative related to the contingent consideration is accounted for as a liability and remeasured to fair value as of each balance sheet date or settlement date and the related remeasurement adjustment is recognized as other income (expense), net in the statement of operations. See note 3 for further details regarding settlement of the Earn-Out Payment in March 2015. The Company determined the fair value of the two contingent consideration scenarios (the Earn-Out Payment and the Compound Transaction Payment) using a probability-weighted discounted cash flow approach. A probability weighted value was determined by summing the probability of achieving a contingent payment threshold by the respective contingent payment. The expected cash flows were discounted at a rate selected to capture the risk of achieving the contingent payment thresholds and earning the contingent payments. This risk is comprised of InteKrin's continued development, a specific risk factor associated with meeting the contingent consideration threshold and related payout and counterparty risk associated with the payment of the contingent consideration.

Customer Concentration

Customers whose collaboration and license revenue accounted for 10% or more of total revenues were as follows:

	Three Months Ended March 31,	
	2015	2014
Daiichi Sankyo - related party (1)	*	14%
Baxter	91%	86%

* less than 10%

(1) Represents revenue from Daiichi Sankyo Company, a holder of more than 10% of our common stock until the closing of our IPO on November 12, 2014.

Revenue Recognition

The Company recognizes revenue when persuasive evidence of an arrangement exists; transfer of technology has been completed, services have been performed or products have been delivered; the fee is fixed and determinable; and collection is reasonably assured.

The Company enters into collaboration and license agreements for the development and commercialization of biosimilar products. The Company's performance obligations under the terms of these agreements may include (i) transfer of intellectual

property rights (licenses), (ii) providing research and development services, (iii) the manufacture of drug materials for development purposes and (iv) participation on certain committees with the collaborators. Payments to the Company under these agreements may include nonrefundable upfront license fees, payments for research and development services, payments for the manufacture of drug materials, payments based upon the achievement of defined collaboration objectives and royalties on product sales. Under these agreements, the Company may convey the right to sell products resulting from the collaborative efforts of the parties in specific geographic territories.

For revenue agreements with multiple elements, the Company identifies the deliverables included within the agreement and evaluates which deliverables may represent separate units of accounting based on the achievement of certain criteria, including whether the delivered element has stand-alone value to the collaborator. Deliverables under the arrangement are a separate unit of accounting if (i) the delivered item 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 and delivery or performance of the undelivered items are considered probable and substantially within the Company's control.

The Company determines how to allocate arrangement consideration to identified units of accounting based on the selling price hierarchy provided under the relevant guidance. The selling price used for each unit of accounting is based on vendor-specific objective evidence, if available, third party evidence if vendor-specific objective evidence is not available or estimated selling price if neither vendor-specific nor third-party evidence is available. Management may be required to exercise considerable judgment in determining whether a deliverable is a separate unit of accounting and in estimating the selling prices of identified units of accounting under its agreements.

Upfront payments received in connection with licenses of the Company's technology rights are deferred if facts and circumstances dictate that the license does not have stand-alone value. Such payments are recognized as license revenue over the estimated period of performance that is generally consistent with the terms of the research and development obligations contained in the specific collaboration and license agreement. The Company regularly reviews the estimated period of performance based on the progress made under each arrangement. Amounts received as funding of research and development activities are recognized as revenue if the collaboration arrangement involves the sale of the Company's research or development services. However, such funding is recognized as a reduction in research and development expense when the Company engages in a research and development project jointly with another entity, with both entities participating in project activities and sharing costs and potential benefits of the arrangement.

Payments that are contingent upon the achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved, assuming all other revenue recognition criteria are met. Milestones are defined as an event that can only be achieved based on the Company's performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones under accounting guidance. The Company's evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the Company's performance to achieve the milestone, or (2) 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, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Other contingent payments in which a portion of the payment is refundable or adjusts based on future performance or non-performance (e.g., through a penalty or claw-back provision) are not considered to relate solely to the Company's past performance, and therefore, not considered substantive. Non-substantive contingent payments are classified as deferred revenue if they are ultimately expected to result in revenue recognition. The Company recognizes non-substantive contingent payments over the remaining estimated period of performance once the specific objective is achieved. Any portion of the non-substantive contingent payments which may be required to be refunded to the collaborator are not included in deferred revenue and instead are reflected as contingent liability to collaborator on the condensed consolidated balance sheets.

Contingent payments associated with the achievement of specific objectives in certain contracts that are not considered substantive because the Company does not contribute effort to the achievement of such milestones are recognized as revenue upon

achievement of the objective, as long as there are no undelivered elements remaining and no continuing performance obligations by the Company, assuming all other revenue recognition criteria are met.

The government contract with the Russian government is an agreement that provides the Company with payments for certain types of expenditures in return for research and development activities over a contractually defined period. Revenue from the government contract is recognized in the period during which the related costs are incurred and the related services are rendered, provided that the funds received are not refundable and applicable conditions under the government contract have been met. Funds received in advance are recorded as deferred revenue.

Comprehensive Loss

Comprehensive loss is composed of two components: net loss and other comprehensive loss. Other comprehensive loss refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' equity, but are excluded from net loss. The other comprehensive loss included foreign currency translation adjustments for the three months ended March 31, 2015 and 2014.

Net Loss per Share Attributable to Coherus

Basic net loss per share attributable to Coherus is calculated by dividing the net loss attributable to Coherus by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive common shares. Since the Company was in a loss position for all periods presented, basic net loss per share attributable to Coherus is the same as diluted net loss per share attributable to Coherus as the inclusion of all potential dilutive common shares would have been anti-dilutive. Shares of founders' common stock subject to repurchase are excluded from the calculation of weighted average shares as the vesting of such shares is contingent upon continued services being rendered by such holders.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2016, at which time the Company may adopt the new standard under the full retrospective method or the modified retrospective method. Early adoption is not permitted. In April 2015, the FASB issued for public comment a proposed ASU that would defer the effective date of ASU 2014-09 by one year. The proposed deferral of ASU 2014-09 would permit public companies to apply the new revenue standard to annual reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact that the adoption of ASU 2014-09 will have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today's guidance. ASU 2014-15 is effective for the Company in the first quarter of 2016 with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2014-15 will have on its consolidated financial statements and related disclosures.

The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or no material effect is expected on the condensed consolidated financial statements as a result of future adoptions.

3. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts payable and other current liabilities approximate their fair value due to their short maturities. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting guidance describes a fair value hierarchy based

on three levels of inputs that may be used to measure fair value, of which the first two are considered observable and the last is considered unobservable. These levels of inputs are the following:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's financial instruments consist of Level 1 assets and Level 3 liabilities. Where quoted prices are available in an active market, securities are classified as Level 1. Level 1 assets consist of highly liquid money market funds that are included in cash and cash equivalents, and restricted cash. There were no unrealized gains and losses in the Company's investments in these money market funds.

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3. Level 3 liabilities consist of the contingent consideration.

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements are as follows (in thousands):

	Fair Value Measurements March 31, 2015			
	Total	Level 1	Level 2	Level 3
Assets:				
Certificate of deposit denominated in U.S. Dollars	$ 700	$ 700	$ —	$ —
Certificate of deposit denominated in Russian Rubles	345	345	—	—
Money market funds	113,853	113,853	—	—
Restricted cash (money market funds)	60	60	—	—
Total financial assets	$ 114,958	$ 114,958	$ —	$ —
Liabilities:				
Contingent consideration	$ 860	$ —	$ —	$ 860

	Fair Value Measurements December 31, 2014			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 147,952	$ 147,952	$ —	$ —
Restricted cash (money market funds)	60	60	—	—
Total financial assets	$ 148,012	$ 148,012	$ —	$ —
Liabilities:				
Contingent consideration	$ 6,495	$ —	$ —	$ 6,495

There were no transfers between Level 1 and Level 3 during the periods presented.

Contingent Consideration

As part of the InteKrin acquisition in February 2014, the Company recognized contingent consideration associated with payments to be made to the former InteKrin stockholders upon the achievement of certain events specified in the purchase agreement.
The InteKrin purchase agreement provides for contingent consideration to be paid upon (i) the first dosing of a human subject in the first Phase 2 Clinical Trial for INT-131 ("Earn-Out Payment") and (ii) per a compound transaction agreement as defined in the purchase agreement (the "Compound Transaction Payment").

On March 6, 2015, the Company achieved the first dosing of a human subject in a phase 2 clinical trial for INT-131 in multiple sclerosis patients, triggering the obligation to settle the contingent Earn-Out Payment to former InteKrin stockholders. As a result, the Company issued 358,384 shares of its common stock valued at $27.48 per share and cash of $1,000 for the aggregate amount value of $9.8 million to former InteKrin stockholders. Contemporaneously, the Company recognized the additional fair value of the Earn-Out Payment of $4.1 million to other expense, net in the condensed consolidated statement of operations on March 6, 2015 and reclassified the contingent consideration liability balance to equity in the condensed consolidated balance sheet.

This fair value measurement of the Compound Transaction Payment uses a probability-weighted discounted cash flow approach based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The Compound Transaction analysis applied a 25% risk-adjusted discount rate to measure present value and also captured an additional 6% credit spread for counterparty credit risk given the cash payment. The Company's management estimates of probability of occurrence and timing were used to formulate an expected cash flow. The value of the consideration is tiered based on the value of a license or similar agreement with a third party and the timing of such agreement. The change in the fair value of the Compound Transaction Payment of $0.1 million was recognized in other expense, net within the condensed consolidated statement of operations for the three months ended March 31, 2015.

The following table sets forth a summary of changes in the estimated fair value of the contingent consideration (in thousands):

Balance as of December 31, 2014	$ 6,495
Change in fair value of the contingent consideration liability	4,214
Fair value of Earn-Out Payment	(9,849)
Balance as of March 31, 2015	$ 860

4. Balance Sheet Components

Prepaid Assets

Prepaid assets are as follows (in thousands):

	March 31, 2015	December 31, 2014
Prepaid clinical, material, manufacturing and other - related parties	$ 4,363	$ 5,990
Prepaid clinical, material and manufacturing	13,294	12,149
Prepaid other	2,457	2,346
Prepaid assets	$ 20,114	$ 20,485

Property and Equipment, Net

Property and equipment, net are as follows (in thousands):

	March 31, 2015	December 31, 2014
Machinery and equipment	$ 4,678	$ 4,317
Computer equipment and software	414	286
Furniture and fixtures	307	288
Leasehold improvements	1,211	399
Construction in progress	—	474
Total property and equipment	6,610	5,764
Accumulated depreciation and amortization	(1,506)	(1,292)
Property and equipment, net	$ 5,104	$ 4,472

Depreciation expense was $232,000 and $116,000 for the three months ended March 31, 2015 and 2014, respectively.

Accrued and Other Liabilities

Accrued and other liabilities are as follows (in thousands):

	March 31, 2015	December 31, 2014
Accrued clinical, manufacturing and other - related parties	$ 5,911	$ 2,997
Accrued compensation	2,155	3,435
Accrued professional and consulting fees	383	252
Accrued other	4,822	4,547
Accrued liabilities	$ 13,271	$ 11,231

5. Collaboration and License Agreements

The Company recognized revenue related to the collaboration and license agreements for the periods presented as follows (in thousands):

	Three Months Ended March 31,	
	2015	2014
Baxter	$ 5,313	$ 3,090
Daiichi Sankyo - related party (1)	497	506
Total collaboration and license revenue	$ 5,810	$ 3,596

(1) Represents revenue from Daiichi Sankyo Company, a holder of more than 10% of our common stock until the closing of our IPO on November 12, 2014.

Daiichi Sankyo

In January 2012, the Company entered into a license agreement with Daiichi Sankyo, under which the Company granted certain licenses to Daiichi Sankyo to develop and commercialize biosimilar forms of etanercept and rituximab in Japan, Taiwan, and South Korea with an option to develop in China. Upon execution of the agreement, Daiichi Sankyo paid a non-refundable, upfront license fee of $10.0 million which was recorded as deferred revenue and is being amortized over the remaining estimated performance period under the agreement using the straight line method.

In June 2013, the Company and Daiichi Sankyo entered into a Memorandum of Understanding No. 1 (the “MOU 1”) in which both parties agreed to cooperate and share costs to conduct a global Phase 1 study of a biosimilar form of etanercept. This program was not originally contemplated in the license agreement. The amounts received from Daiichi Sankyo under the MOU 1 are recognized as a reduction in research and development expense as the Company engages in a research and development project jointly with Daiichi Sankyo, with both parties incurring costs while actively participating in development activities and both parties sharing costs and potential benefits of the arrangement.

In January 2014, the Company and Daiichi Sankyo entered into the Memorandum of Understanding No. 2 (the “MOU 2”) in which both parties agreed to cooperate to conduct a global Phase 3 clinical trial in rheumatoid arthritis and that Daiichi Sankyo will be responsible for a minimum of 20% of the cost of the clinical trial. Also, both parties entered into a clinical supply agreement contemporaneously with the MOU 2 in which the Company will supply finished study drug and study comparator drug for Daiichi Sankyo’s use in the Japanese portion of the product’s clinical trial. Daiichi Sankyo reimburses these research and development costs in quarterly advance payments, for which the Company recorded $1.2 million as advance payments under license agreement in the condensed consolidated balance sheet at March 31, 2015. The Company will recognize the advance payment as a reduction in the research and development expense when the research and development activity has been performed.

As of March 31, 2015, $3.9 million of revenue was deferred under all arrangements with Daiichi Sankyo, of which $1.6 million was included in current liabilities and $2.3 million was included in non-current liabilities in the condensed consolidated balance sheet. As of December 31, 2014, $4.3 million of revenue was deferred under all arrangements with Daiichi Sankyo, of which $1.6 million was included in current liabilities and $2.7 million was included in non-current liabilities in the condensed consolidated balance sheet.

The Company recognized in its condensed consolidated statements of operations a reduction of research and development expense related to the costs reimbursed by Daiichi Sankyo of $1.4 million and $1.2 million for the three months ended March 31, 2015 and 2014, respectively.

Baxter

In August 2013, the Company entered into a license agreement with Baxter to develop and commercialize an etanercept biosimilar molecule, CHS-0214, worldwide, excluding the United States, Japan, Taiwan, South Korea, China and most of the Caribbean and South American nations. Under the terms of the license agreement, the Company will conduct the development and the regulatory activities, and Baxter will conduct the commercialization of the etanercept biosimilar product.

In consideration of the exclusive, royalty-bearing license to develop, commercialize and use the etanercept biosimilar product, Baxter made an upfront payment of $30.0 million to the Company. Additionally, the Company is eligible to receive up to $216.0 million in contingent payments composed of $96.0 million in clinical development payments and up to $120.0 million in regulatory milestone payments. In February 2014, the agreement was amended to increase the payment by $5.3 million. Therefore, the Company is eligible to receive up to $221.3 million in contingent payments comprised of $101.3 million in clinical development payments and up to $120.0 million in regulatory milestone payments.

The upfront payment of $30.0 million and clinical development payments of up to $101.3 million include $71.3 million of contingent payments that are intended to cover development related expenses incurred by the Company, but which are potentially reimbursable, in part, to Baxter under certain limited circumstances. Additionally, the amounts that are contingent payments also contain a claw-back feature providing that, in the event that the Company commercializes the etanercept biosimilar molecule in the U.S., fifty percent (50%) of those contingent payments are refundable to Baxter. Therefore, the Company recorded the portion of the non-substantive contingent payment that contains the claw-back feature as the contingent liability to collaborator on the condensed consolidated balance sheets, and the portion of the non-substantive milestone payments that does not contain the claw-back feature was recorded as deferred revenue and recognized as collaboration and license revenue on a straight-line basis over the remaining estimated performance period. The $120.0 million of regulatory milestone payments which was considered substantive will be recognized as revenue when each specific event is achieved.

As of March 31, 2015, $53.1 million of revenue was deferred under the arrangements with Baxter, of which $21.2 million was included in current liabilities and $31.9 million was included in non-current liabilities in the condensed consolidated balance sheet. As of March 31, 2015, $27.7 million was recorded as contingent liability to collaborator due to the potential refund of such amount to Baxter in the future.

As of December 31, 2014, $58.4 million of revenue was deferred under the arrangements with Baxter, of which $21.2 million was included in current liabilities and $37.2 million was included in non-current liabilities in the condensed consolidated balance sheet. As of December 31, 2014, $27.7 million was recorded as contingent liability to collaborator in the condensed consolidated balance sheet due to the potential refund to Baxter.

In April 2015, The Company and Baxter executed an amendment to the license agreement entered into in August 2013 (see Note 10 for further details regarding this amendment).

6. Commitments and Contingencies

Purchase Commitments

The Company enters into contracts in the normal course of business with contract research organizations for preclinical studies and clinical trials and contract manufacturing organizations (“CMOs”) for the manufacture of clinical trial materials. As of March 31, 2015, the Company had a commitment of $8.0 million with CMOs for the manufacture of clinical trial material due within a year. The Company has an agreement with Medpace, Inc. (“Medpace”), a CRO, which provides for a minimum fee commitment of $35.0 million, in aggregate, for clinical trial services; however, the agreement is cancelable without cause by either party upon 30 days prior notification. As of March 31, 2015, $24.1 million of the services related to this agreement had been performed.

Guarantees and Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company would assess the likelihood of any adverse judgments or related claims, as well as ranges of probable losses. In the cases where the Company believes that a reasonably possible or probable loss exists, it will disclose the facts and circumstances of the claims, including an estimate range, if possible. As of March 31, 2015, the Company does not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

7. Common Stock and Stock-Based Compensation

Common Stock

On March 6, 2015, the Company achieved the first dosing of a human subject in a phase 2 clinical trial for INT-131 in multiple sclerosis patients, triggering the obligation to settle the contingent Earn-Out Payment to former InteKrin stockholders (see Note 3). As a result, the Company issued 358,384 shares of its common stock valued at $27.48 per share and cash of $1,000 for the aggregate fair value of $9.8 million to former InteKrin stockholders.

Follow-on Offering

In March 2015, the Company's registration statement on Form S-1 (File No. 333-202936) relating to its Follow-on Offering of its common stock was declared effective by the SEC. The price of the shares sold in the Follow-on Offering was $29.00 per share. The Follow-on Offering closed on April 7, 2015, pursuant to which the Company sold 4,137,931 shares of common stock. The Company granted the underwriters the option to purchase up to an additional 620,689 shares of common stock at the public offering price less underwriting discounts and commissions, which expired on April 30, 2015. The Company received total gross proceeds from the offering of $120.0 million. After deducting underwriting discounts and commissions of $7.2 million and offering expenses of approximately $0.6 million, the net proceeds were approximately $112.2 million.

Stock Based Compensation

During 2010 and 2011, the Company issued shares of restricted common stock to its founders under the Founders' Shares agreements. These Founders' Shares agreements require continued rendering of service to the Company in order for the shares to vest. As such, shares of restricted common stock subject to future vesting are not deemed outstanding for accounting purposes until the shares vest. The Company recognizes stock-based compensation over the vesting term of four years based on the fair value of the common stock on the dates of issuance. As of March 31, 2015, there were 5,311 shares subject to repurchase.

The stock-based compensation expense recorded related to shares of common stock granted pursuant to the Founders' Shares agreements was as follows (in thousands):

	Three Months Ended March 31,	
	2015	2014
Research and development	$ 6	$ 103
General and administrative	—	1
	$ 6	$ 104

The stock-based compensation expense recorded related to options granted to employees and nonemployees was as follows (in thousands):

	Three Months Ended March 31,	
	2015	2014
Research and development	$ 1,176	$ 222
General and administrative	1,000	269
	$ 2,176	$ 491

In March 2014, the Company issued warrants to purchase 553,274 shares of common stock with the exercise price of $1.667 per share to two employees and one consultant for past services. Due to the immediate vesting and exercisability of the warrants upon issuance, the Company immediately recognized $1.3 million and $1.4 million of stock-based compensation in research and development expense and general and administrative expense, respectively, in the condensed consolidated statement of operations. As a result of the Company's IPO, the warrants were net exercised immediately prior to the Company's close of the IPO on November 12, 2014.

8. Net Loss Per Share Attributable to Coherus

The following table sets forth the computation of the basic and diluted net loss per share attributable to Coherus (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2015	2014
Numerator:		
Net loss attributable to Coherus	$ (40,725)	$ (25,170)
Denominator:		
Weighted-average common shares outstanding	33,390,930	4,830,840
Less: weighted-average unvested common shares subject to repurchase (1)	(13,632)	(653,610)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	33,377,298	4,177,230
Net loss per share attributable to Coherus, basic and diluted	$ (1.22)	$ (6.03)

(1) Shares were excluded as such shares represent restricted common stock granted pursuant to the Founders' Shares agreements which vest contingently upon the holders' continued services to the Company.

The following outstanding dilutive potential shares have been excluded from the calculation of diluted net loss per share attributable to Coherus due to their anti-dilutive effect:

	March 31,	
	2015	2014
Stock options outstanding	6,154,625	5,058,841
Convertible preferred stock	—	10,122,570
Convertible preferred stock warrants	—	4,638,644
Common stock warrants	—	553,274
Total	6,154,625	20,373,329

In addition, 358,384 shares of common stock contingently issuable upon the successful achievement of an objective associated with contingent consideration payable to former InteKrin stockholders have been excluded from the calculation of diluted net loss per share attributable to Coherus for the three months ended March 31, 2014. On March 6, 2015, the contingent issuable shares were settled (see Note 3).

9. Related Party Transactions

Daiichi Sankyo

The Company entered into a license agreement with Daiichi Sankyo, under which the Company issued 2,867,426 shares of Series B convertible preferred stock to Daiichi Sankyo. As such, Daiichi Sankyo was deemed to be a related party by ownership of more than 10% of the Company's equity. Accordingly, the Company recognized related party transactions of $0.5 million as collaboration and license revenue–related party in the Company's statements of operations for the three months ended March 31, 2014. In addition, the Company recognized $1.2 million as a reduction of research and development expense related to the costs reimbursed by Daiichi Sankyo in the Company's condensed consolidated statements of operations for the three month period ended March 31, 2014. Upon the consummation of the Company's initial public offering, Daiichi Sankyo's ownership percentage decreased to less than 10% of the Company's equity; therefore as of November 2014, Daiichi Sankyo was no longer considered a related party. As a result, the condensed consolidated financial statements as of March 31, 2015 and for the three months ended March 31, 2015, do not reflect transactions with Daiichi Sankyo as related party transactions.

Transactions Associated with Cook

In January and December 2012, the Company issued a total of 2,150,569 shares of Series B convertible preferred stock to Cook Pharmica LLC ("Cook") as consideration for past and future services. As such, Cook was deemed to be a related party by ownership of more than 10% of the Company's equity. The Company recognized services rendered by Cook within research and development in the condensed consolidated statements of operations of $2.9 million during the three months ended March 31, 2014. During the second quarter of 2014, Cook divested a majority of its shares of the Company's Series B convertible preferred stock; therefore, as of December 31, 2014, Cook was no longer considered a related party. As a result, the condensed consolidated financial statements as of March 31, 2015 and for the three months ended March 31, 2015, do not reflect transactions with Cook as related party transactions.

Transactions Associated with Medpace Agreement

One member of the Company's board of directors is also the chief executive officer of Medpace. As such, Medpace was deemed to be a related party. As March 31, 2015, the Company had $4.2 million in prepaid assets (prepaid clinical, material, manufacturing and other–related parties), $3.6 million in accounts payable–related parties, and $5.8 million in accrued and other liabilities (accrued clinical, manufacturing and other–related parties), all reflected on the Company's condensed consolidated balance sheet associated with Medpace. As of December 31, 2014, the Company had $6.0 million in prepaid assets (prepaid clinical, material, manufacturing and other–related parties), $1.9 million in accounts payable–related parties, and $3.0 million in accrued and other liabilities (accrued clinical, manufacturing and other–related parties), all reflected on the Company's condensed consolidated balance sheet associated with Medpace. The Company recognized $11.5 million and $2.6 million during the three months ended March 31, 2015 and 2014, respectively, for services rendered by Medpace within research and development expense in the condensed consolidated statements of operations. The Company also has an agreement with Medpace which provides for a minimum fee commitment of $35.0 million for clinical trial services, which is further discussed in Note 6. As of March 31, 2015, $24.1 million of the services related to the fee commitment under this agreement has been performed.

Recruiting Services

One member of the Board of Directors was the chief executive officer of a company that provided recruiting services to the Company. As of March 31, 2015, the Company had $172,000 in prepaid assets (prepaid clinical, material, manufacturing and other–related parties), $172,000 in accounts payable-related parties, and $66,000 in accrued and other liabilities (accrued clinical and manufacturing–related parties) reflected on the Company's condensed consolidated balance sheet. As of December 31, 2014, the Company had $90,000 in accounts payable-related parties reflected on the Company's condensed consolidated balance sheet. The Company recorded in general and administrative expense in its condensed consolidated statements of operations $66,000 and $0 for the three months ended March 31, 2015 and 2014, respectively, for services rendered by the recruiting company.

Convertible Notes — Related Parties

In the third quarter of 2013, the Company entered into Bridge Loans with certain investors, including existing stockholders, some members of the Board of Directors and their affiliated companies and some members of management, for a total aggregate amount of $10.0 million and issued the 2013 Warrants to purchase shares of the Company's preferred stock at an exercise price of

$0.0167 per share. As such, $7.1 million of the total aggregate amount of the Bridge Loans were from related parties. In May 2014, the Company completed a preferred stock financing and contemporaneously the Bridge Loans and the related accrued interest were automatically converted into Series C preferred stock. For the three months ended March 31, 2014, the Company recognized $1.9 million of interest expense related to the debt and the amortization of the debt discount within interest expense in the Company's condensed consolidated statements of operations.

InteKrin

In February 2014, the Company completed the acquisition of InteKrin for total consideration of $5.0 million. Mr. Dennis M. Lanfear, the chief executive officer of the Company, was the chairman of the board and acting president of InteKrin at the time of the acquisition. As such, the InteKrin acquisition was a related party transaction. Mr. Lanfear also owns 10% of the outstanding securities of InteKrin Russia.

Other Assets – Related Party

In December 2014, the Company entered into an agreement with an officer of the Company, in which the officer irrevocably transferred his rights to a certain number of shares with an aggregate value of $1.7 million reflected in the Company's condensed consolidated balance sheet at March 31, 2015 as other assets-related party. This transaction is expected to settle on or about, July 10, 2015.

10. Subsequent Events

Baxter License Agreement

In April 2015, the Company and Baxter executed an amendment (the "Amendment") to the license agreement entered into in August 2013. Under the terms of the Amendment, the revised milestone structure totaling $130.0 million replaced certain existing milestones and Baxter funding obligations under the original agreement. If the Company achieves all of the new milestones pursuant to the Amendment, the total payments to the Company prior to a European market approval may exceed the aggregate of funding and milestone payments under the existing agreement by approximately $12.2 million. The Amendment also provides that Baxter will purchase $10.0 million of the Company's common stock within six months of execution of the Amendment at a price per share equal to the closing trading price on the date of such purchase. Pursuant to the Amendment, the Company received $35.0 million of the milestone payment in May 2015 due to the completion of the enrollment for CHS-0214 Phase 3 clinical studies in rheumatoid arthritis and psoriasis.

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

The interim financial statements included in this Quarterly Report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2014, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Annual Report on Form 10-K filed with the SEC pursuant to Rule 424(b)(4) on March 23, 2015. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements are subject to risks and uncertainties, including those discussed in the section titled "Risk Factors," set forth in Part II – Other Information, Item 1A below and elsewhere in this report that could cause actual results to differ materially from historical results or anticipated results.

Overview

We are a late-stage clinical biologics platform company focused on the global biosimilar market. Biosimilars are an emerging class of protein-based therapeutics with high similarity to approved originator products on the basis of various physicochemical and structural properties, as well as in terms of safety, purity and potency. Our goal is to become a global leader in the biosimilar market by leveraging our team's collective expertise in key areas such as process science, analytical characterization, protein production and clinical-regulatory development.

Our clinical-stage biosimilar pipeline includes the following three product candidates:

- ***CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate).*** Our long-acting G-CSF product candidate, CHS-1701, is being developed as a pegfilgrastim (Neulasta) biosimilar. We have initiated a pivotal pharmacokinetic (PK) and pharmacodynamics (PD) study for CHS-1701 in the United States (U.S.), which, if positive, we believe will support the planned filing of a biologics license application (BLA) in the U.S. An additional immunogenicity study is planned in healthy volunteers pursuant to this BLA and is projected to be concluded in 2015.
- ***CHS-0214 (our etanercept (Enbrel) biosimilar candidate).*** CHS-0214 is a product candidate that we have partnered with Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, or together, Baxter, and Daiichi Sankyo Company, Limited, or Daiichi Sankyo, to develop and commercialize in key markets outside of the United States. We are currently enrolling two Phase 3 clinical trials in rheumatoid arthritis and psoriasis. We expect results of these trials, if positive, combined with data from our Phase 1 studies, will support the expected filing of a marketing application in Europe and Japan in 2016. We have retained the development and commercial rights in the U.S. However, the therapeutic protein in etanercept is subject to certain originator-controlled U.S. patents expiring in 2028 and 2029. Assuming these patents are valid and enforceable, and that we would be unable to obtain a license to them, we do not expect to commercialize CHS-0214 in the U.S. prior to their expiration. On April 14, 2015, we obtained positive results of a repeat Phase 1 PK bioequivalence study for CHS-0214. This study was initiated due to the change in the manufacturing location from the U.S. to the European Union (E.U.) of CHS-0214, and compared the E.U. produced CHS-0214 to a lot of Enbrel manufactured in Europe. In May 2015, the Company completed the enrollment of the Phase 3 studies, as such received $35.0 million of the milestone payment from Baxter.
- ***CHS-1420 (our adalimumab (Humira) biosimilar candidate).*** Our second anti-TNF product candidate, CHS-1420, is being developed as an adalimumab (Humira) biosimilar. This product successfully completed a pivotal Phase 1 PK study in August 2014 by meeting the primary study endpoint. We plan to initiate a Phase 3 study in psoriasis in mid-2015 to support the planned filing of a marketing application in the U.S. in 2016 and the E.U. in 2017.

Our revenue to date has been generated primarily from collaboration and license payments pursuant to our license agreements with Daiichi Sankyo and Baxter. We have not generated any commercial product revenue. We have incurred significant losses in the past and expect to incur significant and increasing losses in the foreseeable future as we advance our product candidates into later stages of development and, if approved, commercialization. Our net losses were $40.8 million and $25.2 million for the three months ended March 31, 2015 and 2014, respectively. As of March 31, 2015, we had an accumulated deficit of $227.5 million.

In March 2015, the Company's registration statement on Form S-1 (File No. 333-202936) relating to its Follow-on Offering of its common stock was declared effective by the SEC. The price of the shares sold in the Follow-on Offering was $29.00 per share. The Follow-on Offering closed on April 7, 2015, pursuant to which the Company sold 4,137,931 shares of common stock. The Company granted the underwriters the option to purchase up to an additional 620,689 shares of common stock at the public offering price less underwriting discounts and commissions, which expired on April 30, 2015. The Company received total gross proceeds from the

offering of $120.0 million. After deducting underwriting discounts and commissions of $7.2 million and offering expenses of approximately $0.6 million, the net proceeds were approximately $112.2 million.

Financial Operations Overview

Revenue

We have not generated any revenue from commercial product sales to date. Our revenue has been generated from license and collaboration agreements, which is composed of license payments and milestone and other contingent payments under our license agreements.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred. We currently track only the external research and development costs incurred for each of our product candidates. Our external research and development expenses consist primarily of:

- expenses incurred under agreements with consultants, third-party contract research organizations, or CROs, and investigative sites where a substantial portion of our preclinical studies and all of our clinical trials are conducted;
- costs of acquiring originator comparator materials and manufacturing pre-clinical study and clinical trial supplies and other materials from contract manufacturing organizations, or CMOs, and related costs associated with release and stability testing; and
- costs associated with manufacturing process development activities.

Internal costs are associated with activities performed by our research and development organization and generally benefit multiple programs. These costs are not separately allocated by product candidate. Unallocated, internal research and development costs consist primarily of:

- personnel-related expenses, which include salaries, benefits and stock-based compensation; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization of leasehold improvements and equipment and laboratory and other supplies.

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical development of our product candidates. We expect these expenses to increase in absolute dollars in the future as we continue to invest in research and development activities related to our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming. Furthermore, in the past we have entered into collaborations with third parties to participate in the development and commercialization of our product candidates, and we may enter into additional collaborations in the future. In situations in which third parties have substantial influence over the development activities for product candidates, the estimated completion dates are not fully under our control. For example, pursuant to our collaboration agreements with respect to CHS-0214, our partners in licensed territories may exert considerable influence on the regulatory filing process globally. Therefore, we cannot forecast with any degree of certainty the duration and completion costs of these or other current or future clinical trials of our product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. In addition, we may enter into other collaboration arrangements for our other product candidates, which could affect our development plans or capital requirements.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, allocated facilities costs and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation. We expect to incur increased expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, or The NASDAQ Global Market, or NASDAQ, additional insurance expenses, investor relations activities and other administration and professional services.

Interest Expense

Interest expense consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount associated with our various debt agreements. The convertible notes issued in 2013 were converted into shares of our Series C convertible preferred stock in May 2014.

Other Expense, Net

Other expense, net consists of gains and losses resulting from the remeasurement of the fair value of our convertible preferred stock warrant liability and our contingent consideration. In November 2014, in connection with the closing of our IPO, all of our outstanding warrants for convertible preferred stock were exercised for cash or on a net basis, and the convertible preferred stock warrant liability was reclassified to equity. As such, we no longer record adjustments to reflect the remeasurement of the fair values. In March 2015, the contingent consideration related to the Earn-Out Payment was settled for shares and cash, and the contingent liability related to the Earn-Out Payment was reclassified to equity. As such, we ceased recording adjustments to reflect the remeasurement of the Earn-Out Payment to fair value. We will still continue to record adjustments to the estimated fair value of our contingent consideration related to the Compound Transaction Payment until the contingency settles or expires.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. On an on-going basis, we evaluate our critical accounting policies and estimates. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes to our accounting policies during the three months ended March 31, 2015, as compared to the significant accounting policies described in our Annual Report on Form 10-K filed with the SEC on March 23, 2015. We believe that the accounting policies discussed in that Annual Report are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2016, at which time we may adopt the new standard under the full retrospective method or the modified retrospective method. Early adoption is not permitted. In April 2015, the FASB issued for public comment a proposed ASU that would defer the effective date of ASU 2014-09 by one year. The proposed deferral of ASU 2014-09 would permit public companies to apply the new revenue standard to annual reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact that the adoption of ASU 2014-09 will have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today's guidance. ASU 2014-15 is effective for us in the first quarter of 2016 with early adoption permitted. We are currently evaluating the impact that the adoption of ASU 2014-15 will have on its consolidated financial statements and related disclosures.

We have reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or no material effect is expected on the condensed consolidated financial statements as a result of future adoptions.

Results of Operations

Comparison of Three Months Ended March 31, 2015 and 2014

Collaboration and License Revenue

	Three Months Ended March 31,		
	2015	2014	Change
	(in thousands)		
Revenue:			
Collaboration and license revenue	$ 5,810	$ 3,090	$ 2,720
Collaboration and license revenue - related party (1)	—	506	(506)
Total collaboration and license revenue	5,810	3,596	2,214

(1) Represent revenue from Daiichi Sankyo, a holder of more than 10% of our common stock until the closing of our IPO on November 12, 2014.

Collaboration and license revenue for the three months ended March 31, 2015 was $5.8 million compared to $3.6 million for the same period in 2014, an increase of $2.2 million. The increase was primarily due to $2.2 million of increased revenue recognized in connection with the amortization of deferred revenue under our license agreement with Baxter.

Research and Development Expenses

	Three Months Ended March 31,		
	2015	2014	Change
	(in thousands)		
Research and development	$ 36,467	$ 13,936	$ 22,531

Research and development expenses for the three months ended March 31, 2015 was $36.5 million compared to $13.9 million for the same period in 2014, an increase of $22.5 million. The increase in research and development expenses was primarily due to:

- an increase of $10.7 million in costs incurred for CHS-0214 due to the ongoing Phase 3 clinical trial, which is net of an increase of $0.2 million in cost reimbursements from Daiichi Sankyo that was recognized as a reduction of research and development expense;
- an increase of $6.9 million related to initiating BLA-enabling studies for CHS-1701;
- an increase of $1.5 million to advance CHS-1420 to a Phase 3 study in psoriasis;
- an increase of $0.6 million to initiate an INT-131 proof-of concept Phase 2 clinical study.
- an increase of $2.0 million in personnel, stock-based compensation, consulting and other related expenses due to a net increase of 27 employees in research and development; and
- an increase of $0.8 million in facilities, supplies and materials and other infrastructure to support our research and development growth.

General and Administrative Expenses

	Three Months Ended March 31,		
	2015	2014	Change
	(in thousands)		
General and administrative	$ 6,091	$ 3,421	$ 2,670

General and administrative expenses for the three months ended March 31, 2015 was $6.1 million compared to $3.4 million for the same period in 2014, an increase of $2.7 million. The increase was primarily due to an increase of $1.7 million in legal, accounting, recruiting and other professional services and $0.3 million in facilities, supplies and materials to support our growing infrastructure as we expand our operations as a public company. Additionally, the increase was related to a $0.6 million increase in

personnel and consulting related expenses as a result of an increase in headcount of 11 employees in general and administrative functions, partially offset by a decrease in stock-based compensation related to common stock warrants that were granted during the first quarter of 2014.

Interest Expense

	Three Months Ended March 31,		
	2015	2014	Change
	(in thousands)		
Interest expense	$ —	$ 2,741	$ (2,741)

There was no interest expense for the three months ended March 31, 2015 compared to $2.7 million for the same period in 2014, a decrease of $2.7 million. The decrease was due to the conversion of our 2013 convertible notes into shares of our Series C convertible preferred stock in May 2014 resulting in no interest expense during the first quarter of 2015 compared to the recognition of non-cash interest expense and amortization of the debt discount during the first quarter of 2014.

Other Expense, Net

	Three Months Ended March 31,		
	2015	2014	Change
	(in thousands)		
Other expense, net	$ 4,091	$ 8,668	$ (4,577)

Other expense, net for the three months ended March 31, 2015 was $4.1 million compared to $8.7 million for the same period in 2014, a decrease of $4.6 million. The decrease is primarily due to the change in fair value of our convertible preferred stock warrant liability in the first quarter of 2014 of $8.7 million which converted into equity contemporaneously with the closing of our IPO on November 12, 2014. This decrease was partially offset by the change in fair value of our contingent consideration related to the InteKrin acquisition of $4.2 million.

Liquidity and Capital Resources

Due to our significant research and development expenditures, we have generated significant operating losses since our inception. We have funded our operations primarily through the issuance of debt, equity financing (IPO, Follow-On Offering), sales of our convertible preferred stock and payments received under our collaboration and license agreements.

In April 2015, we completed our Follow-on Offering and raised net proceeds of approximately $112.2 million, after deducting underwriting discounts and commissions and offering expenses.

