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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2016

**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

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**Coherus BioSciences, Inc.**

*(Exact name of registrant as specified in its charter)*

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**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**27-3615821**  
*(I.R.S. Employer  
Identification No.)*

**333 Twin Dolphin Drive, Suite 600  
Redwood City, California 94065  
(650) 649-3530**

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

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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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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, 2016, 43,652,743 shares of the registrant's common stock were outstanding.

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COHERUS BIOSCIENCES, INC.  
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2016  
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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the timing and the success of the design of the clinical trials and planned clinical trials of CHS-1701 (our pegfilgrastim (Neulasta®) biosimilar candidate); CHS-0214 (our etanercept (Enbrel®) biosimilar candidate); and CHS-1420 (our adalimumab (Humira®) biosimilar candidate);
- whether the results of our trials will be sufficient to support domestic or global regulatory approvals for CHS-1701, CHS-0214 and CHS-1420;
- whether additional trials will be required to support domestic or global regulatory approvals for CHS-1701, CHS-0214 and CHS-1420;
- our ability to obtain and maintain regulatory approval of CHS-1701, CHS-0214 and CHS-1420 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 agreement with Daiichi Sankyo Company will be sufficient to fund our operations for at least the next 12 months;
- our ability to maintain and establish collaborations or obtain additional funding;
- the implementation of strategic plans for our business and product plans;
- 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 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-1701, CHS-0214 and CHS-1420;
- the rate and degree of market acceptance of CHS-1701, CHS-0214 and CHS-1420 or any future product candidates;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to manufacture CHS-1701, CHS-0214 and CHS-1420 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 Neulasta, Enbrel and Humira and other products in our pipeline that are in preclinical stages of development;
- 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)**

	September 30, 2016 <u>(unaudited)</u>	December 31, 2015 <u>(1)</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 159,677	\$ 158,226
Restricted cash	60	60
Receivables from collaboration and license agreement	419	1,560
Prepaid assets (includes related parties of \$5,771 and \$10,901 as of September 30, 2016 and December 31, 2015, respectively)	16,645	34,743
Other assets	518	2,797
Total current assets	<u>177,319</u>	<u>197,386</u>
Property and equipment, net	10,675	10,504
Intangible assets	2,620	2,620
Goodwill	943	943
Restricted cash, non-current	785	785
Other assets, non-current	15	146
Total assets	<u>\$ 192,357</u>	<u>\$ 212,384</u>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 22,883	\$ 25,948
Accounts payable - related parties	2,860	3,548
Accrued liabilities (includes related parties of \$6,041 and \$6,122 as of September 30, 2016 and December 31, 2015, respectively)	24,875	24,133
Advance payments under license agreement	1,150	1,330
Deferred revenue	1,377	49,621
Contingent consideration	4,990	1,245
Other liabilities	251	193
Total current liabilities	<u>58,386</u>	<u>106,018</u>
Deferred revenue, non-current	595	45,338
Convertible notes	74,953	—
Convertible notes - related parties	24,985	—
Contingent liability to collaborator	—	66,255
Other liabilities, non-current	1,716	1,702
Total liabilities	<u>160,635</u>	<u>219,313</u>
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	4	4
Additional paid-in capital	494,831	404,175
Accumulated other comprehensive loss	(562)	(401)
Accumulated deficit	(461,401)	(409,985)
Total Coherus stockholders' equity (deficit)	<u>32,872</u>	<u>(6,207)</u>
Non-controlling interest	(1,150)	(722)
Total stockholders' equity (deficit)	<u>31,722</u>	<u>(6,929)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 192,357</u>	<u>\$ 212,384</u>

(1) The consolidated balance sheet as of December 31, 2015 has been derived from the audited consolidated balance sheet included in the Company's 2015 Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 29, 2016.

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,	
	2016	2015	2016	2015
<b>Revenue:</b>				
Collaboration and license revenue	\$ 162,835	\$ 7,167	\$ 189,262	\$ 19,843
<b>Operating expenses:</b>				
Research and development (includes related party of \$7,899 and \$10,034 for the three months ended September 30, 2016 and 2015, respectively; and \$32,019 and \$33,919 for the nine months ended September 30, 2016 and 2015, respectively)	64,573	68,218	195,430	161,629
General and administrative (includes related party of \$30 and \$168 for the three months ended September 30, 2016 and 2015, respectively; and \$80 and \$511 for the nine months ended September 30, 2016 and 2015, respectively)	13,645	10,166	36,303	25,074
Total operating expenses	78,218	78,384	231,733	186,703
Income (loss) from operations	84,617	(71,217)	(42,471)	(166,860)
Interest expense (includes related party of \$590 and \$0 for the three months ended September 30, 2016 and 2015, respectively; and \$1,388 and \$0 for the nine months ended September 30, 2016 and 2015, respectively)	(2,420)	(33)	(5,611)	(33)
Other income (expense), net	1,647	(235)	(3,762)	(4,465)
Net income (loss)	83,844	(71,485)	(51,844)	(171,358)
Net loss attributable to non-controlling interest	95	151	428	489
Net income (loss) attributable to Coherus	\$ 83,939	\$ (71,334)	\$ (51,416)	\$ (170,869)
<b>Net income (loss) per share attributable to Coherus:</b>				
Basic	\$ 1.93	\$ (1.86)	\$ (1.25)	\$ (4.68)
Diluted	\$ 1.67	\$ (1.86)	\$ (1.25)	\$ (4.68)
<b>Weighted-average number of shares used in computing net income (loss) per share attributable to Coherus:</b>				
Basic	43,469,986	38,426,734	41,096,783	36,510,756
Diluted	51,581,298	38,426,734	41,096,783	36,510,756

See accompanying notes to condensed consolidated financial statements.

Coherus BioSciences, Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net income (loss)	\$ 83,844	\$ (71,485)	\$ (51,844)	\$ (171,358)
Other comprehensive income (loss):				
Foreign currency translation adjustments, net of tax	(38)	47	(161)	52
Comprehensive income (loss)	83,806	(71,438)	(52,005)	(171,306)
Comprehensive loss attributable to non-controlling interest	95	151	428	489
Comprehensive income (loss) attributable to Coherus	<u>\$ 83,901</u>	<u>\$ (71,287)</u>	<u>\$ (51,577)</u>	<u>\$ (170,817)</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,	
	2016	2015
<b>Operating activities</b>		
Net loss	\$ (51,844)	\$ (171,358)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,199	1,268
Remeasurement of fair-value of contingent consideration	3,745	4,414
Non-cash interest expense (income) from amortization of debt discount (receivable)	723	(38)
Impairment of property and equipment	8	128
Provision for other receivables	(1,300)	—
Stock-based compensation expense	19,736	11,547
Changes in operating assets and liabilities:		
Receivables from collaboration and license agreement	1,141	1,877
Notes receivable	—	1,853
Prepaid assets	18,111	(11,194)
Other assets	3,579	(2,331)
Other assets, related party	—	1,691
Other assets, non-current	88	42
Accounts payable	(1,642)	19,100
Accounts payable - related parties	(688)	1,072
Accrued and other liabilities	(75)	13,771
Deferred revenue	(93,013)	(383)
Advance payments under license agreements	(180)	(1,192)
Contingent liability to collaborator	(66,255)	15,850
Other liabilities, non-current	14	326
Net cash used in operating activities	<u>(165,653)</u>	<u>(113,557)</u>
<b>Investing activities</b>		
Purchases of property and equipment	(2,949)	(4,720)
Increase in restricted cash	—	(785)
Net cash used in investing activities	<u>(2,949)</u>	<u>(5,505)</u>
<b>Financing activities</b>		
Proceeds from issuance of convertible notes	75,000	—
Proceeds from issuance of convertible notes - related parties	25,000	—
Proceeds from follow-on offering, net of underwriters discounts and commissions	—	112,800
Proceeds from private placement	—	10,000
Proceeds from common stock offering, net of underwriters discounts and commissions	69,472	—
Payments of convertible notes issuance costs	(739)	—
Payments of common stock offering issuance costs	(510)	—
Proceeds from issuance of common stock upon exercise of stock options	1,957	1,015
Payments of initial public offering costs	—	(855)
Payments of follow-on offering costs	—	(601)
Net cash provided by financing activities	<u>170,180</u>	<u>122,359</u>
Effect of exchange rate changes in cash and cash equivalents	(127)	2
Net increase in cash and cash equivalents	1,451	3,299
Cash and cash equivalents at beginning of period	158,226	150,392
Cash and cash equivalents at end of period	<u>\$ 159,677</u>	<u>\$ 153,691</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”) 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.

