

**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 September 30, 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**  
(State or other jurisdiction of  
incorporation or organization)

**27-3615821**  
(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 October 31, 2015, 38,892,650 shares of the registrant's common stock were outstanding.

COHERUS BIOSCIENCES, INC.  
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2015  
INDEX

	<u>Page</u>
<a href="#">CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS</a>	3
<b>PART I</b> <a href="#">FINANCIAL INFORMATION</a>	5
<b>ITEM 1</b> <a href="#">Unaudited Condensed Consolidated Financial Statements</a>	5
<a href="#">Condensed Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014</a>	5
<a href="#">Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2015 and 2014</a>	6
<a href="#">Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2015 and 2014</a>	7
<a href="#">Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014</a>	8
<a href="#">Notes to Condensed Consolidated Financial Statements</a>	9
<b>ITEM 2</b> <a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	23
<b>ITEM 3</b> <a href="#">Quantitative and Qualitative Disclosure About Market Risk</a>	30
<b>ITEM 4</b> <a href="#">Controls and Procedures</a>	30
<b>PART II</b> <a href="#">OTHER INFORMATION</a>	32
<b>ITEM 1.</b> <a href="#">Legal Proceedings</a>	32
<b>ITEM 1A.</b> <a href="#">Risk Factors</a>	32
<b>ITEM 2</b> <a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	70
<b>ITEM 3</b> <a href="#">Defaults Upon Senior Securities</a>	70
<b>ITEM 4</b> <a href="#">Mine Safety Disclosures</a>	70
<b>ITEM 5</b> <a href="#">Other Information</a>	70
<b>ITEM 6.</b> <a href="#">Exhibits</a>	70
<a href="#">Signatures</a>	71
<a href="#">Exhibit Index</a>	72

## 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,” “potential,” “seek,” “should,” “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 Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH, together Baxalta, will be sufficient to fund our operations for at least the next 12 months;
- 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 supply our product candidates for us;
- our reliance on third-party contract research organizations to conduct clinical trials of our product candidates;
- 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 1. Unaudited Condensed Consolidated Financial Statements

**Coherus BioSciences, Inc.**  
**Condensed Consolidated Balance Sheets**  
(in thousands, except share and per share data)

	September 30, 2015 (unaudited)	December 31, 2014
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 153,691	\$ 150,392
Restricted cash	60	60
Receivables from collaboration and license agreement	540	2,417
Notes receivable	—	1,815
Prepaid assets	31,678	20,485
Other assets	3,333	2,276
Other assets - related party	—	1,691
Total current assets	<u>189,302</u>	<u>179,136</u>
Property and equipment, net	8,652	4,472
Intangible assets	2,620	2,620
Goodwill	943	943
Restricted cash, non-current	785	—
Other assets, non-current	10	50
Total assets	<u>\$ 202,312</u>	<u>\$ 187,221</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 25,186	\$ 8,778
Accounts payable - related parties	3,092	2,020
Accrued liabilities	25,170	11,231
Advance payments under license agreement	—	1,192
Deferred revenue	28,848	22,800
Contingent consideration	—	5,710
Other liabilities	223	52
Total current liabilities	<u>82,519</u>	<u>51,783</u>
Deferred revenue, non-current	33,447	39,899
Contingent liability to collaborator	43,500	27,650
Contingent consideration, non-current	1,060	785
Other liabilities, non-current	1,746	347
Total liabilities	<u>162,272</u>	<u>120,464</u>
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; Shares authorized: 5,000,000 at September 30, 2015; Shares issued and outstanding: no shares at September 30, 2015 and December 31, 2014	—	—
Common stock, \$0.0001 par value; Shares authorized: 300,000,000 at September 30, 2015; Shares issued and outstanding: 38,806,306 and 33,257,978 at September 30, 2015 and December 31, 2014, respectively	4	3
Additional paid-in capital	398,636	254,048
Accumulated other comprehensive loss	(473)	(525)
Accumulated deficit	(357,594)	(186,725)
Total Coherus stockholders' equity	<u>40,573</u>	<u>66,801</u>
Non-controlling interest	(533)	(44)
Total stockholders' equity	<u>40,040</u>	<u>66,757</u>
Total liabilities and stockholders' equity	<u>\$ 202,312</u>	<u>\$ 187,221</u>

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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
<b>Revenue:</b>				
Collaboration and license revenue	\$ 7,167	\$ 15,620	\$ 19,843	\$ 23,168
Collaboration and license revenue - related party (1)	—	432	—	1,445
Total revenue	7,167	16,052	19,843	24,613
<b>Operating expenses:</b>				
Research and development (includes related party of \$10,034 and \$4,917 for the three months ended September 30, 2015 and 2014, respectively; and \$33,919 and \$15,698 for the nine months ended September 30, 2015 and 2014, respectively)	68,218	18,496	161,629	51,357
General and administrative (includes related party of \$168 and \$362 for the three months ended September 30, 2015 and 2014, respectively; and \$511 and \$507 for the nine months ended September 30, 2015 and 2014, respectively)	10,166	3,979	25,074	11,378
Total operating expenses	78,384	22,475	186,703	62,735
Loss from operations	(71,217)	(6,423)	(166,860)	(38,122)
Interest expense (includes related party of \$0 and \$2,687 for the nine months ended September 30, 2015 and 2014, respectively)	(33)	(1)	(33)	(3,900)
Other expense, net	(235)	(1,490)	(4,465)	(16,132)
Net loss	(71,485)	(7,914)	(171,358)	(58,154)
Net loss attributable to non-controlling interest	151	42	489	155
Net loss attributable to Coherus	\$ (71,334)	\$ (7,872)	\$ (170,869)	\$ (57,999)
Net loss per share attributable to Coherus, basic and diluted	\$ (1.86)	\$ (1.79)	\$ (4.68)	\$ (13.62)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	38,426,734	4,409,703	36,510,756	4,258,770

(1) Represents revenue from Daiichi Sankyo through November 12, 2014 as a related party, a holder of more than 10% of our common stock until the closing of our initial public offering (“IPO”).

See accompanying notes to condensed consolidated financial statements.

**Coherus BioSciences, Inc.**

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Net loss	\$ (71,485)	\$ (7,914)	\$ (171,358)	\$ (58,154)
Other comprehensive loss:				
Foreign currency translation adjustments, net of tax	47	(160)	52	(128)
Comprehensive loss	(71,438)	(8,074)	(171,306)	(58,282)
Comprehensive loss attributable to non-controlling interest	151	42	489	155
Comprehensive loss attributable to Coherus	<u>\$ (71,287)</u>	<u>\$ (8,032)</u>	<u>\$ (170,817)</u>	<u>\$ (58,127)</u>

See accompanying notes to condensed consolidated financial statements.