As of March 31, 2015, we had an accumulated deficit of $227.5 million and cash and cash equivalents of $115.1 million. We believe that our current available cash and cash equivalents together with the cash received from the IPO and Follow-on Offering will be sufficient to fund our planned expenditures and meet our obligations through at least the next twelve months. However, if anticipated operating results are not achieved in future periods, the planned expenditures may need to be reduced in order to extend the time period over which the then-available resources would be able to fund the operations. We will need to raise additional funds in the future; however there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable**.**

Summary Statement of Cash Flows

The following table summarizes our cash flows for the periods presented:

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Net cash (used in) provided by operating activities	$ (33,062)	$ 14,745
Net cash (used in) provided by investing activities	(1,313)	2,074
Net cash (used in) provided by financing activities	(729)	8
Effect of exchange rate changes in cash and cash equivalents	(152)	(64)
Net (decrease) increase in cash and cash equivalents	$ (35,256)	$ 16,763

Net cash (used in) provided by operating activities

Cash used in operating activities was $33.1 million for the three months ended March 31, 2015, reflecting a net loss of $40.8 million, which was partially offset by non-cash charges of $4.2 million for the remeasurement of our contingent consideration obligations, $2.2 million for stock-based compensation and $0.2 million for depreciation and amortization. Cash used in operating activities also reflected an increase in net operating assets of $1.2 million primarily due to accounts payable and accounts payable-related parties increased by $4.7 million and accrued and other liabilities increased by $1.9 million as a result of the increase in clinical activities and timing of vendor payments, a decrease in receivables from collaboration and license agreement of $0.4 million, and other current assets decreased by $0.4 million. This increase was partially offset by a decrease in deferred revenue of $5.5 million as we recognized the revenue from Baxter and Daiichi Sankyo collaboration agreements and an increase in other assets of $0.8 million.

Cash provided by operating activities was $14.7 million for the three months ended March 31, 2014 reflecting a net loss of $25.2 million, which was partially offset by non-cash charges of $8.7 million for the remeasurement of our convertible preferred stock warrant liability, $2.7 million of non-cash interest expense and amortization of debt discount, $3.3 million for stock-based compensation and $0.1 million for depreciation and amortization. Cash provided by operating activities reflected an increase in net operating assets of $25.1 million primarily due to an increase in deferred revenue of $9.4 million and an increase in contingent liability to collaborators of $12.7 million both related to the additional payments received from Baxter under our licensing agreement. In addition, accounts payable and accounts payable-related parties increased by $5.8 million as a result of the increase in clinical activities and timing of vendor payments and an increase of $1.2 million related to advance payments from Daiichi Sankyo for funds received for which we have not performed services. These increases were partially offset by an increase in prepaid assets of $1.4 million related to the increase in prepaid clinical, material and manufacturing as a result of an increase in clinical activities and a decrease in accrued and other liabilities of $2.5 million related to a decrease in clinical, material and manufacturing accrual.

Net *cash (used in) provided by investing activities*

Cash used in investing activities of $1.3 million for the three months ended March 31, 2015 was due to the purchase of capital equipment and leasehold improvements.

Cash provided by investing activities of $2.1 million for the three months ended March 31, 2014 was related to net cash acquired from the acquisition of InteKrin in February 2014 of $2.3 million, partially offset by cash used for purchase of capital equipment of $0.3 million.

Net cash (used in) provided by financing activities

Cash used in financing activities of $0.7 million for the three months ended March 31, 2015 was primarily for payments of costs related to our IPO and Follow-on Offering of $0.9 million partially offset by the proceeds resulting from the exercise of stock options of $0.2 million.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

JOBS Act Accounting Election

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected to opt out of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of March 31, 2015, we had cash and cash equivalents of $115.1 million. A portion of our cash equivalents, which are in money market funds, may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our cash equivalents are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

We are exposed to market risk related to changes in foreign exchange rates. We contract with CROs and contract manufacturers globally and thus we face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars. Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. An adverse movement in foreign exchange rates could have a material effect on payments made to foreign suppliers and for license agreements. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our financial statements.

We acquired InteKrin in February 2014, which has a subsidiary based in Russia and thus subjects us to foreign currency rate fluctuations against the Russian Ruble. As of March 31, 2015, we had 27.9 million Rubles in cash, which was equal to $0.5 million at that date. This cash is located in Russia.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

We carried out an evaluation, under the supervision of our Chief Executive Officer and our Chief Financial Officer, and evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were, in design and operation, effective.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than as described above.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history in an emerging regulatory environment on which to assess our business, have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a biopharmaceutical company with a limited operating history in an emerging regulatory environment. We have incurred net losses in each year since our inception in September 2010, including net losses of $87.2 million and $53.6 million for the years ended December 31, 2014 and 2013, respectively; and $40.8 million for the three months ended March 31, 2015. As of March 31, 2015, we had an accumulated deficit of $227.5 million.

We have devoted substantially all of our financial resources to identify and develop our product candidates, including conducting, among other things, analytical characterization, process development and manufacture, formulation and clinical studies, and providing general and administrative support for these operations. To date, we have financed our operations primarily through the sale of equity securities and convertible notes, as well as through our license agreements with Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, or together, Baxter, and Daiichi Sankyo Company, Limited, or Daiichi Sankyo. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings or strategic collaborations. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are in Phase 3 or other BLA-enabling clinical development with two of our lead products, CHS-0214 (our etanercept (Enbrel) biosimilar candidate) and CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate). We are in earlier stages of clinical development with our other lead product candidate, namely CHS-1420 (our adalimumab (Humira) biosimilar candidate) for which we have not commenced a Phase 3 clinical trial. It may be several years, if ever, before we complete Phase 3 or other BLA-enabling clinical trials and have a product candidate ready to file for market approval with the relevant regulatory agencies. If we obtain regulatory approval to market a biosimilar product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors and adequate market share for our product candidates in those markets. However, even if one or more of our product candidates gain regulatory approval and are commercialized, we may never become profitable.

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

- continue our nonclinical and clinical development of our product candidates;
- expand the scope of our current clinical studies for our product candidates;
- advance our programs into more expensive clinical studies;
- initiate additional nonclinical, clinical or other studies for our product candidates;
- change or add contract manufacturers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify, assess, acquire and/or develop other biosimilar product candidates or products that may be complementary to our products;
- make upfront, milestone, royalty or other payments under any license agreements;
- seek to create, maintain, protect and expand our intellectual property portfolio;

- engage legal counsel and technical experts to help us evaluate and avoid infringing any valid and enforceable intellectual property rights of third parties;
- engage in litigation including patent litigation with originator companies or others that may hold patents;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including but not limited to failed studies, conflicting results, safety issues, manufacturing delays, litigation or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies in order to pursue marketing approval.

Further, 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 quarter-to-quarter and year-to-year due to factors including the timing of clinical trials, any litigation that we may initiate or that may be initiated against us, the execution of collaboration, licensing or other agreements and the timing of any payments we make or receive thereunder.

We have never generated any revenue from product sales and may never be profitable.

Although we have received upfront payments, milestone and other contingent payments and/or funding for development from some of our collaboration and license agreements (e.g., Baxter and Daiichi Sankyo), we have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product candidates. We cannot predict when we will begin generating revenue from product sales, as this depends heavily on our success in many areas, including but not limited to:

- attracting, hiring and retaining qualified personnel;
- completing nonclinical and clinical development of our product candidates;
- developing and testing of our product formulations;
- obtaining regulatory and marketing approvals for product candidates for which we complete clinical studies;
- developing a sustainable and scalable manufacturing process for any approved product candidates and establishing and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) products to support clinical development and the market demand for our product candidates, if approved;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with collaboration partners or distributors;
- obtaining adequate third-party coverage and reimbursements for our products;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing and developing (or acquiring/in-licensing) new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- defending against any litigation including patent infringement lawsuits, that may be filed against us.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs to commercialize any such product. Our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, other regulatory agencies, domestic or foreign, or by any unfavorable outcomes in intellectual property litigation filed against us, to change our manufacturing processes or assays or to perform clinical, nonclinical or other types of studies in addition to those that we currently anticipate. In cases where we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the number of biosimilar competitors in

such markets, the accepted price for the product, the ability to get reimbursement at any price, the nature and degree of competition from originators and other biosimilar companies (including competition from large pharmaceutical companies entering the biosimilar market that may be able to gain advantages in the sale of biosimilar products based on brand recognition and/or existing relationships with customers and payors) and whether we own (or have partnered) the commercial rights for that territory. If the market for our product candidates (or our share of that market) is not as significant as we expect, the indication approved by regulatory authorities is narrower than we expect or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are unable to successfully complete development and obtain regulatory approval for our lead products, namely CHS-0214, CHS-1420 and CHS-1701, our business may suffer. Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable.

We expect that we will need to raise substantial additional funding. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We are currently advancing our CHS-0214, CHS-1420 and CHS-1701 product candidates through clinical development. Developing our product candidates is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates through late-stage clinical studies.

As of March 31, 2015, our cash and cash equivalents were $115.1 million. We expect that our existing cash and cash equivalents, together with funding we expect to receive under our license agreements with Daiichi Sankyo and Baxter, will be sufficient to fund our current operations for the next 12 months; however, we expect that we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates. In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress, results and cost of our clinical studies, nonclinical testing and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies, of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any milestone and royalty payments thereunder; and
- the cost, timing and outcomes of any litigation that we may file or that may be filed against us by third parties.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute the share ownership of our existing stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, 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. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the clinical success, regulatory approval and commercial success of our product candidates. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

To date, we have invested substantially all of our efforts and financial resources to identify, acquire and develop our product candidates. Our future success is dependent on our ability to develop, obtain regulatory approval for, and then commercialize and obtain adequate third party coverage and reimbursement for one or more product candidates. We currently do not have any approved products and generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product.

Our product candidates are in varying stages of development and will require additional clinical development, management of nonclinical, clinical and manufacturing activities, regulatory approval, adequate manufacturing supplies, commercial organization and significant marketing efforts before we generate any revenue from product sales. CHS-0214 and CHS-1701 have entered Phase 3 or other BLA-enabling clinical development, and CHS-1420 is expected to advance into a Phase 3 study in 2015. CHS-0214 and CHS-1701 are our only product candidate that have advanced into pivotal studies. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

Our clinical trials must use originator products as comparators, and such supplies may not be available on a timely basis to support such trials.

Although certain of our employees have prior experience with submitting marketing applications to the FDA or comparable foreign regulatory authorities, neither we nor our collaboration partners have submitted such applications for our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we and our collaboration partners do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We, together with our collaboration partners, generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union, or E.U., and in additional foreign countries where we or our partners have commercial rights. To obtain regulatory approval, we and our collaboration partners must comply with numerous and varying regulatory requirements of such countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical studies, commercial sales and pricing and distribution of our product candidates. Even if we and our collaboration partners are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we and our collaboration partners are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and the regulatory approval requirements for biosimilars are evolving. If we and our collaboration partners are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, marketing, distribution, post-approval monitoring and reporting and export and import of biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, by the EMA and EEA Competent Authorities in the European Economic Area, or EEA, and by other regulatory authorities in other countries, which regulations differ from country to country. Neither we nor any collaboration partner is permitted to market our product candidates in the United States until we and our collaboration partners receive approval from the FDA, or in the EEA until we and our collaboration partners receive E.U. Commission or EEA Competent Authority approvals.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, may take many years following the completion of clinical studies and depends upon numerous factors. In addition, approval policies, 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, which may cause delays in the approval or the decision not to approve an application. Neither we nor any collaboration partner has obtained regulatory approval for any of our product candidates, and it is possible that none of our current or future product candidates will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a BLA, a biosimilar product application under the 351(k) pathway of the Public Health Service Act, or PHSA, a biosimilar marketing authorization under Article 6 of Regulation (EC) No. 726/2004 and/or Article 10(4) of Directive 2001/83/EC in the EEA or other submission or to obtain regulatory approval in the United States, the EEA or elsewhere;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, nonclinical studies or clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical studies, may result in our failure to obtain regulatory approval to market any of our product candidates, which would significantly harm our business. Moreover, any delays in the commencement or completion of clinical testing could significantly impact our product development costs and could result in the need for additional financing.

In addition, if we change the regulatory pathway through which we intend to seek approval of any of our product candidates, we may have to conduct additional clinical trials, which may delay our ability to submit a marketing application for the product. Even if we or our collaboration partners were to obtain approval for any of our product candidates, regulatory agencies may limit the scope of such approval for fewer or more limited indications than we request, may grant approval contingent on the completion of costly additional clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we are not able to demonstrate biosimilarity of our biosimilar product candidates to the satisfaction of regulatory authorities, we will not obtain regulatory approval for commercial sale of our biosimilar product candidates and our future results of operations would be adversely affected.

Our future results of operations depend, to a significant degree, on our ability to obtain regulatory approval for and to commercialize our proposed biosimilar products. To obtain regulatory approval for the commercial sale of these product candidates, we will be required to demonstrate to the satisfaction of regulatory authorities, among other things, that our proposed biosimilar products are highly similar to biological reference products already licensed by the regulatory authority pursuant to marketing applications, notwithstanding minor differences in clinically inactive components, and that they have no clinically meaningful differences as compared to the marketed biological products in terms of the safety, purity and potency of the products. Each individual jurisdiction may apply different criteria to assess biosimilarity, based on a preponderance of the data that can be interpreted subjectively in some cases. In the EEA, the similar nature of a biosimilar and a reference product is demonstrated by comprehensive comparability studies covering quality, biological activity, safety and efficacy. For example, a determination of biosimilarity for CHS-0214 will be based on our demonstration of its high similarity to Enbrel.

Although our Phase 1 PK / PD trial for CHS-1701 met its primary endpoint and was satisfactory for purposes of pursuing a 351(a) (novel biologic) approval pathway (which does not require bioequivalence to the originator drug), we believe the results of the trial are indicative of the challenges in developing biosimilar drugs insofar as the data from the trial did not establish bioequivalence to Neulasta sufficient to support a 351(k) (biosimilar) approval pathway. However, on October 9, 2014 we met with the FDA to discuss our development plan for CHS-1701. We informed the agency of our decision to transition from a 351(a) (novel biologic) approval pathway to a 351(k) (biosimilar) pathway. We believe the 351(k) (biosimilar) approval pathway may enable us to file for U.S.

regulatory approval for CHS-1701 in the 4th quarter of 2015 or 1st quarter of 2016, approximately 6 to 12 months earlier than we project under a 351(a) (novel biologic) approval pathway. In March 2015, we received written feedback from the FDA on our development plan for CHS-1701 and we initiated a pivotal pharmacokinetic and pharmacodynamic study for CHS-1701in the United States, which, if positive, we believe will support the planned filing of a BLA in the United States. An additional immunogenicity study is planned in healthy volunteers pursuant to this BLA and is projected to conclude in 2015. While we believe it may be possible to advance CHS-1701 to such 351(k) approval application without a collaboration or licensing partner, it remains uncertain whether execution of our development plan will result in data supporting our planned 351(k) approval application for CHS-1701.

It is uncertain if regulatory authorities will grant the full originator label to biosimilar product candidates when they are approved. For example, an infliximab (Remicade) biosimilar molecule was approved in Europe for the full originator label but did not receive the full originator label when approved in Canada. A similar outcome could occur with respect to one or more of our product candidates.

In the event that regulatory authorities require us to conduct additional clinical trials or other lengthy processes, the commercialization of our proposed biosimilar products could be delayed or prevented. Delays in the commercialization of or the inability to obtain regulatory approval for these products could adversely affect our operating results by restricting or significantly delaying our introduction of new biosimilars.

The structure of complex proteins used in protein-based therapeutics is inherently variable and highly dependent on the processes and conditions used to manufacture them. If we are unable to develop manufacturing processes that achieve a requisite degree of biosimilarity to the originator drug, and within a range of variability considered acceptable by regulatory authorities, we may not be able to obtain regulatory approval for our products.

Protein-based therapeutics are inherently heterogeneous and their structures are highly dependent on the production process and conditions. Products from one production facility can differ within an acceptable range from those produced in another facility. Similarly, physicochemical differences can also exist among different lots produced within a single facility. The physicochemical complexity and size of biologic therapeutics create significant technical and scientific challenges in the context of their replication as biosimilar products.

The inherent variability in protein structure from one production lot to another is a fundamental consideration with respect to establishing biosimilarity to an originator product to support regulatory approval requirements. For example, the glycosylation of the protein, meaning the manner in which sugar molecules are attached to the protein backbone of a therapeutic protein when it is produced in a living cell, is critical to half-life (how long the drug stays in the body), efficacy and even safety of the therapeutic and is therefore a key consideration for biosimilarity. Defining and understanding the variability of an originator molecule in order to match its glycosylation profile requires significant skill in cell biology, protein purification and analytical protein chemistry. Furthermore, manufacturing proteins with reliable and consistent glycosylation profiles at scale is challenging and highly dependent on the skill of the cell biologist and process scientist.

There are extraordinary technical challenges in developing complex protein-based therapeutics that not only must achieve an acceptable degree of similarity to the originator molecule in terms of characteristics such as the unique glycosylation pattern (attachment of sugars to the protein) critical to therapeutic efficacy, but also the ability to develop manufacturing processes that can replicate the necessary structural characteristics within an acceptable range of variability sufficient to satisfy regulatory authorities.

Given the challenges caused by the inherent variability in protein production, we may not be successful in developing our products if regulators conclude that we have not achieved a sufficient level of biosimilarity to the originator product, or that the processes we use are unable to generate our products within an acceptable range of variability.

Clinical drug development involves a lengthy and expensive process and we may encounter substantial delays in our clinical studies or may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we (and/or our collaboration partners) must conduct clinical studies to demonstrate the safety and efficacy of the product candidates in humans.

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 study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent registration clinical studies. For example, results generated to date in clinical studies for our CHS-0214 product candidate do not ensure that later clinical studies will demonstrate similar positive results.

There is a high failure rate for product candidates proceeding through clinical studies, and product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical studies. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses. We do not know whether any clinical studies we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval.

We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation of human clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an investigational new drug, or IND, application or amendment or equivalent application or amendment, or an inspection of our clinical study operations or study sites or as a result of adverse events reported during a clinical trial;
- delays in recruiting suitable patients to participate in our clinical studies sponsored by us or our partners;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practices requirements or applicable regulatory guidelines in other countries;
- delays in having patients complete participation in a study or return for post-treatment follow-up, or patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding or regulators requiring us to conduct additional clinical studies or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting and/or distributing sufficient stable quantities of our product candidates and originator products for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions.

For example, we intend to alter the manufacturing process for CHS-0214 and will need to provide data to the FDA and foreign regulatory authorities demonstrating that the change in manufacturing process has not changed the product candidate. If we are unable to make that demonstration to the FDA or comparable foreign regulatory authorities, we could face significant delays or fail to obtain regulatory approval to market the product, which could significantly harm our business.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted.

As with most pharmaceutical products, use of our product candidates could be associated with side effects or adverse events which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects such as toxicity or other safety issues and could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits which will harm our business. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, prospects and financial condition.

Additionally, product quality characteristics have been shown to be sensitive to changes in process conditions, manufacturing techniques, equipment or sites and other such related considerations, hence any manufacturing process changes we implement prior to or after regulatory approval could impact product safety and efficacy.

Drug-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance and we are required to maintain product liability insurance pursuant to certain of our license agreements. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- 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 the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

If we receive approval, regulatory agencies including the FDA, EMA, EEA Competent Authorities and other foreign regulatory agency regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA, the EMA, EEA Competent Authorities or other foreign regulatory agencies could

take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

The development, manufacture and commercialization of biosimilar products under various global regulatory pathways pose unique risks.

United States Regulatory Framework for Biosimilars

We and our collaboration partners intend to pursue market authorization globally. In the United States, an abbreviated pathway for approval of biosimilar products was established by the Biologics Price Competition and Innovation Act of 2009, or BPCIA, enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act. The BPCIA established this abbreviated pathway under section 351(k) of the Public Health Service Act, or PHSA. Subsequent to the enactment of the BPCIA, the FDA issued draft guidance regarding the demonstration of biosimilarity as well as the submission and review of biosimilar applications. Moreover, market acceptance of biosimilar products in the United States is unclear. Numerous states are considering or have already enacted laws that regulate or restrict the substitution by state pharmacies of biosimilars for originator products already licensed by the FDA. Market success of biosimilar products will depend on demonstrating to patients, physicians, payors and relevant authorities that such products are similar in quality, safety and efficacy as compared to the reference product.

We will continue to analyze and incorporate into our biosimilar development plans any final regulations issued by the FDA, pharmacy substitution policies enacted by state governments and other applicable requirements established by relevant authorities. The costs of development and approval, along with the probability of success for our biosimilar product candidates, will be dependent upon application of any laws and regulations issued by the relevant regulatory authorities.

Biosimilar products may also be subject to extensive patent clearances and patent infringement litigation, which may delay and could prevent the commercial launch of a product. Moreover, the BPCIA prohibits the FDA from accepting an application for a biosimilar candidate to a reference product within four years of the reference product's licensure by the FDA. In addition, the BPCIA provides innovative biologics with 12 years of exclusivity from the date of their licensure, during which time the FDA cannot approve any application for a biosimilar candidate to the reference product. For example, the FDA would not be able to grant approval of any application submitted for an etanercept (Enbrel) biosimilar, an adalimumab (Humira) biosimilar or a pegfilgrastim (Neulasta) biosimilar, until 12 years after the original BLAs for these drugs were approved, which occurred on September 12, 2002 in the case of Enbrel, December 31, 2002 in the case of Humira and January 31, 2002 in the case of Neulasta.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are evolving and subject to significant uncertainty. Future implementation decisions by the FDA could result in delays in the development or commercialization of our product candidates or increased costs to assure regulatory compliance and could adversely affect our operating results by restricting or significantly delaying our ability to market new biosimilar products.

Regulatory Framework for Biosimilars Outside the United States

In 2004, the European Parliament issued legislation allowing the approval of biosimilar therapeutics. Since then, the European Commission has granted marketing authorizations for more than 20 biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. Because of their extensive experience in the review and approval of biosimilars, Europe has more guidelines for these products than the FDA, including data requirements needed to support approval.

Under current EU regulations, an application for regulatory approval of a biosimilar drug cannot be submitted in the EU until expiration of an eight year data exclusivity period for the reference (originator) product, measured from the date of the reference product's initial marketing authorization. Furthermore, once approved, the biosimilar cannot be marketed until expiration of a 10-year period following the initial marketing authorization of the reference product, such ten year period being extendible to 11 years if the reference product received approval of an additional therapeutic indication, within the first eight years following its initial marketing authorization, representing a significant clinical benefit in comparison with existing therapies. However, we understand that reference products approved prior to November 20, 2005 (which would include, for example, Enbrel, Humira and Neulasta, approved in the EU on March 2, 2000, August 9, 2003 and August 22, 2002, respectively) are subject to a 10 year period of data exclusivity. While the data exclusivity periods for Enbrel, Humira and Neulasta have now expired in Europe, these reference products are presently still subject to unexpired patents.

In Europe, the approval of a biosimilar for marketing is based on an opinion issued by the EMA and a decision issued by the European Commission. Therefore, the marketing approval will cover the entire EEA. However, substitution of a biosimilar for the originator is a decision that is made at the local (national) level on a country-by-country basis. Additionally, a number of countries do not permit the automatic substitution of biosimilars for the originator product. Therefore, even if we obtain marketing approval for the

entire EEA, we may not receive substitution in one or more European nations, thereby restricting our ability to market our products in those jurisdictions.

Other regions, including Canada, Japan and Korea, also have their own legislation outlining a regulatory pathway for the approval of biosimilars. In some cases other countries have either adopted European guidance (Singapore and Malaysia) or are following guidance issued by the World Health Organization (Cuba and Brazil). While there is overlap in the regulatory requirements across regions, there are also some areas of non-overlap. Additionally, we cannot predict whether countries that we may wish to market in, which do not yet have an established or tested regulatory framework could decide to issue regulations or guidance and/or adopt a more conservative viewpoint than other regions. Therefore, it is possible that even if we obtain agreement from one health authority to an accelerated or optimized development plan, we will need to defer to the most conservative view to ensure global harmonization of the development plan. Also, for regions where regulatory authorities do not yet have sufficient experience in the review and approval of a biosimilar product, these authorities may rely on the approval from another region (e.g., the United States or the E.U.), which could delay our approval in that region. Finally, it is possible that some countries will not approve a biosimilar without clinical data from their population and/or may require that the biosimilar product be manufactured within their region.

If other biosimilars of etanercept (Enbrel), adalimumab (Humira) or pegfilgrastim (Neulasta) are approved and successfully commercialized before our product candidates for these originator products (CHS-0214, CHS-1420 or CHS-1701, respectively), our business would suffer.

We expect other companies to seek approval to manufacture and market biosimilar versions of Enbrel, Neulasta or Humira. If other biosimilars of Enbrel, Humira or Neulasta are approved and successfully commercialized before CHS-0214, CHS-1420 or CHS-1701, respectively, we may never achieve significant market share for these products, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer.

If other biosimilars of etanercept (Enbrel), adalimumab (Humira) or pegfilgrastim (Neulasta) are determined to be interchangeable and our biosimilars candidates for these originator products are not, our business would suffer.

The FDA or other relevant regulatory authorities may determine that a proposed biosimilar product is "interchangeable" with a reference product, meaning that the biosimilar product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, if the application includes sufficient information to show that the product is biosimilar to the reference product and that it can be expected to produce the same clinical result as the reference product in any given patient. If the biosimilar product may be administered more than once to a patient, the applicant must demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar product candidate and the reference product is not greater than the risk of using the reference product without such alternation or switch. To make a final determination of interchangeability, regulatory authorities may require additional confirmatory information beyond what we plan to initially submit in our applications for approval, such as more in-depth analytical characterization, animal testing or further clinical studies. Provision of sufficient information for approval may prove difficult and expensive.

We cannot predict whether any of our biosimilar product candidates will meet regulatory authority requirements for approval not only as a biosimilar product but also as an interchangeable product in any jurisdiction. Furthermore, legislation governing interchangeability could differ by jurisdiction on a state or national level worldwide.

The concept of "interchangeability" is important because, in the United States for example, the first biosimilar determined to be interchangeable with a particular reference, or originator, product for any condition of use is eligible for a period of market exclusivity that delays an FDA determination that a second or subsequent biosimilar product is interchangeable with that originator product for any condition of use until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). Thus, a determination that another company's product is interchangeable with the originator biologic before we obtain approval of our corresponding biosimilar product candidates may delay the potential determination that our products are interchangeable with the originator product, which could materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue.

Failure to obtain regulatory approval in any targeted regulatory jurisdiction would prevent us from marketing our products to a larger patient population and reduce our commercial opportunities.

We and our collaboration partners have not initiated marketing efforts in any regulatory jurisdiction. Subject to product approvals and relevant patent expirations, we or our collaboration partners intend to market our etanercept (Enbrel) biosimilar product, CHS-0214 in Japan (through our licensee Daiichi Sankyo), Europe (through our licensee Baxter) and certain Latin American countries (through our licensee, Orox). We intend to market our pegfilgrastim (Neulasta) biosimilar product, CHS-1701 and our adalimumab (Humira) biosimilar in the United States without collaboration partners, and have not decided on whether to enter into collaborations for marketing of CHS-1701 or CHS-1420 outside the United States.

In order to market our products in the E.U., the United States and other jurisdictions, we and our collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The EMA is responsible for the centralized procedure for the regulation and approval of human medicines. This procedure results in a single marketing authorization that is valid in all E.U. countries, as well as in Iceland, Liechtenstein and Norway. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We or our collaboration partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products within the United States or in any market outside the United States. Failure to obtain these approvals would materially and adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, BLA or marketing authorization application, or MAA. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we or our collaboration partners receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. If our product candidates are approved, we must submit new or supplemental applications and obtain approval for certain changes to the approved products, product labeling or manufacturing process. We or our collaboration partners could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval is obtained via an accelerated biosimilar approval pathway, we could be required to conduct a successful post-marketing clinical study to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other possibilities:

- issue warning letters;
- impose civil or criminal penalties;

- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We may elect to seek licensure of our biosimilar products under the 351(a) (novel biologic) approval pathway instead of the 351(k) (biosimilar) approval pathway. This approval pathway may require us to undertake more expensive clinical trials and may present greater risk of failure than the 351(k) (biosimilar) approval pathway.

While we have elected to proceed under the 351(k) (biosimilar) approval pathway for CHS-0214, our etanercept (Enbrel) biosimilar, CHS-1420, our adalimumab (Humira) biosimilar and for CHS-1701, our pegfilgrastim (Neulasta) biosimilar, we may elect for future products to pursue a 351(a) (novel biologic) approval pathway for a variety of clinical, regulatory and business reasons. The 351(a) (novel biologic) approval pathway generally requires three study phases (as contrasted with the two study phases required under the 351(k) (biosimilar) pathway). Moreover, the 351(a) pathway generally does not allow for the possibility that a clinical trial in one indication can be extrapolated to multiple indications as is generally the case under the 351(k) (biosimilar) approval pathway. Pursuing licensure under the 351(a) (novel biologic) approval pathway may present disadvantages in terms of the requirements for additional clinical and nonclinical studies, clinical trial cost and failure risk, as well as the likelihood that multiple clinical trials would be required to obtain approval for all of the indications approved for the originator biologic.

Adverse events involving an originator product, or other biosimilars of such originator product, may adversely affect our business.

In the event that use of an originator product, or other biosimilar for such originator product, results in unanticipated side effects or other adverse events, it is likely that our biosimilar product candidate will be viewed comparably and may become subject to the same scrutiny and regulatory sanctions as the originator product or other biosimilar, as applicable. Accordingly, we may become subject to regulatory supervisions, clinical holds, product recalls or other regulatory actions for matters outside of our control that affect the originator product, or other biosimilar, as applicable, if and until we are able to demonstrate to the satisfaction of our regulators that our biosimilar product candidate is not subject to the same issues leading to the regulatory action as the originator product or other biosimilar, as applicable.

Risks Related to our Ability to Hire Highly Qualified Personnel and our Reliance on Third Parties

We are highly dependent on the services of our key executives and personnel, including our President and Chief Executive Officer, Dennis M. Lanfear, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.

We are highly dependent on the principal members of our management and scientific and technical staff. The loss of service of any of our management or key scientific and technical staff could harm our business. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management, particularly our President and Chief Executive Officer, Mr. Lanfear, and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

We will need to expand and effectively manage our managerial, scientific, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of March 31, 2015, we had 75 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical and clinical studies and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, current good clinical practices, or cGCP, and Good Laboratory Practices, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we, any of our CROs, service providers or investigators fail to comply with applicable regulations or cGCPs, the data generated in our nonclinical and clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional nonclinical and clinical studies 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 studies comply with cGCP regulations. In addition, our clinical studies must be conducted with product generated under cGMP regulations. Failure to comply by any of the participating parties or ourselves with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process. Moreover, our business may be implicated if our CRO or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going nonclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we strive to carefully manage our relationships with our CROs, there can be no

assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on third parties, and in some cases a single third party, to manufacture nonclinical and clinical supplies of our product candidates and to store critical components of our product candidates for us. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product candidates or fail to do so at acceptable quality levels or prices.

We do not currently have the infrastructure or capability internally to manufacture supplies of our product candidates for use in our nonclinical and clinical studies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We rely on third party manufacturers to manufacture and supply us with our product candidates for our preclinical and clinical studies. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is time consuming and we may not be able to achieve such transfer or do so in a timely manner. Moreover, the availability of contract manufacturing services for protein-based therapeutics is highly variable and there are periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce our product candidates on a timely basis or on commercially viable terms. Although we will plan accordingly and generally do not begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete such study, any significant delay or discontinuation in the supply of a product candidate for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.

Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third party manufacturers may not be able to comply with cGMP or similar regulatory requirements outside the United States. Our failure or the failure of our third party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or any other product candidates or products that we may develop. Any failure or refusal to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

If any of our product candidates are approved, in order to produce the quantities necessary to meet anticipated market demand, any contract manufacturer that we engage may need to increase manufacturing capacity. If we are unable to produce our product candidates in sufficient quantities to meet the requirements for the launch of these products or to meet future demand, our revenue and gross margins could be adversely affected. Although we believe that we will not have any material supply issues, we cannot be certain that we will be able to obtain long-term supply arrangements for our product candidates or materials used to produce them on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

We have entered into collaborations with third parties in connection with the development of certain of our product candidates. Even if we believe that the development of our technology and product candidates is promising, our partners may choose not to proceed with such development.

We have collaborations with several partners for the development and commercialization of certain of our product candidates. Our existing agreements with our collaboration partners are generally subject to termination by the counterparty on short notice under certain circumstances. Accordingly, even if we believe that the development of certain product candidates is worth pursuing, our partners may choose not to continue with such development. If any of our collaborations are terminated, we may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner on short notice, and the terms of any additional collaborations or other arrangements that we establish may not be favorable to us or available at all.

We are also at risk that our collaborations or other arrangements may not be successful. Factors that may affect the success of our collaborations include the following:

- our collaboration partners may incur financial, legal or other difficulties that force them to limit or reduce their participation in our joint projects;
- our collaboration partners may be pursuing alternative technologies or developing alternative products that are competitive to our technology and products, either on their own or in partnership with others. For example, in December 2014 Momenta Pharmaceuticals, or Momenta, announced acceptance by the UK of a clinical trial application for M923, an adalimumab (Humira) biosimilar being developed by Momenta in collaboration with Baxter;
- our collaboration partners may terminate their collaborations with us, which could make it difficult for us to attract new partners or adversely affect perception of us in the business and financial communities. For example, in July 2014 our partner Daiichi terminated its license with us pertaining to a rituximab (Rituxan) biosimilar; and
- our collaboration partners may pursue higher priority programs or change the focus of their development programs, which could affect their commitment to us.

If we cannot maintain successful collaborations, our business, financial condition and operating results may be adversely affected.

We are dependent on Daiichi Sankyo, Baxter and Orox for the commercialization of our biosimilar products candidates in certain major markets, and their failure to commercialize in those markets could have a material adverse effect on our business and operating results.

Our exclusive licensee, Baxter, is responsible for commercialization of CHS-0214 in Europe, Brazil and other jurisdictions outside the U.S. (excluding Japan and certain Caribbean and Latin American countries). Our exclusive licensee, Daiichi Sankyo, is responsible for commercialization of CHS-0214 in Japan. Our exclusive licensee, Orox Pharmaceuticals B.V., or Orox, is responsible for commercialization of certain of our products, including CHS-0214, CHS-1420 and CHS-1701, in certain Caribbean and Latin American countries (excluding Brazil). If these entities fail to exercise commercially reasonable efforts to market and sell our products in their respective licensed jurisdictions or are otherwise ineffective in doing so, our business will be harmed and we may not be able to adequately remedy the harm through negotiation, litigation, arbitration or termination of the license agreements. Moreover, any disputes with our collaboration partners concerning the adequacy of their commercialization efforts will substantially divert the attention of our senior management from other business activities and will require us to incur substantial legal costs to fund litigation or arbitration proceedings.

We are subject to a multitude of manufacturing risks. Any adverse developments affecting the manufacturing operations of our biosimilar product candidates could substantially increase our costs and limit supply for our product candidates.

The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including but not limited to:

- product loss due to contamination, equipment failure or improper installation or operation of equipment or vendor or operator error; and
- equipment failures, labor shortages, natural disasters, power failures and numerous other factors associated with the manufacturing facilities in which our product candidates are produced.

Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects and other supply disruptions. For example, we have experienced failures with respect to the manufacturing of certain lots of each of our product candidates resulting in delays prior to our taking corrective action. Additionally, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

For example in October 2014, as part of our quality process and upon routine visual inspection during storage, four syringes containing CHS-0214 (our etanercept (Enbrel) biosimilar candidate) from a production lot in use in our ongoing Phase 3 clinical trials were observed to contain small dark particles. We immediately initiated a visual inspection of remaining unlabeled inventory of this lot as well as a subsequent lot. While none of the approximately 8,000 unlabeled syringes inspected exhibited any such particulate, we decided in the interests of patient safety, to temporarily stop dosing in the ongoing Phase 3 clinical trials of CHS-0214 in order to determine a potential cause and incidence of the observed phenomenon. Based on our investigation, including a chemical analysis of

the particles by a qualified independent laboratory, we concluded that the particulates did not result from any instability in the CHS-0214 protein product or its formulation, but were most likely a result of a non-recurring anomaly related to first use of new process equipment. We therefore concluded that the approximately 7,000 unlabeled syringes that were 100% inspected and found free of any particulates were safe for patient use in our clinical trials. In consultation with the FDA, our Phase 3 trial was resumed in December 2014 and is ongoing.

Any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We currently engage single suppliers for manufacture, clinical trial services, formulation development and product testing of our product candidates. The loss of any of these suppliers or vendors could materially and adversely affect our business.

For each of our lead products, CHS-0214, CHS-1701 and CHS-1420, we currently engage a distinct vendor or service provider for each of the principal activities supporting our manufacture and development of these lead products, such as manufacture of the biological substance present in each of the products, manufacture of the final filled and finished presentation of these products, as well as laboratory testing, formulation development and clinical testing of these products. Because we currently have not engaged back up suppliers or vendors for these single-sourced services, and although we believe that there are alternate sources that could fulfill these activities, we cannot assure you that identifying and establishing relationships with alternate suppliers and vendors would not result in significant delay in the development of our product candidates. Additionally, we may not be able to enter into arrangements with alternative service providers on commercially reasonable terms or at all. A delay in the development of our product candidates, or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers, could have a material adverse impact on our business.

We and our collaboration partners and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaboration partners or our contract manufacturers must supply all necessary documentation in support of a BLA or MAA on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers may have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaboration partners and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our collaboration partners and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we, our collaboration partners or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new biologic product, withdrawal of an approval or suspension of production. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through a BLA supplement or MAA variation or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

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 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, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaboration partners, advisors, employees 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, such as 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.

Risks Related to Commercialization of Our Product Candidates

Our biosimilar product candidates, if approved, will face significant competition from the reference products and from other pharmaceuticals approved for the same indication as the originator products. Our failure to effectively compete may prevent us from achieving significant market penetration and expansion.

We expect to enter highly competitive pharmaceutical markets. Successful competitors in the pharmaceutical market have demonstrated the ability to effectively discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as an ability to effectively commercialize, market and promote approved products. Numerous companies, universities and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors are large, experienced pharmaceutical companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources. These companies also have greater brand recognition and more experience in conducting preclinical testing and clinical trials of product candidates and obtaining FDA and other regulatory approvals of products.

If an improved version of an originator product, such as Enbrel, Humira or Neulasta, is developed or if the market for the originator product significantly declines, sales or potential sales of our biosimilar product candidates may suffer.

Originator companies may develop improved versions of a reference product as part of a life cycle extension strategy and may obtain regulatory approval of the improved version under a new or supplemental BLA filed with the applicable regulatory authority. Should the originator company succeed in obtaining an approval of an improved biologic product, it may capture a significant share of the collective reference product market in the applicable jurisdiction and significantly reduce the market for the reference product and thereby the potential size of the market for our biosimilar product candidates. In addition, the improved product may be protected by additional patent rights that may subject our follow-on biosimilar to claims of infringement.

Biologic reference products may also face competition as technological advances are made that may offer patients a more convenient form of administration or increased efficacy or as new products are introduced. As new products are approved that compete with the reference product to our biosimilar product candidates, or sales of the reference originator products may be adversely impacted or rendered obsolete. If the market for the reference product is impacted, we may lose significant market share or

experience limited market potential for our approved biosimilar products or product candidates, and the value of our product pipeline could be negatively impacted. As a result of the above factors, our business, prospects and financial condition could suffer.

If efforts by manufacturers of originator products to delay or limit the use of biosimilars are successful, our sales of biosimilar products may suffer.