**Need to Raise Additional Capital**

As of September 30, 2016, the Company had an accumulated deficit of \$461.4 million and cash and cash equivalents of \$159.7 million. In February 2016, the Company issued and sold \$100.0 million aggregate principal amount of 8.2% senior convertible notes due March 31, 2022 (see Note 6). In May and June 2016, the Company issued and sold 4,025,000 shares of its common stock at \$18.00 per share for net proceeds of \$69.0 million (see Note 8). The Company believes that its current available cash and cash equivalents together with funding it expects to receive under its license agreement with Daiichi Sankyo will be sufficient to fund its planned expenditures and meet the obligations through at least the next 12 months. In November 2016, the Company entered into an ATM Offering Program with Cowen and Company, LLC (“Cowen”), as its sales agent, pursuant to which the Company may sell, through Cowen, up to an aggregate of \$100.0 million in shares of its common stock (see Note 11). 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. If the Company is unable to obtain adequate financing when needed, it may have to delay, reduce the scope of or suspend one or more of its clinical trials, research and development programs or commercialization efforts.

**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, 2016: Coherus Intermediate Corp, Coherus Oncology, Inc., Orphonix, Inc., 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 only 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 February 29, 2016.

**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 stock-based compensation, valuation of deferred tax assets, impairment of goodwill and long-lived assets, the valuation of acquired intangible assets, clinical trial accruals, revenue recognition period, contingent consideration, 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, 2016 and 2015, were net losses of \$45,000 and \$123,000, respectively, and for the nine months ended September 30, 2016 and 2015 were net losses of \$401,000 and \$162,000, 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,	
	2016	2015	2016	2015
United States	\$ 162,537	\$ 6,807	\$ 188,292	\$ 18,599
Rest of world	298	360	970	1,244
Total revenue	<u>\$ 162,835</u>	<u>\$ 7,167</u>	<u>\$ 189,262</u>	<u>\$ 19,843</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,	
	2016	2015	2016	2015
Baxalta	99.8%	95.0%	99.5%	93.7%

## 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.

Contingent payments associated with the achievement of specific objectives in certain contracts that are not considered substantive because the Company does not contribute effort to the achievement of such milestones are recognized as revenue upon achievement of the objective, as long as there are no undelivered elements remaining and no continuing performance obligations by the Company, assuming all other revenue recognition criteria are met.

Revenue from a 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 Income (Loss)**

Comprehensive income (loss) is composed of two components: net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' equity, but are excluded from net income (loss). The Company's other comprehensive income (loss) includes foreign currency translation adjustments for the three and nine months ended September 30, 2016 and 2015.

#### **Net Income (Loss) per Share Attributable to Coherus**

Basic net income (loss) per share attributable to Coherus is calculated by dividing the net income (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. Diluted net income (loss) per share is computed by dividing the net income (loss) per share by the weighted average number of common shares outstanding for the period plus any dilutive potential common shares outstanding for the period determined using the treasury stock method for options to purchase common stock and using the if-converted method for the convertible notes. For all periods presented, except for the three months ended September 30, 2016, the Company was in a net loss position and 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 for those periods presented (see Note 9). 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 method and the impact that the adoption of ASU 2014-09 will have on its consolidated financial statements and related disclosures.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers, Identifying Performance Obligations and Licensing* (ASU 2016-10). The amendments in this update clarify the following two aspects: identifying performance obligations and clarifying the licensing implementation guidance. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. The Company is currently evaluating the impact that the adoption of ASU 2016-10 will have on its consolidated financial statements and related disclosures.

In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers, Narrow-Scope Improvements and Practical Expedients* (ASU 2016-12). The amendments in this update, which were issued in response to the feedback received by the FASB-IASB joint revenue recognition transition resource group, clarify the following aspects: collectibility, presentation of sales tax and other similar taxes collected from customers, noncash consideration, contract modifications and completed contracts at transition, and transition technical correction. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. The Company is currently evaluating the impact that the adoption of ASU 2016-12 will have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*. ASU 2014-15 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 has not elected to early adopt this standard. When adopted, ASU 2014-15 will require management to evaluate whether there is substantial doubt about the Company’s ability to continue as a going concern for at least 12 months from the issuance date of the financial statements and to provide related footnote disclosures.

In January 2016, the FASB issued ASU No. 2016-1, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU 2016-1 makes amendments to the classification and measurement of financial instruments and revises the accounting related to: (1) the classification and measurement of investments in equity securities, and (2) the presentation of certain fair value changes for financial liabilities measured at fair value. In addition, the update also amends certain disclosure requirements associated with the fair value of financial instruments. ASU 2016-1 is effective for the Company’s interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoptions of certain amendments within the update are permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-1 will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-2, *Leases*. ASU 2016-2 is aimed at making leasing activities more transparent and comparable, and requires substantially that all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-2 is effective for the Company’s interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-2 will have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-9, *Compensation-Stock Compensation: Improvements to Employee Share-Based Payment Accounting*. ASU 2016-9 simplifies several aspects of the accounting for share-based payment award transactions, including: (1) the income tax consequences, (2) classification of awards as either equity or liabilities, and (3) classification on the statement of cash flows. ASU 2016-9 is effective for the Company’s interim and annual reporting periods during the year ending December 31, 2017, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-9 will have on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* (ASU 2016-15). The amendment to this update addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-15 will have on its consolidated financial statements and related disclosures.

As of January 1, 2016, the Company adopted ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs*, that requires debt issuance costs related to a recognized debt liability to be presented in the consolidated balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This ASU 2015-03 requires retrospective application. ASU 2015-03 is limited to the presentation of debt issuance costs applied retrospectively to all prior periods presented in the consolidated financial statements and does not affect the recognition and measurement of debt issuance costs.

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

### 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 receivable, 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, 2016			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money market funds	\$ 128,870	\$ 128,870	\$ —	\$ —
Restricted cash (money market funds)	845	845	—	—
Total financial assets	<u>\$ 129,715</u>	<u>\$ 129,715</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Contingent consideration	<u>\$ 4,990</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,990</u>

**Fair Value Measurements  
December 31, 2015**

	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money market funds	\$ 157,784	\$ 157,784	\$ —	\$ —
Restricted cash (money market funds)	845	845	—	—
Total financial assets	<u>\$ 158,629</u>	<u>\$ 158,629</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Contingent consideration	<u>\$ 1,245</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,245</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 potential payments to be made to the former InteKrin stockholders upon the achievement of certain events specified in the agreements. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy.

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 CHS-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 CHS-131 in multiple sclerosis patients, triggering the obligation to settle the first contingent Earn-Out Payment to former InteKrin stockholders. As a result, 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 related to the Earn-Out Payment to equity.