**Coherus BioSciences, Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
(in thousands)  
(unaudited)

	Nine Months Ended September 30,	
	2015	2014
<b>Operating activities</b>		
Net loss	\$ (171,358)	\$ (58,154)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	1,268	439
Remeasurement of contingent consideration	4,414	2,740
Remeasurement of convertible preferred stock warrants	—	15,373
Preferred stock issued in exchange for services	—	147
Non-cash interest (income) expense and amortization of (receivable) debt discount	(38)	3,897
Impairment of property and equipment	128	—
Gain on extinguishment of 2013 Notes	—	(2,048)
Stock-based compensation expense	11,547	7,236
Changes in operating assets and liabilities:		
Receivables from collaboration and license agreement	1,877	—
Receivables from related party	—	278
Notes receivable from related parties	—	107
Notes receivable	1,853	—
Prepaid assets	(11,194)	(12,157)
Other assets	(2,331)	—
Other assets - related party	1,691	—
Other assets - non-current	42	(476)
Accounts payable	19,100	552
Accounts payable - related parties	1,072	4,580
Accrued and other liabilities	13,771	498
Deferred revenue	(383)	25,885
Advance payments under license agreements	(1,192)	—
Contingent liability to collaborator	15,850	20,150
Other liabilities, non-current	326	311
Net cash (used in) provided by operating activities	<u>(113,557)</u>	<u>9,358</u>
<b>Investing activities</b>		
Net cash acquired from acquisition of InteKrin Therapeutics, Inc.	—	2,334
Purchases of property and equipment	(4,720)	(2,360)
Increase in restricted cash	(785)	—
Net cash used in investing activities	<u>(5,505)</u>	<u>(26)</u>
<b>Financing activities</b>		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	54,660
Proceeds from issuance of convertible preferred stock upon exercise of warrants	—	74
Proceeds from follow-on offering, net of underwriters discounts and commissions	112,800	—
Proceeds from private placement	10,000	—
Proceeds from issuance of common stock upon exercise of stock options	1,015	19
Repurchase of restricted common stock	—	(2)
Payments of initial public offering costs	(855)	(2,561)
Payments of follow-on offering costs	(601)	—
Net cash provided by financing activities	<u>122,359</u>	<u>52,190</u>
Effect of exchange rate changes in cash and cash equivalents	<u>2</u>	<u>(201)</u>
Net increase in cash and cash equivalents	3,299	61,321
Cash and cash equivalents at beginning of period	150,392	39,554
Cash and cash equivalents at end of period	<u>\$ 153,691</u>	<u>\$ 100,875</u>

See accompanying notes to condensed consolidated financial statements.



Notes to Condensed Consolidated Financial Statements  
(unaudited)

**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. In October 2015, the Company completed a pivotal pharmacokinetic (PK) and pharmacodynamics (PD) study for CHS-1701 in the United States (U.S.), which the Company believes will support the planned filing of a biologics license application (“BLA”) in the U.S. An additional immunogenicity study is underway in healthy volunteers pursuant to this BLA, which is projected to be submitted to the U.S. Food and Drug Administration (“FDA”) in the first quarter of 2016.
- 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 Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH, (collectively “Baxalta”) and Daiichi Sankyo Company, Limited (“Daiichi Sankyo”) to develop and commercialize in key markets outside of the U.S. In October 2015, the Company completed part 1 of a Phase 3 clinical study in psoriasis comparing CHS-0214 to Enbrel. This study is on-going, but this study met all its primary efficacy endpoints. There were no clinically important safety issues in either treatment group. The Company expects that results from these studies, if positive, combined with data from our Phase 1 studies and Phase 3 study in psoriasis, will support the expected filing of a marketing application in Europe and Japan in 2016. The Company has retained the development and commercial rights to this product 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.
- 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 initiated a Phase 3 study in psoriasis in August 2015 to support the planned filing of a marketing application in the U.S. in 2016 and the E.U. in 2017. A bridging PK study comparing the Phase 3 CHS-1420 material to adalimumab (Humira) is planned for during the first half of 2016.

**Need to Raise Additional Capital**

As of September 30, 2015, the Company had an accumulated deficit of \$357.6 million and cash and cash equivalents of \$153.7 million. The Company believes that its current available cash and cash equivalents, together with funding it expects to receive under its license agreements with Daiichi Sankyo and Baxalta, 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 September 30, 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 these 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.

The foreign exchange gains and losses recorded in other expense, net in the condensed consolidated statements of operations for the three months ended September 30, 2015 and 2014, was a net loss of \$123,000 and a net gain of \$246,000, respectively, and for the nine months ended September 30, 2015 and 2014, was a net loss of \$162,000 and a net gain of \$164,000, respectively.

### Segment Reporting and Customer Concentration

The Company operates and manages its business as one reportable and operating segment, which is the business of developing and commercializing biosimilar products, and, as part of the InteKrin acquisition, small molecules. 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
United States	\$ 6,807	\$ 15,620	\$ 18,599	\$ 23,168
Rest of world	360	432	1,244	1,445
Total revenue	<u>\$ 7,167</u>	<u>\$ 16,052</u>	<u>\$ 19,843</u>	<u>\$ 24,613</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Baxalta	95%	97%	94%	94%

## 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) upon 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 a 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.

## 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.

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. A milestone is defined as an event that can only be achieved based on the Company’s performance where 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.

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. Other comprehensive loss includes foreign currency translation adjustments for the three and nine months ended September 30, 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. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers: Deferral of the Effective Date* ("ASU 2015-14"). Under the amendments in ASU 2015-14, the FASB deferred the effective date of ASU 2014-09 for public business entities to fiscal years beginning after December 15, 2017, including interim reporting periods within that reporting period, with early adoption permitted on the original effective date of fiscal years beginning after December 15, 2016. The Company may adopt the new standard under the full retrospective method or the modified retrospective method. The Company is currently evaluating the impact that the adoption of ASU 2014-09 will have on its condensed 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's annual reporting period ending December 31, 2016 and all annual and interim reporting periods thereafter, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2014-15 will have on its condensed 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			
	September 30, 2015			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money market funds	\$ 153,367	\$ 153,367	\$ —	\$ —
Restricted cash (money market funds)	845	845	—	—
Total financial assets	<u>\$ 154,212</u>	<u>\$ 154,212</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Contingent consideration	<u>\$ 1,060</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,060</u>

  

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

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. For the three and nine months ended September 30, 2014, the Company recognized \$1.0 million and \$2.7 million, respectively, in other expense, net in the condensed consolidated statement of operations for the change in the fair value of the Earn-Out Payment.

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 was recognized in other expense, net within the condensed consolidated statement of operations of \$135,000 and \$275,000 for the three and nine months ended September 30, 2015, respectively, and \$25,000 and \$70,000 for the three and nine months ended September 30, 2014, respectively.

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	4,414
Fair value of Earn-Out Payment settled in common stock on March 6, 2015	(9,849)
Balance as of September 30, 2015	<u>\$ 1,060</u>

#### 4. Balance Sheet Components

##### Prepaid Assets

Prepaid assets are as follows (in thousands):

	September 30, 2015	December 31, 2014
Prepaid clinical, material, manufacturing and other - related parties	\$ 7,116	\$ 5,990
Prepaid clinical, material and manufacturing	22,048	12,149
Prepaid other	2,514	2,346
Prepaid assets	<u>\$ 31,678</u>	<u>\$ 20,485</u>

##### Property and Equipment, Net

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

	September 30, 2015	December 31, 2014
Machinery and equipment	\$ 6,594	\$ 4,317
Computer equipment and software	967	286
Furniture and fixtures	325	288
Leasehold improvements	1,212	399
Construction in progress	2,220	474
Total property and equipment	11,318	5,764
Accumulated depreciation and amortization	(2,666)	(1,292)
Property and equipment, net	<u>\$ 8,652</u>	<u>\$ 4,472</u>

Depreciation and amortization expense was \$636,000 and \$192,000 for the three months ended September 30, 2015 and 2014, respectively, and \$1,268,000 and \$439,000 for the nine months ended September 30, 2015 and 2014, respectively.