Many manufacturers of originator products have increasingly used legislative, regulatory and other means, such as litigation, to delay regulatory approval and to seek to restrict competition from manufacturers of biosimilars. These efforts may include or have included:

- settling patent lawsuits with biosimilar companies, resulting in such patents remaining an obstacle for biosimilar approval by others;
- submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted biosimilar applications;
- appealing denials of Citizen Petitions in United States federal district courts and seeking injunctive relief to reverse approval of biosimilar applications;
- restricting access to reference brand products for equivalence and biosimilarity testing that interferes with timely biosimilar development plans;
- attempting to influence potential market share by conducting medical education with physicians, payors, regulators and patients claiming that biosimilar products are too complex for biosimilar approval or are too dissimilar from originator products to be trusted as safe and effective alternatives;
- implementing payor market access tactics that benefit their brands at the expense of biosimilars;
- seeking state law restrictions on the substitution of biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification;
- seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic;
- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug and biologic standards;
- obtaining new patents covering existing products or processes which could extend patent exclusivity for a number of years or otherwise delay the launch of biosimilars; and
- influencing legislatures so that they attach special patent extension amendments to unrelated federal legislation.

In 2012, Abbott Laboratories filed a Citizen Petition with the FDA asking the agency to refrain from accepting biosimilar applications under the BPCIA arguing that to approve such applications, without compensation to the originator, would constitute an unconstitutional taking of an originator company's valuable trade secrets under the fifth amendment of the United States constitution. The FDA has not yet acted on this petition and its outcome is uncertain. If the FDA grants Abbott Laboratories' petition, we may be precluded from applying for approval of CHS-0214, CHS-1420 and CHS-1701 under the 351(k) pathway. Even if the FDA rejects Abbott Laboratories' petition, we think it is likely that Abbott will file appeals to the federal courts and ultimately pursue its appeals to the United States Supreme Court. Other originator companies may file Citizen Petitions in an effort to restrict or prevent the introduction of biosimilars.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Some of the pharmaceutical and biotechnology companies we expect to compete with include, for example, Sandoz International GmbH, or Sandoz, Hospira, Inc., or Hospira, Amgen, Pfizer Inc., or Pfizer, Boehringer Ingelheim GmbH, or Boehringer, Teva Pharmaceutical Industries, Ltd., or Teva, Samsung Bioepis, Ltd., or Bioepis, (a Merck/Biogen/Samsung biosimilar venture) and Hanwha Chemical Corporation, or Hanwha Momenta, as well as other smaller companies. We are currently aware that such competitors are engaged in the development of biosimilar product candidates to etanercept (Enbrel), adalimumab (Humira) and pegfilgrastim (Neulasta). For example, we understand that Sandoz, Samsung Group and Hanwha are each currently engaged in the development of competing biosimilar product candidates for etanercept (Enbrel). Each

of Sandoz, Bioepis and Hanwha appear to have ongoing Phase 3 clinical trials for an etanercept (Enbrel) biosimilar product candidate which they initiated earlier than our own Phase 3 clinical trials. Similarly, we understand that Sandoz is engaged in the development of a pegfilgrastim (Neulasta) biosimilar product candidate and believe such development has completed two Phase 3 clinical trials. Boehringer, Amgen, and Pfizer are examples of companies engaged in development of biosimilar product candidates for adalimumab (Humira). We understand Boehringer Ingelheim's program is in Phase 1, Pfizer's program is in Phase 3, and that Amgen's program has successfully completed Phase 3.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop; they may also obtain patent protection that could block our products; and they may obtain regulatory approval, product commercialization and market penetration earlier than we do. Biosimilar product candidates developed by our competitors may render our potential product candidates uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors. Competitors may also assert in their marketing or medical education programs that their biosimilar products demonstrate a higher degree of biosimilarity to the originator products than do ours or other competitor's biosimilar products, thereby seeking to influence health care practitioners to select their biosimilar products, versus ours or other competitors.

We currently have no marketing and sales organization. If we are unable to establish sales and marketing capabilities in jurisdictions for which we choose to retain commercialization rights or if we are unable to enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We currently have no marketing or sales organization. Although our employees may have sold other biologic products in the past while employed at other companies, our products have not yet been approved for sale, and thus we as a company have no experience selling and marketing our product candidates. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If our product candidates receive regulatory approval, we intend to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in major markets where we may choose to retain commercialization rights. Doing so will be expensive, difficult and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

Further, given our lack of prior experience in marketing and selling biopharmaceutical products, our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize our product candidates. As such, we may be required to hire substantially more sales representatives to adequately support the commercialization of our product candidates or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If our future collaboration partners do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We expect competition from companies such as Sandoz, Teva, Boehringer, Hospira, Pfizer and Amgen that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

We may need to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of our product candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business could be adversely affected.

Because we have limited or no internal capabilities for late-stage product development, manufacturing, sales, marketing and distribution, we have found it necessary to enter into alliances with other companies. For example, we entered into a collaboration agreement with Baxter for the development and commercialization of CHS-0214 in Europe, Brazil and other jurisdictions outside the United States. Similarly, we entered into a collaboration agreement with Daiichi Sankyo for the development and commercialization of CHS-0214 in Japan. For commercialization of our biosimilar product candidates in certain Caribbean and Latin American countries, we entered into an exclusive distribution arrangement with Orox. In the future, we may also find it necessary to form alliances or joint ventures with major pharmaceutical companies to jointly develop and/or commercialize specific biosimilar product candidates. In such alliances, we would expect our collaboration partners to provide substantial capabilities in clinical development,

manufacturing, regulatory affairs, sales and marketing. We may not be successful in entering into any such alliances. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. If we are unable to secure or maintain such alliances we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business.

In addition to product development and commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our product candidates. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop a particular product candidate internally or to bring product candidates to market. Failure to bring our product candidates to market will prevent us from generating sales revenue, and this may substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. As a result, our business and operating results may be adversely affected.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our product candidates will depend in part on the medical community, patients and third-party payors accepting our product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety and efficacy of the product as demonstrated in clinical studies and potential advantages over competing treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- the possibility that a competitor may achieve interchangeability and we may not;
- relative convenience and ease of administration;
- the extent to which our product may be more or less similar to the originator product than competing biosimilar product candidates;
- policies and practices governing the naming of biosimilar product candidates;
- prevalence of the disease or condition for which the product is approved;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- publicity concerning our products or competing products and treatments;
- the extent to which third-party payors provide adequate third-party coverage and reimbursement for our product candidates, if approved; and
- our ability to maintain compliance with regulatory requirements.

Even if a potential product displays a favorable efficacy and safety profile in nonclinical and clinical studies, market acceptance of the product will not be fully known until after it is launched and may be negatively affected by a potential poor safety experience and the track record of other biosimilar product candidates. Our efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources, may be under-resourced compared to large well-funded pharmaceutical entities and may never be successful. If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

Policies and practices governing the naming of biosimilar product candidates are neither fully established nor fully harmonized and are subject to debate and change. Failure to achieve a non-proprietary name sufficiently close to the reference product or be competitively disadvantaged in this regard, could adversely affect the commercial performance of our biosimilar product candidate.

United States Adopted Name, and International Nonproprietary Names, or INN, two important bodies involved in nonproprietary nomenclature, have no policy for the naming of biosimilar product candidates, and products are named on a case-by-case basis. Non-glycosylated proteins can follow the approach established for small molecule generics, which is to retain the same non-proprietary name if it is synthesized by a different route provided the substance is the same. Glycosylated proteins from different sources are given distinct names, as these proteins are expected to differ in their glycosylation profile. The same approach is valid for all other modifications to the protein that can occur in a cell after the cell has finished making the protein. A system currently under discussion at the World Health Organization that would enable the clear definition of all Similar Biotherapeutic Proteins would include the INN of the reference product in the first part of the name, and some form of biological qualifier that could uniquely identify the substance. Currently the FDA and EMA have final authority regarding names in the United States and the E.U. respectively, and it is unclear how they will handle nonproprietary nomenclature in the future. However, if they adopt policies requiring non-proprietary names that are distinct from the reference product or chose to assign a competing biosimilar product candidate to a Coherus product with a lower degree of nomenclature distinction from the reference product, payors, providers and patients may be more hesitant to use our biosimilar product candidate, believing the difference in nomenclature to be indicative of an important difference in quality of function from the reference product or the competing biosimilar product candidate. If this were to occur, our business could be negatively affected.

The third-party coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

Pricing, coverage and reimbursement of our biosimilar product candidates, if approved, may not be adequate to support our commercial infrastructure. Our per-patient prices may not be sufficient to recover our development and manufacturing costs and potentially achieve profitability. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford expensive treatments such as ours, if approved. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government authorities, private health insurers and other third-party payors. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to allow us to establish or maintain pricing sufficient to realize a return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older or those who are disabled or suffering from end-stage renal disease. The Medicaid program, which varies from state to state, covers certain individuals and families who have limited financial means. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our biosimilar product candidates, if approved. In addition, in the United States, no uniform policy of coverage and reimbursement for biologics exists among third-party payors. Therefore, coverage and reimbursement for biologics can differ significantly from payor to payor. As a result, the process for obtaining favorable coverage determinations often is time-consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Outside the United States, pharmaceutical businesses are generally subject to extensive governmental price controls and other market regulations. We believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. While cost containment practices generally benefit biosimilars, severe cost containment practices may adversely affect our product sales. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

Our biosimilar product candidates, if approved, could face price competition from other biosimilars of the same reference products for the same indication. This price competition could exceed our capacity to respond, detrimentally affecting our market share and revenue as well as adversely affecting the overall financial health and attractiveness of the market for the biosimilar.

We expect to enter highly competitive biosimilar markets. Successful competitors in the biosimilar market have the ability to effectively compete on price through payors and their third-party administrators who exert downward pricing pressure. It is possible our biosimilar competitors' compliance with price discounting demands in exchange for market share could exceed our capacity to respond in kind and reduce market prices beyond our expectations. Such practices may limit our and our collaboration partners' ability to increase market share and will also impact profitability.

Risks Related to Intellectual Property

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in large part on avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. The companies that originated the products for which we intend to introduce biosimilar versions, such as Amgen and AbbVie Inc., or AbbVie, as well as other competitors (including other companies developing biosimilars) have developed, and are continuing to develop, worldwide patent portfolios of varying sizes and breadth, many of which are in fields relating to our business, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. While we have conducted freedom to operate analyses with respect to our lead product candidates CHS-0214, CHS-1420 and CHS-1701, we cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. We have not yet completed freedom to operate analysis on products we are evaluating for inclusion in our future biosimilar product pipeline and therefore we do not know to what extent these products may be subject to unexpired patents.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions which do not require publication of patent applications until 18 months after filing. Moreover, we face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. In addition, coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid and/or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our

management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial monetary damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on commercially acceptable terms or at all. If, as a result of patent infringement claims or to avoid potential claims, we choose or are required to seek licenses from third parties, these licenses may not be available on acceptable terms or at all. Even if we are able to obtain a license, the license may obligate us to pay substantial license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would likely involve substantial litigation expense and would likely be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may, in addition to being blocked from the market, have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, inter partes review, or IPR, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the E.U. states (including Switzerland) seeking to extend certain patent protection which, if approved, may interfere with or delay the launch of one or more of our biosimilar products.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. The companies that originated the products for which we intend to introduce biosimilar versions, as well as other competitors (including other biosimilar companies) may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

So called "submarine" patents may be granted to our competitors that may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether.

The term "submarine" patent has been used in the pharmaceutical industry and in other industries to denote a patent issuing from an application that was not published, publically known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may issue to our competitors covering our biosimilar product candidates or our pipeline candidates and thereby cause significant market entry delay, defeat our ability to market our products or cause us to abandon development and/or commercialization of a molecule.

Examples of submarine patents include Brockhaus, *et al*., U.S. patents 8,063,182 and 8,163,522 (controlled by Amgen), which are directed to the fusion protein in Enbrel. If challenges to the scope, validity or enforceability of the Brockhaus patents are not initiated, or, if initiated, are not successful, these patents, unless licensed to us by Amgen, will preclude our ability to introduce an etanercept (Enbrel) biosimilar product candidate in the U.S. market until at least 2029.

The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a biosimilar candidate into the U.S. market.

We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products or pipeline molecules. We may incorrectly determine that our products are not covered by a third party patent.

Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of an originator product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect which may negatively impact our ability to develop and market our products.

Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

Although we are not currently involved in any litigation, we may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Although we have no issued patents, when and if we do obtain issued patents, we may discover that competitors are infringing those patents. Expensive and time-consuming litigation may be required to abate such infringement. Although we are not currently involved in any litigation to enforce patents, if we or one of our collaboration partners, such as Baxter, Daiichi Sankyo or Orox, were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome 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 we cannot obtain a license from the prevailing party on commercially reasonable terms. Third parties may request an IPR of our patents in the USPTO. An unfavorable decision may result in the revocation of our patent or a limitation to the scope of the claims of our patents. Our defense of litigation, interference or IPR proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during any litigation we initiate to enforce our patents. There could also 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 material adverse effect on the price of our common stock.

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

We employ individuals, retain independent contractors and consultants and members on our board of directors or Scientific Advisory Board who were previously employed at universities or other pharmaceutical companies, including our competitors or

potential competitors. For example, our Chief Executive Officer, Dennis M. Lanfear, and our Chief Technical Officer, Peter K. Watler, Ph.D., are former employees of Amgen. Our Chief Scientific Officer, Alan C. Herman, Ph.D., is a former employee of Amgen and Genentech. Mr. Lanfear and Drs. Watler and Herman were employed at Amgen during periods when Amgen's operations included the development and commercialization of Neupogen, Neulasta and Enbrel. Our Chief Medical Officer, Barbara K. Finck, M.D., is a former employee of Immunex Corporation, or Immunex (the company that initially discovered the drug Enbrel and was later acquired by Amgen). Dr. Finck was involved in the clinical development of etanercept (Enbrel) while at Immunex and is a named inventor on at least four U.S. patents assigned to Amgen directed to the use of etanercept (Enbrel) for the treatment of psoriasis and psoriatic arthritis. Our board of directors and Scientific Advisory Board include members that were former employees of Genentech, Amgen and Abbott Laboratories. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us and we are not currently subject to any claims that they have done so, we may in the future be subject to such claims. 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 or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we are unable to obtain and maintain effective patent rights for our product candidates or any future product candidates, we may not be able to prevent competitors from using technologies we consider important in our successful development and commercialization of our product candidates, resulting in loss of any potential competitive advantage our patents may have otherwise afforded us.

While our principal focus in matters relating to intellectual property is to avoid infringing the valid and enforceable rights of third parties, we also rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our own intellectual property related to our product candidates and development programs. Our ability to enjoy any competitive advantages afforded by our own intellectual property depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications.

The patent positions of biopharmaceutical companies generally are highly uncertain and involve complex legal and factual questions for which legal principles remain unresolved. As a result, the patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries for many reasons. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patent claims being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. 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, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates. In addition, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to prevent competitive products using our proprietary technology. Further, because patent

applications in the United States and most other countries are confidential for a period of time, typically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications claiming the same invention are filed by different parties. A third party that files a patent application in the USPTO before we do could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party.

The change to "first-to-file" from "first-to-invent" is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We do not have any issued patents, but we have filed patent applications, which are currently pending, covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened or infringed by third parties. Any successful actions by third parties to challenge the validity or enforceability of any patents which may issue to us could deprive us of the ability to prevent others from using the technologies claimed in such issued patents. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

While our business is based primarily on the timing of our biosimilar product launches to occur after the expiration of relevant patents, we have filed a number of patents covering our own proprietary formulations and processes for our product candidates when we have believed securing such patents may afford a competitive advantage. For example, the companies that originated Enbrel and Humira (Amgen and AbbVie, respectively) own patents directed to formulations for these products. Rather than wait for the expiration of these formulation patents, we have developed our own proprietary formulations for these products which we believe are not covered by third party patents, including Amgen or AbbVie's formulation patents; and we have filed patent applications covering our formulations. We cannot guarantee that our proprietary formulations will avoid infringement of third party patents. Moreover, because competitors may be able to develop their own proprietary product formulations, it is uncertain whether issuance of any of our pending patent applications directed to formulations of etanercept (Enbrel) and adalimumab (Humira) would cover the formulations of any competitors. For example, we are aware that Sandoz is developing biosimilar versions of etanercept (Enbrel) and adalimumab (Humira) and has filed patent applications directed to formulations of etanercept (Enbrel) and adalimumab (Humira). We are also aware that Boehringer-Ingelheim is developing a biosimilar version of adalimumab (Humira) and has filed a patent application directed to formulations of adalimumab (Humira). We have also filed patent applications, none of which have yet issued, directed to aspects of our manufacturing processes for CHS-0214. In contrast to our patent applications directed to formulations of CHS-0214 and CHS-1420, the proprietary technologies embodied in our process-related patent filings, while directed to inventions we believe may provide us with competitive advantage, were not developed by us to avoid third party patents. As in the case of our formulation patent filings, it is highly uncertain and we cannot predict whether our patent filings on process enhancements will afford us a competitive advantage against third parties.

We do not consider it necessary for us or our competitors to obtain or maintain a proprietary patent position in order to engage in the business of biosimilar development and commercialization. Hence, while our ability to secure patent coverage on our own proprietary developments may improve our competitive position with respect to the product candidates we intend to commercialize, we do not view our own patent filings as a necessary or essential requirement for conducting our business nor do we rely on our own patent filings or the potential for any commercial advantage they may provide us as a basis for our success.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in

abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

Filing, prosecuting, defending and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners such as Baxter or Daiichi Sankyo may chose not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that 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 foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, 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 foreign jurisdictions, whether or not successful, 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. Governments of some foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. 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.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the United States Congress, the Federal Courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

If we are unable to maintain effective (non-patent) proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, for example, our employees, consultants, scientific advisors, board members, contractors, potential collaborators and investors. However we cannot be certain that such agreements have been entered into with all relevant parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or

security measures may be breached, and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

Although we expect all of our employees and consultants to assign their inventions to us, and 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 provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential 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. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the "first-to-file" laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

We may be subject to claims challenging the inventorship of our patent filings and other intellectual property.

Although we are not currently aware of any claims challenging the inventorship of our patent applications or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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 such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to certain non-exclusive intellectual property license agreements with Genentech (pertaining to the production of monoclonal antibodies) and Selexis SA (pertaining to cell lines for CHS-0214 and CHS-1420) that are important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our product candidates.

In the event we breach any of our obligations related to such agreements, we may incur significant liability to our licensing partners. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patents and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could have a material adverse effect on our business.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property, through licenses from third parties and under patent applications that we own, to develop CHS-0214 and CHS-1420. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Our ability to market our products in the United States may be significantly delayed or prevented by the BPCIA patent dispute resolution mechanism.

The Biologics Price Competition and Innovation Act of 2009, Title VII, Subtitle A of the Patent Protection and Affordable Care Act, Pub.L.No.111-148, 124 Stat.119, Sections 7001-02 signed into law March 23, 2010, and codified in 42 U.S.C. §262, or the BPCIA, created an elaborate and complex patent dispute resolution mechanism for biosimilars that could prevent us from launching our product candidates in the United States or could substantially delay such launches. The BPCIA mechanism required for 351(k) biosimilar applicants may pose greater risk that patent infringement litigation will disrupt our activities, as compared to the litigation risk to which we might be exposed under a traditional 351(a) BLA regulatory pathway.

The BPCIA mandates patent disclosure and briefing requirements that are demanding, time-sensitive and, to date, untested. The following is an overview of the patent exchange and patent briefing procedures required by the BPCIA:

1. Disclosure of the Biosimilar Application. Within 20 days after the FDA publishes a notice that its application has been accepted for review, a 351(k) biosimilar applicant must provide a copy of its application to the originator.
2. Identification of Pertinent Patents. Within 60 days of the date of receipt of the application the originator must identify patents owned or controlled by the originator which it believes could be asserted against the biosimilar applicant.
3. Statement by the Biosimilar Applicant. Following the receipt of the originator's patent list, the biosimilar applicant must state either that it will not market its product until the relevant patents have expired or alternatively provide its arguments that the patents are invalid, unenforceable or would not be infringed by the proposed biosimilar product candidate. The biosimilar applicant may also provide the originator with a list of patents it believes the brand-name firm could assert against the reference product.
4. Statement by the Originator. In the event the biosimilar applicant has asserted that the patents are invalid, unenforceable or would not be infringed by the proposed follow-on product, the originator must provide the biosimilar applicant with a response within 60 days. The response must provide the legal and factual basis of the opinion that such patent will be infringed by the commercial marketing of the proposed biosimilar.
5. Patent Resolution Negotiations. If the originator provides its detailed views that the proposed biosimilar would infringe valid and enforceable patents, then the parties are required to engage in good faith negotiations to identify which of the discussed patents will be the subject of a patent infringement action. If the parties agree on the patents to be litigated, the brand-name firm must bring an action for patent infringement within 30 days.
6. Simultaneous Exchange of Patents. If those negotiations do not result in an agreement within 15 days, then the biosimilar applicant must notify the originator of how many patents (but not the identity of those patents) that it wishes to litigate. Within five days, the parties are then required to exchange lists identifying the patents to be litigated. The number of patents identified by the originator may not exceed the number provided by the biosimilar applicant. However, if the biosimilar applicant previously indicated that no patents should be litigated, then the originator may identify one patent.
7. Commencement of Patent Litigation. The originator must then commence patent infringement litigation within 30 days. That litigation will involve all of the patents on the originator's list and all of the patents on the follow-on applicant's list.

The follow-on applicant must then notify the FDA of the litigation. The FDA must then publish a notice of the litigation in the Federal Register.

8. Notice of Commercial Marketing. The BPCIA requires the biosimilar applicant to provide notice to the originator 180 days in advance of its first commercial marketing of its proposed follow-on biologic. The originator is allowed to seek a preliminary injunction blocking such marketing based upon any patents that either party had preliminarily identified, but were not subject to the initial phase of patent litigation. The litigants are required to "reasonably cooperate to expedite such further discovery as is needed" with respect to the preliminary injunction motion.

Biosimilar companies such as ours have the option of applying for U.S. regulatory approval for our products under either a traditional 351(a) BLA approval route, or under the recently enacted streamlined 351(k) approval route established by the BPCIA. The factors underpinning such a decision are extremely complex and involve, among other things, balancing legal risk (in terms of, e.g., the degree and timing of exposure to potential patent litigation by the originator) versus regulatory risks (in terms of, e.g., the development costs and the differing scope of regulatory approval that may be afforded under 351(a) versus 351(k)).

A significant legal risk in pursuing regulatory approval under the 351(k) regulatory approval route is that the above-summarized patent exchange process established by the BPCIA could result in the initiation of patent infringement litigation prior to FDA approval of a 351(k) application, and such litigation could result in blocking the market entry of our products. In particular, while the 351(k) route may be more attractive to us (versus 351(a)) for reasons related to development time and costs and the potential broader scope of eventual regulatory approval for our proposed biosimilar candidates, the countervailing risk in such a regulatory choice is that the complex patent exchange process mandated by the BPCIA could ultimately prevent or substantially delay us from launching our products in the United States.

Moreover, the disclosure process required in Step 1 of the process outlined above, which requires the biosimilar applicant to disclose not only the regulatory application but also the applicant's manufacturing process, has the potential to afford originators an easier path than traditional infringement litigation for developing any factual grounds they may require to support allegations of infringement. The rules established in the BPCIA's patent dispute procedures (versus the rules governing traditional patent infringement litigation) place biosimilar firms at a significant disadvantage by affording originators a much easier mechanism for factual discovery, thereby increasing the risk that a biosimilar product could be blocked from the market more quickly than under traditional patent infringement litigation processes.

Preparing for and conducting the patent exchange, briefing and negotiation process outlined above will require extraordinarily sophisticated legal counseling and extensive planning, all under extremely tight deadlines. Moreover, it may be difficult for us to secure such legal support if large, well-funded originators have already entered into engagements with highly qualified law firms or if the most highly qualified law firms choose not to represent biosimilar applicants due to their long standing relationships with originators.

Furthermore, we could be at a serious disadvantage in this process as an originator company, such as Amgen (in the case of CHS-1420 or CHS-0214) or AbbVie (in the case of CHS-1420) may be able to apply substantially greater legal and financial resources to this process than we could.

We are aware that some biosimilar companies, namely Sandoz and Celltrion, Inc., or Celltrion, have engaged in legal challenges against originators to establish their right to bring declaratory judgment actions against such originators outside the complex framework of the BPCIA patent exchange rules in order to challenge the validity of the originators' patents *prior* to the filing of any biosimilar regulatory application. For example, in the Sandoz case against the originator Amgen (relating to Sandoz' proposed etanercept (Enbrel) biosimilar) the Federal District Court ruled that Sandoz did not have the right to bring a declaratory judgment action against Amgen to challenge the validity of certain Amgen-controlled patents directed to Enbrel, but instead determined that Sandoz must use the patent exchange mechanism established in the BPCIA. Sandoz appealed this decision to the United States Court of Appeals for the Federal Circuit, and on December 5, 2014 the Federal Circuit Court ruled that Sandoz had not met the legal requirements to pursue a declaratory judgment action against Amgen. The Federal Circuit Court did not address whether the patent resolution mechanism established in the BPCIA would preclude Sandoz from filing its declaratory judgment action against Amgen if and when it files an FDA application under the BCPIA for its etanercept biosimilar.

In October 2014, Amgen filed suit in federal district court against Sandoz alleging that Sandoz unlawfully refused to follow the patent resolution provisions of the BPCIA in connection with Sandoz' July 2014 regulatory approval application under 351(k) for its Neupogen (filgrastim) biosimilar, Zarxio. Amgen sought declaratory and injunctive relief. In October 2014 Amgen also filed a Citizen's Petition with the FDA asking that the FDA require biosimilar applicants to comply with the BCPIA by providing to the reference product sponsor a copy of the biosimilar application accepted for review, together with information that fully describes the manufacture of the proposed biosimilar product, within 20 days after being informed by the FDA that the biosimilar application has

been accepted for review. On March 19, 2015, the district court refused Amgen's request to enjoin Sandoz' launch of Zarxio and ruled that the patent resolution provisions of the BPCIA (summarized above in paragraphs 1 through 8) are optional insofar as it is permissible for a 351(k) applicant to decide not to provide its BLA and/or manufacturing information to the originator. The court also held that a biosimilar applicant need not wait until it receives BLA approval to provide the 180 prior day notice of commercial marketing set forth in the BPCIA provisions (see paragraph 8 above), but instead may provide such notice to the originator, if at all, prior to receiving FDA approval. The FDA has denied Amgen's Citizen's Petition.

While the ability to file declaratory judgment actions outside the framework of the BPCIA, or to treat the patent resolution mechanism of this framework as optional, may be attractive to us for addressing and resolving patent infringement risks prior to the expenditure of substantial development and regulatory costs, we see substantial risk that the Federal Appeals Court could reverse the District Court's decision in the Amgen v. Sandoz case and instead decide that the patent resolution framework of the BPCIA is mandatory, and that Sandoz violated this framework by refusing to follow it. These pending court cases may ultimately require biosimilar applicants to test (or defend against) originator patents ***only*** in the BPCIA process, ***after*** they have filed for regulatory approval under 351(k). We believe this required order of events may expose biosimilar applicants to more patent litigation risk than they might otherwise be exposed to in litigation conducted outside the BPCIA framework, such as (i) under a regulatory application that we might choose to pursue under 351(a), where an originator would not be able to use the BPCIA procedures to potentially block the launch of a biosimilar product candidate; or (ii) under a 351(k) application in which federal court rulings may conclude it is permissible for biosimilar applicants to "opt out" of the BCPIA patent resolution mechanism, as has Sandoz in its 351(k) application for Zarxio.

Whether courts will ultimately view the BPCIA process as the *sole* and mandatory framework for a biosimilar entity and the originator to identify and potentially initiate patent litigation prior to launch of a biosimilar product remains highly uncertain. We see substantial risk that a final outcome to that effect in the Sandoz and Celltrion cases could increase patent infringement risks for companies, including ours, seeking to introduce biosimilar versions of originator products.

If we file a 351(k) regulatory approval application for one or more of our products, we may consider it necessary or advisable to adopt the strategy of selecting one or more patents of the originator to litigate in the above described BPCIA process (for example in steps 3 and 7, of the process, as outlined above), either to assert our non-infringement of such patents or to challenge their validity; but we may ultimately not be successful in that strategy and could be prevented from marketing the product in the United States.

Under the complex, and uncertain rules of the BPCIA patent provisions, coupled with the inherent uncertainty surrounding the legal interpretation of any originator patents that might be asserted against us in this new process, we see substantial risk that the BPCIA process may significantly delay or defeat our ability to market our products in the United States.

Risks Related to Our Business Operations

We may not be successful in our efforts to identify, develop or commercialize additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our existing product candidates, the success of our business also depends upon our ability to identify, develop and commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our development efforts may fail to yield additional product candidates suitable for clinical development and commercialization for a number of reasons, including but not limited to the following:

- we may not be successful in identifying potential product candidates that pass our strict screening criteria;
- we may not be able to overcome technological hurdles to development or a product candidate may not be capable of producing commercial quantities at an acceptable cost or at all;
- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in nonclinical or clinical testing;
- our potential product candidates may fail to show sufficient biosimilarity to originator molecules; and
- competitors may develop alternatives that render our product candidates obsolete or less attractive or the market for a product candidate may change such that a product candidate may not justify further development.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs or we may not be able to identify, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission, or SEC, and The NASDAQ Global Market, or NASDAQ, have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and pay parity. Recent legislation permits smaller "emerging growth companies" such as us to implement many of these requirements over a longer period and up to five years from the pricing of our IPO on November 6, 2014. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we will be required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report, commencing in our annual report on Form 10-K for the year ending December 31, 2015, on the effectiveness of our internal controls over financial reporting, if then required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group and rely on independent contractors for control monitoring and for the preparation and review of our consolidated financial statements. We are actively seeking additional accounting and financial staff with appropriate public company experience and technical accounting knowledge to augment our current staff. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we identify or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act and rules adopted by the SEC and by NASDAQ, would likely result in increased costs to us as we respond to their requirements.

We have experienced a material weakness in our internal controls over financial reporting.

In connection with the audit of our financial statements from inception through December 31, 2013, we identified a material weakness in our internal control over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness related to a deficiency in the design and operating effectiveness of our internal control related to the valuation of complex securities.

We implemented changes to our disclosure controls and procedures and internal control over financial reporting to remediate the material weakness identified above. We strengthened the operation of our internal controls over the accounting for non-routine, complex equity transactions, including increasing the depth and experience within our accounting and finance organization, as well as designing and implementing improved processes and internal controls to identify such matters. We have hired additional personnel to build our financial management and reporting infrastructure, including the hiring of our Chief Financial Officer and Vice President of Finance, in the third and fourth quarter of 2014, respectively.

Although we have taken steps that we believe have addressed the underlying causes of the material weakness described above and there were no material weaknesses identified in connection with the audit of our financial statements for the three months ended March 31, 2015, other material weaknesses or deficiencies in our control environment may be identified in the future and we may be unable to accurately report our financial results, or report them within the time frames required by law or exchange regulations.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or together, the PPACA, was passed, which substantially changes the way health care is financed by both governmental and private insurers and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, adds a provision to increase the Medicaid rebate for line extensions or reformulated drugs, establishes annual fees and taxes on manufacturers of certain branded prescription drugs and promotes a new Medicare Part D coverage gap discount program.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to certain providers, including physicians, hospitals and cancer treatment centers. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

We may be subject, directly or indirectly, to federal and state healthcare laws, including fraud and abuse, false claims, physician payment transparency and health information privacy and security laws. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly or indirectly through our customers subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or in return for the purchase, recommendation, order or furnishing of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent and which may apply to entities that provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal physician "sunshine" requirements under the PPACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians and teaching hospitals and ownership

and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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 health care reform legislation has strengthened these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The international aspects of our business expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

We currently have limited international operations of our own and have a number of international collaborations. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaboration partners to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations by us or our collaboration partners;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems by our collaboration partners;
- limits in our or our collaboration partners' ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act its books and records provisions or its anti-bribery provisions.

Sanctions against Russia, and Russia's response to those sanctions, could materially adversely affect our business, financial condition and results of operations.

Due to Russia's recent military intervention in Ukraine, the United States and the E.U. have imposed sanctions on certain individuals and one financial institution in Russia and have proposed the use of broader economic sanctions. In response, Russia has imposed entry bans on certain U.S. lawmakers and officials. Our wholly owned subsidiary, InteKrin Therapeutics, Inc., or InteKrin, which we acquired in February 2014 is majority owner of a Russian pharmaceutical development entity, ZAO InteKrin, which holds $1.2 million of cash in Russian banks as of March 31, 2015. This Russian subsidiary of InteKrin conducts research and development activities for a product we acquired as part of our acquisition of InteKrin. The product is a small molecule peroxisome proliferator-activated receptor, or PPAR, gamma inhibitor that may hold promise in treatment of multiple sclerosis, or MS. While not a biosimilar, this PPAR gamma inhibitor compound may be complementary to biosimilar products for treatment of MS the Company is currently evaluating for inclusion in its pipeline. If the United States and the E.U. were to impose sanctions on Russian businesses, or if Russia were to take retaliatory action against U.S. companies operating in Russia, our research and development activities related to the InteKrin PPAR gamma inhibitor product could be materially adversely affected.

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 have a material adverse effect on the success of our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly cleanup and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and laboratory are located in the San Francisco Bay Area and in Southern California (Camarillo), respectively, and one of our collaboration partners, Daiichi Sankyo, is located in Japan. These locations have in the past experienced severe earthquakes and other natural disasters. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations or those of our collaboration partners and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure (such as the manufacturing facilities of our third-party contract manufacturers) or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and purchasers of our common stock could incur substantial losses.

The market price of our common stock has been highly volatile since our initial public offering and the intraday sales price per share has ranged from $12.27 to $33.30 per share during the period from November 6, 2014 through May 8, 2015 and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section of this Annual Report on Form 10-K and others such as:

- adverse results or delays in preclinical or clinical studies;
- any inability to obtain additional funding;
- any delay in filing an IND, NDA, BLA or other regulatory submission for any of our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory agency's review of that IND, NDA, BLA or other regulatory submission;
- the perception of limited market sizes or pricing for our product candidates;
- failure to successfully develop and commercialize our product candidates;
- post-marketing safety issues relating to our product candidates or biosimilars generally;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to our products;
- any inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- lawsuits, including stockholder litigation and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;
- the outcomes of any citizens petitions filed by parties seeking to restrict or limit the approval of biosimilar products;
- if securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- issuance of patents to third parties that could prevent our ability to commercialize our product candidates;
- reductions in the prices of originator products that could reduce the overall market opportunity for our product candidates intended as biosimilars to such originator products;

- the loss of one or more employees constituting our leadership team; and
- changes in biosimilar regulatory requirements that could make it more difficult for us to develop our product candidates.

In addition, biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of March 31, 2015, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 59% of our voting stock (assuming no exercise of outstanding options). These stockholders have the ability to influence us through their ownership positions, which may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

We are an "emerging growth company" and, due to the reduced reporting requirements applicable to emerging growth companies, certain investors may find investing in our common stock less attractive.

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, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10-K and our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have total annual gross revenue of $1.0 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, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. We cannot predict if investors will find our common stock less attractive because we may rely on this exemption. 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.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell or indicate an intention to sell substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale lapse, the market price of our common stock could decline. As of March 31, 2015, there were 33,701,017 shares of common stock outstanding. The lock-up agreements pertaining to the Follow-On Offering which closed on April 7, 2015, will expire (i) on June 29, 2015 for our executive officers and directors, following which 2,139,999 shares of common stock will be eligible for sale in the public market, and (ii) on May 30, 2015 for certain stockholders affiliated with our directors, following which 8,876,799 shares of common stock will be eligible for sale in the public market. All 11,016,798 shares subject to lock-up agreements pertaining to the Follow-On Offering are held or beneficially owned by current directors and executive officers or their affiliates and may be subject to Rule 144 limitations under the Securities Act of 1933, as amended (the "Securities Act").

In addition, as of March 31, 2015, approximately 8.3 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans became eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold or if it is perceived that they will be sold in the public market, the market price of our common stock could decline.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales.

These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2014 Equity Incentive Award Plan, or the 2014 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Under the 2014 Plan, the number of shares of our common stock initially reserved for issuance is 2,300,000 plus the number of shares remaining available for future awards under the 2010 Plan. The number of shares available for future grant under the 2014 Plan will be increased by (i) the number of shares pursuant to outstanding awards under the 2010 Plan that are forfeited or lapse unexercised and which following the effective date are not issued under the 2010 Plan and (ii) an annual increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 4% of the shares of stock outstanding as of the last day of the preceding fiscal year, or such smaller number of shares as determined by our board of directors. Pursuant to our 2014 Employee Stock Purchase Plan, or 2014 ESPP, eligible employees are able to acquire shares of our common stock at a discount to the prevailing market price, and an aggregate of 320,000 shares are initially available for issuance under the 2014 ESPP. The number of shares available for issuance under the 2014 ESPP will automatically increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 1% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year or such smaller number of shares as determined by our board of directors. If our board of directors elects to increase the number of shares available for future grant under the 2014 Plan or the 2014 ESPP, our stockholders may experience additional dilution, which could cause our stock price to fall.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and bylaws include provisions that:

- 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 corporate secretary pursuant to a resolution adopted by a majority of our board 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 other than nominations made by or at the direction of the board of directors or a committee of the board of directors;
- provide that our directors may be removed only for cause or without cause by the holders of 66 2/3% of the voting power of all then outstanding shares of voting stock;
- 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;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and
- require holders of 66 2/3% of the voting power of all then outstanding shares of voting stock to amend specified provisions of our amended and restated certificate of incorporation except for the provision making it possible for our board of directors to issue "blank check" preferred stock, and amended and restated bylaws.

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

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our amended and restated certificate of incorporation or amended and restated bylaws 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Recent Sales of Unregistered Equity Securities

In March 2015, with the Company achieved the first dosing of a human subject in a phase 2 clinical trial for INT-131 in multiple sclerosis patients, triggering the obligation to settle the contingent earn-out payment to InteKrin stockholders, and as a result, the Company issued 358,384 shares of its common stock to former InteKrin stock holders on March 6, 2015. The issuance of such shares of common stock was exempt from the registration requirements of the Securities Act pursuant to Section 3(a)(9) and Section 4(a)(2) of the Securities Act.

(b) Not applicable.

(c) Not applicable.

ITEM 3. Defaults Upon Senior Securities

Not applicable

ITEM 4. Mine Safety Disclosures

Not applicable

ITEM 5. Other Information

Not applicable

ITEM 6. Exhibits

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits files as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by reference.

SIGNATURES

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

COHERUS BIOSCIENCES, INC.