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 8% 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. During the second quarter of 2016, the Company reported positive Phase 2b efficacy data on CHS-131, in relapsing remitting multiple sclerosis, and as such management's probability of occurrence increased from 10% to 33%. In September 2016, the Company determined it would conduct additional non-clinical studies prior to executing a Compound Transaction, and as such, the Company revised its expected completion date of the compound transaction earn-out by nine months which resulted in a \$1.6 million change in the fair value of the Compound Transaction Payment from June 30, 2016 to September 30, 2016. Generally, increases or decreases in the probability of occurrence would result in a directionally similar impact in the fair value measurement of the Compound Transaction Payment and it is estimated that a 1% increase (decrease) in the probability of occurrence would result in a fair value fluctuation of approximately \$0.2 million.

The change in the fair value of the Compound Transaction Payment for the three and nine months ended September 30, 2016, was a \$1.6 million gain and a \$3.7 million loss, respectively, and for the three and nine months ended September 30, 2015, a \$135,000 loss and a \$275,000 loss, respectively was recognized in other income (expense), net within the condensed consolidated statement of operations.

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, 2015	\$ 1,245
Change in fair value of the contingent consideration liability	3,745
Balance as of September 30, 2016	<u>\$ 4,990</u>

## Convertible Notes

The estimated fair value of the 8.2% Convertible Senior Notes Due 2022, which the Company issued on February 29, 2016 (see Note 6) is based on an income approach. The estimated fair value was approximately \$164.5 million (par value \$100.0 million) as of September 30, 2016 and represents a Level 3 valuation. When determining the estimated fair value of the Company's long-term debt, the Company uses a single factor binomial lattice model which incorporates the terms and conditions of the convertible notes and market based risk measurement that are indirectly observable, such as credit risk. The lattice model produces an estimated fair value based on changes in the price of the underlying common shares price over successive periods of time. An estimated yield based on market data is used to discount straight debt cash flows.

## 4. Balance Sheet Components

### Prepaid Assets

Prepaid assets are as follows (in thousands):

	September 30, 2016	December 31, 2015
Prepaid clinical, material, manufacturing and other - related parties (see Note 10)	\$ 5,771	\$ 10,901
Prepaid clinical, material and manufacturing	9,501	21,191
Prepaid other	1,373	2,651
Prepaid assets	<u>\$ 16,645</u>	<u>\$ 34,743</u>

### Property and Equipment, Net

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

	September 30, 2016	December 31, 2015
Machinery and equipment	\$ 9,815	\$ 7,809
Computer equipment and software	1,381	1,276
Furniture and fixtures	637	596
Leasehold improvements	4,092	4,343
Total property and equipment	15,925	14,024
Accumulated depreciation and amortization	(5,250)	(3,520)
Property and equipment, net	<u>\$ 10,675</u>	<u>\$ 10,504</u>

Depreciation and amortization expense was \$753,000 and \$636,000 for the three months ended September 30, 2016 and 2015, respectively, and \$2,199,000 and \$1,268,000 for the nine months ended September 30, 2016 and 2015, respectively.

### Accrued Liabilities

Accrued liabilities are as follows (in thousands):

	September 30, 2016	December 31, 2015
Accrued clinical, manufacturing and other - related parties (See Note 10)	\$ 6,041	\$ 6,122
Accrued clinical and manufacturing	10,725	11,681
Accrued compensation	5,505	4,666
Accrued other	2,604	1,664
Accrued liabilities	<u>\$ 24,875</u>	<u>\$ 24,133</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,	
	2016	2015	2016	2015
Baxalta	\$ 162,537	\$ 6,807	\$ 188,292	\$ 18,599
Daiichi Sankyo	298	360	970	1,244
Total collaboration and license revenue	<u>\$ 162,835</u>	<u>\$ 7,167</u>	<u>\$ 189,262</u>	<u>\$ 19,843</u>

### 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, 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 of research and development expense when the research and development activity has been performed.

In July 2016, the Company entered into two memoranda of understanding (the "MOU 4" and the "MOU 5", with Daiichi Sankyo. Under MOU 4 and MOU 5, the Company will receive up to \$1.9 million for reimbursements of certain past costs incurred and to be incurred and the Company will recognize these reimbursements as a reduction of research and development expenses when the research and development activity is performed.

As of September 30, 2016, \$1.8 million of revenue was deferred under all arrangements with Daiichi Sankyo, of which \$1.2 million was included in current liabilities and \$0.6 million was included in non-current liabilities in the condensed consolidated balance sheet. As of December 31, 2015, \$2.8 million of revenue was deferred under all arrangements with Daiichi Sankyo, of which \$1.5 million was included in current liabilities and \$1.3 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 \$3.1 million and \$4.0 million for the three months ended September 30, 2016 and 2015, respectively, and \$7.1 million and \$7.9 million for the nine months ended September 30, 2016 and 2015, respectively.



## **Baxalta**

The Company entered into a license agreement in August 2013 and two subsequent amendments thereto with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively “Baxalta”) (then Baxter International, Inc., part of Shire plc as of June 2016), 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 (as amended, the “Baxalta Agreement”). On September 26, 2016, Shire issued a termination notice of the Baxalta Agreement, in its entirety as part of its strategic portfolio review after its acquisition of Baxalta.

Under the Baxalta Agreement, the Company received an upfront payment of \$30.0 million and was eligible to receive up to \$335.3 million in contingent payments. If the Company commercialized CHS-0214, its etanercept biosimilar product, in the United States, the Company would have been required to refund a portion of the milestone payments received from Baxalta. Therefore, the Company recorded the portion of the contingent payments that contained the claw-back feature as a liability and would have continued to record such liability until the earlier 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 was included in the contingent liability to collaborator on the condensed consolidated balance sheet.

Upon the termination of the Baxalta Agreement, the Company regained from Shire all development and commercial rights previously licensed under the CHS-0214. There were no further contractual obligations. Therefore, the Company recognized the outstanding balances of deferred revenue of \$85.8 million and contingent liability to collaborator of \$76.7 million as revenue in its condensed consolidated statements of operations for the three months ended September 30, 2016.

As of December 31, 2015, \$92.0 million of revenue was deferred under the arrangements with Baxalta, of which \$48.0 million was included in current liabilities and \$44.0 million was included in non-current liabilities in the condensed consolidated balance sheet. As of December 31, 2015, \$66.3 million was recorded as contingent liability to collaborator in the condensed consolidated balance sheet due to the potential refund to Baxalta.

## **6. Convertible Notes**

On February 29, 2016, the Company issued and sold \$100.0 million aggregate principal amount of its 8.2% Convertible Senior Notes (the “Convertible Notes”) and received total net proceeds of approximately \$99.2 million, after deducting issuance costs of \$0.8 million. The Convertible Notes constitute general, senior unsubordinated obligations of the Company and are guaranteed by certain subsidiaries of the Company. The Convertible Notes bear interest at a fixed coupon rate of 8.2% per annum payable quarterly in arrears on March 31, June 30, September 30 and December 31 of each year, which commenced on March 31, 2016, and mature on March 31, 2022, unless earlier converted, redeemed or repurchased. If the Company fails to satisfy certain registration or reporting requirements, then additional interest will accrue on the Convertible Notes at a rate of up to 0.50% per annum in the aggregate. The Convertible Notes also bear a premium of 9% of their principal amount, which is payable when the Convertible Notes mature or are repurchased or redeemed by the Company.

The Convertible Notes were issued to Healthcare Royalty Partners III, L.P., for \$75.0 million in aggregate principal amount, and to three related party investors, KKR Biosimilar L.P., MX II Associates LLC, and KMG Capital Partners, LLC, for \$20.0 million, \$4.0 million, and \$1.0 million, respectively, in aggregate principal amount.

The Convertible Notes are convertible at the option of the holder at any time prior to the close of business on the business day immediately preceding March 31, 2022 at the initial conversion rate of 44.7387 shares of common stock per \$1,000 principal amount of Convertible Notes, which is equivalent to an initial conversion price of approximately \$22.35 per share, and is subject to adjustment in certain events. Upon conversion of the Convertible Notes by a holder, the holder will receive shares of the Company’s common stock together, if applicable, with cash in lieu of any fractional share.