In July 2015, the Company entered into a new lease agreement with its landlord for its new headquarters facility in Redwood City, California (see Note 6). It is expected that the Company will move into the new facility in December 2015. Construction in progress at September 30, 2015 includes \$2.2 million of leasehold improvements related to the new headquarters.

### Accrued Liabilities

Accrued liabilities are as follows (in thousands):

	September 30, 2015	December 31, 2014
Accrued clinical, manufacturing and other - related parties	\$ 6,678	\$ 2,997
Accrued clinical and manufacturing	12,199	2,396
Accrued compensation	3,108	3,435
Accrued professional and consulting fees	688	252
Accrued other	2,497	2,151
Accrued liabilities	<u>\$ 25,170</u>	<u>\$ 11,231</u>

### 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Baxalta	\$ 6,807	\$ 15,620	\$ 18,599	\$ 23,168
Daiichi Sankyo - related party (1)	360	432	1,244	1,445
Total collaboration and license revenue	<u>\$ 7,167</u>	<u>\$ 16,052</u>	<u>\$ 19,843</u>	<u>\$ 24,613</u>

- (1) Represents revenue from Daiichi Sankyo through November 12, 2014 as a related party, a holder of more than 10% of our common stock until the closing of our IPO.

### 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 records as advance payments under license agreement in the condensed

consolidated balance sheet. The Company recognizes the advance payments as a reduction in the research and development expense when the research and development activity has been performed.

In June 2015, the Company and Daiichi Sankyo entered into the Memorandum of Understanding No. 3 (the “MOU 3”) in which both parties agreed to cooperate further on a global Phase 3 clinical in rheumatoid arthritis. Under the MOU 3, Daiichi Sankyo will be responsible for a minimum of 20% of the cost of an open label, safety extension study (“OLSES”) in rheumatoid arthritis. The Company also entered into a clinical supply agreement as part of the MOU 3 in which the Company will supply finished study drug and study comparator drug for Daiichi Sankyo’s use in the Japanese portion of the clinical trial. Daiichi Sankyo will pre-pay these research and development costs quarterly, and they are recorded by the Company as advance payments in the condensed consolidated balance sheet. The Company recognizes the advance payments as a reduction of research and development expense when the research and development activity has been performed.

As of September 30, 2015, \$3.1 million of revenue was deferred under all arrangements with Daiichi Sankyo, of which \$1.4 million was included in current liabilities and \$1.7 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 \$4.0 million and \$1.2 million for the three months ended September 30, 2015 and 2014, respectively, and \$7.9 million and \$3.6 million for the nine months ended September 30, 2015 and 2014, respectively.

## **Baxalta**

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. In the second quarter of 2015, Baxter assigned its rights and obligations under the license agreement to affiliated entities that are under common control of Baxalta. Under the terms of the license agreement, the Company will conduct the development and the regulatory activities, and Baxalta 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, Baxalta 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. As of December 31, 2014, the Company received a total of \$85.3 million in clinical development 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 Baxalta 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., 50% of those contingent payments are refundable to Baxalta. 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.

In April 2015, the Company and Baxalta, entered into a second amendment (the “Second Amendment”) to the license agreement. Under the terms of the Second Amendment, a revised milestone payment structure totaling \$130.0 million replaced certain existing milestone and funding obligations under the license agreement as originally executed. The Second Amendment does not provide for any change in the contracted deliverables set forth in the license agreement. As a result, the original assessment of the standalone value for the deliverables remains unchanged and the deferred revenue previously recorded prior to the Second Amendment continues to be recognized as revenue on a straight-line basis over the remaining expected performance period. Likewise, the contingent liability from the incremental milestones received under the license agreement prior to Second Amendment has not been adjusted.



If the Company commercializes CHS-0214, its etanercept biosimilar product, in the United States, the Company will be required to refund a portion of the milestone payments received from Baxalta as specified in the Second Amendment. A portion of each of the \$130.0 million milestones would be subject to refund. The Company concluded that the payments that contain potentially reimbursable amounts to Baxalta are not substantive milestones under the relevant accounting guidance, since the guidance does not allow the substantive milestone components of a payment to be bifurcated from non-substantive milestone components. Therefore, the Company will record the portion of the contingent payment that contains the claw-back feature as a liability for the potential reimbursement of such funds to Baxalta until the earlier to occur of: (1) expiration of the license agreement pursuant to its terms in August 2023, (2) the earlier termination of the license agreement, or (3) the determination, pursuant to the terms of the license agreement, of the third party to commercialize CHS-0214 in the U.S. This liability is included in the contingent liability to collaborator on the condensed consolidated balance sheets. The portion of the milestone payment that does not contain the claw-back feature will be recorded as deferred revenue and recognized as license revenue on a straight-line basis over the remaining estimated performance period. The Company determined that there is no other method that is more appropriate than the straight-line method of revenue recognition for this agreement given there is no discernable pattern of performance under the arrangement.

Pursuant to the Second Amendment, the Company received a \$35.0 million milestone payment in May 2015 in connection with the completion of the enrollment for CHS-0214 Phase 3 clinical studies in rheumatoid arthritis and psoriasis. Approximately \$31.7 million of this \$35.0 million milestone payment is subject to the 50% claw-back feature. Therefore, the Company recorded \$15.8 million as contingent liability to collaborator and \$19.2 million as deferred revenue which is being amortized over the remaining estimated performance period using the straight line method.

The Second Amendment also provides that Baxalta will purchase \$10.0 million of the Company's common stock within six months of execution of the Second Amendment at a price per share equal to the closing trading price on the date of such purchase. As a result, on September 10, 2015, the Company entered into a Stock Purchase Agreement (the "Purchase Agreement") with Baxalta. Pursuant to the Purchase Agreement, the Company sold Baxalta an aggregate of 390,167 shares of common stock for aggregate gross proceeds of approximately \$10 million. See Note 7 for further details.

As of September 30, 2015, \$59.0 million of revenue was deferred under the arrangements with Baxalta, of which \$27.2 million was included in current liabilities and \$31.8 million was included in non-current liabilities in the condensed consolidated balance sheet. As of September 30, 2015, \$43.5 million was recorded as contingent liability to collaborator due to the potential refund of such amount to Baxalta in the future.

As of December 31, 2014, \$58.4 million of revenue was deferred under the arrangements with Baxalta, 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 Baxalta.

## **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 September 30, 2015, the Company had a commitment of \$13.5 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 the aggregate for clinical trial services; however, the agreement is cancelable without cause by either party upon 30 days prior notification. As of September 30, 2015, the Company has fulfilled the minimum fee commitment related to this agreement.