Date: May 11, 2015

/s/ Dennis M. Lanfear

Dennis M. Lanfear
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 11, 2015

/s/ Jean-Frédéric Viret

Jean-Frédéric Viret, Ph.D.
Chief Financial Officer
(Principal Financial and Accounting Officer)

INDEX TO EXHIBITS

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
3.1	Amended and Restated Certificate of Incorporation.	8-K	11/12/2014	3.1	
3.2	Amended and Restated Bylaws.	8-K	11/12/2014	3.2	
10.1†	Amended and Restated License Agreement, effective April 10, 2015, by and among Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare SA and Coherus BioSciences, Inc.				X
10.2(a)†	Master Services Agreement, effective February 27, 2015, by and between a contract research organization and Coherus BioSciences, Inc.				X
10.2(b)†	Work Order #1, effective March 31, 2015, by and between a contract research organization and Coherus BioSciences, Inc.				X
31.1	Certification of Principal Executive Officer Required under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).				X
31.2	Certification of Principal Financial Officer under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).				X
32.1	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350 and Securities Exchange Act Rule 13a-14(b).				X
101	The following materials from Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, formatted in eXtensible Business Reporting Language (XBRL) includes: (i) Condensed Balance Sheets at March 31, 2015 (unaudited) and December 31, 2014, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2015 and 2014, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three months ended March 31, 2015 and 2014, (iv) Condensed Statements of Cash Flows (unaudited) for the three months ended march 31, 2015 and 2014, and (v) Notes to the Condensed Financial Statements.				X

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

Exhibit 10.1

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

AMENDED AND RESTATED LICENSE AGREEMENT

by and among

COHERUS BIOSCIENCES, INC.,

BAXTER INTERNATIONAL INC.,

BAXTER HEALTHCARE CORPORATION,

AND

BAXTER HEALTHCARE SA

dated

April 10, 2015

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AMENDED AND RESTATED LICENSE AGREEMENT

THIS AMENDED AND RESTATED LICENSE AGREEMENT (the **"Agreement"**) is made and entered into as of April 10, 2015 (the **"Effective Date"**) among **COHERUS BIOSCIENCES, INC.**, a Delaware corporation with a principal place of business at 201 Redwood Shores Parkway, Suite 200, Redwood City, California 94065, United States of America (**"Coherus"**), on the one hand, and **BAXTER INTERNATIONAL, INC.**, a Delaware corporation with a principal place of business at 1 Baxter Parkway, Deerfield, IL 60015, United States of America (**"BII"**), **BAXTER HEALTHCARE SA**, a Swiss corporation with a principal place of business at Postfach 8010 Zurich, Switzerland ("**BHSA**") and **BAXTER HEALTHCARE CORPORATION**, a Delaware corporation with a principal place of business at 1 Baxter Parkway, Deerfield, IL 60015, United States of America ("**BHC**" and, together with BII and BHSA, **"Licensee"**), on the other hand. Coherus and Licensee are sometimes referred to herein individually as a **"Party"** and collectively as the **"Parties"**.

RECITALS

WHEREAS, Coherus is a global biotechnology company that conducts research, development, manufacturing and commercialization and is developing various biosimilar products for the potential treatment of rheumatoid arthritis, psoriasis and other diseases and conditions;

WHEREAS, Licensee has existing development and commercialization capabilities in the Territory (as defined below); and

WHEREAS, Coherus and Licensee wish to collaborate for the development and commercialization of the Product (as defined below) in the Territory in accordance with the terms and conditions hereof.

AGREEMENT

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

1. DEFINITIONS. As used herein, the following terms shall have the following meanings:

1.1 "Accounting Standards" shall mean GAAP or IFRS, as applicable, consistently applied.

1.2 **"Affiliate"** means a corporation, partnership, trust or other entity that directly, or indirectly through one or more intermediates, controls, is controlled by or is under common control with a specified Party but only for so long as such relationship exists. For such purposes, "control," "controlled by" and "under common control with" shall mean the possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting equity, voting member or partnership interests, control of a majority of the board of directors or other similar body, by contract or otherwise. In the case of a corporation, the direct or indirect ownership of fifty percent (50%) or more of its outstanding voting shares or the ability otherwise to elect a majority of the board of directors or other managing authority of the entity shall in any event be presumptively deemed to confer control, it being understood that the direct or indirect ownership of a lesser percentage of such shares shall not necessarily preclude the existence of control. Notwithstanding the preceding provisions, once an entity ceases to be an Affiliate of Licensee, then such entity shall, without any further action, cease to have any rights, including license and sublicense rights, under this Agreement that it has by reason of being an Affiliate and any and all Coherus Know-How or Confidential Information of Coherus transferred to such entity while it was an Affiliate under this Agreement shall be returned to Licensee within thirty (30) days of the time such entity ceases to be an Affiliate.

1.3 **"Applicable Laws"** means all applicable laws, rules, and regulations, including any rules (including stock exchange rules), regulations, guidelines or other requirements of the Regulatory Authorities or other governmental authorities, that may be in effect from time to time in any relevant legal jurisdiction.

1.4 **"[***] Opt-In"** has the meaning set forth in Exhibit 1.4.

1.5 **"Business Day"** means a day other than Saturday, Sunday or any day on which commercial banks located in the State of New York, U.S.A. are authorized or obligated by Applicable Laws to close.

1.6 **"Calendar Quarter"** means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31; *provided, however*, that: (a) the first Calendar Quarter of the Term will extend from the Effective Date to the end of the first complete Calendar Quarter thereafter and (b) the last Calendar Quarter of the Term will end upon the expiration or termination of this Agreement.

1.7 **"Calendar Year"** means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.8 **"CDA"** has the meaning set forth in **Section 11.1 (Confidentiality; Exceptions)**.

1.9 **"Chairperson"** has the meaning set forth in **Section 3.1(b) (Membership; Meetings)**.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.10 **"Clinical Trials"** means human clinical trials conducted up through receipt of Regulatory Approval, including Phase 1 Clinical Trials, Phase 3 Clinical Trials, bioequivalence trials, and/or variations of such trials (for example, phase 2/3 studies). For clarity, the term 'Clinical Trials' shall not include Phase 4 Clinical Trials.

1.11 **"Coherus Biosimilar Candidate(s)"** means: (a) [***] ([***] biosimilar), (b) [***] ([***] biosimilar), and (c) CHS-1701 (pegfilgrastim biosimilar); *provided, however,* a Rejected Biosimilar Candidate shall no longer be considered a Coherus Biosimilar Candidate for any purposes under this Agreement.

1.12 **"Coherus Indemnitees"** has the meaning set forth in **Section 10.1 (Coherus' Right to Indemnification)**.

1.13 **"Coherus Inventions"** means all Inventions made, conceived, reduced to practice, authored or otherwise discovered solely by employees, independent contractors, or agents of Coherus, it Affiliates or sublicensees.

1.14 **"Coherus Know-How"** means all Information that is: (a) Controlled by Coherus as of the Effective Date or during the Term that is not publicly known, even though parts thereof may be known, and (b) useful or necessary to Develop, Manufacture and/or Commercialize the Product in the Field in the Territory. "Coherus Know-How" does not include Coherus Patent Rights.

1.15 **"Coherus-Owned Joint Inventions"** has the meaning set forth in **Section 8.3(a)(i)**.

1.16 **"Coherus-Owned Licensee Inventions"** has the meaning set forth in **Section 8.3(a)(i)**.

1.17 **"Coherus Patent Rights"** means any Patent and/or Patent Application that: (a) is Controlled by Coherus as of the Effective Date or during the Term (including Patents and Patent Applications covering Coherus Inventions, Coherus-Owned Licensee Inventions and Coherus- Owned Joint Inventions) and (b) claims a product, method, apparatus, material, manufacturing process, or other technology necessary or useful for Development, Process Development, Manufacture and/or Commercialization of the Product in the Field in the Territory. "Coherus Patent Rights" includes, but is not limited to, any of Coherus' interest in any Patents and Patent Applications covering Inventions. "Coherus Patent Rights" as of the Effective Date are set forth in **Exhibit 1.17 (Coherus Patent Rights)** which shall be updated from time to time.

1.18 **"Coherus Trademarks**" means the trademarks set forth in **Exhibit 1.18 (Coherus Trademarks)**, which may be updated by Coherus from time to time during the Term by providing notice to Licensee.

1.19 **"Commercial Readiness Costs"** means costs incurred for activities which are requested by Baxter to implement the Commercialization Plan that [***]. Such costs include, but are not be limited to, [***]. For clarity, the term Commercial Readiness Costs does not include [***].

1.20 **"Commercially Reasonable Efforts"** means the carrying out of obligations or tasks consistent with the reasonable practices of a company within the biopharmaceutical industry for the development, manufacture or marketing of a biopharmaceutical product having similar market potential or profit potential in the Territory as the Product, based on conditions then prevailing and taking into consideration issues of safety, efficacy, product profile, the competitiveness of the marketplace in the Territory, the regulatory structure involved and other relevant commercial factors. Commercially Reasonable Efforts requires that the Party, at a minimum: (a) determine the general industry practices in the Territory with respect to the applicable activities; (b) reasonably promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on- going basis; (c) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations; and (d) make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

1.21 **"Commercialization"** or **"Commercialize"** means any and all activities directed to the marketing, advertising, promotion, offering for sale, selling, distribution, importing and exporting (but not exporting to territories outside of the Territory) the Product for sale in the Territory, including costs associated with key opinion leaders engaged by or on behalf of Licensee.

1.22 **"Commercialization Plan"** means the plan for Commercialization of the Product in the Field in the Territory and the activities to be conducted by Licensee relating thereto (including the budget associated with such Commercialization activities), which includes the activities to be conducted prior to First Commercial Sale, planning for launch of the Product, and activities to be conducted after launch of the Product, as well as detailed near-term plans, for example detailed plans for sales and marketing after launch of the Product.

1.23 **"Competitor"** means a Third Party that develops, manufactures, markets, distributes, or promotes, for itself or for others: (a) [***]; or (b) [***].

1.24 **"Confidential Information"** has the meaning set forth in **Section 11.1 (Confidentiality; Exceptions)**.

1.25 **"Control"** means, with respect to any item of Information, Patent, Patent Application, or other intellectual property right, the right to grant a license or sublicense with respect thereto as provided for in this Agreement without violating the terms of any agreement or other arrangement with, or any legal rights of, any Third Party.

1.26 **"CRO"** means a Third Party contract research organization, as that term is defined in 21 C.F.R. Part 312.3(b).

1.27 **"CSR"** or **"Clinical Study Report"** means the final clinical study report generated in connection with a Clinical Trial containing all Information generated by the Clinical Trial, cleaned and statistically analyzed.

1.28 **"Damages"** has the meaning set forth in **Section 10.1 (Coherus' Right to Indemnification)**.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.29 **"Develop"** or **"Development"** means all pre-clinical, clinical, and regulatory activities relating to obtaining a Regulatory Approval in the Territory. Development includes, for example,[***] [***]. For the avoidance of doubt, the term 'Development' specifically excludes [***] and [***].

1.30 **"Development Budget"** means the budget associated with Development activities with respect to the Product, on a Calendar Quarter basis, and includes the Global Studies Budget. The Development Budget approved as of the Effective Date is set forth in Exhibit 1.30 which is incorporated herein

1.31 **"Development Costs"** means: (a) the costs invoiced by Third Parties to Coherus after the Effective Date in connection with enabling and supporting Development efforts for the Product in the Territory [***] as set forth in the Development Plan or otherwise approved by the JSC, and (b) any other costs and expenses [***] to Coherus after the Effective Date to enable or support the Development of the Product, as reasonably determined and required by the JDC and approved by the JSC. For the avoidance of doubt, the term 'Development Costs' shall exclude [***].

1.32 **"Development Plan"** means the plan for conduct of Development activities with respect to the Product, including planning timelines, and the activities to be carried out by each Party relating thereto, and including a Development Budget as amended from time to time by the Parties and approved by the JSC pursuant to **Article 3** for the [***] identified in Exhibit 1.32 which is attached hereto and incorporated herein. The Development Plan shall include a multi-year plan for conducting anticipated Development activities, including the following anticipated activities or events: (a) [***], (b) [***], (c) [***], and (d) [***], if applicable.

1.33 **"Disputes"** has the meaning set forth in **Section 14.1** (**Exclusive Dispute Resolution Mechanism)**.

1.34 **"Dollar"** means a U.S. dollar, and **"$"** shall be interpreted accordingly.

1.35 **"Enforcement Action"** has the meaning set forth in **Section 8.7(b) (Enforcement Actions Against Third Parties)**.

1.36 **"Executive Officers"** means the [***] of Coherus and the [***] of Licensee.

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

1.38 **"Field"** means the treatment of human diseases and conditions.

1.39 **"First Commercial Sale"** means the first sale of the Product by Licensee, its Affiliates or Sublicensees to a Third Party end user (other than a Sublicensee) in a bona fide arm's length transaction for which payment has been received in any country in the Territory after all applicable Regulatory Approvals and Pricing and Reimbursement Approvals (if applicable) have been obtained for such country have been granted by the applicable Regulatory Authority in such country.

1.40 **"GAAP"** means accounting principles generally accepted in the United States, consistently applied and employed by Licensee or its Affiliates or Sublicensees in the applicable country in the Territory.

1.41 **"Global Brand Trademark"** has the meaning set forth in **Section 6.3(b) (Global Brand Trademark)**.

1.42 **"Global Clinical Database"** has the meaning set forth in **Section 4.7 (Coherus Global Clinical Database)**.

1.43 **"Global Psoriasis Study"** means the Phase 3 Clinical Trial of the Product in psoriasis conducted by or on behalf of Coherus directed toward obtaining Regulatory Approval for the Product with respect to psoriasis inside and outside the Territory.

1.44 **"Global RA Study"** means the Phase 3 Clinical Trial of the Product in rheumatoid arthritis conducted by or on behalf of Coherus directed toward obtaining Regulatory Approval for the Product with respect to rheumatoid arthritis inside and outside the Territory.

1.45 **"Global Study Budget"** means the overall budget for the Global Studies, included in the Development Budget.

1.46 **"Global Study(ies)"** means the studies set forth on Exhibit 1.32 including but not limited to the Global Psoriasis Study and the Global RA Study.

1.47 **"Grant-Back IP"** means any [***], or other [***] and [***] covering [***]. For the avoidance of doubt, Grant-Back IP shall [***].

1.48 **"IFRS"** shall mean International Financial Reporting Standards, consistently applied and employed by Licensee or its Affiliates or Sublicensees in the applicable country in the Territory.

1.49 **"Illustrative Development Plan/Budget"** means the documents attached to this Agreement as **Exhibit 1.49** setting forth certain Development activities and the budget related thereto which were included for illustrative purposes for the JDC and JSC to review at their initial meetings in connection with its preparation of the actual Development Plan and related budget. As of the Effective Date the approved revised Development Plan is set forth in Exhibit 1.32 and the approved revised Development Budget is set forth in Exhibit 1.30.

1.50 **"Indemnification Claim"** has the meaning set forth in **Section 10.3 (Process for Indemnification)**.

1.51 **"Indemnitee"** has the meaning set forth in **Section 10.3 (Process for Indemnification)**.

1.52 **"Indemnitor"** has the meaning set forth in **Section 10.3 (Process for Indemnification)**.

1.53 **"Initial Development Activities"** means the key development activities and related expenditures anticipated in the thirty (30) days following the Effective Date as set forth in **Exhibit 1.53 (Initial Development Activities)**, attached hereto.

1.54 **"Information"** means ideas, Inventions, discoveries, concepts, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, designs, drawings, computer programs, skill, experience, documents, results, clinical and regulatory strategies, test data, including pharmacological, toxicological and clinical and non- clinical data, analytical and quality control data, manufacturing data and descriptions, Patent and legal data, market data, financial data or descriptions, assay protocols, chemical formulas, sequence listings, specifications, and the like, in written, electronic or other form, now known or hereafter developed, whether or not patentable, relating to the Product.

1.55 **"Initial Review Period"** means a period of ninety (90) days following the Effective Date.

1.56 **"Initiation"** means:

(a) with respect to the Global Psoriasis Study, the first dosing of a patient in such Global Psoriasis Study;

(b) with respect to the Global RA Study, the first dosing of a patient in such Global RA Study; and

(c) with respect to a Phase 3 Clinical Trial for the Product other than in the Global Psoriasis Study or the Global RA Study, the first dosing of a patient in such Phase 3 Clinical Trial.

1.57 **"Inventions"** means any and all inventions [***] by or on behalf of either Party, its Affiliates or Sublicensees in the course of activities performed under or contemplated by this Agreement.

1.58 **"Joint Commercialization Committee"** or **"JCC"** has the meaning set forth in **Section 3.4 (Joint Commercialization Committee).**

1.59 **"Joint Development Committee"** or **"JDC"** has the meaning set forth in **Section 3.1(f) (Joint Development Committee)**.

1.60 **"Joint Inventions"** means all Inventions [***] by employees, independent contractors, or agents of both Licensee and Coherus (including their respective Affiliates or sublicensees).

1.61 **"Joint Patent Rights"** has the meaning set forth in **Section 8.5 (Joint Patent Filings)**.

1.62 **"Joint Process Development and Manufacturing Committee"** or **"JPDMC"** has the meaning set forth in **Section 3.3 (Joint Process Development and Manufacturing Committee)**.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.63 **"Joint Steering Committee"** or **"JSC"** has the meaning set forth in **Section 3.1(a) (General)**.

1.64 **"Licensee Indemnitees"** has the meaning set forth in **Section 10.2 (Licensee's Right to Indemnification)**.

1.65 **"Licensee Inventions"** means all Inventions [***] solely by employees, independent contractors, or agents of Licensee, it Affiliates or sublicensees.

1.66 **"Licensee Know-How"** means all Information that is: (a) Controlled by Licensee or its Affiliates as of the Effective Date or during the Term that is not publicly known, even though parts thereof may be known, and (b) necessary to develop, make, have made, use, sell, offer to sell, have sold, import or export the Product. "Licensee Know-How" does not include Licensee Patent Rights.

1.67 **"Licensee Patent Rights"** means any Patent and/or Patent Application that is: (a) Controlled by Licensee or its Affiliates as of the Effective Date or during the Term (including Patents and Patent Applications covering Licensee Inventions that are owned by Licensee pursuant to **Section 8.3(a)(ii)**) and (b) claims a product, method, apparatus, material, manufacturing process, or other technology necessary to develop, make, have made, use, sell, offer to sell, have sold, import or export the Product. "Licensee Patent Rights" includes, but is not limited to, any of Licensee's interest in any Patents and Patent Applications covering Inventions.

1.68 **"Licensee Trademarks"** means any trademark, other than a Product Trademark, that is: (a) Controlled by Licensee or its Affiliates and (b) used in the Commercialization.

1.69 **"Major EU Country(ies)"** means the [***].

1.70 **"Manufacture"** or **"Manufacturing"** means all manufacturing activities, undertaken with respect to the Product in support of clinical and commercial supply of the Product, as applicable, including manufacture of formulated bulk, fill and finish operations, sterilization, lyophilization, packaging, labeling, storing, transporting (with respect to the Product used in the Global Trials) quality control, quality assurance, and release but specifically excluding Process Development activities.

1.71 **"Manufacturing and Supply Agreement"** has the meaning set forth in **Section 5.1 (Manufacturing and Supply Agreement).**

1.72 **"Manufacturing Cost"** means the costs of Manufacturing bulk drug substance or Units (including Product contained in such Unit). Manufacturing Costs shall include the cost of [***] ([***]) ([***]), costs associated with [***], [***]. For the avoidance of doubt, the term 'Manufacturing Cost' shall [***].

1.73 **"Manufacturing Regulatory Filings"** means any and all regulatory applications, filings, approvals and associated correspondence required to Manufacture the Product in the country in which it is Manufactured as well as to import the Product into each country or jurisdiction in the Territory.

1.74 **"Net Sales"** means, on a country-by-country basis, the gross revenues invoiced by Licensee, its Affiliates and Sublicensees in connection with the sale, lease or other transfer for value of Product in a bona fide arm's-length transaction with unaffiliated Third Parties; less the following items to the extent actually incurred or accrued in accordance with the Accounting Standards and to the extent not already deducted in the amount invoiced: (a) trade and quantity and/or cash discounts actually allowed or taken; (b) governmental customs, duties, sales, withholding and similar taxes (including, for the avoidance of doubt value added or import/export taxes, sales taxes and excise taxes but excluding taxes based on income), if any, imposed on the Product, to the extent directly related to such sale; (c) amounts actually allowed or credited by reason of rejections, return of goods (including as a result of recalls), any retroactive price reductions or allowances specifically identifiable as relating to the Product (including those resulting from inventory management or similar agreements with wholesalers); (d) amounts incurred resulting from government-mandated rebate programs, including programs mandated by any agency thereof; (e) rebates actually given to a Third Party specifically for Product; (f) freight, postage, shipping and applicable insurance charges, to the extent same are separately itemized in the invoice price and charged to the buyer; (g) patient discount programs, administrative fees and chargebacks or similar price concessions related to the sale of the Product; and (h) [***].

Net Sales shall not include a sale or transfer of Product to an Affiliate or Sublicensee or if done for clinical, regulatory or governmental purposes where no consideration is received, but resale by such Affiliate or Sublicensee to a Third Party end user shall be included in Net Sales.

If any Product is sold in combination with one or more other products (*e.g.* a delivery device) or active ingredients which are not the subject of this Agreement (as used in this definition of Net Sales, a **"Combination"**), then the gross amount invoiced for that Product shall be calculated by multiplying the gross amount invoiced for such Combination by the fraction A/(A+B), where "A" is the gross amount invoiced for the Product sold separately and "B" is the gross amount invoiced for the other active ingredient(s) sold separately. In the event that the other active ingredient is not sold separately, then the gross amount invoiced for that Product shall be calculated by multiplying the gross amount invoiced for the Combination by the fraction A/C, where "A" is the gross invoice amount for the Product, if sold separately, and "C" is the gross invoice amount for the Combination. In the event that no such separate sales are made, Net Sales for royalty determination shall be determined by the Parties in good faith.

1.75 **"Non-Negative Central Scientific Advice"** means receipt of guidance from the central Regulatory Authority in the European Union as part of the central scientific advice response [***] the Development Plan as approved by the JSC.

1.76 **"Opting-In Party"** has the meaning set forth in **Section 8.4(b) (Opt-In Rights)**.

1.77 **"Opting-Out Party"** has the meaning set forth in **Section 8.4(b) (Opt-In Rights)**.

1.78 **"Patent"** means: (a) letters patent (or other equivalent legal instrument), including utility and design patents, and including any extension, substitution, registration, confirmation,

reissue, re-examination or renewal thereof, and (b) all foreign or international equivalents of any of the foregoing in any country.

1.79 "Patent Application" means: (a) an application for letters patent, including a provisional patent application, a reissue application, a re-examination application, a continuation application, a continued prosecution application, a continuation-in-part application, a divisional application or any equivalent thereof that is pending at any time during the Term before a government patent agency and (b) all foreign or international equivalents of any of the foregoing in any country.

1.80 "Phase 1 Clinical Trial" means a human clinical trial of the Product, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, as described in 21 C.F.R. 312.21(a), or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.

1.81 "Phase 1 Results" means: (a) [***]; (b) [***] and [***] [***]; (c) [***]; and (d) [***].

1.82 "Phase 3 Clinical Trial" means a confirmatory safety and efficacy human clinical trial of the Product performed after evidence suggesting effectiveness of the compound has been obtained pursuant to [***]: (a) that portion of an FDA submission and approval process which provides for the continued trials of a product on sufficient numbers of human patients to confirm with statistical significance the safety and efficacy of a product sufficient to support a Regulatory Approval for the proposed indication, as more fully described in 21 C.F.R. 312.21(c), or (b) equivalent Regulatory Filings with similar requirements in a country other than the United States, or a similar human clinical study prescribed by the Regulatory Authorities in a foreign country. For clarity, **'Phase 3 Clinical Trial'** includes [***].

1.83 "Phase 4 Clinical Trial" means a human clinical trial of the Product in the Territory commenced following receipt of Regulatory Approval in the Territory not for the purpose of satisfying a condition imposed by a Regulatory Authority to obtain Regulatory Approval or receipt of Pricing and Reimbursement Approvals in the Territory, but only to support the marketing of the Product.

1.84 "Post-Regulatory Approval Activities" means the following activities conducted following receipt of Regulatory Approval: (a) any clinical trials required to receive or maintain Regulatory Approvals or receipt of Pricing and Reimbursement Approvals in the Territory; (b) open label extension studies; (c) any Phase 4 Clinical Trial; (d) studies required to support pharmacovigilance activities in the Territory; and (e) the equivalent in any country within the Territory of U.S. post-approval commitment studies and risk evaluation and mitigation strategies ("REMS") programs.

1.85 "Pricing and Reimbursement Approval" means any approval received from a Regulatory Authority in a country or region relating to (a) the price that may be charged to a third party for the sale of a medical product or (b) the amount to be reimbursed (directly or indirectly) to the seller of such a medical product pursuant to the Applicable Laws in such country or region.

1.86 **"Process Development"** means all process development activities undertaken with respect to the Product, including activities related to [***]. **"Process Development Costs"** means all costs invoiced by Third Parties to Coherus and/or its Affiliates for Process Development activities after the Effective Date directly resulting from any Process Development efforts as set forth in the Process Development Plan or otherwise approved by the JSC. Process Development Costs shall include [***], such as [***]. For the avoidance of doubt, the term 'Process Development Costs' shall include [***].

1.87 **"Process Development Plan"** means the plan for conduct of Process Development activities with respect to the Product, and the activities to be carried out by each Party relating thereto, including the budget therefor.

1.88 **"Product"** means Coherus' product known as CHS-0214 that is intended to be a "biosimilar medicine" product of Enbrel (etanercept) pursuant to the EMEA guidance document 837805 dated 27th of September 2012.

1.89 **"Product Trademark"** has the meaning set forth in **Section 6.3(a) (Product Trademark; Licensee Trademark)**.

1.90 **"Regulatory Approval"** means approval by the Regulatory Authority having jurisdiction in the applicable country of a Regulatory Approval Application and satisfaction of all related applicable regulatory and notification requirements and such other approvals that are necessary to Commercialize the Product in such country. [***].

1.91 **"Regulatory Approval Application"** means: (a) the application or set of applications in the applicable country that is comparable to a Biologic License Application, as defined by the FDA in 21 CFR Part 601, or other applicable filing for a biological product to commercialize such product in the applicable country and (b) any related registrations with or notifications to such Regulatory Authority, and any amendments or supplements to either of the foregoing and any substitutes therefor.

1.92 **"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 the Product in the Territory, including the equivalent in the Territory to the FDA.

1.93 **"Regulatory Filings"** means any and all Regulatory Approval Applications and other regulatory applications, filings and associated correspondence required to obtain Regulatory Approval or receipt of Pricing and Reimbursement Approvals to Develop, Commercialize, import the Product in, or into, or export the Product from the applicable country or jurisdiction.

1.94 **"Reimbursable Costs**" means (subject to **Section 4.1 (Development Activities; Process Development Activities and Funding**)): (a) [***], (b) [***], (c) the [***], or (d) [***]; but, in each case, excluding, for the avoidance of doubt, any costs and expenses solely related to [***].

1.95 **"Renewal Period"** has the meaning set forth in **Section 12.2 (Extension of Term).**

1.96 **"Responsible Party"** has the meaning set forth in **Section 8.5 (Joint Patent Filings)**.

1.97 **"ROFR Agreement"** means a definitive agreement entered into by Coherus and Licensee related to either a Coherus Biosimilar Candidate or Product X pursuant to **Section 2.4 (Licensee Rights of First Refusal)**.

1.98 **"Rules"** has the meaning set forth in **Section 14.3(b) (Arbitration)**.

1.99 **"Second Review Period"** has the meaning set forth in **Section 2.4(e) (Product Opt-Out)**.

1.100 **"Sublicensee"** means any person or entity to which Licensee grants a sublicense to the extent permitted under **Section 2.2 (Sublicense Rights)** (other than Coherus or Affiliates of Coherus).

1.101 **"Term"** has the meaning set forth in **Section 12.1 (Term)**.

1.102 **"Territory"** means worldwide, excluding the following countries: Japan, the United States (including its territories and protectorates), [***].

1.103 **"Third Party"** means any person or entity other than Licensee, Coherus, or an Affiliate of either of them.

1.104 **"Third Party Payments"** has the meaning set forth in Exhibit 7.1(D) (Royalties on Net Sales; Third Party Payments).

1.105 **"Trademark"** means any word, name, symbol, color, designation or device or any combination thereof, whether registered or unregistered, including any trademark, trade dress, service mark, service name, brand mark, trade name, brand name, logo or business symbol.

1.106 **"Unit"** means one (1) filled, finished, labeled, and released dosage form comprised of one of the following: (a) [***] Product, or (b) [***] Product, or (c) [***] Product, or (d) another mutually agreed upon [***].

1.107 **"Vendors"** means [***].

2. LICENSES; LICENSEE RIGHT OF FIRST REFUSAL.

2.1 License Grants.

(a) **Development and Commercialization License to Licensee.** Subject to the terms and conditions of this Agreement including **Sections 2.1(b) (Licenses to Coherus)** and **Section 2.3 (No Implied Rights or Licenses; Retained Rights**), Coherus hereby grants to Licensee and its Affiliates an exclusive, royalty-bearing license, under the Coherus Know-How and Coherus Patent Rights, to Develop, Commercialize and use the Product in the Field in the Territory. The foregoing license does not include the right to Manufacture, or have Manufactured, the Product, or to conduct, or have conducted, any Process Development activities.

(b) Licenses to Coherus. Subject to the terms and conditions of this Agreement, Licensee hereby grants to Coherus and its Affiliates: (i) a fully-paid, non-exclusive license, under the Licensee Know-How and Licensee Patent Rights, to perform Coherus' obligations under this Agreement; (ii) a fully-paid, non-exclusive, perpetual, irrevocable license (with full rights to grant sublicenses through multiple tiers), under any Grant-Back IP, to develop, make, have made, use, sell, offer to sell, have sold and import the Product outside of the Territory; and (iii) a fully-paid, non-exclusive, perpetual, irrevocable license (with full rights to grant sublicenses through multiple tiers) under any Licensee Inventions owned by Licensee pursuant to **Section 8.3(a)(ii) (Generally)** solely to the extent necessary to make, have made, use, sell, offer to sell, have sold and import the Product (whether inside and outside the Territory).

2.2 Sublicense Rights. Licensee shall not have the right to grant sublicenses under the licenses granted to it under **Section 2.1(a) (Development and Commercialization License to Licensee)** and **Section 6.3(d) (Use of Coherus Trademark)**, without the prior written consent of Coherus, which consent may be withheld [***], except with respect to [***], in which case [***]. For the avoidance of doubt, it shall be [***] with respect to [***]. If Coherus consents in writing to allow Licensee to grant a sublicense, then Licensee may grant such sublicense, through [***], subject to the following: (a) each Sublicensee shall agree to be bound by all of the applicable terms and conditions of this Agreement; (b) the terms of each sublicense granted by Licensee shall provide that the Sublicensee shall be subject to the terms and conditions of this Agreement; (c) Licensee's grant of any sublicense shall not relieve Licensee from any of its obligations under this Agreement; (d) Licensee shall be liable for any breach of a sublicense by a Sublicensee to the extent that such breach would constitute a breach of this Agreement, and any breach of the sublicense by such Sublicensee shall be deemed a breach of this Agreement by Licensee to the extent that such breach would constitute a breach of this Agreement as if Licensee had committed such breach; *provided, however,* that in each instance of any breach, Licensee and/or Sublicensee shall have the right to cure any such breach pursuant to the terms of this Agreement; and (e) Licensee will notify Coherus of the identity of any Sublicensee, and the territory in which it has granted such sublicense, promptly after entering into any sublicense. Notwithstanding anything to the contrary in this Agreement, for clarity, Licensee shall not have the right to grant sublicenses under **Section 2.1 (License Grants)** to any Third Party to Manufacture Products or to conduct Process Development.

2.3 No Implied Rights or Licenses; Retained Rights. Neither Coherus nor Licensee grants to the other Party any rights or licenses in or to any Patent, Information, Trademark, or other intellectual property right, whether by implication, estoppel or otherwise, except to the extent expressly set forth in this Agreement. All rights not expressly granted to Coherus or Licensee (as applicable) in this Agreement are hereby retained by the Party that owns such rights. Notwithstanding the foregoing, Licensee expressly acknowledges that Coherus will use the Regulatory Filings (including any Regulatory Approvals in the Territory) in Manufacturing, obtaining Regulatory Approvals outside the Territory and selling the Product outside the Territory.

2.4 Licensee Rights of First Refusal.

(a) Right of First Refusal for Coherus Biosimilar Candidates. During the Initial Review Period, Licensee will be granted [***] to [***]. Within forty-five (45) days of the

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

commencement of the Initial Review Period, Licensee shall provide written notice (the **"Rejection Notice"**) of one (1) Coherus Biosimilar Candidate in which it has no interest in developing and/or commercializing with Coherus (a **"Rejected Biosimilar Candidate"**) and such Rejected Biosimilar Candidate shall no longer be subject to the rights set forth in this **Section 2.4**. In addition, during the Initial Review Period, Licensee may elect, by providing written notice of such election (the **"Election Notice"**) to Coherus during the Initial Review Period, to enter into an agreement with Coherus for the development and commercialization of one (1) of the remaining Coherus Biosimilar Candidates in the Field in a territory which is not, as of the Effective Date, subject to a development and/or commercialization license from Coherus to a Third Party [***]. Alternatively, Licensee may elect, by providing an Election Notice to Coherus during the Initial Review Period, to enter into a joint venture or other commercial arrangement with Coherus for the development and commercialization of a biosimilar compound (**"Product X"**); *provided, however,* that, at the time of such election by Licensee, [***]. If Product X is the product selected in the Election Notice, the identity of Product X, and Licensee's election to proceed with a joint venture or other commercial arrangement, must be made within the Initial Review Period; Coherus [***]. The Coherus Biosimilar Candidate or Product X which Licensee selects during the Initial Review Period shall be known as the **"ROFR Candidate."** For clarity, Licensee is not obligated to select a ROFR Candidate during the Initial Review Period and Licensee is allowed to select only one ROFR Candidate during the Initial Review Period unless the provisions set forth in **Section 2.4 (Product Opt-Out)** are operative.

(b) Coherus/Licensee Product X Compounds as of Effective Date. As of the Effective Date [***] the following compounds which shall be eligible to be named as a Product X during the Initial Review Period (each, an **"Available Product X"**): [***]. Between the Effective Date and the expiration of the Initial Review Period, [***]. For clarity, the list of Available Product Xs set forth in this **Section 2.4(b)** is [***] named by Licensee and[***] Licensee may [***].

(c) [***] After the Initial Review Period. After the Initial Review Period, Coherus may permit Third Parties to [***] with respect to any such Coherus Biosimilar Candidates until at least thirty (30) days following the end of the Initial Review Period. Following receipt of the Rejection Notice, Coherus may permit Third Parties to [***].

(d) Negotiation Periods.

(i) If the Election Notice identifies one of the Coherus Biosimilar Candidates as the ROFR Candidate, the Parties shall enter into a period of [***] negotiations of thirty (30) days which shall commence on the date that Licensee delivers to Coherus the applicable Election Notice, with the goal of [***] by Coherus [***]. If a [***] during such thirty (30)-day period, the Parties shall promptly enter into a period of [***] negotiations of not more than sixty (60) days following the [***] mutually acceptable financial and other terms under which Coherus would [***] license to Licensee such intellectual property rights.

(ii) If the Election Notice identifies a Product X as the ROFR Candidate, the Parties shall enter into a period of [***] negotiations of not more than six (6) months following the receipt by Coherus of the applicable Election Notice with the goal of executing a definitive license agreement setting forth the mutually acceptable financial and other terms under which

Coherus would exclusively license to Licensee the intellectual property rights related to Product X that are Controlled by Coherus.

(e) Product Opt-Out. Licensee shall have a period of forty-five (45) days (which shall be extended by Coherus by an additional fifteen (15) days upon the reasonable request of Licensee) following [***] **"Product Opt-Out Period"**) to make a decision not to proceed with Development solely based on: (i) the failure of the Phase 1 Results to demonstrate pharmacokinetic bio- equivalence [***]; (ii) material safety issues with the Product which are evident in the Phase 1 Results and which issues cannot be remedied or overcome; or (iii) quality audits of the Vendors conducted between the Effective Date and the expiration of the Product Opt-Out Period ([***]) that provide findings identifying violations of applicable GXP of such a severity or number that they would, in the aggregate, preclude the ability of one or both of the Vendors to qualify under Licensee's standard vendor qualification policies and procedures taking into account the performance of reasonable remediation efforts in a timely manner. The Parties will work together in good faith to remediate any such findings. The Parties will share any reports generated in connection with the quality audits under **subsection (iii)** above, to the extent not otherwise prohibited by any Third Party consultants utilized in such quality audits. If Licensee makes a decision not to proceed with Development pursuant to this **Section 2.4**, it shall, prior to the expiration of the Product Opt-Out Period, provide written notice of such decision to Coherus (an **"Opt-Out Notice"**), setting forth in reasonable detail the basis on which it has made its decision. If Licensee delivers an Opt-Out Notice during the Product Opt-Out Period, Licensee shall have an additional sixty (60)-day period following delivery of the Opt-Out Notice (the **"Second Review Period"**) to elect to enter into one or more [***] term sheets and/or ROFR Agreements (as contemplated below) with Coherus for the development and commercialization of additional product candidates as follows:

(i) Coherus shall promptly [***];

(ii) If Licensee selected a ROFR Candidate within the Initial Review Period, Licensee may, during the Second Review Period, select [***], such that, [***], Licensee may [***]; whereas if [***], Licensee must [***];

(iii) If Licensee did not select a ROFR Candidate within the Initial Review Period, Licensee may, during the Second Review Period, select [***]; *provided, however,* that [***];

(iv) The identity of Product X, and Licensee's election to proceed with [***] must be made within the Product Opt-Out Period;

(v) For clarity, the expiration of the Initial Review Period shall not impact Licensee's ability to select one or more Coherus Biosimilar Candidates or Product X during the Second Review Period following delivery by Licensee of an Opt-Out Notice during the Product Opt-Out Period; and

(vi) [***] of the Upfront Payment paid to Coherus pursuant to **Exhibit 7.1 Section A (Upfront License Payment)** shall be [***] under the definitive ROFR Agreement(s) to be negotiated pursuant to this **Section 2.4 (Product Opt-Out)**; *provided, however,* that: (A) [***], (B)

[***]; and (C) [***]. For clarity, this [***] is only applicable in the event of Product Opt-Out by Licensee.

(f) [***] Term Sheet and/or Definitive Agreements to be Negotiated. Any [***] term sheet or ROFR Agreement between Coherus and Licensee related to either a Coherus Biosimilar Candidate or Product X will be negotiated in good faith, within the timeframes for completing negotiations set forth in **Section 2.4 (Licensee Rights of First Refusal)**, subject to extension by mutual agreement of the Parties, and will provide for mutually acceptable financial and other terms; *provided, however,* that it is anticipated that any ROFR Agreement(s) for Product X shall [***]; *provided, however,* that, [***]:

(i) with respect to any ROFR Agreement for the first Coherus Biosimilar Candidate, Coherus shall [***]; and

(ii) with respect to any ROFR Agreement for [***], Coherus shall not bear any internal or external development costs.