The Convertible Notes are redeemable in whole, and not in part, at the Company’s option on or after March 31, 2020, if the last reported sale price per share of common stock exceeds 160% of the conversion price on 20 or more trading days during the 30 consecutive trading days preceding the date on which the Company sends notice of such redemption to the holders of the Convertible Notes. At maturity or redemption, if not earlier converted, the Company will pay 109% of the principal amount of the Convertible Notes maturing or being redeemed, together with accrued and unpaid interest, in cash.

The Convertible Notes contain customary events of default (as defined in the Convertible Note purchase agreement), the occurrence of which could result in the acceleration of all amounts due under the Convertible Notes. These events of default include, among others, certain failures to pay amounts due on the Convertible Notes, to deliver the consideration due upon conversion or to settle uninsured judgments, decrees or orders exceeding \$10.0 million, and certain defaults on other indebtedness for money borrowed of at least \$10.0 million, insolvency-related events and breaches of representations, subject, in some cases, to a cure period. The Convertible Notes also contain covenants restricting the Company's ability to incur additional indebtedness for borrowed money or convertible preferred stock and to pay dividends or make distributions on the Company's equity interests, subject to certain exceptions. As of September 30, 2016, the Company was in full compliance with these covenants and there were no events of default under the Convertible Notes.

The Convertible Notes are accounted for in accordance with ASC Subtopic 470-20, *Debt with Conversion and Other Options*. Pursuant to ASC Subtopic 470-20, the Company evaluated the features embedded in the Convertible Notes and concluded that the embedded features are not required to be bifurcated and accounted for separately from the host debt instrument.

The Company granted the holders of the Convertible Notes certain registration rights requiring the Company to register, under the Securities Act of 1933, as amended, the resale of the shares of common stock issuable upon conversion or settlement of the Convertible Notes.

The following table summarizes information about the components of the Convertible Notes as of September 30, 2016 (in thousands):

	<b>September 30, 2016</b>
Principal amount of the Convertible Notes	\$ 81,750
Unamortized debt discount and debt issuance costs	(6,797)
Convertible Notes	<u>\$ 74,953</u>
Principal amount of the Convertible Notes - related parties	\$ 27,250
Unamortized debt discount and debt issuance costs - related parties	(2,265)
Convertible Notes - related parties	<u>\$ 24,985</u>
Total Convertible Notes	<u>\$ 99,938</u>

The following table presents the components of interest expense for the three and nine month periods ended September 30, 2016 (in thousands):

	<b>Three Months Ended September 30, 2016</b>	<b>Nine Months Ended September 30, 2016</b>
Stated coupon interest	\$ 1,538	\$ 3,621
Accretion of debt discount and debt issuance costs	233	542
Interest expense	<u>\$ 1,771</u>	<u>\$ 4,163</u>
Stated coupon interest - related parties	\$ 512	\$ 1,207
Accretion of debt discount and debt issuance costs - related parties	78	181
Interest expense - related parties	<u>\$ 590</u>	<u>\$ 1,388</u>
Total interest expense	<u>\$ 2,361</u>	<u>\$ 5,551</u>

The remaining unamortized debt discount and debt offering costs related to the Company's Convertible Notes of approximately \$9.1 million as of September 30, 2016, will be amortized using the effective interest rate over the remaining term of the Convertible Notes of 5.50 years. The annual effective interest rate is 9.48% for the Convertible Notes.

Future payments on the Convertible Notes as of September 30, 2016 are as follows (in thousands):

<b>Year ending December 31,</b>	
Remainder of 2016	\$ 2,050
2017	8,200
2018	8,200
2019	8,200
2020	8,200
2021 and thereafter	119,250
<b>Total minimum payments</b>	<b>154,100</b>
Less amount representing interest	(45,100)
<b>Convertible Notes, principal amount</b>	<b>109,000</b>
Less debt discount and debt issuance costs on Convertible Notes	(9,062)
<b>Net carrying amount of Convertible Notes</b>	<b>\$ 99,938</b>

## 7. 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, 2016, the Company had a commitment of \$14.5 million with CMOs for the manufacture of clinical trial material due within a year.

### Facility Leases

The Company leases office spaces for its corporate headquarters in Redwood City, California and for laboratory facilities in Camarillo, California under operating lease agreements. On September 21, 2016, the Company entered into the Second Amendment (the “Second Amendment”) to its existing corporate headquarters with its current landlord to lease additional office space of approximately 12,809 square feet such that the total headquarters lease space is approximately 40,341 square feet (“Combined Lease Space”). The Second Amendment commenced on October 24, 2016, and ends on November 30, 2022, which coincides with the original lease termination date. The Combined Lease Space contains a one-time option to extend the lease term for five years.

The Second Amendment provides for annual base rent on the additional office space of approximately \$0.75 million in the first year of the Second Amendment term, which increases on an annual basis up to approximately \$0.87 million for the final year of the Second Amendment term and provides for certain limited rent abatements on the additional office space. The Company is also entitled to a one-time improvement allowance of approximately \$0.2 million that can be applied towards specified items, including tenant improvement work and base rent.

Rent expense is recognized on a straight-line basis over the term of the leases and accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as deferred rent liability.

The future minimum lease payments for all of our lease facilities as of September 31, 2016 are as follows (in thousands):

<b>Year ending December 31,</b>	
Remainder of 2016	\$ 439
2017	1,891
2018	2,462
2019	2,518
2020	2,595
2021 and thereafter	5,190
<b>Total minimum lease payments</b>	<b>15,095</b>

## 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. The Company is subject to one claim and consequently recorded a related liability of \$50,000 in 2015. The claim was settled and agreed to by both parties in July 2016.

## 8. Common Stock and Stock-Based Compensation

### Common Stock

In January 2016, the Company's shelf registration statement on Form S-3 (File No. 333-208625) (the "Shelf Registration Statement") was declared effective by the SEC. In May and June 2016, the Company issued and sold 4,025,000 shares of common stock at a price of \$18.00 per share. The Company received total gross proceeds from the offering of \$72.5 million. After deducting underwriting discounts and commissions of \$3.0 million and offering expense of \$0.5 million, the net proceeds were \$69.0 million.

### 2016 Employment Commencement Incentive Plan

In June 2016, the Company adopted the 2016 Employment Commencement Incentive Plan (the "2016 Plan"). The 2016 Plan is designed to comply with the inducement exemption contained in Nasdaq's Rule 5635(c)(4), which provides for the grant of non-qualified stock options, restricted stock units, restricted stock awards, performance awards, dividend equivalents, deferred stock awards, deferred stock units, stock payment and stock appreciation rights to a person not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with the Company. The Company reserved for future issuance under the 2016 Plan a total of 1,000,000 shares of its common stock for new employees. The 2016 Plan does not provide for any annual increases in the number of shares available. As of September 30, 2016, there were 307,000 options issued and outstanding under the 2016 Plan.

### Stock-Based Compensation

During 2010 and 2011, the Company issued shares of restricted common stock to its founders under our founders' shares agreements (such shares, the "Founders' Shares"). As of September 30, 2016, all shares were fully vested and there were no shares subject to repurchase. The Company recognized stock-based compensation expense within its condensed consolidated statement of operations of \$0 and \$9,000 for the three and nine months ended September 30, 2015, respectively, and recognized no expense in 2016 related to shares of common stock granted pursuant to the Founders' Shares agreements.