### **Facility Leases**

#### *New Lease Agreement*

On July 6, 2015, the Company entered into a new office lease (the "New Lease") with Hudson 333 Twin Dolphin Plaza, LLC (the "Landlord") to lease approximately 27,532 square feet of office space located in Redwood City, California (the "Premises") for the Company's new corporate headquarters. The Company currently leases office space located in Redwood City, California, pursuant to a lease dated September 26, 2011 (as amended, the "Current Lease"), which expires pursuant to the terms described below under "Amendment to Current Lease."

The New Lease commences on the earlier of (i) the first date on which Tenant conducts business in the Premises, or (ii) the later of (a) October 22, 2015, or (b) the date on which the Landlord substantially completes certain improvements to the Premises (the “Commencement Date”). The New Lease terminates on the last day of the calendar month following the date that is 84 months after the Commencement Date (the “Lease Term”), unless terminated earlier. It is expected that the Company will move into the new facility in December 2015.

The New Lease provides for annual base rent of approximately \$1.6 million in the first year of the Lease Term, which increases on an annual basis up to approximately \$1.9 million for the final year of the Lease Term. The New Lease also provides for certain limited rent abatements in the second year of the Lease Term. The Company will be entitled to a one-time improvement allowance of approximately \$1.2 million for costs related to the design and construction of Company improvements that are permanently affixed to the Premises. See the future minimum lease payment schedule for all facility leases below.

In addition, the Company obtained a standby letter of credit (the “Letter of Credit”) in an amount of approximately \$0.8 million, which may be drawn down by the Landlord to be applied for certain purposes upon the Company’s breach of any provisions under the New Lease. Provided that no default occurs under the terms of the New Lease, the Company will be entitled to periodically reduce the amount of the Letter of Credit down to approximately \$0.3 million as of the last day of the sixtieth full calendar month of the Lease Term. The Company has recorded the \$0.8 million Letter of Credit in restricted cash, non-current within its condensed consolidated balance sheet at September 30, 2015.

#### *Amendment to Current Lease*

On July 6, 2015, the Company entered into the Seventh Amendment to the Current Lease (the “Seventh Amendment”) with its current landlord. The Seventh Amendment provides for early termination of the Current Lease effective on the later of October 25, 2015 or the date three business days after the Commencement Date of the New Lease. The Company will not be required to pay the landlord a termination payment in connection with the early termination of the lease. Prior to the execution of the Seventh Amendment, the Current Lease had been scheduled to expire on April 30, 2017.

The future minimum lease payments for all the Company’s facility leases, which takes into consideration the termination of the Current Lease and the commencement of the New Lease in December 2015, as of September 30, 2015 are as follows (in thousands):

<b>Year ending December 31,</b>		
2015 (three months remaining)	\$	324
2016		1,692
2017		1,276
2018		1,669
2019 and thereafter		7,033
Total minimum lease payments	\$	<u>11,994</u>

#### **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 September 30, 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**

##### *InteKrin Earn-Out*

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 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 \$0.6 million, the net proceeds were \$112.2 million.

### Private Placement with Baxalta

On September 10, 2015, the Company completed a private placement and entered into the Purchase Agreement with Baxalta. Pursuant to the Purchase Agreement, the Company sold Baxalta an aggregate of 390,167 shares of common stock for aggregate gross proceeds of approximately \$10 million. The purchase price for each share was \$25.63, which was equal to the closing trading price of the Company's common stock on the NASDAQ Global Market on the day of pricing, September 9, 2015. The securities sold and issued in connection with the private placement are not registered under the Securities Act or any state securities laws and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from the registration requirements. In connection with the Purchase Agreement, the Company entered into a Registration Rights Agreement (the "Registration Rights Agreement") with Baxalta GmbH. Pursuant to the Registration Rights Agreement, the Company agreed to prepare and file a registration statement with the SEC no later than December 4, 2015 for purposes of registering the resale of the shares and agreed to use its reasonable best efforts to cause this registration statement to be declared effective by the SEC within 60 days after its filing.

### 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 September 30, 2015, all shares were fully vested and there were no 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development	\$ —	\$ 973	\$ 9	\$ 1,208
General and administrative	—	1	—	4
	<u>\$ —</u>	<u>\$ 974</u>	<u>\$ 9</u>	<u>\$ 1,212</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development	\$ 2,146	\$ 871	\$ 5,602	\$ 1,561
General and administrative	2,598	890	5,936	1,767
	<u>\$ 4,744</u>	<u>\$ 1,761</u>	<u>\$ 11,538</u>	<u>\$ 3,328</u>

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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
<b>Numerator:</b>				
Net loss attributable to Coherus	\$ (71,334)	\$ (7,872)	\$ (170,869)	\$ (57,999)
<b>Denominator:</b>				
Weighted-average common shares outstanding	38,426,734	4,624,437	36,515,581	4,691,201
Less: weighted-average unvested common shares subject to repurchase (1)	—	(214,734)	(4,825)	(432,431)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	38,426,734	4,409,703	36,510,756	4,258,770
Net loss per share attributable to Coherus, basic and diluted	\$ (1.86)	\$ (1.79)	\$ (4.68)	\$ (13.62)

- (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:

	September 30,	
	2015	2014
Stock options outstanding	7,924,249	5,550,190
Convertible preferred stock	—	21,131,217
Convertible preferred stock warrants	—	186,982
Common stock warrants	—	553,274
Total	7,924,249	27,421,663

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 and nine months ended September 30, 2014. On March 6, 2015, the contingent issuable shares were settled (see Note 3).

## 9. Related Party Transactions

### Daiichi Sankyo

In January 2012, 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 \$0.4 million and \$1.4 million as collaboration and license revenue-related party in the Company's statements of operations for the three and nine months ended September 30, 2014. In addition, the Company recognized \$1.2 million and \$3.6 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 and nine months ended September 30, 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 September 30, 2015 and for the three and nine months ended September 30, 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 a credit of \$0.1 million and an expense of \$4.1 million during the three and nine months ended September 30, 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 September 30, 2015 and for the three and nine months ended September 30, 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 September 30, 2015, the Company had \$7.1 million in prepaid assets (prepaid clinical, material, manufacturing and other-related parties), \$3.0 million in accounts payable-related parties, and \$6.7 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 \$10.0 million and \$6.2 million during the three months ended September 30, 2015 and 2014, respectively, and \$33.7 million and \$14.9 million during the nine months ended September 30, 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 September 30, 2015, the Company has fulfilled the minimum fee commitment related to this agreement.

### **Recruiting Services**

One member of the Company's board of directors was the chief executive officer of a company that provided recruiting services to the Company. As of September 30, 2015 and December 31, 2014, the Company had \$50,000 and \$90,000, respectively, in accounts payable-related parties on the Company's condensed consolidated balance sheet. The Company recorded in its condensed consolidated statements of operations \$168,000 and \$362,000 for the three months ended September 30, 2015 and 2014, respectively, and \$511,000 and \$507,000 for the nine months ended September 30, 2015 and 2014, respectively, in general and administrative expense; \$0 for both the three month periods ended September 30, 2015 and 2014, respectively, and \$258,000 and \$241,000 for the nine months ended September 30, 2015 and 2014, respectively, in research and development expense 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 Company's 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. 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 and nine months ended September 30, 2014, the Company recognized \$0 million and \$2.7 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, a majority owned subsidiary of InteKrin.