3. GOVERNANCE.

3.1 Joint Steering Committee.

(a) Generally. As soon as practicable after the Effective Date, but in any event within fifteen (15) days of the Effective Date, the Parties shall establish a joint steering committee (the **"Joint Steering Committee" or "JSC**") to oversee the Development, Process Development, Manufacturing, Process Development and Commercialization activities of the Parties with respect to Product in the Territory during the Term as further detailed in this **Article 3 (GOVERNANCE)**. The JSC shall have review and coordination responsibilities for Development, Manufacturing, Process Development and Commercialization activities and in connection therewith shall review and provide advice regarding the overall progress thereof. The JSC shall also provide a forum for sharing advice, progress, and results relating to such activities and shall attempt to facilitate the resolution of any disputes between the Parties, as described in **Section 3.1(d) (Decision-Making; Deciding Vote).**

(b) Membership; Meetings. The JSC shall be composed of three (3) representatives of Licensee and three (3) representatives of Coherus or such other number as the Parties may agree. During the Term, the JSC shall meet at least [***] per [***], or more often as the JSC shall determine, in person, by teleconference, or by video- teleconference. There will be an annually rotating chairperson (the **"Chairperson**") with the first Chairperson to be designated by Licensee. In-person meetings shall alternate between Coherus and Licensee locations whenever possible unless otherwise agreed by the Parties. The first such meeting shall be held within ninety (90) days after the Effective Date. Any member of the JSC may designate a substitute to attend with prior written notice to the other Party. Ad hoc guests who are employees of neither Licensee nor Coherus but who are subject to written confidentiality obligations commensurate in scope to the provisions in **Article 11 (CONFIDENTIALITY)** may, subject to the other Party's consent (not to be unreasonably withheld, conditioned or delayed), attend the JSC meetings. Each Party may replace its JSC members with other of its employees, at any time, upon prior written notice to the other Party.

(c) Sub-Committees. No later than its initial meeting, the JSC shall agree upon the formation of certain sub-committees to address specific issues in greater detail (each, a **"Sub-Committee"**) including the JDC, JPDMC and JCC (each, as hereinafter defined) with each Sub-Committee consisting of an equal number of representatives from Coherus and Licensee. In connection therewith, the JSC shall establish and appoint members to the Sub-Committees and each such Sub-Committee shall hold its first meeting in person as set forth in the applicable sections below at such location designated by the JSC. [***]. For clarity, either Party may, as appropriate and reasonable, invite additional employees or other ad-hoc guests who are subject to written confidentiality obligations commensurate in scope to the provisions in **Article 11 (CONFIDENTIALITY)** to the meetings of the Sub-Committees.

(d) Decision-Making; Deciding Vote. Except as otherwise expressly set forth in this **Section 3.1(d)**, decisions of the JSC and each Sub-Committee shall be made by consensus, with each Party having, collectively, one (1) vote in all decisions. In the event that the JSC or any Sub-Committee is unable to reach a consensus decision on a matter that is within its decision-making authority within fifteen (15) days after it has met and attempted to reach such decision, then either Party may submit such matter for resolution to the Executive Officers in accordance with **Section 14.2 (Resolution by Executive Officers)**, and, except as set forth below in this **Section 3.1(d)**, the dispute resolution procedure set forth in **Article 14 (DISPUTE RESOLUTION)** shall apply.

(i) The JDC will report to the JSC. Any disagreement between the Parties' members on the JDC will be submitted for resolution to the JSC. If the JSC is unable to resolve such disagreement, such disagreement will be escalated to the Executive Officers for their resolution in accordance with **Section 14.2 (Resolution by Executive Officers)**; *provided, however,* that if the disagreement that is escalated to the Executive Officers relates to [***] [***], then the Executive Officers shall [***]; *provided further,* [***].

(ii) The JPDMC will report to the JSC, and any disagreement between the Parties' members on the JPDMC will be submitted for resolution to the JSC and, if necessary, for subsequent escalation to and resolution by the Executive Officers in accordance with **Section 14.2 (Resolution by Executive Officers)**; *provided, however*, that if the Executive Officers are unable to reach resolution in accordance with **Section 14.2 (Resolution by Executive Officers)**, then no further escalation of dispute resolution under **Article 14 (DISPUTE RESOLUTION)** shall apply and [***] shall have the final deciding vote.

(iii) The JCC will report to the JSC, and any disagreement between the Parties' members on the JCC will be submitted for resolution to the JSC and, if necessary, for subsequent escalation to and resolution by the Executive Officers in accordance with **Section 14.2 (Resolution by Executive Officers)**; *provided, however*, that if the Executive Officers are unable to reach resolution in accordance with **Section 14.2 (Resolution by Executive Officers)**, then no further escalation of dispute resolution under **Article 14 (DISPUTE RESOLUTION)** shall apply and [***] shall have the final deciding vote.

(e) Limitations on JSC and Sub-Committees. The JSC and each Sub- Committee shall have only such powers as are specifically delegated to it in this Agreement and such powers shall be subject to the terms and conditions set forth in this Agreement. Without limiting the generality of the

foregoing, neither the JSC nor any Sub-Committee thereof shall have any power to amend, modify or waive compliance with this Agreement though the JSC or any Sub-Committee may make recommendations to the Parties regarding any such amendments, modifications or waivers.

(f) Secretary; Minutes. The Chairperson of the JSC and the chairperson of each Sub-Committee shall designate a secretary who will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and circulating minutes within fifteen (15) days after each meeting of the JSC setting forth, among other things, a description, in reasonable detail, of the discussions at the meeting and a list of any actions, decisions, or determinations approved by the JSC or the applicable Sub-Committee. Definitive minutes of all meetings shall be finalized no later than thirty (30) days after the meeting to which the minutes pertain. Such minutes shall be effective only after being approved by both Parties.

3.2 Joint Development Committee.

(a) No later than its initial meeting, the JSC shall establish a joint Development committee (the **"Joint Development Committee"** or **"JDC"**) which shall hold its initial meeting within fifteen (15) days of its establishment. At its first meeting, the JDC shall: (i) [***], and (ii) review, modify as necessary and recommend for approval to the JSC a Development Plan (including the Development Budget). The Illustrative Development Plan/Budget is an illustrative indication of the activities and the budget to be considered and addressed in the first Development Plan and shall not be binding on the Parties, the JSC or the JDC. Following its initial meeting, the JDC will meet in person, by teleconference or by video- teleconference at least [***] per [***] to [***].

(b) Without limiting the foregoing, the JDC shall be responsible for: (i) reviewing, consulting with the Parties on and modifying (as appropriate) the Development Plan including the Development Budget; (ii) recommending the Development Plan including the Development Budget (as modified) for approval by the JSC; (iii) communicating with the JCC regarding the interrelationship between Development activities and potential Commercialization; (iv) reviewing and monitoring the activities and progress against the Development Plan; (v) reviewing and monitoring the costs and expenses of Development against the Development Budget; (vi) finalizing the Product specifications for inclusion in the Regulatory Filings for the Territory and Regulatory Approvals and Pricing and Reimbursement Approvals for the Territory; and (vii) communicating with the Parties regarding all of the foregoing. For the avoidance of doubt, the CRO used for Clinical Trials shall be selected by Coherus, and such selection shall not be subject to the dispute escalation process under **Section 3.1(d) (Decision-Making; Deciding Vote).**

3.3 Joint Process Development and Manufacturing Committee. At its initial meeting, the JSC shall establish a joint Process Development and Manufacturing committee (the **"Joint Process Development and Manufacturing Committee"** or **"JPDMC"**) which shall, as noted above, hold its initial meeting within fifteen (15) days of its establishment. Following its initial meeting, the JPDMC will meet in person, by teleconference or by video-teleconference at least [***] per [***] to review and discuss material decisions and key activities that relate to the matters set forth below. The JPDMC will be responsible for reviewing Process Development, progress and development of analytical methods and analysis, Product formulations, coordination of Process Development and Manufacturing related activities and the review, modification as necessary and recommendation for

approval to the JSC of a Process Development Plan. For the avoidance of doubt, the Third Party contract manufacturer for clinical and commercial supplies of Product in the Territory shall be selected by Coherus, and such selection shall not be subject to the dispute escalation process under **Section 3.1(d) (Decision-Making; Deciding Vote)**.

3.4 Joint Commercialization Committee. Upon a decision by the JSC to activate the joint Commercialization committee, but in no case later than eighteen (18) months prior to the projected First Commercial Sale (the **"Joint Commercialization Committee"** or **"JCC"**), the Parties shall establish the JCC. The JCC shall hold its initial meeting within thirty (30) days of its establishment. Following its initial meeting, the JCC will meet in person, by teleconference or by video-teleconference at least [***] per [***] to review and discuss material decisions and key activities that relate to the matters set forth below. The JCC will be responsible for the communication, review and discussion of the Commercialization Plan and other Commercialization matters, including marketing strategy and planning, pricing, commercial manufacture, and [***], in each case in the Territory. Without limiting the foregoing, the JCC shall be responsible for: (a) reviewing and consulting with Coherus on the Commercialization Plan prior to adoption of the Commercialization Plan or changes by Licensee; (b) recommending the Commercialization Plan for approval by the JSC prior to adoption of the Commercialization Plan; (c) communicating with the JDC regarding the interrelationship between Development activities and potential Commercialization activities; (d) reviewing and monitoring the activities and progress against the Commercialization Plan; (e) monitoring and reporting on the competitive landscape for the Product in the Territory; (f) establishing appropriate processes for coordinating review of promotional materials for the Territory to ensure compliance with Applicable Laws and industry best practices; (g) overseeing the trademark and publication strategies for the Territory; and (h) communicating with the Parties regarding all of the foregoing.

4. DEVELOPMENT AND REGULATORY MATTERS.

4.1 Development Activities; Process Development Activities and Funding.

(a) Coherus Responsibilities. Subject to the oversight of the JDC, the JPDMC and the JSC ([***]), Coherus shall be solely responsible for carrying out all activities set forth in the Development Plan and the Process Development Plan. Coherus shall use Commercially Reasonable Efforts to conduct all Development and Process Development activities in accordance with the Development Plan or the Process Development Plan (as applicable) and the terms of this Agreement. Without limiting the generality of the foregoing, Coherus' responsibility with respect to Development shall include: (a) preparing Regulatory Approval Applications for submission in the Territory by and in the name of Licensee to the relevant Regulatory Authorities in the Territory; (b) carrying out all major Development tasks to be conducted prior to submission of filings for such Regulatory Approvals; (c) identifying key Development objectives, expected associated resources, risk factors, timelines, decision points and relevant decision criteria; (d) carrying out all aspects of all Clinical Trials (including bioequivalence Clinical Trials) necessary to obtain Regulatory Approval and receipt of Pricing and Reimbursement Approvals in the Territory including: (i) designing study protocols, developing [***], (ii) establishing and contracting with Clinical Trial sites, investigators and CROs, (iii) enrolling Clinical Trial subjects, (iv) organizing investigator meetings, scientific meetings, advisory panel workshops and regulatory meetings, and (v) analyzing and summarizing Clinical Trial

results; (e) performing any other additional clinical research in support of the Development; (f) [***]; (g) reporting on study design, study outcome, other communications and Regulatory Filings in the Territory to the appropriate Regulatory Authority in the Territory; and (h) submitting all Clinical Trial results and any other clinical data to the Global Clinical Database pursuant to **Section 4.7 (Coherus Global Clinical Database)**. For clarity, any Post-Regulatory Approval Activities shall be conducted by Licensee and Licensee shall [***]; *provided*, that to the extent Coherus had responsibility for [***] unless otherwise agreed.

(b) Clinical Trials in the Territory. Except as contemplated by the Global Studies and such other Phase 3 Clinical Trials being conducted by or on behalf of Coherus in support of Regulatory Approvals or Pricing and Reimbursement Approvals in the Territory, [***].

(c) Expense Reports for Reimbursable Costs. The parties acknowledge and agree that Licensee was responsible for [***]. [***] Coherus shall deliver to Licensee, within thirty (30) days of the end of each Calendar Quarter, a report setting forth in reasonable detail the Reimbursable Costs for such Calendar Quarter. Licensee shall promptly notify Coherus of any good faith dispute regarding an invoice submitted pursuant to this **Section 4.1**, and the Parties shall work in good faith to exchange information to resolve such dispute; *provided, however,* [***].

(d) Cost Reimbursement.. . **[***]**, in the event that [***], the Parties shall [***] as follows: [***] ; *provided, however,* that [***]. For clarity, [***]. For the avoidance of doubt [***]. Licensee shall, [***], provided, that [***]. Except as set forth in this Section 4.1(d), [***].

(e) Cost Reimbursement Limitations. Notwithstanding anything else contained in this Agreement and in this **Section 4.1** in particular, the Parties agree as follows:

(i) Licensee [***].

(ii) Licensee [***].

(iii) For clarity, all Reimbursable Costs incurred by Coherus directly resulting from Coherus' preparation of: (A) the Regulatory Filing for the EU Regulatory Approval and (B) Regulatory Filings for the [***] countries within the Territory other than the EU for which Regulatory Approval is sought, shall be included as Reimbursable Costs. Except as set forth in the immediately preceding sentence, Licensee shall be responsible for and shall pay all Reimbursable Costs incurred by Coherus directly resulting from Coherus' preparation of Regulatory Filings for all other countries in the Territory that are approved by the JSC.

(f) Coherus Reimbursement of Licensee Development Costs and Expenses. If the Product is commercialized in the United States other than by entering into a commercial arrangement therefor with Licensee, Coherus shall reimburse Licensee the following amounts determined as:

(i) [***]% of the Reimbursable Costs incurred for execution of the Development Plan, as set forth in Exhibit 1.32, [***]; plus

(ii) [***]% of that portion of Reimbursable Costs, if any, incurred for execution of the Development Plan, as set forth in Exhibit 1.32, [***]; plus

(iii) [***]% of the Reimbursable Costs incurred for the [***]; plus

(iv) [***]% of that portion of Reimbursable Costs, if any, incurred for the [***]

Such amount would be due to Licensee whether Coherus commercializes the Product in the United States with a Third Party or Coherus commercializes the Product without a Third Party. In either case, reimbursement to the Licensee shall be due forty five (45) days after the first commercial sale of the Product in the United States whether for Coherus' own account or by a Third Party. Exhibit 4.1(f) is attached hereto and incorporated herein to show for illustrative purposes the reimbursement agreement between the Parties.

As used herein EMA Required Studies means: [***].

(g) Process Validation Lots. In the event that any Product produced from the process validation activities is sold for commercial use by Licensee, then Licensee shall pay Coherus in accordance with the terms of the Manufacturing Supply Agreement.

4.2 Development Plans. Coherus shall provide to the JDC, in advance of its first meeting, a draft Development Plan. The draft Development Plan may [***]. If modifications or changes to the draft Development Plan are proposed by either Party, the JDC shall review and recommend any modifications or changes thereto and shall make its recommendation to the JSC for review and approval of the draft Development Plan (as modified by the JDC). For clarity, the Illustrative Development Plan/Budget is illustrative of the activities and the budget to be considered and addressed in the draft Development Plan to be provided by Coherus to the JDC. Following approval by the JSC, the Development Plan shall be updated and/or amended by the JDC no less frequently than [***], with any such updates and amendments being subject to the approval of the JSC. The Development Plan shall be consistent with and shall not contradict the terms of this Agreement without the written consent of the Parties, and in the event of any inconsistency between the Development Plan and this Agreement, the terms of this Agreement shall prevail. Notwithstanding the foregoing, if a Regulatory Authority or Applicable Laws requires a change to a Development Plan, the JDC shall, subject to the approval of the JSC, revise the Development Plan. For the avoidance of doubt, no Development Plan shall be binding on the Parties unless and until it has been approved by the JSC. For clarity, the currently approved Development Plan is set forth in Exhibit 1.32.

4.3 Efforts. Coherus shall use Commercially Reasonable Efforts to Develop the Product in the Territory in accordance with the Development Plan and the terms of this Agreement, including the preparation, for Licensee's subsequent submission to Regulatory Authorities in the Territory, of all Regulatory Filings (including Regulatory Approval Applications) covering the Product in the Territory.

4.4 Regulatory Filings.

(a) Responsibilities. Coherus shall, subject to the oversight of the JDC and approval of the JSC, have primary responsibility for preparing each Regulatory Filing in the Territory, and shall also be responsible for establishing and managing timelines for completion of each such Regulatory Filing (including drafting of responses to Regulatory Authority questions during the Regulatory Approval Application review period) until receipt of the applicable Regulatory Approval for the applicable country or region in the Territory. With respect to the Territory, and notwithstanding Coherus' obligation to prepare such filings pursuant to the preceding sentence: (i) all Regulatory Filings in the Territory shall be prepared in the name of Licensee or an Affiliate of Licensee, (ii) Licensee shall be the owner of all Regulatory Filings and all Regulatory Approvals and Pricing and Reimbursement Approvals relating thereto, and (iii) Licensee shall be responsible for submitting the Regulatory Approval Applications in the Territory to the Regulatory Authorities for approval within the timing set forth in **subsection (b)** below.

(b) Review and Submission of Regulatory Approval Applications.

(i) European Union. Coherus shall deliver to Licensee the Regulatory Approval Application [***] for initial review. Licensee shall promptly review and provide comments to the initial draft in a time-frame that is consistent with the document review and development plan. Subsequently, Coherus will develop a final draft of the Regulatory Approval Application and shall deliver to the Licensee for final review and approval. Within thirty (30) days of delivery of such Regulatory Approval Application, Licensee shall provide any comments for Coherus' reasonable consideration of inclusion in such Regulatory Approval Application. Failure to provide any comments within such thirty (30)-day period shall be deemed Licensee's consent to the filing of such Regulatory Approval Application, as previously delivered to Licensee, with the Regulatory Authorities in the European Union. Coherus and Licensee shall work in good faith to resolve any comments provided by Licensee within such thirty (30)-day period. If Coherus and Licensee are unable to resolve any Licensee comments within such thirty (30)-day period, any delay involved in the filing beyond the initial thirty (30)-day period shall be credited to Coherus, on a day-for-day basis, in determining the order of entrance to market for the EU Regulatory Approval Milestone.

(ii) All Other Countries. All other Regulatory Filings for the Product in the Territory shall be subject to [***] prior to submission to Regulatory Authorities in the Territory.

(c) Responsible Party.

(i) Prior to submission of a Regulatory Approval Application in the name of Licensee or its Affiliate in the applicable country or jurisdiction in the Territory, Coherus shall be the responsible Party for all interactions concerning the Product with Regulatory Authorities in such country or jurisdiction, including relating to Regulatory Filings for the Global Studies and for interactions related to the design and conduct of the Global Studies and Regulatory Authority inspections of the manufacturing facilities and/or Clinical Trial sites. Coherus will be responsible for the inspection(s) findings and resulting commitments to Regulatory Authorities. Coherus shall keep Licensee reasonably informed of all communications received from Regulatory Authorities in the Territory.

(ii) After submission of a Regulatory Approval Application in the name of Licensee or its Affiliate in the applicable country or jurisdiction in the Territory, Licensee shall be the responsible Party for all interactions concerning the Product with Regulatory Authorities in such country or jurisdiction except for Regulatory Authority inspections related to the Clinical Studies and manufacturing facilities. Licensee shall keep Coherus reasonably informed of all communications received from Regulatory Authorities in the Territory.

(iii) Parties shall consult and cooperate to maximize the possibility of receipt of the Full Label in the period after filing of a Regulatory Approval Application and prior to receipt of Regulatory Approval in each country or jurisdiction in the Territory.

(d) Face-to-Face Meetings.

(i) Prior to submission of the Regulatory Approval Application in the name of Licensee or its Affiliate in the applicable country or region in the Territory, Licensee shall, at its sole cost and expense, have the right to send one (1) representative to attend all face- to-face meetings relating to the Product with any Regulatory Authority in the Territory. After submission of the Regulatory Approval Application in the name of Licensee or its Affiliate in the applicable country or region in the Territory, Coherus shall have the right to send one (1) representative to all face-to-face meetings relating to the Product with any Regulatory Authority in the Territory.

(ii) Licensee shall, at its sole cost and expense, have the right to send one (1) representative to attend all face-to-face meetings relating to the Product, solely as an observer, with Regulatory Authorities for unpartnered territories for the Product. In addition, Coherus will request that each Third Party partner of Coherus for the Product permit the participation of one (1) Licensee representative in such meetings within such partner's territories.

(e) Manufacturing Facility and/or Clinical Site Inspections. Prior to and following Regulatory Approval of the Product, Licensee shall, at its sole cost and expense, have the right to send one (1) representative to attend all Regulatory Authority inspections of manufacturing facility(ies) and/or Clinical Trial sites.

(f) Regulatory Communications.

(i) Except as otherwise provided for in this **Section 4.4(f)**, each Party shall provide summaries for each Calendar Quarter to the other Party of any oral or any substantive written communications to or from Regulatory Authorities on matters relating to the Product in the Territory. Notwithstanding the foregoing, each Party shall notify the other Party of any oral communications with, and provide such other Party with copies of any written communications to or from, Regulatory Authorities on matters which may reasonably be deemed to impact Development, Manufacture, Process Development, Commercialization or Regulatory Approval and Pricing and Reimbursement Approvals as soon as reasonably practicable (but in all events within seventy two (72) hours of receipt of such communication, or such earlier date as required by Applicable Laws). Moreover, in each such case, each Party shall give the other Party reasonable opportunity to review and comment on any proposed response to any such oral or written communications relating to the Product to or

from Regulatory Authorities prior to submitting any response thereto, and provide such other Party with a copy of the final response as specified herein.

(ii) Coherus shall promptly notify Licensee of all communications received by Coherus from Regulatory Authorities [***] and Coherus shall [***].

(g) Regulatory Reports. Each Party shall provide the other Party, at such other Party's request and expense, with summary documents related to the Product in the Territory for Regulatory Filings, Regulatory Approvals and Pricing and Reimbursement Approvals and key interactions with Regulatory Authorities relating thereto for which it is the responsible Party. In addition, each Party shall keep the other Party informed on a regular basis ([***]) of Regulatory Filings in the Territory.

4.5 Development Reports. At least [***] per [***], Coherus will provide the JDC with written Development reports or presentations. Each report or presentation shall include, but not be limited to, the Development activities accomplished by or on behalf of Coherus since the previous JDC meeting, including a summary of significant results and Information generated, significant challenges anticipated and [***]. Upon request by Licensee, Coherus shall provide Licensee additional information with respect to the material experimental data underlying such summary, summaries of available clinical protocols, investigator brochures, regulatory submissions and correspondence from Regulatory Authorities with respect to the Product. Upon request of either Party, the other Party's JDC members shall meet with the requesting Party's JDC members to discuss any aspects of such reports within a reasonable time period after such request. Coherus shall keep, and shall require its Affiliates, agents and Third Party service providers to keep (all in accordance with the Accounting Standards), accurate records in sufficient detail to allow Reimbursable Costs and Development Costs to be determined for a period of at least three (3) Calendar Years to facilitate the audits contemplated under **Section 7.8 (Audit Request)**.

4.6 Right of Reference.

(a) Coherus hereby grants to Licensee, its Affiliates and Sublicensees a right of reference (including the right to inspect) to any Regulatory Filings for the Product [***].

(b) Licensee hereby grants to Coherus, its Affiliates and licensees a right of reference (including the right to inspect) to any Regulatory Filings for the Product [***].

4.7 Coherus Global Clinical Database.

(a) Subject to **Section 4.8 (Pharmacovigilance)**, Coherus shall create a global database for all Clinical Trial results and clinical data related to the Product submitted by Coherus and/or its licensees throughout the world to applicable Regulatory Authorities (the **"Global Clinical Database"**). The purpose of the Global Clinical Database will be for Coherus and its exclusive licensees who submit data to the Global Clinical Database to share such data in support of their Regulatory Filings, and, in the case of Coherus, for any purpose generally related to enhancing Coherus' understanding of, or to improving, the Product.

(b) Coherus shall have the right to submit all clinical data pertaining to the Product in the Territory [***].

(c) Coherus shall be responsible for managing, maintaining, and updating the Global Clinical Database in accordance with Applicable Laws and shall have the right to share any and all de-identified information received from Licensee under this **Section 4.7** with Coherus' Affiliates, and with all licensees of Coherus outside the Territory relating to the Product who submit data to the Global Clinical Database.

(d) Licensee shall have reasonable access to the Global Clinical Database in connection with the activities contemplated by this Agreement including for use in its Regulatory Filings, without cost (other than any cost charged by the Third Party database provider associated with the transfer of data from the Global Clinical Database to Licensee for its use in connection with Regulatory Filings), and shall have the right to share any and all Information in the Global Clinical Database with Licensee's Affiliates and Sublicensees in the Territory.

4.8 Pharmacovigilance. Ninety days prior to the submission of a Regulatory Approval Application in any country in the Territory but in no event later than twelve (12) months after the Effective Date, the Parties shall enter into a pharmacovigilance agreement concerning all matters relating to the pharmacovigilance and the exchange of all relevant Information that relates to the safety of the Product worldwide and especially all adverse events. Generally, (a) Licensee shall be responsible for reporting all adverse drug reactions required to be reported to the Regulatory Authorities in the applicable countries in the Territory, in accordance with Applicable Laws; and (b) Coherus, its Affiliates or licensees or sublicensees shall be responsible for submitting all Regulatory Filings and for reporting of all adverse drug reactions, relating to the Product required to be reported to the appropriate Regulatory Authorities outside of the Territory in accordance with the Applicable Laws of the relevant countries. Coherus shall have the right to share any and all information received from Licensee under this **Section 4.8** with Coherus' Affiliates and licensees and sublicensees outside the Territory. Licensee shall have the right to share any and all information received from Coherus under this **Section 4.8** with Licensee's Affiliates and Sublicensees in the Territory. The JSC shall review from time to time Licensee's pharmacovigilance policies and procedures.

4.9 Formulation Development. Coherus shall be responsible for [***] development of Product formulations and performance of stability analyses on such formulations.

4.10 Initial Development Activities. The Parties acknowledge that during the thirty (30)-day period immediately following the Effective Date, Coherus will undertake the activities set forth in **Exhibit 1.29 (Initial Development Activities)**, pursuant to which Coherus will incur the Reimbursable Costs included therein.

4.11 Development Partners. To the extent that Coherus is not, as of the Effective Date, contractually obligated to use a specific Third Party for any Development activities contemplated by this Agreement, the Parties shall discuss and consider in good faith the Third Parties to be used for such activities at meetings of the JDC.

5. MANUFACTURING.

5.1 Manufacturing and Supply of Product. Within one hundred eighty (180) days following completion of enrollment in the Global RA Study, the Parties shall negotiate in good faith and enter into a definitive written commercial supply agreement (the **"Manufacturing and Supply Agreement"** or **"MSA"**) and a quality agreement related thereto, pursuant to which Coherus, either directly or through its designee, shall Manufacture and supply to Licensee, its Affiliates and Sublicensees (as applicable) all of Licensee's, its Affiliates' and Sublicensees' requirements of Units for Commercialization in the Territory. The MSA will provide, among other things, that all Product supplied thereunder will meet the Product specifications set forth in the applicable Regulatory Filings and Regulatory Approvals and any Pricing and Reimbursement Approvals in the Territory and shall contain customary terms and conditions including: [***] and shall otherwise be consistent with the terms and conditions in this **Article 5**. The Manufacturing and Supply Agreement shall provide that Coherus shall have the right to supply Product or Units produced at facilities licensed under Licensee's Regulatory Approval to its ex-Territory licensees of Product. The MSA shall also include [***].

5.2 Manufacturing Regulatory Filings. Coherus shall be solely responsible for the preparation and submission of all Manufacturing Regulatory Filings, including with respect to the use of any Third Party to Manufacture and supply the Product. Licensee shall provide Coherus such reasonable cooperation as may be requested by Coherus in connection with any such Manufacturing Regulatory Filings, and Coherus shall [***]. In addition, upon the written request of Coherus, Licensee shall provide to Coherus one (1) complete copy of each Regulatory Filing and each Regulatory Approval for Coherus', its Affiliates' or licensees' use in Manufacturing the Product for sale or use outside the Territory, and Licensee hereby grants to Coherus, its Affiliates and licensees the right to provide each such Regulatory Filing and Regulatory Approval to Regulatory Authorities outside the Territory.

5.3 Process Development and Capital Expenditures.

(a) Process Development. Coherus, through the JPDMC, shall develop a Process Development Plan (as well as the anticipated associated budget) for review by the JPDMC and subsequent approval by the JSC. The Process Development Plan shall include the plan for implementing Process Developments [***] and such Process Development Plan shall include provisions for [***]. Any amendment or update to an approved Process Development Plan is subject to review by the JPDMC and approval by the JSC. The Process Development Plan shall be consistent with and shall not contradict the terms of this Agreement without the written consent of the Parties, and in the event of any inconsistency between the Process Development Plan and this Agreement, the terms of this Agreement shall prevail. Notwithstanding the foregoing, if a Regulatory Authority or Applicable Laws requires a change to a Process Development Plan, the JPDMC shall revise the Process Development Plan to the extent necessary to comply with such requirement and shall promptly submit the revised Process Development Plan to the JSC for approval. Licensee shall bear all costs and expenses for the activities contemplated in the Process Development Plan.

(b) Process Development Plan. Coherus shall retain sole responsibility for performing any activities under an approved Process Development Plan[***].

(c) Capital Expenditures for Post Launch Expansion. [***] associated with the construction of all Manufacturing facilities necessary to satisfy Licensee's, its Affiliates' and Sublicensees' requirements for Product pursuant to **Section 5.1** and the MSA. For clarity, the [***] are separate and distinct from, and shall not include, the costs and expenses for Process Development borne by Licensee.

5.4 Records. Each Party shall, and shall require its Affiliates, subcontractors and sublicensees to, maintain records of all work conducted by such Party in connection with the Process Development activities and the Manufacture of Product or Units and all results, Information, and developments made in conducting such activities in accordance with Applicable Laws. Such records shall be complete and accurate and shall fully and properly reflect all such work done and all results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

5.5 [***] Technology Transfer. The Parties shall agree on a process for, and shall prepare appropriate documentation pertaining to, the implementation of a technology transfer of all know-how (including all Coherus Know-How) necessary for a Third Party to Manufacture or have Manufactured the Product for Commercialization in [***], and the Parties shall execute an agreement thereon (the **"Technology Transfer Agreement"**). The Technology Transfer Agreement shall specify, among other items: (i) the composition of the technology transfer teams, and (ii) a timeline for technology transfer and (iii) the responsibilities of the Parties with respect thereto. The costs and expenses of executing the technology transfer pursuant to the Technology Transfer Agreement shall be borne solely by Licensee[***].

6. COMMERCIALIZATION.

6.1 Efforts. Licensee shall be responsible for Commercialization of the Product in the Territory, and, as between the Parties, shall book all sales of the Product in the Territory. Licensee shall use Commercially Reasonable Efforts to Commercialize the Product in each of the Major EU Countries, [***] in accordance with the Commercialization Plan and the terms of this Agreement. Without limiting the obligation set forth in the immediately preceding sentence, Licensee shall initiate Commercialization activities within each of the Major EU Countries within three (3) months following [***] for the Product in the applicable Major EU Country.

6.2 Commercialization Plan.

(a) Initial Commercialization Plan. No later than eighteen (18) months prior to the anticipated commercial launch of the Product in the Territory, Licensee will provide to the JCC for review its initial Commercialization Plan for the Territory. Such initial Commercialization Plan will describe Licensee's plans for activities to be conducted for the Territory on a country-by-country basis. The Commercialization Plan shall include the details of activities to be performed by Licensee, its Affiliates and/or Sublicensees relative to the applicable stage of Commercialization (*e.g.*, pre-launch, launch planning, launch, or post-launch) during the time period covered by such Commercialization Plan and subsequent time periods.

(b) Updated Commercialization Plan Prior to First Commercial Sale. Prior to the First Commercial Sale in the Territory, Licensee will provide to the JCC for review and subsequent review and approval by the JSC, an updated Commercialization Plan for the Territory on a country-by-country basis. Such updated Commercialization Plan will include Licensee's updated plans for activities to be conducted for the Territory, on a country-by-country basis, prior to launch as well as activities to be conducted in connection with such launch.

(c) Updated Commercialization Plan After First Commercial Sale. Promptly after the first anniversary of the First Commercial Sale in the Territory and thereafter on each subsequent anniversary during the Term, Licensee will provide to the JCC for review an updated Commercialization Plan for the Territory on a country-by-country basis. Such updated Commercialization Plan will include, but not be limited to, Licensee's plans for Commercialization activities for the Territory, on a country-by-country basis, for the twelve (12) month period following the date of delivery of such Commercialization Plan.

(d) General. Each Commercialization Plan shall be consistent with and shall not contradict the terms of this Agreement [***], and in the event of any inconsistency between the Commercialization Plan and this Agreement, the terms of this Agreement shall prevail. Notwithstanding the foregoing, if a Regulatory Authority or Applicable Laws requires a change to the Commercialization Plan, the JSC shall revise the Commercialization Plan to the extent necessary to comply with such requirement and shall promptly provide the revised Commercialization Plan to the JSC for approval.

6.3 Trademarks.

(a) Product Trademark; Licensee Trademark. Subject to **Section 6.3(d) (Use of Coherus Trademarks)**, all Product, including all packaging, promotional materials, package inserts, and labeling for the Product, shall bear one or more Trademark(s) that pertain specifically to the Product in the Territory, to be determined by the JSC and owned by Licensee (**"Product Trademark"**). Further, to the extent allowed by Applicable Laws, the Licensee may include on such packaging, promotional materials, package inserts, and labeling for the Product additional Licensee Trademarks**.**

(b) Global Brand Trademark. Licensee shall have the option[***] to use one or more Trademark(s) Controlled by Coherus that pertain specifically to the Product outside of the Territory for the Product in the Territory (the "**Global Brand Trademark**") in place of using the Product Trademark under **Section 6.3(a) (Product Trademark; Licensee Trademark)**. Such Global Brand Trademark may be used in the Territory including on all packaging, promotional materials, package inserts, and labeling for the Product.

(c) Trademark Prosecution and Maintenance. Licensee shall [***] be responsible for filing, prosecuting and maintaining (including searching and policing) any and all Product Trademarks and Licensee Trademarks, and conducting litigation with respect thereto. Coherus shall [***] be responsible for filing, prosecuting and maintaining (including searching and policing) any and all Global Brand Trademarks and Coherus Trademarks, and conducting litigation with respect thereto.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(d) Use of Coherus Trademark. To the extent permitted by Applicable Laws [***] (but subject to the remainder of this **Section 6.3**), Licensee may include on the packaging, promotional materials, package inserts, and labeling for the Product, the Coherus Trademark. In connection therewith and subject to the terms and conditions of this Agreement, Coherus hereby grants to Licensee a non-exclusive, royalty-free license, under the Coherus Trademarks and, subject to Licensee's option under **Section 6.3 (Global Brand Trademark)**, under the Global Brand Trademarks, with the right to grant sublicenses in accordance with **Section 2.2 (Sublicense Rights)**, throughout the Territory, to use and display the Coherus Trademarks in connection with the Commercialization throughout the Territory, as provided under and in accordance with this **Section 6.3**. All representations of the Coherus Trademark(s) that Licensee so uses, if intended to be disclosed to Third Parties and not previously approved by Coherus, will first be submitted to Coherus for approval[***], and Coherus will have fifteen (15) Business Days to review and approve each such representation of the Coherus Trademark(s). [***]. Licensee shall not use any Coherus Trademark outside the scope of this Agreement, and shall not knowingly take any action that would materially adversely affect the value of any Coherus Trademark. Coherus shall retain the right to monitor the quality of the goods on or with which any Coherus Trademark is used solely to the extent necessary to maintain Coherus' Trademark rights. For clarity, should Applicable Laws only permit one Trademark (*i.e.* Licensee Trademark or Coherus Trademark) on the Product, the Licensee Trademark shall be the Trademark used.

7. PAYMENT OBLIGATIONS.

7.1 Payment Structure. In consideration for the rights granted to Licensee under this Agreement, Licensee shall pay Coherus the amounts set forth in **Exhibit 7.1 (Payment Structure)**.

7.2 Coherus Reports. During the Term following the First Commercial Sale, within forty five (45) days after the end of each Calendar Quarter, Coherus shall provide a report showing the Manufacturing Cost per Unit for each configuration of Units supplied to Licensee for the immediately preceding Calendar Quarter.

7.3 Licensee Reports and Payments. During the Term following the First Commercial Sale, within sixty (60) days after the end of each Calendar Quarter, Licensee shall pay to Coherus the Coherus Royalty (as such term is defined in **Exhibit 7.1**) and shall provide a report showing, on a country-by-country basis, the items set forth below in this **Section 7.3**. If no Coherus Royalty is due for any period hereunder, Licensee shall so report, otherwise the report shall set forth:

(a) the gross amount invoiced for and the Net Sales during such Calendar Quarter reporting period, including the specific deductions applied in the calculation of such Net Sales amounts;

(b) the Manufacturing Cost per Unit (as provided by Coherus in its quarterly report);

(c) the related Coherus Royalty in Dollars which shall have accrued hereunder with respect to such Net Sales; and

(d) the rate of exchange used by Licensee in determining the amounts payable hereunder in Dollars.

7.4 Sublicensing. In the event Licensee grants one or more sublicenses under **Section 2.2 (Sublicense Rights)** to a Sublicensee to offer to sell or sell Product in the Territory each sublicense agreement shall require the applicable Sublicensee to account for and report its net sales of the Product on the same basis as if such sales were Net Sales by Licensee, and Licensee shall pay a Coherus Royalty on such sales as if the net sales of the Sublicensees were Net Sales of Licensee.

7.5 Currency of Payment. All payments to be made under this Agreement shall be made in Dollars. Net Sales made in foreign currencies shall be converted into Dollars using [***] for each of the three calendar months included in the Calendar Quarter in which such Net Sales were made.

7.6 Records; Accounting.

(a) Licensee shall keep, and shall require its Affiliates and Sublicensees to keep (all in accordance with the Accounting Standards and Licensee's applicable policies and practices as such may be modified from time to time), complete and accurate records in sufficient detail to properly reflect the Net Sales and to enable the Coherus Royalty payable hereunder (if any) to be determined for a period of at least [***] Years or as otherwise necessary to facilitate the audits contemplated under **Section 7.8 (Audit Request)**.

(b) Licensee shall determine Net Sales consistent with the Accounting Standards and Licensee's applicable policies and practices as such may be modified from time to time. In the case of amounts to be determined by Third Parties (for example, net sales by Sublicensees), such amounts shall be determined in accordance with the Accounting Standards in effect in the country in which such Third Party is engaged. Licensee retains the right to modify its policies and practices to comply with specific changes in the Accounting Standards and as otherwise deemed necessary or appropriate by Licensee but shall not do so solely to reduce the amount of payments due to Coherus hereunder. Where Coherus notifies Licensee that the change is material to Coherus, Licensee shall provide an explanation of the change and an accounting of the effect of the change on the relevant revenue, cost, or expense category.

(c) In the event of the payment or receipt of non-cash consideration in connection with the performance of activities under this Agreement, Licensee shall advise Coherus of such transaction, including Licensee's assessment of the fair market value of such non-cash consideration and the basis therefor. Such transaction shall be accounted for on a cash equivalent basis, as mutually agreed by the Parties in good faith.

7.7 Withholding Tax. Licensee shall bear any and all taxes required to be paid on amounts due to Coherus, and Licensee shall not be entitled to deduct such payments from such amounts payable to Coherus under **Section 7.1 (Payment Structure)**. For clarity, amounts due to Coherus under **Section 7.1** shall be based on amounts due to Coherus prior to any deduction as a result of taxes payable by Licensee. Coherus shall reasonably cooperate with Licensee to facilitate

appropriate proceedings required by tax authorities in the Territory relating to the payments hereunder.