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,	
	2016	2015	2016	2015
Research and development	\$ 4,399	\$ 2,146	\$ 9,842	\$ 5,602
General and administrative	3,871	2,598	9,894	5,936
	<u>\$ 8,270</u>	<u>\$ 4,744</u>	<u>\$ 19,736</u>	<u>\$ 11,538</u>

## 9. Net Income (Loss) Per Share Attributable to Coherus

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
<b>Basic net income (loss) per share</b>				
<b>Numerator:</b>				
Net income (loss) attributable to Coherus	\$ 83,939	\$ (71,334)	\$ (51,416)	\$ (170,869)
<b>Denominator:</b>				
Weighted-average common shares outstanding	43,469,986	38,426,734	41,096,783	36,515,581
Less: weighted-average unvested common shares subject to repurchase (1)	—	—	—	(4,825)
Denominator for basic net income (loss) per share attributable to Coherus	43,469,986	38,426,734	41,096,783	36,510,756
Basic net income (loss) per share attributable to Coherus	\$ 1.93	\$ (1.86)	\$ (1.25)	\$ (4.68)
<b>Diluted net income (loss) per share</b>				
<b>Numerator:</b>				
Net income (loss) attributable to Coherus	\$ 83,939	\$ (71,334)	\$ (51,416)	\$ (170,869)
Add: interest expense on convertible debt, net of tax	2,361	—	—	—
Adjusted net income (loss) attributable to Coherus	\$ 86,300	\$ (71,334)	\$ (51,416)	\$ (170,869)
<b>Denominator:</b>				
Denominator for basic net income (loss) per share attributable to Coherus	43,469,986	38,426,734	41,096,783	36,510,756
<b>Add effect of potential dilutive securities:</b>				
Stock options	3,637,441	—	—	—
Convertible debt	4,473,871	—	—	—
Denominator for diluted net income (loss) per share attributable to Coherus	51,581,298	38,426,734	41,096,783	36,510,756
Diluted net income (loss) per share attributable to Coherus	\$ 1.67	\$ (1.86)	\$ (1.25)	\$ (4.68)

- (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 potentially dilutive securities consisting of stock options and the shares issuable upon conversion of the Convertible Notes are considered to be potential shares but are excluded from the calculation of diluted net loss per share because their effect would be antidilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stock options	4,989,524	7,924,249	10,020,561	7,924,249
Shares issuable upon conversion of Convertible Notes	—	—	4,473,871	—
Total	4,989,524	7,924,249	14,494,432	7,924,249

## **10. 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, 2016, the Company had \$5.8 million in prepaid assets (prepaid clinical, material, manufacturing and other-related parties), \$2.9 million in accounts payable-related parties, and \$6.0 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. As of December 31, 2015, the Company had \$10.9 million in prepaid assets (prepaid clinical, material, manufacturing and other-related parties), \$3.5 million in accounts payable-related parties, and \$6.1 million in accrued and other liabilities (accrued clinical, manufacturing and other-related parties), all reflected on the Company's consolidated balance sheet associated with Medpace. The Company recognized \$7.9 million and \$10.0 million during the three months ended September 30, 2016 and 2015, respectively, and \$31.9 million and \$33.7 million during the nine months ended September 30, 2016 and 2015, respectively, for services rendered by Medpace within research and development expense in the condensed consolidated statements of operations.

### **Recruiting Services**

One member of the Company's board of directors is a partner of a company that provided recruiting services to the Company. As of September 30, 2016 and December 31, 2015, the Company did not have any related party balances in the Company's condensed consolidated balance sheet related to recruiting services. The Company recorded in research and development expense in its condensed consolidated statements of operations, \$0 for both three month periods ended September 30, 2016 and 2015, and \$131,000 and \$258,000 for the nine months ended September 30, 2016 and 2015, respectively, for services rendered by the recruiting company. The Company recorded in general and administrative expense in its condensed consolidated statements of operations, \$30,000 and \$168,000 for the three months ended September 30, 2016 and 2015, respectively, and \$80,000 and \$511,000 for the nine months ended September 30, 2016 and 2015, respectively, for services rendered by the recruiting company.

### **Convertible Notes**

In February 2016, the Company issued Convertible Notes to certain related parties (some companies affiliated with members of the Company's board of directors), for an aggregate principal amount of \$25.0 million (see Note 6 for related party disclosure).

## **11. Subsequent Events**

On October 28, 2016, the Company entered into a sales agreement (the "Sales Agreement") with Cowen to sell shares of the Company's common stock, with aggregate gross sales proceeds of up to \$100,000,000, from time to time, through an at-the-market equity offering program under which Cowen will act as its sales agent (the "ATM Offering Program"). Cowen is entitled to compensation for its services equal to 3.0% of the gross proceeds of any shares of common stock sold through Cowen under the Sales Agreement. The Company has no obligation to sell any shares under the Sales Agreement, and may at any time suspend solicitation and offers under the Sales Agreement. The shares will be issued pursuant to the Company's Shelf Registration Statement. The Company filed a prospectus supplement, dated October 28, 2016, with the SEC in connection with the offer and sale of the shares pursuant to the Sales Agreement.

## 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, 2015, 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 on February 29, 2016. 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, or the 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 February 2016, an immunogenicity study in healthy volunteers pursuant to the CHS-1701 BLA met its primary endpoints. In July 2016, a follow-on pharmacokinetic/pharmacodynamics (“PK/PD”) study met all its co-primary endpoints. The safety profiles of CHS-1701 and Neulasta were very similar. There were no serious adverse events related to either study drug or clinical meaningful difference between CHS-1701 or Neulasta leading to study drug discontinuations. The U.S. Food and Drug Administration (“FDA”) accepted a biologics license application (“BLA”) for CHS-1701 in October 2016.
- CHS-0214 (our etanercept (Enbrel) biosimilar candidate). CHS-0214 is an anti-TNF product candidate for which we have partnered with Daiichi Sankyo Company, Limited (“Daiichi Sankyo”), to develop and commercialize in Japan. In September 2016, we regained development and commercial rights from Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH, (collectively “Baxalta”, part of Shire plc as of June 2016) for Europe, Canada, Brazil, the Middle East and other territories. We completed two Phase 3 clinical trials with CHS-0214 in rheumatoid arthritis and psoriasis, which met their primary clinical endpoints in November 2015 and January 2016, respectively. In October 2016, we completed two bridging Phase 1 PK studies of CHS-0214, one comparing CHS-0214 to Enbrel manufactured in Europe, and the other providing additional relative bioavailability data for CHS-0214. We expect that results from these trials, combined with data from four Phase 1 studies, will support the expected submission of a marketing application in Europe in the first quarter of 2017 and in Japan in the first half of 2017. We anticipate completing a study to compare the relative bioavailability data of CHS-0214 at two different concentrations in 2017, also in support of the expected submission of a marketing application in Japan. 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 are 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 candidate successfully completed a pivotal Phase 1 PK study in August 2014 by meeting the primary PK bioequivalence 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. We initiated a bridging PK study comparing the Phase 3 CHS-1420 material to U.S. manufactured adalimumab (Humira) during the first quarter of 2016. In August 2016, we reported that our Phase 3 study in psoriasis met its primary endpoint. We anticipate filing a BLA for CHS-1420 in the first half of 2017, directly after completing and obtaining key clinical data and completing discussions with the FDA.
- We reported positive Phase 2b efficacy data on CHS-131, an oral, small-molecule drug candidate, in relapsing remitting multiple sclerosis (“MS”). This six-month study demonstrated significant reduction in contrast-enhancing lesions meeting its primary endpoint. CHS-131 was generally well-tolerated and without evidence of immune suppression or the side-effects commonly seen in other oral MS therapies. We seek to partner CHS-131 for further development.

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 \$51.8 million and \$171.4 million for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, we had an accumulated deficit of \$461.4 million.