### **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. This amount is reflected in the Company's condensed consolidated balance sheet at December 31, 2014 as "other assets-related party". This transaction was settled in July 2015.

**10. Subsequent Event**

On October 15, 2015, the Company received a \$30.0 million milestone payment from Baxalta, pursuant to the Second Amendment. The milestone payment relates to the successful demonstration of drug product stability for CHS-0214, the Company's etanercept biosimilar candidate.

## 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. In October 2015, we have completed a pivotal pharmacokinetic (PK) and pharmacodynamics (PD) study for CHS-1701 in the United States (U.S.), which we believe will support the planned filing of a biologics license application (BLA) in the U.S. An additional immunogenicity study is underway in healthy volunteers pursuant to this BLA, which is projected to be submitted to the U.S. Food and Drug Administration ("FDA") in the first quarter of 2016.
- **CHS-0214 (our etanercept (Enbrel) biosimilar candidate).** CHS-0214 is a product candidate that we have partnered with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH, (collectively "Baxalta") and Daiichi Sankyo Company, Limited ("Daiichi Sankyo"), to develop and commercialize in key markets outside of the United States. In October 2015, we completed part 1 of a Phase 3 clinical study in psoriasis comparing CHS-0214 to Enbrel. This study is on-going but has met all its primary efficacy endpoints at 12 weeks. There were no clinically important safety issues noted in either treatment group. This study is on-going. We are currently conducting a Phase 3 clinical study in rheumatoid arthritis. We further expect primary efficacy and safety results from this study, in the first quarter of 2016. We expect that results from these studies, if positive, combined with data from our Phase 1 studies and Phase 3 study in psoriasis, will support the expected filing of a marketing application in Europe and Japan in 2016. We have retained the development and commercial rights to this product 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.
- **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 initiated a Phase 3 study in psoriasis in August 2015 to support the planned filing of a marketing application in the U.S. in 2016 and the E.U. in 2017. A bridging PK study comparing the Phase 3 CHS-1420 material to adalimumab (Humira) is planned for during the first half of 2016.

Our revenue to date has been generated primarily from collaboration and license payments pursuant to our license agreements with Daiichi Sankyo and Baxalta. 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 \$171.4 million and \$58.2 million for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, we had an accumulated deficit of \$357.6 million.

In March 2015, our registration statement on Form S-1 (File No. 333-202936) relating to the follow-on offering of our 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 we sold 4,137,931 shares of common stock. We 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 \$0.6 million, the net proceeds were \$112.2 million.

In September 2015, the Company completed a private placement with Baxalta, in which the Company sold an aggregate of 390,167 shares of common stock for aggregate gross proceeds of approximately \$10.0 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 initial public offering (“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 nine months ended September 30, 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. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers: Deferral of the Effective Date* (“ASU 2015-14”). Under the amendments in ASU 2015-14, the FASB deferred the effective date of this standards update to fiscal years beginning after December 15, 2017, including interim reporting periods within that reporting period, with early adoption permitted on the original effective date of fiscal years beginning after December 15, 2016. We are currently evaluating the impact that the adoption of ASU 2014-09 will have on our condensed 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 our annual reporting period ending December 31, 2016 and all annual and interim reporting periods thereafter, with early adoption permitted. We are currently evaluating the impact that the adoption of ASU 2014-15 will have on our condensed 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 and Nine Months Ended September 30, 2015 and 2014

#### Collaboration and License Revenue

	Three Months Ended			Nine Months Ended		
	September 30,			September 30,		
	2015	2014	Change	2015	2014	Change
<i>(in thousands)</i>						
Revenue:						
Baxalta	\$ 6,807	\$ 15,620	\$ (8,813)	\$ 18,599	\$ 23,168	\$ (4,569)
Daiichi Sankyo - related party (1)	360	432	(72)	1,244	1,445	(201)
Total collaboration and license revenue	<u>\$ 7,167</u>	<u>\$ 16,052</u>	<u>\$ (8,885)</u>	<u>\$ 19,843</u>	<u>\$ 24,613</u>	<u>\$ (4,770)</u>

- (1) Represents revenue from Daiichi Sankyo through November 12, 2014 as a related party, a holder of more than 10% of our common stock until the closing of our IPO.

Collaboration and license revenue for the three months ended September 30, 2015 was \$7.2 million compared to \$16.1 million for the same period in 2014, a decrease of \$8.9 million. The decrease was primarily due to the \$10.0 million receipt received for the achievement of a substantive milestone in the third quarter of 2014 under our license agreement with Baxalta. The decrease was partially offset by increased revenue recognized in connection with the amortization of deferred revenue under our license agreement with Baxalta.

Collaboration and license revenue for the nine months ended September 30, 2015 was \$19.8 million compared to \$24.6 million for the same period in 2014, a decrease of \$4.8 million. The decrease was primarily due to the \$10.0 million receipt received for the achievement of a substantive milestone in the third quarter of 2014 under our license agreement with Baxalta. The decrease was partially offset by increased revenue recognized in connection with the amortization of deferred revenue under our license agreement with Baxalta.

#### Research and Development Expenses

	Three Months Ended			Nine Months Ended		
	September 30,			September 30,		
	2015	2014	Change	2015	2014	Change
<i>(in thousands)</i>						
Research and development	<u>\$ 68,218</u>	<u>\$ 18,496</u>	<u>\$ 49,722</u>	<u>\$ 161,629</u>	<u>\$ 51,357</u>	<u>\$ 110,272</u>

Research and development expenses for the three months ended September 30, 2015 were \$68.2 million compared to \$18.5 million for the same period in 2014, an increase of \$49.7 million. The increase in research and development expenses was primarily due to:

- an increase of \$21.5 million in costs incurred for CHS-0214 due to the ongoing Phase 3 clinical studies, which is net of an increase of \$2.8 million in cost reimbursements from Daiichi Sankyo that were recognized as a reduction of research and development expense;
- an increase of \$13.4 million related to initiating BLA-enabling studies for CHS-1701;
- an increase of \$7.6 million to advance CHS-1420 to a Phase 3 clinical study in psoriasis;
- an increase of \$2.4 million in personnel, consulting and other related expenses, and \$0.3 million in stock-based compensation due to a net increase of approximately 38 employees, annual salaries increases and additional stock options granted in the first three quarters of 2015, partially offset by higher stock-based compensation expense related to consultants in the third quarter of 2014 than in the third quarter of 2015;
- an increase of \$2.2 million to advance other product candidates in our pipeline;
- an increase of \$1.5 million in facilities, supplies and materials and other infrastructure to support our research and development growth; and
- an increase of \$0.8 million to initiate an INT-131 proof-of concept Phase 2 clinical study.