7.8 Audit Request. Each Party shall, at its sole cost and expense (except as provided below), have the right one (1) time each Calendar Year to audit, during regular business hours and upon not less than fifteen (15) days prior written notice to the other Party, the books and records maintained by such other Party to determine with respect to any Calendar Year, the accuracy of any report or payment made or expense charged by one Party to the other under this Agreement in the [***] Calendar Years. If a Party desires to audit such records, it shall engage an independent, certified public accountant reasonably acceptable to the other Party, to examine such records under conditions of confidentiality. Such accountant shall be instructed to provide to the auditing Party a report verifying any report made or payment submitted or expense charged by the other Party during such period, but shall not disclose to the auditing Party any Confidential Information of the other Party not necessary to be disclosed. The expense of such audit shall be borne by the auditing Party; *provided, however*, that, if an error of more than five percent (5%) is discovered, then such expenses shall be paid by the other Party. If such accountant concludes that additional payment amounts were owed or additional expenses were charged to the auditing Party during any period, the other Party shall pay such payment amount (including interest thereon pursuant to **Section 7.9 (Interest)** from the date such amounts were payable) within thirty (30) days after the date the auditing Party delivers to the other Party such accountant's written report so concluding, unless such other Party notifies the auditing Party of any dispute regarding the audit and commences proceedings under **Article 14 (DISPUTE RESOLUTION)** within thirty (30) days after delivery of the accountant's report (in which case the payment shall be delayed until conclusion of the proceeding). Such auditors shall not be paid on a contingency basis.

7.9 Interest. Interest shall be payable: (a) on any payments that are not paid on or before the date such payments are due under this Agreement calculated based on the total number of days payment is delinquent and (b) on any errors identified pursuant to the audit conducted pursuant to **Section 7.8 (Audit Request)** calculated from the date such payments were originally made at [***], or the maximum applicable legal rate, if less.

7.10 Stock Purchase. Within six (6) months of execution of this Agreement, Licensee shall purchase from Coherus $10,000,000 of common stock of Coherus in a private placement of restricted securities (the "Private Placement Shares") at a price per share equal to the closing trading price on the NASDAQ Global Market on the date of such purchase. Licensee acknowledges that the sale of the Private Placement Shares to Licensee will be made in compliance with all applicable federal and state securities laws.

8. INTELLECTUAL PROPERTY AND INVENTIONS.

8.1 Intellectual Property. Except as otherwise expressly set forth in this Agreement, neither Party grants to the other Party any right, title, or interest in any Patent, Patent Application, Information, Trademark, or other intellectual property right Controlled by such Party.

8.2 Disclosure. Each Party shall promptly disclose to the other Party any Inventions that it or its employees, sublicensees, Affiliates, independent contractors or agents solely or jointly make,

conceive, reduce to practice, author, or otherwise discover in the course of activities performed under or contemplated by this Agreement.

8.3 Ownership of Inventions.

(a) Generally.

(i) Subject to the license granted in **Section 2.1(a) (Development and Commercialization License to Licensee)**, and as between Coherus and Licensee, Coherus owns: (a) all Coherus Inventions (b) any Joint Inventions to the extent such Joint Inventions relate [***] (the **"Coherus-Owned Joint Inventions"**) and (c) any Licensee Inventions to the extent such Licensee Inventions relate [***] (the **"Coherus- Owned Licensee Inventions"**).

(ii) Subject to the license granted in **Section 2.1(b) (Licenses to Coherus)**, and as between Coherus and Licensee, Licensee owns all Licensee Inventions (excluding Coherus-Owned Licensee Inventions).

(iii) Each Party owns an undivided one half (1/2) interest in: (a) all Joint Inventions (excluding the Coherus-Owned Joint Inventions) and (b) all Patents and Patent Applications claiming all Joint Inventions (excluding those Patents and Patent Applications for the Coherus-Owned Joint Inventions). Coherus' interest in any Patents and Patent Applications covering Joint Inventions shall be included in the Coherus Patent Rights, and Licensee's interest in any Patents and Patent Applications covering Joint Inventions shall be included in the Licensee Patent Rights.

(b) Ownership Disputes. The [***] shall attempt in good faith to resolve any disputes arising hereunder regarding ownership of Inventions, Patents and any other intellectual property. In the event the [***] is unable to resolve such dispute within thirty (30) days after its receipt of notice of the dispute, the dispute resolution procedure set forth in **Article 14 (DISPUTE RESOLUTION)** shall apply.

(c) Assignment and Perfection of Interests. Without additional consideration, each Party hereby assigns to the other Party such of its right, title, and interest in and to any Inventions, Patents, and Patent Applications claiming them, and all other intellectual property rights therein, and shall require its sublicensees and Affiliates, and all independent contractors, employees, or agents of such Party, its Affiliates, or its sublicensees to so assign to the other Party such of their right, title, and interest in and to them, as is necessary to effectuate the allocation of right, title, and interest in and to Inventions as set forth in this **Section 8.3**. Each Party shall, and shall cause its sublicensees and Affiliates, and all independent contractors, employees, and agents of such Party, its Affiliates, or its sublicensees to, cooperate with the other Party and take all reasonable additional actions and execute such agreements, instruments, and documents as may be reasonably required to perfect the other Party's right, title, and interest in and to Inventions, Patents, and Patent Applications and other intellectual property rights thereon or therein as such other Party has pursuant to this **Section 8.3**. If a Party is unwilling or unable to execute any such agreements, instruments, and documents, it hereby appoints the other Party as its attorney-in-fact, which shall be coupled with an

interest, to execute the same on its behalf. Each Party shall also include provisions in its relevant agreements with Third Parties that effect the intent of this **Section 8.3(c)**.

8.4 Individual Patent Filings. Each Party will, to the maximum extent practicable, strive to separate any claims within Patents and Patent Applications that claim Inventions into separate Patents and Patent Applications consisting of claims that claim solely Coherus Inventions, solely Licensee Inventions, or solely Joint Inventions.

(a) Solely Owned Inventions. Coherus shall have sole discretion and responsibility to prepare, file, prosecute, and maintain any and all Patents and Patent Applications within the Coherus Patent Rights. Licensee shall have sole discretion and responsibility to prepare, file, prosecute, and maintain any and all Patents and Patent Applications within the Licensee Patent Rights. At least sixty (60) days prior to the contemplated filing date of any Patent Application in the Territory claiming a Party's solely- owned Invention, such Party [***], [***], and [***], and shall [***] with respect to such Patent Application. Licensee shall [***] pursuant to this **Section 8.4(a)** for Patents and Patent Applications within the Licensee Patent Rights, and Coherus shall [***] pursuant to this **Section 8.4(a)** for Patents and Patent Applications within the Coherus Patent Rights.

(b) Opt-In Rights. If a Party elects, in any country of the Territory, not to file or not to continue to prosecute and thereby abandon a Patent or Patent Application within the patent rights licensed to the other Party under this Agreement, or not to maintain and thereby abandon such a Patent or Patent Application, without the intent to file a continuing or divisional filing or an equivalent thereof or upon advice of patent counsel to optimize the overall patent protection on the Product or Process Development, such Party (the **"Opting-Out Party"**) shall notify the other Party (the **"Opting-In Party"**) not less than thirty (30) days before any relevant deadline, and thereafter such Opting-In Party shall have the right, but not the obligation, to pursue, [***] preparation, filing, prosecution, and maintenance of such Patent or Patent Application; *provided, however*, that the Opting-In Party provides the Opting-Out Party with [***] at least thirty (30) days prior to the proposed submission date and such Opting-Out Party determines[***] that any such submission will not prejudice any other Patents and Patent Applications of such Opting-Out Party.

8.5 Joint Patent Filings. With respect to all Patents and Patent Applications claiming Joint Inventions, but not Coherus Inventions (the **"Joint Patent Rights"**), Coherus shall have the first right, but not the obligation, to file, prosecute, maintain, and defend such Joint Patent Rights on behalf of both Parties (the **"Responsible Party"**). At least sixty (60) days prior to the contemplated filing of any Joint Patent Right, Coherus shall submit a substantially completed draft of such Joint Patent Right to Licensee for its approval, which shall not be unreasonably withheld, delayed, or conditioned. Except as set forth in this **Section 8.5**, below, the Parties shall [***], pursuant to [***] ([***]). If Coherus does not wish to file, prosecute, or maintain any Joint Patent Right or maintain or defend such a Joint Patent Right in a particular country, it shall grant Licensee any necessary authority to file, prosecute, and maintain such Joint Patent Right or maintain or defend such Joint Patent Right in the name of both Parties if Licensee so requests. If either Party elects [***], it shall so notify the other Party, in which case the other Party may proceed with respect to such Joint Patent Right in its own name [***]. In such case, the [***] shall [***] such Joint Patent Right [***].

8.6 Defense of Infringement Claims by Third Parties.

(a) In the event of the institution or threatened institution of any suit by a Third Party against Licensee for infringement involving Commercialization, Licensee shall have the right to defend such suit at its own expense and shall be responsible for all damages (including lost profits) incurred as a result thereof. Coherus hereby agrees to assist and cooperate with Licensee, at Licensee's reasonable request, and Licensee shall reimburse Coherus any reasonable, documented, out-of-pocket costs incurred in connection therewith. Licensee shall solely control the defense of such a claim and shall also have the right to control settlement of such claim; *provided, however*, that any such settlement shall not adversely affect Coherus' rights or interests without Coherus' prior written consent, which shall not be unreasonably withheld, delayed, or conditioned. Subject to such control, Coherus may join any defense and settlement pursuant to this **Section 8.6** with its own counsel at its sole cost.

(b) In the event of the institution or threatened institution of any suit by a Third Party against Coherus for infringement involving the development, Manufacture, or Commercialization of the Product in the Territory, Coherus shall have the right to defend such suit at its own expense and shall be responsible for all damages incurred as a result thereof. Licensee hereby agrees to assist and cooperate with Coherus, at Coherus' reasonable request, and Coherus shall reimburse Licensee any reasonable, documented, out-of-pocket costs incurred in connection therewith. Coherus shall solely control the defense of such a claim and shall also have the right to control settlement of such claim; *provided, however*, that any such settlement shall not adversely affect Licensee's rights or interests without Licensee's prior written consent, which shall not be unreasonably withheld, delayed, or conditioned. Subject to such control, Licensee may join any defense and settlement pursuant to this **Section 8.6** with its own counsel at its sole cost.

(c) If such Third Party asserts that a patent or other intellectual property right owned by it is infringed by the Development, Manufacture or Commercialization of the Product in the Territory by both of the Parties, then the Parties shall meet and confer, and both Parties shall have the sole right to defend against any such assertions with respect to its activities at its respective sole cost. Regardless of which Party is the defending Party (or if both Parties are a defending Party), the defending Party shall seek and reasonably consider the other Party's comments before determining the strategy for such matter. Without limiting the foregoing, the defending Party shall keep the other Party advised of all material communications and actual and prospective filings or submissions regarding such action, and shall provide the other Party copies of and an opportunity to review and comment on any such communications, filings and submissions before delivered or filed. Each Party shall keep the other reasonably informed of all claims and actions governed by this **Section 8.6.**

(d) In the event the Parties mutually agree that a settlement of any suit involving payment of prospective royalties is reasonable and necessary for continued Commercialization of Product in the Territory, the Parties shall consult in good faith and discuss a mutually satisfactory basis for sharing responsibility for such prospective royalties. In the absence of such agreement, the Parties shall share responsibility for such royalties as described in **Exhibit 7.1 (Payment Structure).**

(e) In the event Licensee is required to pay damages and/or lost profits pursuant to paragraph (a) above, Licensee shall be entitled to deduct from Coherus Royalty payments up to **[***]** of the amount of such damages and/or lost profits; *provided, however,* the amount of such deduction

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

applied by Licensee when added to any Third Party Payments in any given Calendar Quarter shall not reduce the Coherus Royalty payment by more than **[***]** in such Calendar Quarter.

8.7 Enforcement Actions Against Third Parties.

(a) If either Party learns of an infringement, unauthorized use, misappropriation, ownership claim, threatened infringement, or other similar claim by a ThirdParty with respect to the Coherus Patent Rights or Coherus Know-How in the Territory, such Party shall promptly notify the other Party in writing and shall promptly provide such other Party with available evidence of such infringement or other such claim.

(b) Coherus shall have the first right, but not the obligation, to institute an infringement suit or take other appropriate action against such Third Party in the Territory. If Coherus does not secure actual cessation of such infringement, misappropriation or institute a proceeding (which may include sending a cease and desist letter if appropriate) against an offending Third Party with respect to infringement of such Coherus Patent Rights or misappropriation of such Coherus Know-How as a result of the development, manufacture, commercialization or use of a product that is competitive with the Product in the Territory **("Enforcement Action"),** Coherus shall notify Licensee as soon as reasonably practicable but in any case no later than sixty (60) days of learning of such infringement. Upon receipt of such notice or absent such notice within such sixty (60) days, Licensee shall have the right at its sole discretion to institute an Enforcement Action in the name of either or both Parties. Each Party shall execute all necessary and proper documents, take such actions as shall be appropriate to allow the other Party to institute and prosecute such infringement actions and shall otherwise cooperate in the institution and prosecution of such actions (including consenting to being named as a nominal party thereto).

(c) The costs and expenses of any such Enforcement Action (including fees of attorneys and other professionals) shall be borne **[***].**

9. REPRESENTATIONS, WARRANTIES, AND COVENANTS.

9.1 Mutual Representations and Warranties. Each Party represents and warrants to the other, as of the Effective Date, as follows:

(a) such Party 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;

(b) the execution and delivery of this Agreement and the performance by such Party of the transactions contemplated hereby have been duly authorized by all necessary corporate action and will not violate: (i) such Party's certificate of incorporation or bylaws, (ii) any agreement, instrument or contractual obligation to which such Party is bound in any material respect, (iii) any requirement of any Applicable Laws, or (iv) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party;

(c) this Agreement is a legal, valid and binding obligation of such Party enforceable against such Party in accordance with its terms and conditions;

(d) such Party is not under any obligation, contractual or otherwise, to any person or entity that conflicts with or is inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder;

(e) to such Party's knowledge, all of its employees, officers, contractors, and consultants have executed agreements requiring assignment to such Party of all Inventions made during the course of and as a result of their association with such Party and obligating each such employee, officer, contractor, and consultant to maintain as confidential the Confidential Information of such Party; and

(f) neither such Party, nor any of its employees, officers, subcontractors or consultants who have rendered or will render services relating to the Product: (i) has ever been debarred (or is subject to debarment) or convicted of a crime for which an entity or person could be debarred under 21 U.S.C. Section 335a or its foreign equivalent or (ii) has ever been under indictment for a crime for which a person or entity could be debarred under any such provision.

9.2 Additional Representations, Warranties, and Covenants of Coherus. Coherus hereby represents, warrants, and covenants to Licensee that:

(a) as of the Effective Date, Coherus is entitled to grant the rights and licenses granted to Licensee as set forth in this Agreement;

(b) Coherus has not granted in the Territory as of the Effective Date, and will not grant during the Term, any right or license in or to any of the Coherus Patent Rights in the Territory that is in conflict with the rights or licenses granted to Licensee under this Agreement;

(c) Coherus has not granted in the Territory as of the Effective Date, and will not knowingly grant during the Term, any right or license in or to any of the Coherus Know-How in the Territory that is in conflict with the rights or licenses granted to Licensee under this Agreement;

(d) Coherus has not granted any liens or security interests to the Coherus Know-How or Coherus Patent Rights other than under any licenses or sublicenses;

(e) there are no existing or, to the knowledge of Coherus, threatened, actions, suits or claims pending with respect to the right of Coherus to enter into and perform its obligations under this Agreement;

(f) Coherus has not received, with respect to the Coherus Know-How or Coherus Patent Rights, any written notice of infringement or misappropriation or any other written communication relating to an alleged infringement or misappropriation of any patent rights or any know-how Controlled by a Third Party; and

(g) [***].

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

9.3 Additional Representations, Warranties, and Covenants of Licensee. Licensee hereby represents, warrants, and covenants to Coherus that:

(a) as of the Effective Date, Licensee is entitled to grant the rights and licenses granted to Coherus as set forth in this Agreement;

(b) Licensee has not granted in the Territory as of the Effective Date, and will not grant during the Term, any right or license in or to any of the Licensee Patent Rights or Grant-Back IP that is in conflict with the rights or licenses granted to Coherus under this Agreement;

(c) Licensee has in place policies related to ensuring that its business operations and practices are compliant with all Applicable Laws in the United States and the Territory relating to anti-corruption, including the Foreign Corrupt Practices Act of 1977, as amended, and those enacted to implement the OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions. Coherus acknowledges that Licensee has provided to Coherus prior to the Effective Date copies of the following Licensee policies: (a) International Anticorruption Policy, (b) International Anticorruption Third Party Policy and (c) Code of Conduct (collectively, as such may be amended from time to time in accordance with Licensee's customary practices, the **"Policies and Codes");**

(d) Licensee will use best efforts to ensure that, throughout the Term, it, its Affiliates, Sublicensees and agents comply with the Policies and Codes;

(e) At Coherus' reasonable request (including to permit Coherus to respond to inquiries regarding compliance with Applicable Laws), Licensee shall promptly provide to Coherus then-current copies of the Policies and Codes; and

(f) Licensee shall use best efforts to ensure that any Third Party who represents Licensee or its Affiliates in connection with, or who will be involved in performing, this Agreement or any related activity, shall certify to compliance with all applicable anti- corruption laws and the obligations set forth in the Policies and Codes prior to any involvement in this Agreement or any related activity.

9.4 Additional Covenants of the Parties. Each Party hereby covenants to the other Party that:

(a) if, during the Term, such Party has reason to believe that it or any of its employees, officers, subcontractors, or consultants rendering services relating to the Product: (a) is or will be debarred, excluded under any United States federal healthcare programs or convicted of a crime under 21 U.S.C. Section 335a or the foreign equivalent thereof, or (b) is or will be under indictment under any such provision, then such Party shall immediately notify the other Party in writing;

(b) all of such Party's employees and officers involved in development of the Product shall be obligated to assign to such Party all Inventions and to maintain as confidential any and all Confidential Information; and

(c) it shall, in performing the activities contemplated to be performed by it under this Agreement, including those in connection with the Development, Process Development, Manufacturing and Commercialization, and shall ensure that each of its Affiliates, subcontractors and agents shall, comply with all Applicable Laws.

9.5 Covenant Not to Challenge Patents. Licensee hereby covenants: (a) not to challenge the validity, scope, or enforceability of or otherwise oppose any Patent or Patent Application included in the Coherus Patent Rights or any foreign counterparts thereof; (b) that it shall include in all of its sublicense agreements relating to the Product the obligation binding on the Sublicensee under such sublicense agreement not to challenge the validity, scope, or enforceability of or otherwise oppose any such Patent or Patent Application; (c) that it shall include provisions in all sublicense agreements relating to the Product providing that, if the Sublicensee challenges the validity, scope, or enforceability of or otherwise opposes any such Patent or Patent Application, Licensee shall have the right to terminate such sublicense agreement, and such Sublicensee shall no longer have any rights under any such Patent or Patent Application. In the event that all or any portion of this **Section 9.5** is determined to be invalid, illegal, or unenforceable, then the Parties will use their best efforts to replace the invalid, illegal, or unenforceable provision(s) with valid, legal, and enforceable provision(s).

10. INDEMNIFICATION AND INSURANCE.

10.1 Coherus' Right to Indemnification. Licensee shall indemnify, defend, and hold harmless Coherus and its Affiliates, and their respective officers, directors, employees, agents, and their respective successors, heirs and assigns and representatives (the **"Coherus Indemnitees"**), from and against any and all damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney's fees), or judgments, whether for money or equitable relief, of any kind (**"Damages"**) resulting from Third Party claims or actions, to the extent arising out of or relating to, directly or indirectly: (a) the negligence, recklessness, or wrongful intentional acts or omissions of Licensee, its Affiliates, and/or its Sublicensees and its or their respective directors, officers, employees, and agents, in connection with Licensee's performance of its obligations or exercise of its rights under this Agreement; (b) any breach by Licensee of any obligation, representation, warranty, or covenant set forth in this Agreement; (c) the Development, Commercialization, transfer, importation or exportation, labeling, handling or storage, or use of, or exposure to, the Product by or for Licensee or any of its Affiliates, Sublicensees, agents, and contractors in the Territory; and (d) the failure by Licensee, or any of its Affiliates, Sublicensees, agents, or subcontractors to comply with Applicable Laws or the failure of Licensee, or any of its Affiliates, Sublicensees, agents, or subcontractors to materially comply with the Policies and Codes then in effect; except in any such case for Damages to the extent reasonably attributable to any Coherus Indemnitee: (i) having committed an act or acts of negligence, recklessness, or willful misconduct; (ii) having failed to materially comply with Applicable Laws; (iii) having materially breached this Agreement; or (iv) to the extent such Damages result from or arise out of any act or omission for which Coherus is found to have an indemnity obligation under **Section 10.2 (Licensee's Right to Indemnification)**.

10.2 Licensee's Right to Indemnification. Coherus shall indemnify, defend, and hold harmless Licensee and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns and representatives (the **"Licensee Indemnitees"**), from and against any and all Damages resulting from Third Party claims or actions, to the extent arising out of or relating to, directly or indirectly: (a) the negligence, recklessness, or wrongful intentional acts or omissions of Coherus and its Affiliates and its or their respective directors, officers, employees, and agents, in connection with Coherus' performance of its obligations or exercise of its rights under this Agreement; (b) any breach by Coherus of any obligation, representation, warranty, or covenant set forth in this Agreement; (c) the development (including Development), commercialization, transfer, importation or exportation, Manufacture, labeling, handling or storage, or use of, or exposure to, the Product by Coherus or any of its Affiliates, Sublicensees, agents, and contractors outside of the Territory; (d) [***] by Coherus or any of its Affiliates, sublicensees, agents, and contractors inside or outside of the Territory, and (e) the failure to comply with Applicable Laws by Coherus, or any of its Affiliates, agents, or subcontractors; except in any such case for Damages to the extent reasonably attributable to any Licensee Indemnitee (i) having committed an act or acts of negligence, recklessness or willful misconduct; (ii) having failed to materially comply with Applicable Laws; (iii) having materially breached this Agreement; or (iv) to the extent such Damages result from or arise out of any act or omission for which Licensee is found to have an indemnity obligation under **Section 10.1 (Coherus' Right to Indemnification)**.

10.3 Process for Indemnification. A claim to which indemnification applies under **Section 10.1 (Coherus' Right to Indemnification)** or **Section 10.2 (Licensee's Right to Indemnification)** shall be referred to herein as an **"Indemnification Claim"**. If a party intends to claim indemnification under **Section 10.1** or **Section 10.2**, such Party (the **"Indemnitee"**) shall notify the other Party (the **"Indemnitor"**) in writing promptly upon becoming aware of any claim that may be an Indemnification Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice shall not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor shall have the right to assume and control the defense of the Indemnification Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; *provided, however*, that the Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of the Indemnification Claim as described in this **Section 10.3** above, the Indemnitee may defend the Indemnification Claim but shall have no obligation to do so. The Indemnitee shall not settle or compromise the Indemnification Claim without the prior written consent of the Indemnitor, and the Indemnitor shall not settle or compromise the Indemnification Claim in any manner that may have an adverse effect on the Indemnitee's interests, without the prior written consent of the Indemnitee, which consent, in each case, shall not be unreasonably withheld, delayed, or conditioned. The Indemnitee shall reasonably cooperate with the Indemnitor at the Indemnitor's expense and shall make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information shall be subject to **Article 11 (CONFIDENTIALITY)**.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

10.4 Insurance. During the Term and for five (5) years thereafter, each Party shall maintain, at its sole expense, such types of insurance coverage as is appropriate and customary in the biopharmaceutical industry in light of the nature of the activities to be performed by such Party hereunder; *provided, however,* that Licensee shall have the right to self-insure. Such insurance shall be in such amounts and subject to such deductibles as are prevailing in the biosimilar industry from time to time, provided that, each Party shall maintain a minimum of an aggregate of [***] and [***] in general comprehensive liability insurance and an aggregate of:

(a) [***] in product liability insurance until receipt of the first Regulatory Approval in a country in the Territory; and (b) [***] in product liability insurance (or such other amount as is mutually agreed upon by the Parties) no later than thirty (30) days following receipt of the first Regulatory Approval in a country in the Territory.

11. CONFIDENTIALITY.

11.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this **Article 11** or otherwise agreed in writing, each Party hereby agrees that, during the Term and for five (5) years thereafter, it shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as explicitly provided for in this Agreement any confidential and proprietary information or materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed to it by the other Party or otherwise received or accessed by a Party under this Agreement [***], including any trade secrets, know-how, Product specifications, formulae, processes, techniques and information relating to a Party's past, present and future marketing, financial, and research and development activities for any product of the other Party and the pricing thereof (collectively, **"Confidential Information"**). Notwithstanding the foregoing, any Confidential Information that constitutes a trade secret shall not be subject to such five (5) year term, but shall continue to be subject to the obligations of confidentiality and non-use set forth in this Agreement for as long as such Confidential Information remains a trade secret under New York law (including New York's version of the Uniform Trade Secrets Act if and when adopted). The terms and conditions of this Agreement shall be deemed to be Confidential Information of each Party. In addition, and notwithstanding the foregoing, if, under **Article 8 (INTELLECTUAL PROPERTY AND INVENTIONS)**, Information relating specifically to Inventions and discoveries are to be owned by one Party, such Information shall be deemed to be Confidential Information of such Party, even if such Information is initially generated and disclosed by the other Party. Notwithstanding the foregoing, Confidential Information shall not include that portion of Information or materials that a Party can demonstrate by contemporaneous written records:

(a) is already lawfully known to such Party, other than under an obligation of confidentiality at the time of disclosure by the other Party as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by such Party;

(b) is generally available to the public or otherwise part of the public domain at the time of its disclosure to such Party;

(c) becomes generally available to the public or otherwise part of the public domain after its disclosure to such Party and other than through any act or omission of such Party or its Affiliates in violation of this Agreement;

(d) is independently developed by such Party as demonstrated by documented evidence prepared contemporaneously with such independent development; or

(e) is lawfully disclosed to such Party, other than under an obligation of confidentiality, by a Third Party who had no obligation not to disclose such information to others.

11.2 Degree of Care; Permitted Use. Each Party shall take reasonable steps to maintain the confidentiality of the Confidential Information of the other Party, which steps shall be no less protective than those steps that such Party takes to protect its own Information and materials of a similar nature, but in no event less than a reasonable degree of care. Neither Party shall use or permit the use of any Confidential Information of the other Party except for the purposes of carrying out its obligations or exercising its rights under this Agreement, and neither Party shall copy any Confidential Information of the other Party except as may be reasonably useful or necessary for such purposes. All Confidential Information of a Party, including all copies and derivations thereof, is and shall remain the sole and exclusive property of the disclosing Party and subject to the restrictions provided for herein. Neither Party shall disclose any Confidential Information of the other Party other than to [***].

11.3 Authorized Disclosure. Notwithstanding **Section 11.1 (Confidentiality; Exceptions)** and **Section 11.2 (Degree of Care; Permitted Use)**, each Party may disclose Confidential Information of other Party:

(a) in its publicly-filed financial statements or other public statements to the extent required by Applicable Laws; *provided, however,*, that: [***];

(b) to the extent it is required to be disclosed in response to a valid order by a court or other governmental body and provided that [***];

(c) to the extent it is required to be disclosed in connection with any legal or regulatory requirements or obligations, including SEC filings or Regulatory Filings inside or outside the Territory; *provided, however,* [***];

(d) to Regulatory Authorities to facilitate the issuance of Regulatory Approvals or receipt of Pricing and Reimbursement Approvals inside or outside the Territory; *provided, however,* that reasonable measures shall be taken to assure confidential treatment of such Confidential Information;

(e) **[***]**

(f) to Third Parties in connection with such Party's efforts to secure financing or enter into strategic partnerships; *provided, however,* [***].

11.4 Publications.

(a) In the event either Party proposes a publication or presentation to a Third Party that includes Confidential Information of the other Party relating to the Product in the Territory, or which otherwise includes Confidential Information of the other Party, such Party shall first submit to [***] an early draft of such publication or presentation, whether they are to be presented orally or in written form, prior to submission for publication or presentation. [***] shall review such proposed publication or presentation in order to avoid the unauthorized disclosure of its Confidential Information and to preserve the patentability of Inventions and shall, as soon as reasonably possible, inform such Party if its proposed publication or presentation:

(i) contains Confidential Information of the other Party, in which case such Party shall delete such Confidential Information from its proposed publication or presentation; or

(ii) could be expected to have a material adverse effect on any Patent or Information of the other Party, then such Party shall delay such proposed publication or presentation sufficiently long to permit the timely preparation and first filing of Patent Application(s) on the Information involved.

(b) This **Section 11.4** shall not apply to any disclosures pursuant to **Section 11.3 (Authorized Disclosure)**.

11.5 Press Releases; Publicity. Except with respect to (i) the press release which will be attached hereto as Exhibit 11.5 (which shall be issued by the Parties at a mutually agreed upon time following execution of this Agreement), and (ii) the matters listed in Exhibit 11.5A which Coherus may disclose to potential investors, collaboration partners, and underwriters on a non- confidential basis, no press release or public announcement shall be made by either Party concerning the execution of this Agreement or the terms and conditions hereof without [***]. Notwithstanding the foregoing, either Party may disclose the existence of this Agreement and the terms and conditions hereof without the prior written consent of the other in connection with a due diligence process associated with any future financing by either Party or the negotiation or exploration of a possible strategic transaction involving such Party; provided that such disclosure is made in the course of such diligence, negotiation or exploration pursuant to confidentiality obligations consistent with those set forth in this Agreement. Each Party may issue a press release or public announcement concerning the development of the Product, provided that such Party shall provide the other Party with a copy of such press release or public announcement at least ten (10) days in advance of its intended publication or release thereof and shall consider in good faith the comments of the other Party which comments shall be provided as promptly as reasonably practicable following receipt of the press release or public announcement from the Party desiring to make the disclosure. Further, each Party agrees that it shall cooperate fully and in a timely manner with the other Party with respect to all disclosures required by the Securities and Exchange Commission of the United States and any other Regulatory Authority, including requests for confidential treatment of Confidential Information of either Party included in any such disclosure. Notwithstanding the foregoing, either Party may issue any public announcement that it is advised by legal counsel is required under applicable Laws, provided that such Party provides to the other Party a copy of such press release or public announcement not less than two (2) business days in advance of its release if legally permissible. In the event [***] wishes to

disclose information in its non-confidential discussions with potential investors, partners and underwriters which is not [***], [***] shall seek [***] written consent for such disclosure and [***] shall consider [***] request in good faith, such consent not to be unreasonably withheld, conditioned or delayed.

11.6 Irreparable Injury. The Parties acknowledge that either Party's breach of this **Article 11** would cause the other Party irreparable injury for which it would not have an adequate remedy at law. In the event of a breach, the nonbreaching Party may seek injunctive relief, whether preliminary or permanent, in addition to any other remedies it may have at law or in equity, without necessity of posting a bond.

12. TERM AND TERMINATION.

12.1 Term. The term of this Agreement shall commence on the Effective Date and, unless sooner terminated or extended as specifically provided in this **Article 12**, shall continue in effect until the tenth (10th) anniversary of the Effective Date (the **"Initial Term"**).

12.2 Extension of Term. If this Agreement has not been earlier terminated with respect to a particular country in the Territory during the Term (including any renewal Periods), the Term for each such non-terminated country shall, at Licensee's discretion, be extended for an additional period of three (3) years (each, a **"Renewal Period"** and, together with the Initial Term, the **"Term"**); *provided, however,* that the JSC has approved the Commercialization Plan for the applicable country/ies in the six (6) months immediately preceding the tenth (10th) anniversary of the Effective Date or in the six (6) months immediately preceding the last day of the third year of a Renewal Period.

12.3 Termination by Licensee.

(a) Opt Out Termination. Licensee shall have the right to terminate this Agreement (in its entirety or on a country-by-country basis as set forth below) by providing written notice to Coherus during the applicable window noted below if Licensee concludes in good faith that: (1) the Development and/or Commercialization in the Territory or such country in the Territory, as applicable, is not commercially viable, and/or (2) there are material safety, efficacy or patient tolerability issues with the Product that cannot be remedied or overcome as follows:

(i) Solely with respect to the entire Territory, within the Product Opt- Out Period; or

(ii) Solely with respect to the entire Territory, within three (3) months following the later to occur of receipt by Licensee of the Clinical Study Report for (A) the Global RA Study and (B) the Global Psoriasis Study; or

(iii) With respect to one or more countries in the Territory, within one (1) month following submission by Licensee of the Regulatory Approval Application for the Product in such country/ies; or

(iv) With respect to one or more countries in the Territory, within ten (10) days following the later to occur of: (A) receipt of Regulatory Approval (if such approval does not include Pricing and Reimbursement Approvals) or (B) receipt of Pricing and Reimbursement Approvals of the Product in such country/ies; or

(v) Licensee shall have the right to terminate this Agreement (in its entirety or with respect to a country within the Territory, as applicable) following the occurrence of each milestone.

For the avoidance of doubt, the provisions of **Section 2.4** allowing Licensee to consider alternative programs during the Initial and/or Second Review Periods shall survive termination of this Agreement.

(b) Other Licensee Termination. Licensee shall also have the right to terminate this Agreement in its entirety, in its sole discretion, as follows:

(i) After First Commercial Sale in the Territory, without cause upon eighteen (18) months prior written notice to Coherus; or

(ii) At any time if the aggregate expenses for which Licensee is responsible for the **Global RA Study** and **Clinical Trials** are reasonably expected to exceed [***]; or

(iii) At any time if the aggregate expenses for which Licensee is responsible for **Process Development and Manufacture Supporting Clinical Trials and Launch** are reasonably expected to exceed [***]; or

(iv) If by [***], the Manufacturing Cost exceeds [***] for one (1) filled, finished, released, labeled dosage form [***]; *provided, however,* such Manufacturing Cost shall be adjusted each January 1 occurring after the Effective Date [***]; or

(v) If by [***], the Manufacturing Cost exceeds [***] for one (1) filled, finished, released, labeled dosage form [***]; *provided, however,* such Manufacturing Cost shall be adjusted each January 1 occurring after the Effective Date [***].

12.4 Termination by Coherus. Coherus shall have the right to terminate this Agreement immediately upon written notice to Licensee in the event that Licensee or any of its Affiliates challenges in a court of competent jurisdiction, the validity, scope or enforceability of, or otherwise opposes, any Patent included in the Coherus Patent Rights. If a Sublicensee of Licensee or its Affiliate challenges the validity, scope or enforceability of or otherwise opposes any Patent included in the Coherus Patent Rights under which such Sublicensee is sublicensed, then Licensee or its Affiliate, as applicable, shall provide written notice to Coherus and shall promptly terminate the sublicense agreement but, for the avoidance of doubt, such challenge by a Sublicensee, unless directed by Licensee, shall not be grounds for termination of this Agreement by Coherus.

12.5 Termination for Material Breach. If either Party believes the other Party is in material breach of this Agreement (which shall include any breach of any payment obligation hereunder), it shall give notice of such breach to such other Party, and such other Party shall have

ninety (90) days in which to remedy any such material breach, or ten (10) Business Days in the case of breach (whether material or not) of any payment obligation hereunder. If such alleged breach is not remedied in the time period set forth above, the nonbreaching Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement upon written notice to the other Party. In the event of a dispute regarding any payments due and owing hereunder, all undisputed amounts shall be paid when due, and the balance, if any, shall be paid promptly after settlement of the dispute, including any accrued interest thereon pursuant to **Section 7.9**. Subject to foregoing (including the right to cure), if Licensee does not materially comply with the obligations set forth in **Section 6.1 (Efforts)** with respect to Commercialization in each of the Major EU Countries, Canada, Brazil, China and Australia, Coherus shall have the right to terminate the Agreement with respect to such country, and **Section 12.7 (Consequences of Expiration or Termination)** shall apply with respect to the Product in such terminated country.

12.6 Termination Upon Insolvency. To the extent permitted under Applicable Laws, either Party may terminate this Agreement if, at any time, the other Party: (a) files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, (b) proposes a written agreement of composition or extension of its debts, (c) is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within forty-five (45) days after the filing thereof, (d) proposes or is a party to any dissolution or liquidation, or (e) makes an assignment for the benefit of its creditors.

12.7 Consequences of Expiration or Termination.

(a) Consequences of Termination of this Agreement with Respect to One or More Country(ies) but Not in the Entire Territory. Upon early termination of this Agreement by Licensee pursuant to **Section 12.3 (Termination by Licensee)** or by Coherus pursuant to **Section 12.5 (Termination for Material Breach)** with respect to a country (but not all countries in a Territory):

(i) the licenses granted to Licensee pursuant to **Section 2.1 (License Grants)** and **Section 6.3 (Trademarks)** with respect to the Product shall terminate in such terminated country, except as otherwise necessary to conduct the activities expressly set forth in **Section 12.7(a)(ii)**;

(ii) promptly after the effective date of such termination, Licensee shall commence winding down its Development and Commercialization activities for such country under the oversight of the JSC, and shall complete any and all such wind-down Development and Commercialization activities within three (3) months after the effective date of such termination;

(iii) Licensee shall and hereby does grant to Coherus, effective as of the effective date of such termination, the exclusive, perpetual, royalty-free, irrevocable license (with full rights to grant sublicenses through multiple tiers), under any Grant-Back IP to develop, make, have made, use, sell, offer to sell, have sold and import the Product in such country;

(iv) Licensee shall and hereby does assign, at its cost, and shall cause its Affiliates (as applicable) to assign, to Coherus, effective as of the effective date of such termination, all of Licensee's (or its Affiliate's) rights, title and interests in and to the Product Trademark and all relevant trademark applications and registrations with respect thereto in such terminated country. Each Party shall execute and deliver or shall cause its Affiliates (as applicable) to execute and deliver to the other Party all documents that are necessary to fulfill the obligations set forth in this **Section 12.7(a)(iv)**;

(v) Licensee shall assign to Coherus or Coherus' designee its entire right in all clinical and related study data based on use or research on such Product and all Regulatory Filings and Regulatory Approvals relating to such Product in the terminated country, and shall provide reasonable assistance to Coherus or its designee to allow such party to become the holder of such Regulatory Approvals; and

(vi) Licensee shall promptly notify Coherus of any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Commercialization activities for any and all countries terminated. At Coherus' request, which request shall be made within three (3) months after the termination of this Agreement with respect to a country, Licensee shall utilize Commercially Reasonable Efforts to assign (or cause its Affiliates to assign) to Coherus, and Coherus shall have the right, but not the obligation, to assume, any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Commercialization activities in such terminated country, including agreements with CROs, clinical sites and investigators, that relate to Clinical Trials in support of Regulatory Approvals in such country(ies), unless such agreement: (A) expressly prohibits such assignment, (B) covers clinical trials for products in addition to the Product, or (C) covers the Product in a country or countries in respect of which this Agreement has not been terminated. In all cases (A)–(C), Licensee shall cooperate with Coherus in all reasonable respects to facilitate the execution of a new agreement between the Coherus and the Third Party.