In February 2016, we issued and sold \$100.0 million aggregate principal amount of our 8.2% senior convertible notes due 2022 (“the Convertible Notes”). These Convertible Notes require quarterly interest distributions at a fixed coupon rate of 8.2% until maturity, redemption or conversion, which will be no later than March 31, 2022. If we fail to satisfy certain registration or reporting requirements, then additional interest will accrue on the Convertible Notes at a rate of up to 0.50% per annum in the aggregate. The holders of the Convertible Notes are Healthcare Royalty Partners III, L.P. and three of its related entities, which hold \$75.0 million in aggregate principal amount, and three related party investors, KKR Biosimilar L.P., which holds \$20.0 million, MX II Associates LLC, which holds \$4.0 million, and KMG Capital Partners, LLC, which holds \$1.0 million. The Convertible Notes are convertible into shares of common stock at an initial conversion rate of 44.7387 shares of common stock per \$1,000 principal amount of the Convertible Notes (equivalent to a conversion price of approximately \$22.35 per share of common stock, representing a 60% premium over the average last reported sale price of our common stock over the 15 trading days preceding the date the Convertible Notes were issued), subject to adjustment in certain events. Upon conversion of the Convertible Notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. After March 31, 2020, the full amount of the Convertible Notes not previously converted are redeemable for cash at our option if the last reported sale price per share of our common stock exceeds 160% of the conversion price on 20 or more trading days during the 30 consecutive trading days preceding the date on which we send notice of such redemption to the holders of the Convertible Notes. At maturity or redemption, if not earlier converted, we will pay 109% of the principal amount of the Convertible Notes, together with accrued and unpaid interest, in cash.

In January 2016, our shelf registration statement on Form S-3 (File No. 333-208625), or the Shelf Registration Statement, was declared effective by the SEC. In May and June 2016, we drew 4,025,000 shares of common stock down from the Shelf Registration Statement and issued and sold 4,025,000 shares of common stock at a price of \$18.00 per share. We received total gross proceeds from the offering of \$72.5 million. After deducting underwriting discounts and commissions of \$3.0 million and offering expense of \$0.5 million, the net proceeds to us were \$69.0 million.

In October 2016, we entered into a sales agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”), under which we may offer and sell shares of our common stock, with aggregate gross sale proceeds of up to \$100.0 million, from time to time through an at-the-market equity offering program under which Cowen will act as our sales agent (the “ATM Offering Program”). Cowen is entitled to compensation for its services equal to 3.0% of the gross proceeds of any shares of common stock sold through Cowen under the Sales Agreement. The shares will be issued pursuant to our Shelf Registration Statement. We filed a prospectus supplement, dated October 28, 2016, with the SEC in connection with the offer and sale of the shares pursuant to the Sales Agreement.

## **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 preclinical 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 incurred increased expenses in 2016 and expect future expenses to increase 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 Convertible Notes and associated non-cash interest related to the accretion of the debt discount and debt issuance costs during the three and nine month periods ended September 30, 2016.

### ***Other Income (Expense), Net***

Other income (expense), net for the three and nine month periods ended September 30, 2016 and 2015 consists primarily of losses resulting from the remeasurement of our contingent consideration and foreign exchange gains and losses resulting from currency fluctuations. In March 2015, the contingent consideration related to the Earn-Out Payment which 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 U.S. 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 condition.

There have been no significant changes to our accounting policies during the nine months ended September 30, 2016, as compared to the significant accounting policies described in our Annual Report on Form 10-K filed with the SEC on February 29, 2016. 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 method and the impact that the adoption of ASU 2014-09 will have on our consolidated financial statements and related disclosures.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers, Identifying Performance Obligations and Licensing* (ASU 2016-10). The amendments in this update clarify the following two aspects: identifying performance obligations and clarifying the licensing implementation guidance. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. We are currently evaluating the impact that the adoption of ASU 2016-10 will have on our consolidated financial statements and related disclosures.

In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers, Narrow-Scope Improvements and Practical Expedients* (ASU 2016-12). The amendments in this update, which were issued in response to the feedback received by the FASB-IASB joint revenue recognition transition resource group, clarify the following aspects: collectibility, presentation of sales tax and other similar taxes collected from customers, noncash consideration, contract modifications and completed contracts at transition, and transition technical correction. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. We are currently evaluating the impact that the adoption of ASU 2016-12 will have on our 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 is effective for our annual reporting period ending December 31, 2016 and all annual and interim reporting periods thereafter, with early adoption permitted. We elected to not early adopt this standard. When adopted, ASU 2014-15 will require management to evaluate whether there is substantial doubt about our ability to continue as a going concern for at least 12 months from the issuance date of the financial statements and to provide related footnote disclosures.

In January 2016, the FASB issued ASU No. 2016-1, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU 2016-1 makes amendments to the classification and measurement of financial instruments and revises the accounting related to: (1) the classification and measurement of investments in equity securities, and (2) the presentation of certain fair value changes for financial liabilities measured at fair value. In addition, the update also amends certain disclosure requirements associated with the fair value of financial instruments. ASU 2016-1 is effective for our interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoptions of certain amendments within the update are permitted. We are currently evaluating the impact that the adoption of ASU 2016-1 will have on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-2, *Leases*. ASU 2016-2 is aimed at making leasing activities more transparent and comparable, and requires substantially that all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-2 is effective for our interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-2 will have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-9, *Compensation-Stock Compensation: Improvements to Employee Share-Based Payment Accounting*. ASU 2016-9 simplifies several aspects of the accounting for share-based payment award transactions, including: (1) the income tax consequences, (2) classification of awards as either equity or liabilities, and (3) classification on the statement of cash flows. ASU 2016-9 is effective for our interim and annual reporting periods during the year ending December 31, 2017, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-9 will have on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* (ASU 2016-15). The amendment to this update addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 is effective for our interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-15 will have on our consolidated financial statements and related disclosures.

As of January 1, 2016, we adopted ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs*, that requires debt issuance costs related to a recognized debt liability to be presented in the consolidated balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This ASU 2015-03 requires retrospective application. ASU 2015-03 is limited to the presentation of debt issuance costs applied retrospectively to all prior periods presented in the consolidated financial statements and does not affect the recognition and measurement of debt issuance costs.

We have reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or that 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, 2016 and 2015

#### Collaboration and License Revenue

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	Change	2016	2015	Change
	<i>(in thousands)</i>					
Revenue:						
Baxalta	\$ 162,537	\$ 6,807	\$ 155,730	\$ 188,292	\$ 18,599	\$ 169,693
Daiichi Sankyo	298	360	(62)	970	1,244	(274)
Total collaboration and license revenue	<u>\$ 162,835</u>	<u>\$ 7,167</u>	<u>\$ 155,668</u>	<u>\$ 189,262</u>	<u>\$ 19,843</u>	<u>\$ 169,419</u>

Collaboration and license revenue for the three months ended September 30, 2016 was \$162.8 million compared to \$7.2 million for the same period in 2015, an increase of \$155.7 million. For the nine months ended September 30, 2016, collaboration and license revenue was \$189.3 million compared to \$19.8 million for the same period in 2015, an increase of \$169.4 million. The increase is primarily due to revenue recognized in connection with regaining all development and commercial rights of CHS-0214 from Baxalta for Europe, Canada, Brazil, the Middle East and other territories.

In June 2016, Shire completed its acquisition of Baxalta and as part of its strategic portfolio review issued a termination notice of the Baxalta Agreement in its entirety on September 26, 2016. As such, we regained from Shire all development and commercial rights previously licensed under CHS-0214. We recognized the outstanding balances of deferred revenue and contingent liability to collaborator of \$85.8 million and \$76.7 million, respectively, as revenue for the three months ended September 30, 2016.