Research and development expenses for the nine months ended September 30, 2015 were \$161.6 million compared to \$51.4 million for the same period in 2014, an increase of \$110.3 million. The increase in research and development expenses was primarily due to:

- an increase of \$46.8 million in costs incurred for CHS-0214 due to the ongoing Phase 3 clinical studies, which is net of an increase of \$4.4 million in cost reimbursements from Daiichi Sankyo that were recognized as a reduction of research and development expense;
- an increase of \$31.9 million related to initiating BLA-enabling studies for CHS-1701;
- an increase of \$13.9 million to advance CHS-1420 to a Phase 3 clinical study in psoriasis;
- an increase of \$7.5 million in personnel, consulting and other related expenses and \$1.6 million in stock-based compensation due to a net increase of approximately 38 employees, annual salaries increases and additional stock options granted in the first three quarters of 2015, partially offset by common stock warrant issued during 2014 and none in 2015, and higher stock-based compensation expense related to consultants during the first nine months of 2014 than during the first nine months of 2015;
- an increase of \$3.4 million in facilities, supplies and materials and other infrastructure to support our research and development growth;
- an increase of \$3.2 million to advance other product candidates in our pipeline; and
- an increase of \$2.0 million to initiate an INT-131 proof-of concept Phase 2 clinical study.

#### General and Administrative Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	Change	2015	2014	Change
	<i>(in thousands)</i>					
General and administrative	\$ 10,166	\$ 3,979	\$ 6,187	\$ 25,074	\$ 11,378	\$ 13,696

General and administrative expenses for the three months ended September 30, 2015 were \$10.2 million compared to \$4.0 million for the same period in 2014, an increase of \$6.2 million. The increase was primarily due to an increase of \$1.7 million in personnel, consulting and other related expenses and \$1.7 million in stock-based compensation as a result of an increase in headcount, annual salaries increases, and costs associated with stock options granted in the first three quarters of 2015. Additionally, the increase was due to an increase of \$2.2 million in legal, accounting, recruiting and other professional services and \$0.6 million in facilities, supplies and materials to support our growing infrastructure as we expanded our operations as a public company.

General and administrative expenses for the nine months ended September 30, 2015 were \$25.1 million compared to \$11.4 million for the same period in 2014, an increase of \$13.7 million. The increase was primarily due to an increase of \$5.1 million in personnel, consulting and other related expenses and \$2.8 million in stock-based compensation as a result of an increase in headcount, annual salaries increases, and costs associated with stock options granted in 2015. The increase in stock-based compensation was driven primarily from additional stock options granted in the first three quarters of 2015, partially offset by common stock warrants issued during the first nine months of 2014. In addition, the increase in general and administrative expenses was due to an increase of \$4.6 million in legal, accounting, recruiting and other professional services and \$1.2 million in facilities, supplies and materials to support our growing infrastructure as we expanded our operations as a public company.

#### Interest Expense

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	Change	2015	2014	Change
	<i>(in thousands)</i>					
Interest expense	\$ 33	\$ 1	\$ 32	\$ 33	\$ 3,900	\$ (3,867)

Interest expense for the three and nine months ended September 30, 2014 was \$1,000 and \$3.9 million, a decrease of \$3.9 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 nine months of 2015 compared to the recognition of non-cash interest expense and amortization of the debt discount during the first nine months of 2014.

#### *Other Expense, Net*

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	Change	2015	2014	Change
	<i>(in thousands)</i>					
Other expense, net	\$ 235	\$ 1,490	\$ (1,255)	\$ 4,465	\$ 16,132	\$ (11,667)

Other expense, net for the three months ended September 30, 2015 was \$0.2 million compared to \$1.5 million for the same period in 2014, a decrease of \$1.3 million. The decrease is primarily due to the change of \$0.7 million in fair value of our convertible preferred stock warrant liability from the third quarter of 2014 which converted into equity contemporaneously with the closing of our IPO on November 12, 2014 and the change in fair value of our contingent consideration related to the InteKrin acquisition of \$0.9 million during the third quarter of 2015 as the Earn-Out Payment portion of the contingent consideration was settled in May 2015. The decrease was partially offset by an increase of \$0.4 million due to a change in foreign exchange rates during the third quarter of 2015 when compared to the third quarter of 2014.

Other expense, net for the nine months ended September 30, 2015 was \$4.5 million compared to \$16.1 million for the same period in 2014, a decrease of \$11.7 million. The decrease is primarily due to the change of \$15.4 million in fair value of our convertible preferred stock warrant liability in the first nine months of 2014 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 \$1.7 million during the first nine months of 2015 as the fair value of the Earn-out Payment portion of the contingent consideration was settled in May 2015 and the gain on extinguishment of our convertible notes issued in 2013 of \$2.0 million in May 2014.

#### *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, sales of our convertible preferred stock and payments received under our collaboration and license agreements.

In April 2015, we completed a follow-on offering of common stock and raised net proceeds of \$112.2 million, after deducting underwriting discounts and commissions and offering expenses. Additionally, in September 2015 we completed a private placement with Baxalta which raised net proceeds of approximately \$10.0 million.

As of September 30, 2015, we had an accumulated deficit of \$357.6 million and cash and cash equivalents of \$153.7 million. We believe that our current available cash and cash equivalents, together with funding we expect to receive under our license agreement with Daiichi Sankyo and Baxalta, 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:

	Nine Months Ended September 30,	
	2015	2014
	<i>(in thousands)</i>	
Net cash (used in) provided by operating activities	\$ (113,557)	\$ 9,358
Net cash used in investing activities	(5,505)	(26)
Net cash provided by financing activities	122,359	52,190
Effect of exchange rate changes in cash and cash equivalents	2	(201)
Net increase in cash and cash equivalents	<u>\$ 3,299</u>	<u>\$ 61,321</u>

### *Net cash (used in) provided by operating activities*

Cash used in operating activities was \$113.6 million for the nine months ended September 30, 2015, reflecting a net loss of \$171.4 million, an increase in prepaid and other assets of \$11.8 million as a result for initiating clinical activities and timing of vendor payments, a decrease of \$1.2 million in advanced payments under license agreement, and a decrease of \$0.4 million in deferred revenue. Cash used in operating activities were partially offset by non-cash charges of \$4.4 million for the remeasurement of our contingent consideration obligations, \$11.5 million for stock-based compensation and \$1.4 million for depreciation and amortization and impairment of property and equipment. Cash used in operating activities were also offset by an increase of \$15.9 million in contingent liability to collaborator, an increase of \$33.9 million in accounts payable, accounts payable-related parties, and accrued and other liabilities as a result of the increase in clinical activities and timing of vendor payments, a decrease of \$1.9 million in receivables from collaboration and license agreement and a decrease of \$1.9 million in notes receivable as it was collected.