(b) Consequences of Expiration or Certain Terminations of this Agreement in its Entirety. Upon expiration of this Agreement under **Section 12.1 (Term),** or early termination of this Agreement in its entirety by Licensee pursuant to **Section 12.3 (Termination by Licensee),** by Coherus pursuant to **Section 12.4 (Termination by Coherus),** by Coherus pursuant to **Section 12.5 (Termination for Material Breach),** or by Coherus pursuant to **Section 12.6 (Termination upon Insolvency):**

(i) the licenses granted to Licensee pursuant to **Section 2.1 (License Grants)** and **Section 6.3 (Trademarks)** shall terminate, except as otherwise necessary to conduct the activities expressly set forth in this **Section 12.7(b)**;

(ii) Licensee shall return to Coherus within three (3) months of the effective date of such expiration or termination (or certify the destruction of) any and all Coherus Know-How or Confidential Information of Coherus transferred to Licensee under this Agreement;

(iii) promptly after the effective date of such termination or expiration, Licensee shall commence winding down its Development and Commercialization activities under

the oversight of the JSC, and shall use best efforts to complete any and all such Development and Commercialization activities within three (3) months after the effective date of such termination or expiration;

(iv) Licensee shall and hereby does grant to Coherus, effective as of the effective date of such termination or expiration, the exclusive, worldwide, perpetual, royalty- free, irrevocable license (with full rights to grant sublicenses through multiple tiers), under any Grant-Back IP, to develop, make, have made, use, sell, offer to sell, have sold and import the Product in or for the Territory;

(v) Licensee shall and hereby does assign, at its cost, and shall cause its Affiliates (as applicable) to assign, to Coherus, effective as of the effective date of such termination or expiration, all of Licensee's (or its Affiliate's) rights, title and interests in and to any and all Product Trademarks and all relevant trademark applications and registrations with respect thereto. Each Party shall execute and deliver or shall cause its Affiliates (as applicable) to execute and deliver to the other Party all documents that are necessary to fulfill the obligations set forth in this **Section 12.7(b)(v)**;

(vi) Licensee shall assign to Coherus or Coherus' designee its entire right in all clinical and related study data based on use or research on the Product and all Regulatory Filings and Regulatory Approvals, and shall provide reasonable assistance to Coherus or its designee to allow such party to become the holder of such Regulatory Filings or Regulatory Approvals; and

(vii) Licensee shall promptly notify Coherus of any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Commercialization activities. At Coherus' request, which request shall be made within three (3) months after the expiration or termination of this Agreement, Licensee shall utilize Commercially Reasonable Efforts to assign (or cause its Affiliates to assign) to Coherus, and Coherus shall have the right, but not the obligation, to assume, any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Commercialization activities, including agreements with CROs, clinical sites and investigators, that relate to Clinical Trials in support of Regulatory Approvals, unless such agreement: (A) expressly prohibits such assignment, or (B) covers clinical trials for products in addition to the Product. In both cases (A) and (B), Licensee shall cooperate with Coherus in all reasonable respects to facilitate the execution of a new agreement between the Coherus and the Third Party.

(c) Consequences of Certain Terminations of this Agreement in its Entirety by Licensee. Upon early termination of this Agreement by Licensee pursuant to **Section 12.5 (Termination for Material Breach),** or by Licensee pursuant to **Section 12.6 (Termination upon Insolvency).**

(i) the licenses granted to Coherus pursuant to **Section 2.1 (License Grants)** shall terminate;

(ii) Coherus shall return to Licensee within three (3) months of the effective date of such termination (or certify the destruction of) any and all Licensee Know-How or Confidential Information of Licensee transferred to Coherus under this Agreement; and

(iii) Coherus shall promptly notify Licensee of any and all agreements between Coherus (and/or its Affiliates) and Third Parties to whom any sublicenses were granted and shall confirm to Licensee that all such sublicenses were terminated as of the effective date of such termination.

(d) For eighteen (18) months following early termination of this Agreement, whether in its entirety or as to one or more countries in the Territory, Licensee may not commercialize in the terminated country(ies) any product that is a biosimilar (or biobetter) of the reference drug for the Product; *provided, however,* this **Section 12.7(c)** shall not apply if Licensee terminates this Agreement under **Section 12.5 (Termination for Material Breach).**

(e) Expiration or termination of this Agreement for any reason shall not: (i) release any Party from any obligation that has accrued prior to the effective date of such expiration or termination (including the obligation to pay amounts accrued and due under this Agreement prior to the effective date of such expiration or termination but that are unpaid or become payable thereafter (including any payments then accrued because the event has occurred but the payment is not yet due)), (ii) preclude any Party from claiming any other damages, compensation, or relief that it may be entitled to upon such expiration or termination, or (iii) terminate any right to obtain performance of any obligation provided for in this Agreement that shall survive expiration or termination

12.8 General Surviving Obligations. The rights and obligations set forth in this Agreement shall extend beyond the expiration or termination of this Agreement only to the extent expressly provided for herein, or to the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. In the event of expiration or termination of this Agreement for any reason, the following provisions shall survive in addition to others specified in this Agreement to survive in such event: **Articles 1, 9, 10, 13 and 14 and Sections 8.3, 8.4, 8.5, 8.6, 8.7 , 11.1, 11.2, 11.3, 12.7, 12.8, 15.5, 15.7, 15.11 15.13 and 15.16.**

13. LIMITATION OF LIABILITY; DISCLAIMER OF WARRANTY.

13.1 LIMITATION OF LIABILITY. EXCEPT IN THE CASE OF A BREACH OF **ARTICLE 11 (CONFIDENTIALITY)**, AND WITHOUT LIMITING THE PARTIES' OBLIGATIONS UNDER **ARTICLE 10 (INDEMNIFICATION AND INSURANCE)**, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS, OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER.

13.2 DISCLAIMER OF WARRANTY. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY PROVIDES ANY WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, REGARDING PRODUCT USED IN PRECLINICAL STUDIES OR CLINICAL TRIALS OR FOR COMMERCIAL USE, AND EACH

PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS AND IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND FREEDOM FROM INFRINGEMENT OF THIRD PARTY RIGHTS.

14. DISPUTE RESOLUTION.

14.1 Exclusive Dispute Resolution Mechanism. In the event that the Parties cannot reach agreement on a matter arising out of or in connection with this Agreement and any other agreement entered into pursuant hereto or in connection herewith (including matters relating to any Party's rights and/or obligations hereunder and/or regarding the construction, interpretation, and enforceability of such agreements), the procedures set forth in this **Article 14** shall be the exclusive mechanism for resolving any dispute, controversy, or claim in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party under this Agreement (collectively, **"Disputes"**) between the Parties or the JSC that may arise from time to time that cannot be resolved through good faith negotiation between the Parties, except as set forth in **Section 14.4 (Preliminary Injunctions)** and/or **Section 14.5 (Patent Disputes)** or unless otherwise set forth herein.

14.2 Resolution by Executive Officers. Except as otherwise provided in this Agreement, in the event of any Dispute, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within ten (10) Business Days after one Party provides notice to the other Party of such Dispute, either Party may, by written notice to the other Party, refer such Dispute to the Executive Officers for attempted resolution by good faith negotiation within thirty (30) days after such notice is received. In the event that any Dispute is not resolved under the foregoing provisions, each Party may, at its sole discretion, seek resolution of such Dispute in accordance with **Article 3 (GOVERNANCE)** or **Section 14.3 (Arbitration)**, as applicable.

14.3 Mediation; Arbitration.

(a) Except as set forth in **Section 14.4 (Preliminary Injunctions)** and/or **Section 14.5 (Patent Disputes),** or unless otherwise set forth herein, any Dispute that is not resolved pursuant to **Section 14.2 (Resolution by Executive Officers)** shall be submitted to the International Institute for Conflict Prevention & Resolution (**"CPR"**) for mediation, and if the matter is not resolved through mediation, then it shall be submitted to CPR for exclusive, final and binding arbitration pursuant to this **Section 14.3**.

(b) Any such mediation or arbitration shall be conducted in New York, New York, United States of America, unless otherwise agreed to by the Parties in writing. Each and any arbitration shall be administered by CPR pursuant to its Arbitration Rules and Procedures (the "**Rules**"), as such Rules may be amended from time to time, or modified by this **Section 14.3** or by agreement of the Parties. At any applicable hearing, the Parties may present testimony (either by live witness or deposition) and documentary evidence and have the right to be represented by counsel. The U.S. Federal Rules of Evidence will apply to any and all matters submitted to final and binding arbitration under this Agreement.

(c) Within ten (10) days after receipt of an arbitration notice from a Party, the Parties shall attempt in good faith to agree on a single neutral arbitrator with relevant industry experience to conduct such arbitration. If the Parties do not agree on a single neutral arbitrator within ten (10) days after receipt of an arbitration notice, each Party shall select one (1) arbitrator and the two (2) Party-selected arbitrators shall select a third arbitrator with relevant industry experience to constitute a panel of three (3) arbitrators to conduct the arbitration in accordance with the Rules. In the event that only one of the Parties selects an arbitrator, then such arbitrator shall be entitled to act as the sole arbitrator to resolve the Dispute or any and all unresolved issues subject to such arbitration. Each and every arbitrator of the arbitration panel conducting the arbitration must and shall agree to render an opinion within thirty (30) days after the final hearing before the panel.

(d) The decision or award of the arbitrator(s) shall be final, binding, and incontestable and may be used as a basis for judgment thereon in any jurisdiction. The arbitrator(s) shall, upon the request of any Party, issue a written opinion of the findings of fact and conclusions of law and shall deliver a copy to each of the Parties. Each Party shall bear its own costs and attorney's fees, and the Parties shall equally bear the fees, costs, and expenses of the arbitrator(s) and the arbitration proceedings; *provided, however*, that the arbitrator(s) may exercise discretion to award costs, including attorney's fees, to the prevailing Party. Without limiting any other remedies that may be available under Applicable Laws, the arbitrator(s) shall have no authority to award provisional remedies of any nature whatsoever, or special, indirect, incidental, punitive, consequential, or any other similar form of damages (including damages resulting from loss of use, loss of profits, interruption or loss of business, or other economic loss).

14.4 Preliminary Injunctions. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction as provided in **Section 15.12 (Governing Law; Jurisdiction)** in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any Dispute.

14.5 Patent Disputes. Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, and enforceability of any Patent or Patent Application in a country within the Territory shall be determined in a court or other governmental authority of competent jurisdiction under the applicable patent laws of such country, as provided in **Section 15.12 (Governing Law; Jurisdiction)**.

14.6 Confidentiality. All proceedings and decisions of the arbitrator(s) shall be deemed to be Confidential Information of each of the Parties, and shall be subject to **Article 11 (CONFIDENTIALITY)**.

15. MISCELLANEOUS.

15.1 Agency. Neither Party is, nor shall be deemed to be, an employee, agent, co- venturer, or legal representative of the other Party for any purpose. Neither Party shall be entitled to enter into any contracts in the name of, or on behalf of the other Party, nor shall either Party be entitled to pledge the credit of the other Party in any way or hold itself out as having the authority to do so.

15.2 Performance by Affiliates. The Parties recognize that each Party may perform some or all of its obligations under this Agreement through Affiliates; *provided, however*, that each Party shall remain responsible for the performance of its Affiliates and shall course its Affiliates to comply with the provisions of this Agreement in connection with such performance.

15.3 Assignment. Neither Party shall have the right to assign this Agreement or any obligation of such Party hereunder without the prior written consent of the other Party, which shall not be unreasonably withheld, delayed, or conditioned, except that a Party may assign this Agreement and the rights, obligations, and interests of such Party: (a) in whole or in part, to any of its Affiliates, (b) to any purchaser of all or substantially all of its assets to which this Agreement relates, or (c) to any successor corporation resulting from any merger, consolidation, share exchange, or other similar transaction. This Agreement shall be binding upon and inure to the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this **Section 15.3** shall be void. Notwithstanding anything to the contrary in this Agreement, in the event of any such assignment, the intellectual property rights of the acquiring party (if other than one of the Parties to this Agreement) shall not be included in the intellectual property rights licensed to the other Party hereunder to the extent held by such acquirer prior to such transaction, or to the extent such intellectual property rights are developed outside the scope of activities conducted with respect to the Product.

15.4 Further Actions. Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.5 Non-Solicitation. While the Parties are performing Development and/or Commercialization activities under this Agreement and for a period of eighteen (18) months thereafter, neither Party shall, without the express written consent of the other Party, recruit, solicit, or induce any employee of the other Party who has performed activities under this Agreement to terminate his or her employment with such other Party. The foregoing provision shall not, however, restrict either Party or its Affiliates from advertising employment opportunities in any manner that does not directly target the other Party or its Affiliates or from hiring any persons who respond to such generalized public advertisements.

15.6 Force Majeure. Neither Party shall be liable to the other for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by epidemic, earthquake, riot, civil commotion, rebellion, insurrection, invasion, fire, acts of God, war, terrorist acts, strike, storm, flood, or governmental acts or restriction, or other cause that is beyond the reasonable control of the respective Party. The Party affected by such force majeure shall provide the other Party with all information relating thereto (including its best estimate of the likely extent and duration of the interference with its activities) as soon as reasonably and practically possible after its occurrence, and shall use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. In such event, the Parties shall meet promptly to determine an equitable solution to the effects of any such event, including the possibility of the termination of this Agreement pursuant to **Section 12.5 (Termination for Material Breach)**. Notwithstanding the foregoing, nothing in this **Section 15.6**

shall excuse or suspend the obligation to make any payment due hereunder in the manner and at the time provided.

15.7 Notices. All notices and other communications hereunder shall be in writing and shall be deemed given: (a) if delivered personally or by facsimile transmission (receipt verified), (b) five (5) days after mailed by registered or certified mail (return receipt requested), postage prepaid, or (c) three (3) days after sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; *provided, however,* that notices of a change of address shall be effective only upon receipt thereof):

If to Licensee, addressed to:

Baxter Healthcare SA
Postfach
8010 Zurich
Switzerland
Attn: Legal Department
Fax: +41 44 878 6520

and

Baxter Healthcare Corporation
1 Baxter Parkway
Deerfield, IL 60015
Attn: General Counsel
Fax: (224) 948-3441

If to Coherus, addressed to:

Coherus Biosciences, Inc.
201 Redwood Shores Parkway, Suite 200
Redwood City, CA, USA 94065
Attn: Dennis M. Lanfear
Fax: (866) 491-7350

With copies to:

Latham & Watkins LLP
140 Scott Drive
Menlo Park, CA 94062
Attn: Alan C. Mendelson
Fax: 650-463-2600

Latham & Watkins LLP
12636 High Bluff Drive, Suite 400
San Diego, CA 92130
Attn: Faye H. Russell
Fax: 858-523-5450

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

15.8 Amendment. No amendment, modification, or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

15.9 Waiver. The waiver by either Party of any right hereunder or 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.

15.10 Counterparts; Electronic Delivery. This Agreement may be executed simultaneously in two counterparts, either one of which need not contain the signature of more than one Party but both such counterparts taken together shall constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

15.11 Construction. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement. 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. The term "including" or "includes" means "including without limitation" or "includes without limitation." 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.

15.12 Governing Law; Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New York, U.S.A., without regard to its or any other jurisdiction's choice of law rules. Any Disputes not subject to **Section 14.3 (Mediation; Arbitration)** shall be brought in the state or federal courts located in the State of New York, U.S.A., and the Parties irrevocably accept the exclusive jurisdiction of such courts solely and specifically for the purpose of adjudicating such Disputes, and in no event shall any Party be deemed to have consented to such jurisdiction for any other purpose. Each Party further agrees that such courts provide a convenient forum for any such action, and waives any objections or challenges to venue with respect to such courts.

15.13 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Laws, but, if any provision of this Agreement is held to be prohibited by or invalid under Applicable Laws, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.

15.14 Compliance with Applicable Laws. Each Party will comply with all Applicable Laws in performing its obligations and exercising its rights hereunder. Nothing in this Agreement shall be deemed to permit Licensee to export, re-export, or otherwise transfer any Information transferred hereunder or Product without complying with Applicable Laws.

15.15 No Re-Importation.

(a) Licensee will ensure that reasonable safeguards are put in place so that Product sold in the Territory is not, directly or indirectly, exported, or marketed, distributed, or sold, outside of the Territory. Licensee shall not, directly or indirectly, offer Product to any Third Party in a country within the Territory that Licensee knows is going to, directly or indirectly, export such Product, or market, distribute, or sell such Product, outside of the Territory. If Licensee becomes aware that any of its customers has, directly or indirectly, imported Product into, exported Product to, or marketed, distributed, or sold Product in, any country outside of the Territory, or has reason to believe that a customer intends to, directly or indirectly, import Product, export Product to, or market, distribute, or sell Product, outside of the Territory, Licensee shall take prompt and reasonable actions to cause such customer to cease such import, export, marketing, distribution, or sales activities; if such customer does not cease such activities, then Licensee shall immediately cease sale or distribution of any and all Product to such customer, unless prohibited by Applicable Laws.

(b) Coherus will ensure that reasonable safeguards are put in place so that Product sold outside the Territory is not, directly or indirectly, exported, or marketed, distributed, or sold, within the Territory. Coherus shall not, directly or indirectly, offer Product to any Third Party in a country outside the Territory that Coherus knows is going to, directly or indirectly, import such Product, or market, distribute, or sell such Product, within the Territory. If Coherus becomes aware that any of its customers or commercial partners has, directly or indirectly, imported Product into, exported Product to, or marketed, distributed, or sold Product in, any country in the Territory, or has reason to believe that a customer intends to, directly or indirectly, import Product, export Product to, or market, distribute, or sell Product, in the Territory, Coherus shall take prompt and reasonable actions to cause such customer or commercial partner to cease such import, export, marketing, distribution, or sales activities; if such customer does not cease such activities, then Coherus shall immediately cease sale or distribution of any and all Product to such customer or commercial partner, unless prohibited by Applicable Laws.

15.16 Entire Agreement of the Parties. This Agreement, including the exhibits attached hereto, constitutes and contains the complete, final and exclusive understanding and agreement of the Parties, and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings, and agreements, whether oral or written, between the Parties respecting the subject matter hereof, including the CDA, and neither Party shall be liable or bound to the other Party with respect to the subject matter of this Agreement in any manner by any representations, warranties, covenants, or agreements except as specifically set forth herein or therein. Nothing in this Agreement, express or implied, is intended to confer upon any party, other than the Parties and their respective successors and assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement. To the extent that anything set forth in an exhibit attached hereto conflicts with the terms of this Agreement, the terms of this Agreement shall prevail.

[Signature Page Follows]

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

COHERUS BIOSCIENCES, INC.

By: /s/ Dennis M. Lanfear

Name: Dennis M. Lanfear

Title: Chief Executive Officer

BAXTER INTERNATIONAL INC.

By: /s/ Ludwig N. Hantson

Name: Ludwig N. Hantson

Title: CVP/President BioScience

BAXTER HEALTHCARE CORPORATION

By: /s/ Ludwig N. Hantson

Name: Ludwig N. Hantson

Title: CVP/President BioScience

BAXTER HEALTHCARE SA

By: /s/ Yvo Aebli

Name: Yvo Aebli

Title: Finance Director

BAXTER HEALTHCARE SA

By: /s/ Benedikt Kubik

Name: Benedikt Kubik

Title: Finance Director

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 1.4 [***]

OPT-IN

For a period of [***] from the Effective Date, Licensee shall have the exclusive right to negotiate and enter into a definitive agreement with a Third Party relating to Commercialization of the Product in [***] in which a technology transfer of Coherus Know- How or other intellectual property rights of Coherus is contemplated (the **"[***] Agreement"**).

If, after such [***] period, Licensee has not entered into a [***] Agreement, Licensee and Coherus shall each have the right to pursue such a [***] Agreement.

In any case, during the period of time that Licensee is selling finished Product directly (or through an Affiliate or Sublicensee) in [***] such that Licensee (or such Affiliate) is booking sales of the Product, the Coherus Royalty for Net Sales in [***] shall be as set forth in **Exhibit 7.1 (Payment Structure).**

If either Party enters into a [***] Agreement, it shall provide written notice to the other Party within [***] thereafter. Coherus shall have [***] following delivery or receipt of such notice to elect to be responsible for a portion of the costs incurred in connection with the associated technology transfer as set forth below (the **"[***] Opt-In"**) by providing written notice to Licensee.

If Coherus notifies Licensee of its election of the [***] Opt-In, the Parties shall share both the costs incurred in connection with executing the technology transfer under the [***] Agreement and the financial payments received under the [***] Agreement in the following proportions:

(a) Licensee, [***] percent ([***]%); and
(b) Coherus, [***] percent ([***]%).

Following a [***] Opt-In, no Coherus Royalties shall be due on Net Sales in [***].

If Coherus does not notify Licensee of its election of the [***] Opt-In within the required period, Coherus shall receive [***] percent ([***]%) of any financial payments received by Licensee under the [***] Agreement and Licensee shall bear all costs incurred in connection with executing the technology transfer under the [***] Agreement.

For the avoidance of doubt, if Licensee enters into a [***] Agreement, Coherus shall be obligated to grant Licensee (or its designee or sublicensee) a license to all Coherus Know-How and Coherus Patent Rights that are necessary or useful to enable Licensee (whether by itself or through an Affiliate or sublicensee) to develop, make, have made, use, sell, offer to sell, have sold or import the Product in [***] (including the right to grant sublicenses therefor). Such license may be set forth in the MSA or in an amendment to this Agreement.

EXHIBIT 1.17

COHERUS PATENT RIGHTS

1. Patent Filings Owned by Coherus

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2. Patents Owned by [***], Licensed To Coherus.

(Note: [***] patents listed below are included within Coherus Patent Rights)

[***]

[***]

[***]

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 1.18

COHERUS TRADEMARKS

Coherus

EXHIBIT 1.30

DEVELOPMENT BUDGET

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 1.32

DEVELOPMENT PLAN TIMELINES AND ACTIVITIES

[***]:

[***]

[***]

[***]

[***]

[***]

[***]

[***]:

- [***]
- [***]
- [***]
- [***]
- [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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EXHIBIT 1.49

ILLUSTRATIVE DEVELOPMENT PLAN/BUDGET

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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EXHIBIT 1.53

INITIAL DEVELOPMENT ACTIVITIES

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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EXHIBIT 4.1(F)

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 5

MANUFACTURING AND SUPPLY BY COHERUS

Coherus will use Commercially Reasonable Efforts to execute a definitive agreement for the Manufacture and supply of Product for the Global Studies within ninety (90) days of the Effective Date.

Coherus will provide a draft of the Manufacturing and Supply Agreement to Licensee prior to execution and will reasonably consider Licensee's comments thereto.

Coherus will use Commercially Reasonable Efforts to supply Units, for Commercialization purposes to Licensee at Coherus' documented Manufacturing Cost [***]. Licensee will also be responsible for [***].

Coherus may Manufacture Units for commercialization outside the Territory using the Third Party manufacturer and/or Manufacturing facility licensed under Licensee's Regulatory Approval in the Territory, [***].

Contemporaneously with the execution of the Manufacturing and Supply Agreement, the Parties will execute a quality agreement in a mutually acceptable form.

The term of the Manufacturing and Supply Agreement shall be coincident with this Agreement

EXHIBIT 7.1

PAYMENT STRUCTURE

A. Upfront Payment.

1. In partial consideration for the rights granted to Licensee under this Agreement, Licensee shall pay to Coherus a one-time, non-refundable payment of Thirty Million Dollars ($30,000,000) within one (1) Business Day after the Effective Date by wire transfer of immediately available funds into an account designated in writing by Coherus. A portion of this Upfront Payment [***] as set forth in Section **2.4(e) (Product Opt-out).**

2. Following delivery of an Opt-Out Notice, [***] the Upfront Payment [***].

3. Following delivery of an Opt-Out Notice, if Licensee does not elect to enter into a ROFR Agreement within the Second Review Period, [***] the Upfront Payment [***].

B. Milestone Payments. In partial consideration for the rights granted to Licensee under this Agreement, the following one-time, non-refundable, non-creditable payments shall be due and payable upon the occurrence of the applicable event (**"Milestone Payment(s)"**), with each such payment to occur within fifteen (15) days of the occurrence of the applicable event by wire transfer of immediately available funds into an account designated in writing by Coherus:

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

[***]	[***]
[***]	[***]
[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 7.1
TABLE 2
CHS-0214 DRUG SUBSTANCE RELEASE SPECIFICATIONS

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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C. **EU Regulatory Approval Payments.** In partial consideration for the rights granted to Licensee under this Agreement, the following one-time, non-refundable, non-creditable payments shall be due and payable upon receipt of Regulatory Approval in the European Union (**"EU Regulatory Approval"**), as follows:

[***]

- **[***]**.
- **[***]**.
- **[***]**.
- **[***]**
  [***].
- [***].

By way of example, if the Product is [***], Coherus would receive [***]. If[***] the Product [***], Coherus would receive [***]. If[***], Coherus would receive [***].

Such EU Regulatory Approval Payments shall be paid by Licensee to Coherus within fifteen (15) days of the occurrence of the applicable event by wire transfer of immediately available funds into an account designated in writing by Coherus.

D. **Royalties on Net Sales; Third Party Payments.** In partial consideration for the rights granted to Licensee under this Agreement, including Patent and know-how licenses and other proprietary rights, Licensee shall pay Coherus non-refundable and non-creditable royalties as set forth in this **Section D**.

1. Licensee shall pay Coherus a royalty rate of [***] Net Sales in the Territory, on a country-by-country basis each Calendar Year, calculated in [***] on a country-by-country basis, in the applicable Calendar Quarter, as follows (the **"Coherus Royalty"**):

(a) [***]; and
(b) [***]; and
(c) [***].

2. Notwithstanding the foregoing, except in connection with the exercise by Coherus of the [***] Opt-In, Licensee shall pay Coherus a Coherus Royalty equal to [***] of Net Sales in [***].

3. In partial consideration for the rights granted to Licensee under this Agreement, including Patent and know-how licenses and other proprietary rights, Licensee shall [***]. In addition, Licensee may reduce the Coherus Royalty by an amount [***] or [***] to any other Third Party in consideration for [***] (payments to other Third Parties shall be referred to as the **"Third Party Payments"**) which [***] is either necessary or commercially reasonable to Develop, Manufacture, or Commercialize; *provided, however,* that in no case shall such reduction (or the aggregate reduction if multiple Third Party licenses are required) for Third Party Payments exceed the greater of: (a) [***] or (b) [***].

EXHIBIT 11.5

PRESS RELEASE
(*See attached.)*

EXHIBIT 11.5A

CERTAIN PUBLICITY MATTERS

The following general matters related to the subject matter of this Agreement may be disclosed by Coherus to potential investors, collaboration partners and underwriters, on a non- confidential basis and without the prior written consent of Licensee:

1. That the size of the overall market that the Product addresses is approximately $3 billion or is a multi-billion market.

2. That the transaction has up fronts and milestones worth approximately $150 million payable between signing and issuance of regulatory approval.

3. That the transaction includes royalties that Coherus expects will be in the double digits.

4. That Coherus will be responsible for manufacturing with its CMO partner, such partner also being a Coherus shareholder.

5. That the transaction has the potential for additional products, and we hope to be able to expand the collaboration.

6. That Licensee will cover 100% of anticipated development costs not covered by other partners and therefore Coherus expects 100% of the development costs for Product to be covered by its partners.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

MASTER SERVICES AGREEMENT

This Master Services Agreement (the "Agreement") is made and entered into as of February 27, 2015 (the "Effective Date"), by and between [***], with offices at [***] (together with its Affiliates, "[***]") and Coherus BioSciences, Inc., with offices at 201 Redwood Shores Parkway Suite 200 Redwood City, CA 94065 ("Sponsor"), both hereinafter referred to as the "Parties".

For purposes of this Agreement, "Affiliates" means any entity that controls, is controlled by or is under common control with, that Party. "Control" means the possession, directly or indirectly, of at least 50% of the share capital or voting rights or of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, by contract or otherwise.

WHEREAS, Sponsor is engaged in the research and development of pharmaceutical products;

WHEREAS, [***] is engaged in providing services to pharmaceutical manufacturers in support of their clinical research and product development activities;

WHEREAS, Sponsor wishes to retain [***], from time to time, to assist in certain product development activities relating to certain of Sponsor's clinical studies (each of which shall be referred to as a "Study"); and

WHEREAS, Sponsor agrees to compensate [***] for its services.

NOW THEREFORE, in consideration of the premises and the mutual promises and undertakings herein contained, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1.0 SERVICES

[***], itself or through one of its Affiliates (if applicable) hereby agrees to perform the services (the "Services") in accordance with the terms of this Agreement and any associated Work Order(s) (as hereinafter defined). In the event that Sponsor requires the performance of Services, it shall enter into a Work Order, defined as a separate written agreement between Sponsor and [***], specifying the basic parameters of a project, including, without limitation, the assumptions, the costs, payment schedule, and the time period for completing a project, or, as applicable, other Services to be performed by [***] for Sponsor (the "Work Order"). The Work Order shall be in form as attached hereto as Exhibit A and shall reference this Agreement and incorporate these terms. To the extent any term or provision of a Work Order conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement shall prevail, except to the extent the Parties agree, or the applicable Work Order expressly and specifically states an intent to supersede this Agreement on a specific matter.

1.1 Performance

[***] shall use its commercially reasonable efforts to perform the Services within the estimated time frame set forth in Attachment D of the applicable Work Order. Such time estimate assumes[***], and to the extent that the Services are delayed due to [***], such time estimates shall be subject to adjustment and resulting costs, as to be agreed to by the Parties in writing.

1.2 Compliance with Laws/Agreements

The Parties shall perform their obligations under this Agreement and each Work Order in accordance with the terms of this Agreement, the applicable Work Order, applicable provisions of the Study protocol, agreed upon Standard Operating Procedures, the current Guidelines for Good Clinical Practice, the Declaration of Helsinki of the 41st World Medical Assembly, South Africa 1996 as amended, and all other applicable laws and regulations.
The Parties and their respective owners, officers, directors, employees or agents have not and shall not pay, give, offer or promise to pay or give, or authorize the payment, directly or indirectly, of any money or anything of value to any foreign government official or employee (including employees of state-owned institutions), for the purpose of (i) influencing any act or decision of such official or of such government, (ii) inducing that person to do or omit doing any act in violation of his or her lawful duty, (iii) securing an improper advantage, or (iv) influencing such official to use his influence with the government to effect or influence the decision of such government, in order to assist Sponsor or [***] in obtaining or retaining business for or with or directing business to any person.

Each Party agrees to comply with all applicable anticorruption laws, rules and regulations. The Parties agree to reasonably cooperate with each other's diligence efforts in order to satisfy each Party's obligations under the United States Foreign Corrupt Practices Act, as amended ("FCPA"), the UK Bribery Act and any implementing legislation under the OECD Convention Against Bribery of Foreign Government Officials in International Business Transactions. Each Party represents, warrants and covenants that it maintains adequate internal controls and accurate books and records to the extent required in order to comply with applicable anti-corruption laws.

1.3 Transfer of Obligations

Each Work Order shall constitute a unique agreement and shall stand alone with respect to any other Work Order entered into under this Agreement. As required under Title 21 CFR Part 312.52, the Parties shall document in writing the transfer by Sponsor to [***] of any of Sponsor's responsibilities under Title 21 CFR Part 312, Subpart D. Notwithstanding the foregoing, Sponsor will retain the ultimate authority and control over and responsibility for each Study.

1.4 Changes

The terms of a Work Order may be amended or modified by mutual written agreement of [***] and Sponsor. Sponsor may request changes to a Work Order or, if [***] believes a change in the scope or scale of Services is necessary or advisable based on changes to mutual assumptions upon which a Work Order, and/or timelines were made, [***] shall so advise Sponsor. In either case, the Parties will [***] and negotiate and execute [***] a proposed change order ("Change Order") to the applicable Work Order [***] days. The Change Order shall be substantially in the form set forth in Exhibit B. In the event [***] provides additional services or expends resources at Sponsor's written request and in strict accordance with Sponsor's requirements, in the absence of a Change Order, Sponsor will compensate and/or reimburse [***] for all reasonable fees and reasonable costs incurred.

2.0 WORK PRODUCT

During the term of each Work Order, [***] shall maintain all materials and all other data or documents included in the Trial Master File obtained or generated by [***] in the course of providing the relevant Services in accordance with [***]'s standard operating procedures, including all computerized records and files ("Work Product"), in a secure area reasonably protected from fire, theft and destruction. At the expiration or termination of a Work Order and subject to satisfaction of the Parties' obligations thereunder, Sponsor shall provide [***] with written instructions as to the disposition of the Work Product created under that Work Order. Such written instructions will provide that [***] (a) deliver the Work Product, in the form in which [***] currently holds them,

to a designated Sponsor location or to such other entity or at such other address as Sponsor may specify, (b) retain the materials for the period of time specified in the Work Order, or (c) destroy all such materials except for those which [***] is required by law or regulation to store or maintain. Upon expiration or termination of a Work Order, any storage, destruction or shipping costs or services relating to such disposition of the Work Product will be [***]. Notwithstanding the foregoing, [***] may retain copies of any portion of the Work Product as may be reasonably necessary for regulatory or insurance purposes and one electronic, archival backup copy in accordance with [***]'s Data Retention Policy, subject to its ongoing obligation to maintain the confidentiality of such materials.

3.0 PAYMENT AND COMPENSATION

The Parties agree that the fees and other reimbursements that [***] will receive for performing the Services hereunder will be outlined in each Work Order and are subject to the following terms and conditions.

3.1 Compensation for Services

As compensation for providing the Services, Sponsor shall pay [***] in accordance with the terms in this Agreement and each applicable Work Order. Each Work Order will include as attachments a Study budget containing [***]'s estimated service fees and Pass-through Expenses (the "Budget"), a payment schedule (the "Payment Schedule") and a timeline showing performance milestones (the "Timeline").

3.2 Pass-through Expenses

Sponsor will reimburse [***] for [***], exclusive of grant payments (described below), incurred by [***] as identified in the Budget or otherwise approved by the Sponsor which [***] will invoice to the Sponsor without mark-up ("Pass-through Expenses"). Pass-through Expenses shall include, but shall not be limited to [***].

3.3 Invoices

[***] shall submit a reasonably detailed separate invoice by email to Sponsor ([***]) on a monthly basis for Services, Pass Through Expenses and Investigator/Institution Fees with appropriate supporting summary documentation. [***]. [***] shall retain original receipts for review by Sponsor upon Sponsor's written request.

3.4 Payment Terms

Sponsor agrees to pay for Services and Pass-through Expenses in accordance with the Payment Schedule outlined in each Work Order or associated Change Order. Sponsor will pay for all Services, Pass-through Expenses and other invoiced items within [***] days of receipt of an invoice. All payments will be made in the currency noted in the Work Order. All fees for Services and Pass-through Expenses under this Agreement are stated [***]. [***].

Payments shall be made by Sponsor via wire transfer or check (at Coherus's option) with the address/wiring instructions set forth in the applicable Work Order.

3.5 Project Delays

In the event Sponsor delays, suspends or places a hold on the Study for any reason, Sponsor shall promptly provide [***] with written notice of such delay, hold or suspension, and Sponsor and [***] will, within [***] days of such notice, agree on appropriate revisions to the applicable Work Order and each Party will complete its respective duties and obligations as described in any resulting Change Order. During the period following [***]'s receipt of Sponsor's notice of delay, hold or suspension, Sponsor will [***].

In the event that a Study is delayed or placed on-hold for more than [***] days, Sponsor shall have the right to retain[***] all [***] for the duration of the delay or on-hold period. If Sponsor does not wish to retain any [***] for the duration of the delay or on-hold period, [***] shall have the right to reallocate any and all [***] after such [***] day period. If the delay or on-hold period continues for [***], either Party may, by provision of written notice, terminate the applicable Work Order.

3.6 Currency Management

For service fees, the bid currencies will be tracked and managed against the contract currency established in each Work Order. At the end of each calendar quarter, a currency review may occur to assess the impact of currency fluctuation by comparing the actual average exchange rate(s) [***] to the currency exchange rate(s) set out in the Work Order If the actual average exchange rate differs (up or down) by more than [***] from the currency exchange rate(s) in the applicable Work Order, [***] will apply this percent difference against the amounts invoiced for fees [***]. Such currency exchange rate adjustment will be added (currency loss) or subtracted (currency gain) against the next invoice issued to Sponsor. If more than one bid currency is being tracked, the currency fluctuation review will compare [***] set out in the applicable Work Order.

3.7 Disputed Invoices

In the event Sponsor disputes one or more items in an invoice, Sponsor will notify [***] in writing within [***] days of receipt of the invoice and such notice shall contain [***]. [***] will respond to Sponsor within [***] days of receipt of the notification. This written communication pattern will continue [***]. Sponsor shall pay the undisputed portion of the invoice in accordance with the payment terms and shall [***] pay the disputed amount within [***] days of resolution of the dispute. In the event the Parties are unable to reach a satisfactory resolution within [***] days of the original invoice, either Party may [***].

4.0 THIRD PARTY AGREEMENTS

[***] may contract with various third parties to perform part of the Services provided that the party agrees in writing to be bound by terms regarding maintaining the confidentiality of proprietary information, and regarding ownership of intellectual property in connection with the Services; provided, however that any subcontracting shall not relieve [***] of its obligations hereunder and [***] hereby agrees to manage the performance of any permitted assignee or subcontractor. For purposes of this Agreement, subcontractors do not include [***], provided that [***]'s agreement with any such third party vendor includes a provision making Sponsor an intended third party beneficiary of the agreement with a right to enforce [***]'s rights under the agreement. Liability of [***] to Sponsor with respect to such third party vendors shall be [***]; however, [***] shall provide to Sponsor any amounts that [***] may recover from such vendors as a result of any error or service failure on the part of such vendors in connection with Services under this Agreement.

If Sponsor requests that [***] use a particular third party and [***] does not wish to contract with that third party based upon [***], then Sponsor shall contract directly with such provider (a "Sponsor Designated Vendor") and, unless otherwise agreed in writing, [***] will have no responsibility for the selection, instruction or supervision of such Sponsor Designated Vendor.

4.1 Institutions/Investigators

[***]'s Services under a Work Order may include identifying potential medical institutions ("Institutions") or clinical investigators ("Investigators") (Institutions and Investigators together, the "Sites") and/or negotiating, executing and/or administering contracts with such parties which will govern their participation in the Study

("Clinical Trial Agreements"). If, pursuant to a Work Order, Sponsor delegates to [***] the responsibility for negotiating and/or executing Clinical Trial Agreements, the following provisions will apply:

(a) Sponsor may provide [***] with a list of suggested Sites to be recruited by [***] for a Study. [***] shall notify Sponsor in writing as to any listed Site with which [***] does not wish to contract.

(b) Selection of all Sites will be subject to approval by Sponsor prior to initiation of any Study-related activities involving that Site or the start of any negotiations with such Site.

(c) The Clinical Trial Agreement used with each Site will be in a form approved in advance by Sponsor.

(d) In the event that local law prohibits Sponsor from being a party to a Clinical Trial Agreement, Sponsor (a) shall have the right to approve the Clinical Trial Agreement template; (b) shall be a named third-party beneficiary to each Clinical Trial Agreement if possible; and (c) shall have the right but no obligation to approve all finalized Clinical Trial Agreements prior to execution by [***].

(e) If a Site requests indemnification from Sponsor, standard indemnification language, generated by the Sponsor, will be provided to the Site. If the Site requests changes to the standard language, [***] will negotiate with the Site on Sponsor's behalf and, if agreed, Sponsor will issue a letter of indemnification directly to the Site. Sponsor acknowledges that [***]. In addition, [***].

(f) The Sponsor may elect that grant payments to Sites be administered on its behalf by [***], acting solely as payment agent unless otherwise agreed to by [***] in writing. [***] shall distribute all payments to Sites according to the provisions of the applicable Clinical Trial Agreement and Work Order. Sponsor acknowledges and agrees that [***] will manage all administration of payments or other obligations to Sites for Services rendered in connection with relevant Studies solely out of funds provided to [***] from Sponsor for this specific purpose. Furthermore, Sponsor acknowledges and agrees that [***] intends to maintain a cash neutral policy with regard to Site payments. In the event [***] or the Sites incur bank fees with respect to the remittance of these grant payments, such fees will be borne by [***]. All payments to Sites and any associated bank fees will be made by [***] solely from the funds that have been specifically provided by Sponsor to [***] for this purpose and not from [***] funds. [***].