#### Research and Development Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	Change	2016	2015	Change
	<i>(in thousands)</i>					
Research and development	<u>\$ 64,573</u>	<u>\$ 68,218</u>	<u>\$ (3,645)</u>	<u>\$ 195,430</u>	<u>\$ 161,629</u>	<u>\$ 33,801</u>

Research and development expenses for the three months ended September 30, 2016 were \$64.6 million compared to \$68.2 million for the same period in 2015, a decrease of \$3.6 million. The decrease in research and development expenses was primarily due to:

- a decrease of \$9.3 million related to BLA-enabling studies for CHS-1701 due to fully enrolled and completed clinical studies;
- a decrease of \$7.3 million in costs incurred for CHS-0214 due to fully enrolling and completing Phase 3 clinical studies, which includes a decrease of \$0.9 million in cost reimbursements from Daiichi Sankyo that were recognized as a reduction of research and development expense; and
- partially offset by an increase of \$7.3 million to start and enroll subjects into a Phase 3 clinical study in psoriasis for CHS-1420;
- an increase of \$2.0 million in personnel, consulting and other related expenses and \$2.3 million in stock-based compensation primarily due to a net increase of 24 employees, annual salary increases and additional stock options granted since the third quarter of 2015; and
- an increase of \$1.3 million to advance other product candidates in our pipeline.

Research and development expenses for the nine months ended September 30, 2016 were \$195.4 million compared to \$161.6 million for the same period in 2015, an increase of \$33.8 million. The increase in research and development expenses was primarily due to:

- an increase of \$31.5 million to start and enroll subjects into a Phase 3 clinical study in psoriasis for CHS-1420;
- an increase of \$10.1 million to advance other product candidates in our pipeline;
- an increase of \$6.6 million in personnel, consulting and other related expenses and \$4.2 million in stock-based compensation due to a net increase of 24 employees, annual salary increases and additional stock options granted since the third quarter of 2015;
- 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 \$0.2 million to initiate and enroll a proof-of concept Phase 2 clinical study for CHS-131;
- partially offset by a decrease of \$14.1 million related to BLA-enabling studies for CHS-1701 due to fully enrolled and completed clinical studies; and
- a decrease of \$6.2 million in costs incurred for CHS-0214 due to fully enrolling and completing Phase 3 clinical studies, which includes a decrease of \$0.8 million in cost reimbursements from Daiichi Sankyo that was recognized as a reduction of research and development expense.

#### General and Administrative Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	Change	2016	2015	Change
	<i>(in thousands)</i>					
General and administrative	\$ 13,645	\$ 10,166	\$ 3,479	\$ 36,303	\$ 25,074	\$ 11,229

General and administrative expenses for the three months ended September 30, 2016 were \$13.6 million compared to \$10.2 million for the same period in 2015, an increase of \$3.5 million. The increase was primarily due to an increase of \$0.8 million in personnel, consulting and other related expenses and \$1.3 million in stock-based compensation as a result of an increase in headcount, and costs associated with stock options granted since the third quarter of 2015. Additionally, the rise in expenses was due to an increase of \$1.6 million in legal and other professional services, partially offset by a decrease of \$0.2 million in facilities, supplies and materials.

General and administrative expenses for the nine months ended September 30, 2016 were \$36.3 million compared to \$25.1 million for the same period in 2015, an increase of \$11.2 million. The increase was primarily due to an increase of \$4.0 million in personnel, consulting and other related expenses and \$4.0 million in stock-based compensation as a result of an increase in headcount, and costs associated with stock options granted since the third quarter of 2015. Additionally, the rise in expenses was due to an increase of \$3.0 million in legal, accounting, and other professional services and \$0.2 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,		
	2016	2015	Change	2016	2015	Change
	(in thousands)					
Interest expense	\$ 2,420	\$ 33	\$ 2,387	\$ 5,611	\$ 33	\$ 5,578

Interest expense was \$2.4 million and \$5.6 million for the three and nine months ended September 30, 2016 compared to \$33,000 during the same periods in 2015. The increase was due to the recognition of interest expense and non-cash accretion of the debt discount and debt issuance costs during the first nine months of 2016 related to the Convertible Notes that we issued on February 29, 2016.

## Other Income (Expense), Net

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	Change	2016	2015	Change
	(in thousands)					
Other income (expense), net	\$ 1,647	\$ (235)	\$ 1,882	\$ (3,762)	\$ (4,465)	\$ 703

Other income (expense), net for the three months ended September 30, 2016 was net income of \$1.6 million compared to net expense of \$0.2 million for the same period in 2015, a net gain of \$1.9 million. The net gain is primarily due to a \$1.6 million decrease in the fair value of our contingent consideration related to the compound transaction payment associated with our InteKrin acquisition, as a result of a revision of our estimated completion date of the compound transaction by nine months, during the third quarter of 2016 when compared to the same period in 2015.

Other expense, net for the nine months ended September 30, 2016 was \$3.8 million compared to \$4.5 million for the same period in 2015, a decrease of \$0.7 million. The decrease is primarily due to the change in fair value of our contingent consideration related to the InteKrin acquisition of \$4.4 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 March 2015. The decrease was partially offset by a \$3.7 million increase in the change in fair value of our contingent consideration related to the compound transaction payment associated with our InteKrin acquisition during the first nine months of 2016, driven by our positive Phase 2b data on CHS-131, and as such, the probability of occurrence was increased from 10% to 33%.

## 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 February 2016, we issued and sold \$100.0 million aggregate principal amount of our Convertible Notes for which we received net cash of \$99.2 million, net of debt discounts and issuance costs. In May and June 2016, we issued and sold 4,025,000 shares of our common stock at \$18.00 per share for net proceeds of \$69.0 million. In October, 2016, we entered into a sales agreement with Cowen, under which we may offer and sell our common stock, having aggregate gross proceeds of up to \$100.0 million, from time to time through Cowen as our sales agent in our ATM Offering Program.

As of September 30, 2016, we had an accumulated deficit of \$461.4 million and cash and cash equivalents of \$159.7 million. We believe that our current available cash and cash equivalents together with the funding we expect to receive under our license agreement with Daiichi Sankyo will be sufficient to fund our planned expenditures and obligations through at least the next 12 months. 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,	
	2016	2015
	<i>(in thousands)</i>	
Net cash used in operating activities	\$ (165,653)	\$ (113,557)
Net cash used in investing activities	(2,949)	(5,505)
Net cash provided by financing activities	170,180	122,359
Effect of exchange rate changes in cash and cash equivalents	(127)	2
Net increase in cash and cash equivalents	<u>\$ 1,451</u>	<u>\$ 3,299</u>

### Net cash used in operating activities

Cash used in operating activities was \$165.7 million for the nine months ended September 30, 2016, which was primarily due to the following:

- a net loss of \$51.8 million,
- non-cash reduction of \$1.3 million in other receivables due to the reversal of a provision,
- decrease in deferred revenue of \$93.0 million as we recognized deferred revenue from our Daiichi Sankyo collaboration agreement and all Baxalta collaboration deferred revenue as a result of the termination of the Baxalta license agreement during the third quarter of 2016,
- decrease in contingent liability to collaborator of \$66.3 million as we recognized revenue as a result of the termination of the Baxalta license agreement during the third quarter of 2016, and
- decrease in accounts payable, accounts payable-related parties, and accrued and other liabilities of \$2.4 million primarily due to the payments to our clinical research organizations and clinical manufacturing organizations as a result of the progression of our Phase 3 clinical trial programs that are winding down, and the timing of the vendor payments.

The cash used in operating activities was partially offset by the following:

- non-cash charges related to stock-based compensation of \$19.7 million, fair value remeasurement of our contingent consideration obligation of \$3.7 million, non-cash interest expense of \$0.7 million, and depreciation and amortization of property and equipment of \$2.2 million, and
- a net decrease in prepaid and other assets of \$21.8 million primarily due to the progression of our Phase 3 clinical trial programs that are winding down and the timing of the vendor payments and a decrease in receivables from collaboration and license agreement of \$1.1 million.