Cash provided by operating activities was \$9.4 million for the nine months ended September 30, 2014 reflecting a net loss of \$58.2 million, which was partially offset by non-cash charges of \$15.4 million for the remeasurement of our convertible preferred stock warrant liability and embedded derivative liabilities, \$2.7 million for remeasurement of our contingent consideration obligations, \$3.9 million of non-cash interest expense, \$7.2 million for stock-based compensation and \$0.4 million for depreciation and amortization, partially offset by the gain on the extinguishment of our convertible notes issued in 2013 of \$2.0 million. Cash provided by operating activities reflected an increase in net operating assets of \$39.7 million primarily due to an increase in deferred revenue of \$25.9 million and an increase in contingent liability to collaborator of \$20.2 million both related to the additional payments received from Baxalta under our license agreement. In addition, accounts payable and accounts payable-related parties increased by \$5.1 million, and accrued and other liabilities increased by \$0.5 million as a result of the increase in clinical activities and timing of vendor payments. The increase was partially offset by an increase in prepaid assets of \$12.2 million as a result of the increase in clinical activities.

### *Net cash used in investing activities*

Cash used in investing activities of \$5.5 million for the nine months ended September 30, 2015 was due to the purchase of capital equipment and leasehold improvements.

Cash used in investing activities of \$26,000 for the nine months ended September 30, 2014 was due to the purchases of capital equipment and leasehold improvements of \$2.4 million, partially offset by the net cash acquired from the acquisition of InteKrin in February 2014 of \$2.3 million.

### *Net cash provided by financing activities*

Cash provided by financing activities of \$122.4 million for the nine months ended September 30, 2015 was primarily related to the net proceeds of \$112.8 million from the issuance of our common stock in connection with our follow-on offering, net proceeds of approximately \$10.0 million from the private placement with Baxalta, and proceeds from the exercise of stock options of \$1.0 million, partially offset by our payments of IPO and follow-on offering costs of \$1.5 million.

Cash provided by financing activities of \$52.2 million for the nine months ended September 30, 2014 was primarily related to the net proceeds from the issuance of our Series C convertible preferred stock of \$54.7 million, offset by our payment of costs related to our initial public offering of \$2.6 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.

## Contractual Commitments - Facility Leases

In July 2015, we entered into a new lease agreement with our current landlord for a new headquarters facility in Redwood City, California. In addition, we entered into the seventh amendment to the existing facility lease with our current landlord which provides for early termination of the existing facility lease upon the commencement of the new lease. It is expected that the Company will move into the new facility in December 2015.

The future minimum lease payments for all of our facility leases, which takes into consideration the termination of the existing facility lease and the commencement of the new lease in December 2015, as of September 30, 2015 are as follows (in thousands):

	Payments Due by Period			
	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years
	<i>(in thousands)</i>			
Operating lease obligations	\$ 11,994	\$ 1,589	\$ 4,658	\$ 3,570
				\$ 2,177

## 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 September 30, 2015, we had cash and cash equivalents of \$153.7 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 September 30, 2015, we had 3.6 million Rubles in cash, which was equal to \$54,000 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 September 30, 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.

On November 9, 2015, we filed in the United States Patent and Trademark Office, pursuant to 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, a petition for Inter Partes Review (“IPR”) of AbbVie’s United States Patent No. 8,889,135 entitled “Methods of Administering Anti-TNF $\alpha$  antibodies” directed to treating rheumatoid arthritis in a human subject via subcutaneous administration, every 13-15 days, of 40 mg of a human anti-TNF $\alpha$  antibody.

### 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 \$171.4 million for the nine months ended September 30, 2015. As of September 30, 2015, we had an accumulated deficit of \$357.6 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 manufacturing, 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. In the second quarter of 2015, Baxter assigned its rights and obligations under our license agreement to Baxalta. 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 all three of our lead products, CHS-0214 (our etanercept (Enbrel) biosimilar candidate), CHS-1420 (our adalimumab (Humira) biosimilar candidate) and CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate). 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., Baxalta 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, 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 three product candidates through late-stage clinical development, which is expensive.

As of September 30, 2015, our cash and cash equivalents were \$153.7 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 Baxalta, 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 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, CHS-1420 and CHS-1701 have entered Phase 3 or other BLA-enabling clinical development.

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 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. 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.

***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 evidence 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.

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, in October 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 first quarter of 2016 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-1701 in the United States, which, if positive, we believe will support the planned filing of a BLA in the United States. An additional immunogenicity study was initiated in the second quarter of 2015 in healthy volunteers pursuant to this BLA. 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 therapeutic efficacy, 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, 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. 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. Nonclinical and clinical data are also 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 CHS-1420 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 and foreign regulatory agencies, 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 or 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 the 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 national level. 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 Baxalta) 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, CHS-1420, in the United States potentially with 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.

***Adverse events involving an originator product, or other biosimilars of such originator product, may negatively 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.

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 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. 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.

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

As of September 30, 2015, we had 107 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, a transition period is necessary when a new CRO commences work, 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, prospects and financial condition

***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 build and stock our product candidates in sufficient quantities to meet the requirements for the launch of these candidates 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 product candidates 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 an adalimumab (Humira) biosimilar being developed by Momenta in collaboration with Baxalta;
- 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, Baxalta and Orox for the commercialization of our biosimilar product 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, Baxalta, 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 costs associated with 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 product candidate, 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 additional 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, Apotex Inc., or Apotex, Sandoz International GmbH, or Sandoz, 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 and Apotex are 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, 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 Baxalta 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, reduce their competitiveness even if they reach the market, and harm our business and operating results.

***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 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. For example, Centers for Medicare & Medicaid Services (“CMS”) issued a proposed Part B rule in the third quarter of 2015 on biosimilar payment and coding which requires that multiple biosimilars to the same reference product be grouped and issued the same J-code for Medicare reimbursement purposes and that the payment amount for a billing code that describes a biosimilar is based on the average sales price (ASP) of all biosimilar products that reference a common biological product’s license application. This reimbursement rule could potentially create greater pricing pressure for biosimilars reimbursed in the medical benefit (Part B) segment. The final CMS rule is expected by the middle of the fourth quarter of 2015.

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.

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. We may also 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 Baxalta, 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. Our patents and patent applications, even if they are unchallenged, 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.

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.

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. 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.

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. We have also filed patent applications, 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 Baxalta or Daiichi Sankyo may choose 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 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 and other vendors (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 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 had we developed our product candidates under a traditional 351(a) BLA regulatory pathway.

The BPCIA mandates patent disclosure and briefing requirements that are demanding, time-sensitive and, to date, still being tested in the federal courts. 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.