The Parties acknowledge and agree that, for the purposes of this Agreement or any Work Order, Sites shall not be considered as employees, agents or subcontractors of [***] and that Sites will be required to exercise their own independent medical judgement. [***]'s responsibilities with respect to Sites shall be limited to those specifically set forth in the applicable Work Order.

5.0 CONFIDENTIAL INFORMATION

The Parties acknowledge and agree that in the course of performing Services hereunder, either Party may be exposed to or be given confidential or proprietary information of the other Party. Confidential Information shall mean all confidential information disclosed by or on behalf of a Party pursuant to this Agreement and/or that certain Mutual Nondisclosure Agreement entered into by the Parties on July 16, 2014 ("Confidential Information"). The Parties agree to hold all Confidential Information in secrecy during the term of this Agreement and for a period of [***] years from the date of disclosure hereof and shall disclose Confidential Information to third parties only on a need-to-know basis. Without limiting the generality of the foregoing, Confidential Information shall include, without limitation, all commercial, technical, scientific, or medical information, trade secrets, know-how, financial information, protocols, brochures, formulations, research and development programs and strategies, methodology, testing techniques, analytical test method, test samples and prototypes, information gathered or viewed during a site visit, audit or inspection of a Party, analyses, software,

source codes and technological or other know-how. All information or data collected or otherwise generated by a Party directly in providing the Services pursuant to this Agreement and or a Work Order shall be Sponsor's Confidential Information. Confidential Information shall be deemed to be all such information given by the disclosing Party to the receiving Party except for information which is (i) publicly available or later becomes publicly available through no fault of the receiving Party; (ii) obtained by the receiving Party from a third Party entitled to disclose it; (iii) already in possession of the receiving Party as indicated in its written records; (iv) independently developed by the receiving Party without use of the Confidential Information; or (v) required by any law, rule, regulation, order, decision, decree, or subpoena or other judicial, administrative, or legal process to be disclosed.

The receiving Party shall use the disclosing Party's Confidential Information only for purposes set forth in the Agreement and the applicable Work Order and shall disclose Confidential Information only to its employees, Affiliates, agents, third party vendors, investigators, consultants and subcontractors who have a need to know. The terms and conditions of this Agreement and any Work Order shall be deemed Confidential Information.

Both Parties shall ensure that all of its officers, employees, consultants, agents, investigators or contractors who receive such Confidential Information understand and shall be bound by a binding written agreement to confidentiality and non-use provisions at least as stringent as the confidentiality and non-use obligations in this Agreement.

Unless otherwise agreed in writing, within [***] days after the termination of the Agreement or the written request by the disclosing Party, and if the disclosing Party is Sponsor, Sponsor's payment of all outstanding invoices, the receiving Party shall return to the disclosing Party all Confidential Information in documentary or permanent form including any and all copies thereof, except for one archival copy that the receiving Party can keep for its records (which may be electronic).

The Parties agree that each Party is and shall remain the exclusive owner of its Confidential Information and all patent, copyright, trade secret and other intellectual property rights therein unless and until a further agreement is executed.The Parties acknowledge that any violation of the terms of this Section 5 may result in irreparable injury and damage to disclosing Party that is not adequately compensable in money damages, and for which disclosing Party may have no adequate remedy at law. Accordingly, the receiving Party agrees that the disclosing Party shall be entitled to seek (without waiving any additional rights or remedies, including monetary damages, otherwise available to the disclosing Party at law, in equity, or by statute) preliminary and permanent injunctive relief in the event of a breach or intended or threatened breach by the receiving Party.

6.0 OWNERSHIP OF DATA AND INTELLECTUAL PROPERTY

Any invention, discovery, or improvement directly related to Sponsor's products or technology which is conceived or reduced to practice as a direct consequence of [***]'s performance of the Services hereunder, which inextricably incorporate Work Product (defined below) and/or Sponsor Confidential Information (the "Inventions") is Sponsor's property and shall be used by Sponsor as Sponsor deems appropriate. [***] hereby assigns to Sponsor any and all right, title and interest in Sponsor's Inventions. [***] agrees to execute and have executed assignments of the Inventions to Sponsor, along with other documents that are necessary or helpful to Sponsor in filing patent applications, or which may relate to any litigation or interference and/or controversy in connection therewith. The entire control, prosecution, and conduct of any patent application filed by Sponsor shall be outside the jurisdiction of and without expense to [***] and its officers, employees, representatives and agents. [***] acknowledges that Sponsor has the exclusive right to file patent applications in connection with the Inventions. [***] warrants that neither it, nor its employees, agents and representatives, will prevent Sponsor from filing patent applications for, or from applying the results of the research carried out for Sponsor hereunder.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

All reports, data, technical information, original works of authorship and all other information, furnished by or on behalf of Sponsor, or created specifically for Sponsor as a deliverable under a Work Order ("Work Product"), shall be the sole property of Sponsor. Nothing under this Section or any other Section of this Agreement shall be construed as (i) granting to any Party any rights under any patent, copyright or other intellectual property right of the other Party (ii) granting to any Party any rights in or to the Confidential Information of the other Party other than the limited right to use such Confidential Information solely for the purposes expressly permitted by Section 5 of this Agreement.

Sponsor acknowledges that all computer programs, applications, algorithms, databases, methods, techniques, processes and other materials and ideas used by [***] in performance of the work under this Agreement, and not supplied to [***] by Sponsor ("[***] Works"), are the exclusive property of [***] or its licensors. Sponsor agrees that any improvements, alterations or enhancements to the [***] Works during the term of this Agreement or the Study shall be the sole property of [***]. Subject to Section 5 hereof, in no event shall [***] be precluded from use of its general knowledge, skills and experience, and any of its ideas, concepts, know-how and techniques used or developed by it in the course of providing Services under this Agreement.

7.0 TERM AND TERMINATION

7.1 Term

This Agreement shall commence on the Effective Date and, unless otherwise terminated, shall continue until the later of three (3) years from the Effective Date or the final payment is received for all Work Orders entered into pursuant hereto. Termination of a Work Order shall not affect any other Work Order; each Work Order shall continue in full force and effect until its expiration date or final payment is received, unless specifically earlier terminated in accordance with the terms of this Agreement or the terms of that Work Order.

7.2 Termination for Material Breach

In the event that either Party commits a material breach in any of the terms or conditions of this Agreement or a Work Order, and that Party fails to cure the breach within thirty (30) days after receipt of notice of the default or breach from the other Party, the Party giving notice may, at its option, immediately terminate this Agreement, or the Work Order, as applicable, at the end of the 30-day period. For the avoidance of doubt, [***].

7.3 Termination by Sponsor without Cause

Sponsor shall have the right to terminate this Agreement or a Work Order (for other than breach by [***]) at any time by giving appropriate written notice at least ninety (90) days prior to the desired termination date.

7.4 Termination by [***] without Cause

[***] shall have the right to terminate this Agreement (for other than breach by Sponsor) at any time by giving appropriate written notice at least ninety (90) days prior to the desired termination date provided, however, if [***] terminates this Agreement while any Work Order remains in effect, the terms of this Agreement will continue in force until [***] has completed the Services under the applicable Work Order and has received full payment therefor.

7.5 Termination for Other Reasons

Sponsor shall have the right to terminate a Work Order effective immediately due to patient safety by giving written notice to [***]. Either Party shall have the right to terminate this Agreement and/or one or more Work Orders at any time upon receipt of written notice to the other Party, if the other Party shall be adjudicated

insolvent or shall petition for or consent to any relief under any insolvency, re-organization, receivership, liquidation, compromise, or any moratorium statute, whether now or hereafter in effect, or shall make an assignment for the benefit of its creditors, or shall petition for the appointment of a receiver, liquidator, trustee, or custodian for all or a substantial part of its assets, or if a receiver, liquidator, trustee or custodian is appointed for all or a substantial part of its assets and is not discharged within thirty (30) days after the date of such appointment. In the event that any of the above events occur, that Party shall immediately notify the other, in writing, of its occurrence.

7.6 Termination Procedures

Upon termination of this Agreement or any Work Order, the Parties will reasonably cooperate with each other to provide for an orderly cessation of [***]'s Services. [***] shall [***] minimize costs associated with the cessation of the Services. In the event a Work Order is terminated, [***] shall [***]. In addition, Sponsor shall [***]. If a Study, Work Order, or the Agreement is cancelled or terminated before the Services have been performed completely, [***]. .

8.0 DEBARMENT CERTIFICATION

[***] certifies that it has not been debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §335a(a) or (b) or any equivalent local law or regulation. In the event that [***] becomes debarred, [***] agrees to notify Sponsor immediately.

[***] certifies that it has not and will not use in any capacity the services of any individual, corporation, partnership, or association which has been debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C §335a (a) or (b) or any equivalent local law or regulation. In the event that [***] becomes aware of or receives notice of the debarment of any individual, corporation, partnership, or association providing services to [***], which relate to the Services being provided under this Agreement, [***] agrees to notify Sponsor immediately.

9.0 RECORDS, AUDITS AND INSPECTIONS

9.1 Records

[***] shall maintain complete and accurate financial records relating to its performance of the Services and Pass-through Expenses incurred in connection therewith for a period of [***] years or such later period as required by law.

9.2 Audits by Sponsor

During the term of each Work Order, [***] will permit representatives of Sponsor [***] to examine, at a reasonable time during normal business hours, subject to at least [***] days prior written notice to [***], and at Sponsor's sole cost and expense: (i) the facilities where the Services are being, will be or have been conducted; (ii) related Study documentation; and (iii) any other relevant information necessary for Sponsor to confirm that the Services are being or will be or have been conducted in conformance with applicable standard operating procedures, the specific Work Orders, this Agreement, and in compliance with applicable laws and regulations. [***] will provide copies of any materials reasonably requested by Sponsor during such inspection.

9.3 Inspection by Regulatory Authorities

During the term of each Work Order, each Party will permit regulatory authorities to examine: (i) the facilities where the Services are being conducted; (ii) Study documentation; and (iii) any other relevant information,

including information that may be designated by one or both of the Parties as confidential, reasonably necessary for regulatory authorities to confirm that the Services are being conducted in compliance with applicable laws and regulations. Each Party will immediately notify the other if any regulatory authority schedules, or without scheduling, begins an inspection that relates to the Services or the Parties' respective obligations hereunder. [***] (i) shall forward to Sponsor within [***] day any correspondence to such inquiry or inspection, (ii) promptly notify Sponsor of any results of any such inquiry or inspection, including requested actions and (iii) Sponsor shall have the opportunity to have a representative present during any inspections where such regulatory or government authority does not object and to comment on proposed responses given to the FDA or other regulatory or government authority prior to communication to the regulatory authority.

10.0 INDEMNIFICATION

10.1 Indemnification by [***]

[***] shall indemnify Sponsor and its officers, directors, employees and agents from any loss, damage, cost or expense (including reasonable attorney's fees) arising from any third party claim, demand, assessment, action, suit or proceeding (a "Claim") caused by [***] (i) negligence or intentional misconduct, (ii) material violation of any law or regulation in the performance of the Services and/or (iii) a material breach of this Agreement or a Work Order, all except to the extent such Claim is caused by Sponsor's negligence or wilful misconduct.

10.2 Indemnification by Sponsor

Sponsor shall indemnify [***] and its Affiliates and their respective officers, directors, employees and agents (the "[***] Group") arising out of any Claim arising from (i) [***] performance of the Services or its obligations under this Agreement, the applicable Work Order, or any protocol related thereto, (ii) the Study drug's harmful or otherwise adverse effect, including, without limitation, a Claim based upon the consumption, sale, distribution or marketing of any substance, including the Study drug, (iii) [***] other than [***] or its agents' materials, Study drugs, study data, and study records ("Materials"); (iv) Sponsor's subsequent use, failure to use, disclose or failure to disclose the results of the Services; or (v) the material breach of this Agreement or the applicable Work Order, or the negligence or intentional misconduct or inaction of Sponsor, except to the extent such Claim is caused by [***] (i) negligence or wilful misconduct (ii) material breach of this Agreement or Work Order and/or (iii) material violation of any law or regulation in the performance of the Services.

In the event [***] incurs costs or expenses as a result of its becoming involved in, or being required to appear or otherwise participate in, a third party matter [***]. The Parties agree to [***].

10.3 Indemnification Procedures

Upon receipt of written notice of any Claim which may give rise to a right of indemnity from the other Party hereto, the Party seeking indemnification (the "Indemnified Party") shall give written notice thereof to the other Party (the "Indemnifying Party"). The Indemnified Party shall permit the Indemnifying Party, at its own option and expense, to assume the complete defense of such Claim, provided that the Indemnified Party will have the right to participate in the defense of any such Claim at its own cost and expense. As to those Claims with respect to which the Indemnifying Party does not elect to assume control, the Indemnified Party will afford the Indemnifying Party an opportunity to participate in such defense, at the Indemnifying Party's own cost and expense. The Indemnifying Party shall make no admission to, nor any settlement or agreement with any third party without the Indemnified Party's prior written consent which consent shall not be unreasonably withheld, provided, however, reasonable concession shall be made to comply with any requirements of the Indemnifying Party's insurance policy.

11.0 LIMITATION OF LIABILITY

Except for the indemnification obligations of either Party under Section 10, under no circumstances shall either Party be liable under this Agreement for any indirect, incidental, special or consequential damages of the other Party resulting from such Party's performance or failure to perform under this Agreement. In addition and except for the indemnification obligations of [***] under Section 10.1 and [***]'s breach of Section 5, in no event shall the collective, aggregate liability of the [***] Group to Sponsor exceed the [***] by [***] from Sponsor pursuant to the Work Order from which such liability arose.

12.0 INSURANCE

For each applicable Work Order, Sponsor hereby represents and warrants that it shall maintain adequate clinical trial and product liability insurance coverage, with insurance companies having an A. M. Best Rating of [***] [***] or better, consistent with industry standards to cover all personal injury, death or loss suffered as a result of the Study drug, participation in the trial or the trial screening process. Other than as set forth in Section 10.1, to the extent that [***] provides depot services to Sponsor, [***]. Sponsor hereby acknowledges that [***]. Sponsor shall provide [***] with a copy of Sponsor's effective Certificate of Insurance or such other documented evidence to confirm that it has such coverage. Sponsor shall maintain such insurance for the entire duration of the Study and shall notify [***] of any changes in coverage which impact the coverage requirements set forth above.

Prior to commencement of any work under this Agreement, [***] shall, at its sole expense, maintain the following insurance on its own behalf, with insurance companies having an A. M. Best Rating of [***], or better:

(1) [***]. The policy must be on an occurrence form and include the following limits: [***].

(2) [***]. This policy must include the following limits: [***].

(3) [***]: [***]. Throughout the term of this Agreement, the [***]. Upon expiration or termination of this Agreement, [***] will either continue to maintain an active insurance policy, or purchase an extended reporting period coverage for claims first made and reported to the insurance company within [***] after the end of the Agreement.

13.0 REPRESENTATIONS AND WARRANTIES

Each Party represents that it is authorized to enter into this Agreement, and any Work Order issued hereunder, and that the terms of this Agreement are not inconsistent with or a violation of any contracted or other legal obligation to which it is subject.

Each Party represents that it has all qualifications, authorizations, licenses or permits which are necessary for performance of its obligations under this Agreement.

14.0 DISCLAIMER

Sponsor acknowledges that the results of the Studies for which the Services are to be provided hereunder are inherently uncertain and that, accordingly, there can be no assurance, representation or warranty by [***] that the product covered by this Agreement can, either during the term of this Agreement or thereafter, be successfully developed or receive the required approval by the regulatory authorities.

Sponsor acknowledges that the development of the protocol concept and scientific rationale shall be the sole responsibility of Sponsor regardless of [***]'s involvement in Study design or protocol-writing (or lack thereof).

15.0 EMPLOYEES; NON-SOLICITATION

[***]'s staff is not, nor shall they be deemed to be at any time during the term of this Agreement, the employees of Sponsor. In consideration of the fees and benefits provided in this Agreement, each Party agrees that, without the other Party's prior written consent, during the term of this Agreement and for a period of [***] following its expiration or other termination, neither Party shall directly or indirectly solicit for employment or contract, attempt to employ or contract with, or assist any other entity in employing, contracting with or soliciting for employment or contract any employee who is at that time employed/contracted by a Party and who had been employed/contracted by such Party in connection with one or more Work Orders issued hereunder. This provision shall not be construed to prohibit the advertisement of employment opportunities or job openings so long as such advertisements are not customized for, directed at or targeted at specific employees of the other Party nor prohibit the use of employment search firms so long as such firms are not directed by the searching party to specifically target the other party's employees, independent contractors, and consultants. In the event of a breach of this Section 15, [***]. The Parties expressly agree that [***]. In the event that legal action becomes necessary for the enforcement of all or any part of this provision or to [***] provided for herein, the prevailing party shall receive in addition to any other damages or relief awarded, its reasonable attorneys' fees, together with appropriate costs and interest. The Parties acknowledge that in the event of a breach of this Section 15, the other Party shall be entitled to recover injunctive relief as well as [***], and that the [***] provision included herein does not provide the Party with an adequate remedy at law for any such breach.

16.0 NOTICES

All notices provided for in this Agreement shall be in English and shall be sent by registered first class mail, postage prepaid, return receipt requested, addressed to the respective Parties as follows:

If to Sponsor:
Coherus BioSciences, Inc.
201 Redwood Shores Parkway Suite 200
Redwood City, CA 94065
ATTN: General Counsel with a cc to the Chief Medical Officer

If to [***]:

c/o [***]
[***]
[***]
ATTN: General Counsel

17.0 MISCELLANEOUS

17.1 Modification

This Agreement may be supplemented, amended or modified only by mutual agreement of the Parties. No supplement, modification or amendment of this Agreement will be binding unless it is in writing and signed by both Parties.

17.2 Assignment

Neither Party shall have the right to assign this Agreement or any of the rights or obligations hereunder without the prior written consent of the other Party, except that (a) [***] and (b) either Party may assign this Agreement to

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(i) an Affiliate or (ii) a purchaser of or successor to that area of its business to which this Agreement is related (or, the case of Sponsor, the outstanding Work Orders relate), upon prior written notice, [***].

17.3 Force Majeure

Neither Sponsor nor [***] shall be liable for delays in performing or any failure to perform any of the terms of this Agreement or a Work Order caused by the effects of natural disaster, strike, war (declared or undeclared), insurrection, acts of terror, government sanction, restriction or prohibition, or other causes reasonably beyond its control and without its fault, but the Party failing to perform shall use all commercially reasonable efforts to resume performance of this Agreement as soon as reasonably feasible. Any episode of force majeure which continues for [***] days from the date of notification of its existence shall give the non-affected Party the right to terminate this Agreement upon [***] days additional notice.

17.4 Severability

If any provision of this Agreement is found by a court to be void, invalid or unenforceable, the same shall either be reformed to comply with applicable laws and regulations or stricken if not so conformable, so as not to affect the validity or enforceability of the remaining provisions of this Agreement, except if the principal intent of this Agreement is frustrated by such reformation or deletion in which case this Agreement shall terminate.

17.6 Entire Agreement

The Parties hereto acknowledge that each has read this Agreement, understands it and agrees to be bound by its terms. The Parties agree that this Agreement, along with each Work Order, is the complete agreement between the Parties on the subject matter and supersedes all proposals (oral or written), letters of intent, understandings, representations, conditions, warranties, covenants and other communications between the Parties relating to the same subject matter.

17.7 Survival

The terms contained in Sections 3, 10, 11and 17of this Agreement shall survive the completion of performance, expiration or termination of this Agreement. Sections 5 and 6shall survive for the period expressly set forth in such Section or, if none, the applicable statute of limitations period applicable to a claim for breach of such provision.

17.8 Governing Law

This Agreement shall be interpreted and enforced in accordance with the laws of the State of California and each Party hereby specifically consents to the personal jurisdiction thereof.

17.9 Waiver

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances will be deemed to be construed as a further or continuing waiver of such term, provision or condition or of any other term, provision or condition of this Agreement.

17.10 Independent Contractors

The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Subject to Section 10.0 and/or as may be expressly agreed otherwise in a Work Order in the case of legal representation in the EU, neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

17.11 Counterparts

This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same instrument. In the event that any signature is delivered by facsimile transmission, by e-mail delivery of a ".pdf" format data file or other electronic means, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such signature page were an original thereof.

17.12 Arbitration

In the event a dispute relating to this Agreement or any Work Order arises between the Parties, the Parties shall confer in good faith to resolve the dispute through negotiations between respective senior executives of the Parties. In the event that the Parties are unable to resolve the dispute, disputes shall be settled by arbitration administered by the American Arbitration Association under its Commercial Arbitration Rules in Los Angeles, California. Judgment shall be rendered by a mutually agreed upon single arbitrator. The provisions of this section may be enforced by any court of competent jurisdiction, and the Party seeking enforcement shall be entitled to an award of all costs, fees and expenses, including reasonable attorneys' fees, to be paid by the party against whom enforcement is ordered.

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

COHERUS BIOSCIENCES, INC.		[***]	
By:	/s/ Dennis M. Lanfear	By:	/s/[***]
Name:	Dennis M. Lanfear	Name:	[***]
Title:	Chief Executive Officer	Title:	[***]
Date:	3/9/2015	Date:	2 March 2015

LIST OF EXHIBITS:

EXHIBIT A-1: Form of Work Order Late Phase
EXHIBIT B: Form of Change Order

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT A-1
FORM OF WORK ORDER
LATE PHASE

WORK ORDER #

PROTOCOL NUMBER:

This Work Order #__ is made and entered as of the _____ day of ____, 201_ (the "Effective Date") by and between _____ ("Sponsor") and [***] [Entity] ("[***]").

WHEREAS, Sponsor and [***] have entered into that certain Master Services Agreement dated _____ __, 201_ (hereinafter referred to as the "Agreement"); and

WHEREAS, pursuant to the Agreement, [***] has agreed to perform certain Services in accordance with Work Orders from time to time entered into by the Parties, as more fully provided in Section 1.0 of the Master Agreement, and Sponsor and [***] now desire to enter into such a Work Order, (the "Work Order").

WHEREAS, [***] and Sponsor desire that [***] provide certain Services with respect to _____, (the "Study") for the study of the drug _____ ("Study Drug").

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the Parties hereby agree as follows:

1. Scope of Services. [***] shall perform the Services described in the Scope of Services, attached to this Work Order as Attachment A ("Scope of Services").

2. Compensation. For performance of these Services, Sponsor shall pay to [***] the amounts set forth in the Budget set forth in Attachment B to this Work Order, which amounts shall be payable pursuant to the Payment Schedule set forth in Attachment C to this Work Order.

3. Term and Termination. The term of this Work Order shall commence upon the effective date stated above and shall continue until completion of Services as described in Attachment A, provided, however, the provisions of the Agreement shall govern its termination prior to completion.

4. Incorporation by Reference; Conflict. The provisions of the Agreement are hereby expressly incorporated by reference into and made a part of this Work Order. In the event of a conflict between the terms and conditions of this Work Order and those of the Agreement, the terms of the Agreement shall take precedence and control over those of this Work Order unless the Work Order expressly and specifically states an intent to supersede the Agreement on a specific matter by reference. Unless otherwise specifically defined herein, each term used herein which is defined in the Agreement shall have the meaning assigned to such term in the Agreement.

5. Timely Completion. The timeline for this Work Order is attached as Attachment D.

6. Currency. All invoices and amounts to be paid shall be in USD.

IN WITNESS WHEREOF, the Parties have hereunto signed this Work Order effective as of the Effective Date.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

[***] [Entity]		Coherus BioSciences, Inc.	
By:	Sample	By:	Sample
Name:		Name:	
Title:		Title:	
Date:		Date:	

LIST OF ATTACHMENTS:

ATTACHMENT A: SCOPE OF SERVICES
ATTACHMENT B: BUDGET
ATTACHMENT C: PAYMENT SCHEDULE
ATTACHMENT D: TIMELINE

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

WORK ORDER ATTACHMENT C
PAYMENT SCHEDULE

1. Service Fees (To be billed separately)

    1.1. Notwithstanding the payment terms in Section 3.4 of the Agreement, [***] of this Work Order, Sponsor will [***] which represents [***]. All subsequent invoices will be submitted to Sponsor by email based on the Payment Schedule. With the exception of [***], which shall be due within xx (xx) days of Sponsor's receipt of an invoice for same, payment terms shall be as defined in the Agreement. Any outstanding balances will be reconciled [***]. Service Fees shall be invoiced separately from Pass-through Expenses and Investigator/Institution Fees.

    1.2. Payment shall be issued by check or wire transfer at Sponsor's option. Wiring instructions are as follows:

    Account Holder:
    Bank Name: Bank Address:
    ABA No.:
    Bank Account No.:
    Routing:
    Swift Code:

2. Pass-through Expenses (To be billed separately)

    2.1. Notwithstanding the payment terms in Section 3.4 of the Agreement, [***] of this Work Order, Sponsor will [***] which represents [***]. [***] will submit subsequent monthly invoices by email for incurred Pass-through Expenses based on actuals. With each subsequent invoice for Pass-through Expenses, [***] will [***]. With the exception of [***], which shall be due within xx (xx) days of Sponsor's receipt of an invoice for same, payment terms shall be as defined in the Agreement. Any outstanding balances will be reconciled [***].

3. Investigator/Institution Fees (To be billed separately)

    3.1. Notwithstanding the payment terms in Section 3.4 of the Agreement, [***] of this Work Order, Sponsor will [***] which represents [***]. Periodically, [***] will invoice Sponsor by email to [***]. The invoice will be accompanied by a report which [***]. If an increase in the amount of anticipated Investigator/Institution grants is necessary, [***] will provide appropriate support justifying such increase. With the exception of [***], which shall be due within xx (xx) days of Sponsor's receipt of an invoice for same, payment terms shall be as defined in the Agreement. Any outstanding balances will be reconciled and provided [***]. For avoidance of doubt, [***] will make all grant payments only from funds received from Sponsor specifically for this purpose. [***] shall not [***].

4. Accounting close out for items 1, 2 and 3 above

    4.1. After [***] days following the end of the study, the presumption shall be that no further payments are owed by Sponsor to [***] for Service Fees. After [***] days following the end of the study, the presumption shall be that no further payments will be made by Sponsor to [***] for Pass-through Expenses. Accordingly, Sponsor shall have a right to a refund of any amounts of the prepayments made in according to sections 1 through 3 above which exceed the aggregate actual expense.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B
FORM OF CHANGE ORDER

Sponsor:	**[***] Project Manager**:
Protocol Number:	**[***] ID**:
Change Order #:	**Date**:

[***] [Entity] ("[***]") and Sponsor Name ("Sponsor") entered into a Work Order dated [effective date] ("Work Order") [as amended by Change Order # 1 effective [effective date]] [and further amended by Change Order # 2 effective [effective date]] in which [***] was to provide certain Services to Sponsor in connection with Study [insert Protocol number] ("Study"). [***] and Sponsor wish to amend the Work Order as follows:

1. Revisions to the Scope of Services including timelines). The Scope of Services has been revised as described below, and [***] will provide the following additional services [will not provide the following services initially contracted]:

Description of Service	Target Completion Date	Costs

2. Revisions to the Study Budget. As a result of the changes to the Services and Scope of Services, this Change Order #[Insert] [increases] [decreases] the Service fees as shown above. A revised total budget value is below.

	Services Fees	Estimated Pass Through Costs	Total
Original Work Order Value:			
Change Order #1 Value:			
[Add additional Change Orders as necessary]			
Revised Contract Value:			

3. Revisions to the Payment Schedule. A revised and restated payment schedule, as amended by Change Order #[Insert#] is detailed below.

Payment Schedule, as amended by Change Order #[Insert]

Except to the extent specifically modified by this Change Order #[Insert], the provisions of the Work Order remain unmodified and the Work Order as amended by this Change Order #[Insert] is confirmed as being in full force and effect. All defined terms within the Work Order shall have the same meaning when used herein.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Authorized representatives of the Parties have executed this Change Order # [insert] effective as of the Effective Date written above.

[***] [Entity]		Coherus BioSciences, Inc.	
By:	Sample	By:	Sample
Name:		Name:	
Title:		Title:	
Date:		Date:	

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

WORK ORDER #1

PROTOCOL NUMBER: CHS-1420-02

This Work Order #1 is made and entered as of the 31st day of March, 2015 (the "Effective Date") by and between Coherus BioSciences, Inc. ("Sponsor") and [***] ("[***]").

WHEREAS, Sponsor and [***] have entered into that certain Master Services Agreement dated February 27, 2015 (hereinafter referred to as the "Agreement"); and

WHEREAS, pursuant to the Agreement, [***] has agreed to perform certain Services in accordance with Work Orders from time to time entered into by the Parties, as more fully provided in Section 1.0 of the Master Agreement, and Sponsor and [***] now desire to enter into such a Work Order, (the "Work Order").

WHEREAS, [***] and Sponsor desire that [***] provide certain Services with respect to CHS-1420-02: A Double-Blind, Randomized, Parallel-Group, Active-Control Study to Compare the Efficacy and Safety of CHS-1420 DP Versus Humira® in Subjects with Chronic Plaque Psoriasis (PsO), (the "Study") for the study of the drug CHS-1420 ("Study Drug").

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the Parties hereby agree as follows:

1. Scope of Services. [***] shall perform the Services described in the Scope of Services, attached to this Work Order as Attachment A ("Scope of Services").

2. Compensation. For performance of these Services, Sponsor shall pay to [***] the amounts set forth in the Budget set forth in Attachment B to this Work Order, which amounts shall be payable pursuant to the Payment Schedule set forth in Attachment C to this Work Order.

3. Term and Termination. The term of this Work Order shall commence upon the Effective Date stated above and shall continue until completion of Services as described in Attachment A, provided, however, the provisions of the Agreement shall govern its termination prior to completion.

4. Incorporation by Reference; Conflict. The provisions of the Agreement are hereby expressly incorporated by reference into and made a part of this Work Order. In the event of a conflict between the terms and conditions of this Work Order and those of the Agreement, the terms of the Agreement shall take precedence and control over those of this Work Order unless the Work Order expressly and specifically states an intent to supersede the Agreement on a specific matter by reference. Unless otherwise specifically defined herein, each term used herein which is defined in the Agreement shall have the meaning assigned to such term in the Agreement.

5. Timely Completion. The timeline for this Work Order is attached as Attachment D.

6. Currency. All invoices and amounts to be paid shall be in USD.

7. Additional Indemnification. The parties agree that Sponsor further agrees to indemnify, defend, and hold harmless Service Provider, its Affiliates and their respective officers, directors, employees, agents and other representatives against any and all claims, expenses or losses (including reasonable attorney's fees) as a result of [***].

IN WITNESS WHEREOF, the Parties have hereunto signed this Work Order effective as of the Effective Date.

[***]		**Coherus BioSciences, Inc.**	
By:	**[***]**	By:	/s/ Jean-Frederic Viret
Name:	**[***]**	Name:	Jean-Frederic Viret
Title:	**[***]**	Title:	Chief Financial Officer
Date:	April 1, 2015	Date:	April 10, 2015

LIST OF ATTACHMENTS:

ATTACHMENT A:	**SCOPE OF SERVICES**
ATTACHMENT B:	**BUDGET**
ATTACHMENT C:	**PAYMENT SCHEDULE**
ATTACHMENT D:	**TIMELINE**

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

WORK ORDER #1

ATTACHMENT A
SCOPE OF SERVICES

Cost Driver	[***]'s Assumptions
Countries, Sites, Patients and CRAs	
[***]	[***]
[***]	[***]
[***]	[***]
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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Back-up Sites	
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Study Duration	
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Project Management	
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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Investigator Meeting	
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Communication	
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Regulatory and Ethics Submissions	
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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Start-up Activities	
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Study Initiation	
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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Study Conduct		
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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Drug Safety / Pharmacovigilance	
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Drug Safety Monitoring Board (DSMB)	
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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Medical Monitoring	
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Data Management	
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Medical Writing	
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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Clinical Assessment and Training	
[***]	[***]
[***]	[***] [***] [***] [***] [***]
IxRS	
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Clinical Trials Materials Handling	
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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

WORK ORDER #1

ATTACHMENT B
BUDGET

[***] Budget					
Client:	**Coherus**				
Study:	**CHS-1420-02: A Double-Blind, Randomized, Parallel-Group, Active-Control Study to Compare the Efficacy and Safety of CHS-1420 DP Versus Humira® in Subjects with Chronic Plaque Psoriasis (PsO)**				
	Services	**Unit**	**# Units**	**Unit Cost USD $**	**[***] Fees USD $**
Clinical Start Up					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
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o	[***]				
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
Sub-Total Study Start Up					**[***]**

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Regulatory Affairs					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]				
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o	[***]	[***]	[***]	[***]	[***]
o	[***]				
	Full	[***]	[***]	[***]	[***]
	Sub-Total Regulatory Affairs				**[***]**
Trial Master File					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Trial Master File				**[***]**
Communication					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
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o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Communication				**[***]**
Vendor Contracting & Management					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Vendor Contracting & Management				**[***]**

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Clinical Monitoring					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
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o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub Total Clinical Monitoring				**[***]**
Grant Payments					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Grant Payments				**[***]**
Drug Safety Services					
o	[***]				
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
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	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Safety				**[***]**
Drug Safety Monitoring Board (DSMB)					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total DSMB				**[***]**

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Medical Monitoring					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Medical Monitoring				**[***]**
Data Management					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]				
	[***]	[***]	[***]	[***]	[***]
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o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Data Management				**[***]**
Biostatistics					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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o	[***]				
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o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Biostatistics				**[***]**
Clinical Writing					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Clinical Writing				**[***]**
Clinical Assessment and Training					
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Clinical Assessment and Training				**[***]**
Clinical Trial Materials Handling					
o	[***]	[***]	[***]	[***]	[***]
o	[***]				
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
o	[***]				
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
o	[***]				
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
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o	[***]				
	[***]	[***]	[***]	[***]	[***]
o	[***]				
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	Sub-Total Clinical Trials Materials Handling				**[***]**
IxRS					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total IxRS				**[***]**
Technology					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Technology				**[***]**

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Project Management					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Project Management				**[***]**
	Total Estimated Service Fees				**[***]**
Estimated Pass-Through Costs					
Clinical Start-Up Pass-through Costs					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Clinical Start Up Pass-through Costs				**[***]**
Regulatory Affairs Pass-through Costs					
o	[***]	[***]	[***]	[***]	[***]
o	[***]				
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
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o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Regulatory Affairs Pass-through Costs				**[***]**
Trial Master File Pass-through Costs					
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Trial Master File Pass-through Costs				**[***]**
Communication Pass-through Costs					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Communication Pass-through Costs				**[***]**
Study Conduct Pass-through Costs					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

o	[***]	[***]	[***]	[***]	[***]
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o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
Sub Total Study Conduct Pass-through Costs					**[***]**
Clinical Assessment and Training Pass-through Costs					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
Sub-Total Clinical Assessment and Training Pass-through Costs					**[***]**
Clinical Trial Materials Handling Pass-through Costs					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
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o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
Sub-Total Clinical Trials Materials Handling Pass-through Costs					**[***]**
IxRS Pass-through Costs					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
Sub-Total IxRS Pass-through Costs					**[***]**
Archiving Pass-through Costs					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
Sub-Total Archiving Pass-through Costs					**[***]**
Project Management Pass-through Costs					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
Sub-Total Project Management Pass-through Costs					**[***]**

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Third Party Vendor Costs					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total Third Party Vendors				**[***]**
PI Fees					
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
o	[***]	[***]	[***]	[***]	[***]
	Sub-Total PI Fees				**[***]**
Total Estimated Pass Through Costs					**[***]**
Total Estimated Budget					**[***]**

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

WORK ORDER #1

ATTACHMENT C
PAYMENT SCHEDULE

1. Service Fees (To be billed separately):

1.1. Notwithstanding the payment terms in Section 3.4 of the Agreement, [***] of this Work Order, Sponsor will [***] (Work Order [***]) which represents [***]. Work Order will be [***]. All subsequent invoices will be submitted to Sponsor by email on a [***] basis for units completed in the previous [***], [***] will [***], until [***]. With the exception of [***], which shall be due within [***] days of Sponsor's receipt of an invoice for same, payment terms shall be as defined in the Agreement. Any outstanding balances will be reconciled at [***]. Service Fees shall be invoiced separately from Pass-through Expenses and Investigator/Institution Fees.

1.2. Bonus and Penalty fees: [Intentionally Omitted]

1.3. Payment shall be issued by [***]. Wiring instructions are as follows:

Account Holder:	[***]
Bank Name:	[***]
Bank Address:	[***]
	[***]
ABA Routing No.:	[***]
Bank Account No.:	[***]
Swift Code:	[***]
Taxpayer ID#:	[***]

2. Pass-through Expenses (To be billed separately):

2.1. Notwithstanding the payment terms in Section 3.4 of the Agreement, [***] of this Work Order, Sponsor will [***] which is the [***], and [***] Pass-Through Expenses. Work Order will be [***].[***] will submit subsequent [***] invoices by email for incurred Pass-through Expenses based on [***]. With each subsequent invoice for Pass-through Expenses, [***] will [***], until [***]. With the exception of [***], which shall be due within [***] days of Sponsor's receipt of an invoice for same, payment terms shall be as defined in the Agreement. Any outstanding balances will be reconciled at [***].

3. Investigator/Institution Fees (To be billed separately):

3.1. Notwithstanding the payment terms in Section 3.4 of the Agreement, [***] of this Work Order, Sponsor will [***] which represents [***]

[***]. Periodically, [***] will invoice Sponsor by email to [***]. The invoice will be accompanied by a report which [***]. If an increase in the amount of anticipated Investigator/Institution grants is necessary, [***] will provide appropriate support justifying such increase. Any outstanding balances will be reconciled and provided [***]. For avoidance of doubt, [***] will make all grant payments only from funds received from Sponsor specifically for this purpose. [***] shall not [***].

4. Accounting close out for items 1, 2 and 3 above:

4.1. After [***] days following the end of the study, the presumption shall be that no further payments are owed by Sponsor to [***] for Service Fees. After [***] days following the end of the study, the presumption shall be that no further payments will be made by Sponsor to [***] for Pass-through Expenses. Accordingly, Sponsor shall have a right to a refund of any amounts of the prepayments made in according to sections 1 through 3 above which exceed the aggregate actual expense.

5. [***]:

The parties shall negotiate in good faith a [***] as part of a change order.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

ATTACHMENT D
TIMELINE

Assumptions Summary	
Milestone	**Date**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dennis M. Lanfear, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Coherus BioSciences, 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 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;

   (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 11, 2015

/s/ Dennis M. Lanfear
Dennis M. Lanfear
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jean-Frédéric Viret, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Coherus BioSciences, 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 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;

   (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 11, 2015

/s/ Jean-Frédéric Viret
Jean-Frédéric Viret, Ph.D.
Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Coherus BioSciences, Inc. (the "Registrant") certify that the Quarterly Report of Coherus BioSciences, Inc. on Form 10-Q for the quarterly period ended March 31, 2015 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that information contained in the Report fairly presents in all material respects the financial condition and results of operations of the Registrant.

Date: May 11, 2015

By: /s/ Dennis M. Lanfear
Name: Dennis M. Lanfear
Title: President and Chief Executive Officer

Date: May 11, 2015

By: /s/ Jean-Frédéric Viret
Name: Jean-Frédéric Viret
Title: Chief Financial Officer

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.