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 or retain 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 day prior 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. Amgen appealed the District Court's decision to the Court of Appeals for the Federal Circuit (CAFC) which heard oral arguments on June 3, 2015. The three judge panel of the CAFC issued an order temporarily blocking Sandoz from selling Zarxio pending decision by the CAFC on Amgen's appeal. On July 21, 2015 the Federal Circuit court, ruling on Amgen's appeal, held in favor of Sandoz that a 351(k) biosimilar applicant may elect not to disclose its BLA and manufacturing information under the BPCIA. Under this aspect of the Court's ruling (assuming it survives all possible appeals), biosimilar applicants will be able to opt out of the patent resolution mechanism of the BPCIA, subject only to the remedy afforded the originator in the BPCIA, namely that it may sue the biosimilar applicant for patent infringement, before approval, under any patent the originator believes may be relevant. However, in a further aspect of its ruling favoring Amgen, the Court held on the facts before it that Sandoz was required to comply with the BPCIA's 180 prior notice of commercial marketing, and that such notice is not effective unless given after FDA licensure. Because Sandoz provided such notice to Amgen on March 6, 2015 (the date Zarxio received regulatory approval under the 351(k) regulatory pathway) the Court ruled that Sandoz would not be able to launch Zarxio until September 6, 2015. In August 2015, both parties requested en banc reconsideration of the Federal Circuit's decision. On October 16, 2015 the Federal Circuit denied the requests for reconsideration. Either party may appeal the Federal Circuit's ruling to the Supreme Court of the United States. Amgen and Apotex are also engaged in BPCIA litigation initiated in the third quarter of 2015 concerning Apotex's biosimilar versions of Neupogen and Neulasta. We believe this litigation, currently in its early stages, may result in eventual appeals to the Federal Circuit, which could result in one or more court decisions regarding interpretations of the BPCIA's patent provisions currently in dispute by those parties. We cannot predict whether or when issues regarding interpretation of the BPCIA will be finally resolved.

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 note that Amgen or Sandoz may appeal to the United States Supreme Court. This case, and other pending or future 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). If biosimilar applicants are ultimately required by final court rulings to engage in the BLA disclosure and patent exchange mechanism of the BPCIA, we believe they may, in some instances, be exposed 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 the applicant 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 BPCIA patent resolution mechanism, as did Sandoz in its 351(k) application for Zarxio.

Notwithstanding the Federal Circuit’s July 21, 2015 ruling that the patent exchange mechanism of the BPCIA is optional, we believe it is not yet certain whether courts will ultimately view the BPCIA process as an optional process, or instead 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. 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. Further, notwithstanding the Federal Circuit’s ruling that the BPCIA’s 180 notice provision is not effective until licensure, and is mandatory for biosimilar applicants that do not engage in the BPCIA patent exchange mechanism, it remains unclear to us whether courts will ultimately interpret the BPCIA to require all biosimilar applicants to provide the BPCIA’s 180 day notice of commercial marketing, and further, whether courts will rule that such notice can only be given after licensure. Such an interpretation would require biosimilar applicants that have received regulatory approval to refrain from marketing during the BPCIA’s 180 notice period.

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 incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.***

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and regulations regarding corporate governance practices. The listing requirements of The NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel must devote a substantial amount of time to ensure that we maintain compliance with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, may also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the Securities and Exchange Commission, or SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We are eligible to retain an emerging growth company status until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO (December 31, 2019), (b) in which we have total annual gross revenue of at least \$1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30<sup>th</sup>, and (2) the date on which we have issued more than an aggregate of \$1.0 billion in non-convertible debt during the prior three-year period. Based on our non-affiliated market capitalization as of June 30, 2015, we will cease to be an emerging growth company on January 1, 2016.

Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may also 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.

***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 reviews of our financial statements for the first, second and third quarters of 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, such as a single reimbursement code for biosimilar products.

***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 \$115,000 of cash in Russian banks as of September 30, 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 that we are currently evaluating for inclusion in our 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 IPO and the intraday sales price per share has ranged from \$12.27 to \$29.40 per share during the period from November 6, 2014 through November 6, 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 Quarterly Report on Form 10-Q 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 September 30, 2015, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 58.6% 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 are eligible to retain an emerging growth company status until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO (December 31, 2019), (b) in which we have total annual gross revenue of at least \$1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30<sup>th</sup>, and (2) the date on which we have issued more than an aggregate of \$1.0 billion in non-convertible debt during the prior three-year period. 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. Based on our non-affiliated market capitalization as of June 30, 2015, we will cease to be an emerging growth company on January 1, 2016.

***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 September 30, 2015, there were 38,806,306 shares of common stock outstanding. Of these shares, the shares of our common stock sold in our IPO and our follow-on offering are currently freely tradable, without restriction (except as otherwise applicable), in the public market.

In addition, as of September 30, 2015, approximately 9.1 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 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 September 2015, we completed a private placement under a Stock Purchase Agreement with Baxalta and sold an aggregate of 390,167 shares of common stock for aggregate gross proceeds of approximately \$10.0 million. The purchase price for each share was \$25.63, which is equal to the closing trading price of our common stock on the NASDAQ Global Market on the day of pricing, September 9, 2015.. The securities sold and issued in connection with the private placement are not registered under the Securities Act or any state securities laws and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from the registration requirements. In connection with the Purchase Agreement, we entered into a Registration Rights Agreement (the "Registration Rights Agreement") with Baxalta GmbH. Pursuant to the Registration Rights Agreement, we agreed to prepare and file a registration statement with the SEC no later than December 4, 2015 for purposes of registering the resale of the shares issued and agreed to use our reasonable best efforts to cause this registration statement to be declared effective by the SEC within 60 days after its filing.

### ***(b) Use of Proceeds***

In September 2015, we completed a private placement with Baxalta and sold an aggregate of 390,167 shares of common stock for aggregate gross proceeds of approximately \$10.0 million. We currently expect to use substantially all of the net proceeds from the private placement to fund the clinical and manufacturing development of CHS-0214, working capital and other general corporate purposes.

## **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 filed 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: November 10, 2015

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

Date: November 10, 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	3.1	11/12/2014	
3.2	Amended and Restated Bylaws.	8-K	3.2	11/12/2014	
4.1	Registration Rights Agreement, dated as of September 10, 2015, by and between Baxalta GmbH and Coherus BioSciences, Inc.	8-K	4.1	9/14/15	
10.1	Seventh Amendment to the Office Lease, effective July 6, 2015 by and between Hudson Towers at Shore Center, LLC, successor in interest to CA-Towers at Shores Center Limited Partnership, and Coherus BioSciences, Inc.	10-Q	10.2	8/10/15	
10.2	New Office Lease, effective July 6, 2015, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.	10-Q	10.3	8/10/15	
10.3	First Amendment, effective August 10, 2015, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.	10-Q	10.4	8/10/15	
10.4	Stock Purchase Agreement dated as of September 10, 2015 by and between Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH and Coherus BioSciences, Inc.	8-K	10.1	9/14/15	
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 September 30, 2015, formatted in eXtensible Business Reporting Language (XBRL) includes: (i) Condensed Balance Sheets at September 30, 2015 (unaudited) and December 31, 2014, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2015 and 2014, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2015 and 2014, (iv) Condensed Statements of Cash Flows (unaudited) for the nine months ended September 30, 2015 and 2014, and (v) Notes to the Condensed Financial Statements.				X



**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: November 10, 2015

/s/ Dennis M. Lanfear

\_\_\_\_\_  
Dennis M. Lanfear

President and Chief Executive Officer

**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: November 10, 2015

/s/ Jean-Frédéric Viret  
\_\_\_\_\_  
Jean-Frédéric Viret, Ph.D.  
Chief Financial Officer

**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 September 30, 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: November 10, 2015

By: /s/ Dennis M. Lanfear  
Name: Dennis M. Lanfear  
Title: President and Chief Executive Officer

Date: November 10, 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.*