Cash used in operating activities was \$113.6 million for the nine months ended September 30, 2015, which was primarily due to the following:

- a net loss of \$171.4 million,
- increase in prepaid and other assets of \$13.5 million resulting from the increase in clinical activities and timing of vendor payments as a result of prepayments for comparator drug and for starting clinical trials,
- decrease in advanced payments under license agreements of \$1.2 million; and
- a decrease in deferred revenue of \$0.4 million.

The cash used in operating activities was partially offset by the following:

- non-cash charges of stock-based compensation of \$11.5 million, \$4.4 million related to the remeasurement of our contingent consideration obligations, and \$1.3 million for depreciation and amortization,
- increase in accounts payable, accounts payable-related parties, and accrued and other liabilities of \$33.9 million as a result of the increase in clinical activities and timing of vendor payments,

- increase in contingent liability to collaborator of \$15.9 million and an increase, and
- a decrease of \$1.9 million in receivables from collaboration and license agreement and a decrease in notes receivable of \$1.9 million as it was collected.

#### *Net cash used in investing activities*

Cash used in investing activities of \$2.9 million for the nine months ended September 30, 2016 was due to the purchase of capital equipment and leasehold improvements.

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 of \$4.7 million, and an increase in restricted cash of \$0.8 million as a result of the new headquarters lease requirements.

#### *Net cash provided by financing activities*

Cash provided by financing activities of \$170.2 million for the nine months ended September 30, 2016 was primarily related to proceeds of \$100.0 million from the issuance of the Convertible Notes, the proceeds of \$69.5 million from the issuance of our common stock, net of underwriting discounts and commissions, and \$2.0 million from the exercise of stock options, partially offset by payments of convertible debt issuance costs of \$0.7 million and offering expenses of \$0.5 million related to the issuance of common stock.

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 \$122.8 million from the issuance of our common stock in connection with our follow-on offering and private placement, and proceeds from the exercise of stock options of \$1.0 million, partially offset by our payments of costs related to our initial public offering and follow-on equity offering of \$1.5 million.

### **Funding Requirements**

We believe that our current available cash and cash equivalents together with the funding we expect to receive under our license agreement with Daiichi Sankyo will be sufficient to fund our planned expenditures and meet our obligations through at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We currently have no credit facility or committed sources of capital although we may receive contingent payments under our current license and collaboration agreements. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional agreements with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our clinical trials, preclinical 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 costs of acquiring originator comparator materials and manufacturing preclinical study and clinical trial supplies and other materials from CMOs and related costs associated with release and stability testing;
- the receipt of any collaboration payments;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies.

We will need to raise additional capital to fund our operations in the near future. Funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. In November 2016, we entered into an ATM Offering Program with Cowen, as our sales agent, pursuant to which we may sell, through Cowen, up to an aggregate of \$100.0 million in shares of our common stock. We will seek to enter into strategic partnerships to commercialize our biosimilar candidates in ex-US territories or globally for certain therapeutic areas. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

### 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 Obligations

In February 2016, we issued and sold \$100.0 million aggregate principal amount of Convertible Notes that require quarterly interest distributions at a fixed coupon rate of 8.2% until maturity, redemption or conversion, which will be no later than March 31, 2022. After March 31, 2020, the full amount of the Convertible Notes not previously converted are redeemable for cash at our option if the last reported sale price per share of our common stock exceeds 160% of the conversion price on 20 or more trading days during the 30 consecutive trading days preceding the date on which we send notice of such redemption to the holders of the Convertible Notes. At maturity or redemption, if not earlier converted, we will pay 109% of the principal amount of the Convertible Notes, together with accrued and unpaid interest, in cash.

The following table summarizes our future contractual obligations as of September 30, 2016:

	Payments Due by Period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
<b>Contractual Obligations</b>	<i>(in thousands)</i>				
Long-term debt obligations (1)	\$ 154,100	\$ 8,200	\$ 16,400	\$ 16,400	\$ 113,100
Operating lease obligations (2)	15,095	1,721	4,956	5,229	3,189
Purchase obligations (3)	14,490	14,490	—	—	—
Contingent payments to InteKrin stockholders	4,990	4,990	—	—	—
<b>Total contractual obligations</b>	<b>\$ 188,675</b>	<b>\$ 29,401</b>	<b>\$ 21,356</b>	<b>\$ 21,629</b>	<b>\$ 116,289</b>

- (1) The long-term debt obligation is comprised of future minimum payments related to the Convertible Notes.
- (2) These amounts are comprised of the rent payments on our facility leases.
- (3) The purchase obligations are comprised of our non-cancelable purchase commitments related to clinical manufacturing.



### **ITEM 3. Quantitative and Qualitative Disclosures About Market Risk**

As of September 30, 2016, we had cash and cash equivalents of \$159.7 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.

### **ITEM 4. Controls and Procedures**

#### **Evaluation of Effectiveness 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.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer, principal financial officer and principal accounting officer, as appropriate, to allow for timely decisions regarding required disclosure.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to correct any material deficiencies that we may discover. Our goal is to ensure that our management has timely access to material information that could affect our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to modify our disclosure 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, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

#### **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, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **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 and December 7, 2015, we filed in the United States Patent and Trademark Office (“USPTO”), pursuant to 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, petitions for Inter Partes Review (“IPR”) of AbbVie’s United States Patent Nos. 8,889,135 (Case No. IPR2016-00172, filed December 7, 2015); 9,017,680 (Case No. IPR2016-00188, filed December 7, 2015); and 9,073,987 (Case No. IPR 2016-00189, filed December 7, 2015), each 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. On May 17, 2016, the Patent Trial and Appeal Board (“PTAB”) of the USPTO instituted our petition for IPR of AbbVie’s U.S. Patent No. 8,889,135. On June 13, 2016, the PTAB instituted our petitions for IPR of AbbVie’s U.S. Patents Nos. 9,017,680 and 9,073,987.

On May 9, 2016, we filed a petition for IPR of AbbVie U.S. Patent 9,114,166 (‘166) entitled “Formulation of Human Antibodies for Treating TNF- $\alpha$  Associated Disorders”. The ‘166 patent generally concerns an isotonic formulation of TNF- $\alpha$  IgG1 antibody at a protein concentration of 50 mg/ml and pH of 4.0 to 8.0. On November 7, 2016, the PTAB did not institute our petition for IPR of the ‘166 patent.

### 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 \$223.9 million and \$87.2 million for the years ended December 31, 2015 and 2014, respectively, and \$51.8 million and \$171.4 million for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, we had an accumulated deficit of \$461.4 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 Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively “Baxalta”, now subsidiaries of Shire plc), and Daiichi Sankyo Company, Limited, or Daiichi Sankyo. In September 2016, we regained development and commercial rights from Baxalta for Europe, Canada, Brazil, the Middle East and other territories. 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 clinical development with CHS-1420 (our adalimumab (Humira) biosimilar candidate). We completed Phase 3 or other BLA-enabling development with two other lead products, CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate) and CHS-0214 (our etanercept (Enbrel) biosimilar candidate). Our BLA for CHS-1701 was accepted by the FDA in October 2016. It may be several months before we file for market approval with the relevant regulatory agencies for CHS-0214 and CHS-1420. We have not yet initiated clinical trials for CHS-5217 (bevacizumab (Avastin) biosimilar) and CHS-3351 (ranibizumab (Lucentis) biosimilar). 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 and Inter Partes Reviews (“IPRs”) 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; or achieving successful outcomes in IPR's that we have filed, or may in the future file, against third parties.

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 products, 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, 2016, our cash and cash equivalents were \$159.7 million. We expect that our existing cash and cash equivalents, together with funding we expect to receive under our license agreement with Daiichi Sankyo, additional projected license agreements that are in negotiation to partner global rights to our immunology (anti-TNF) franchise and expected proceeds from our ATM Offering Program, will be sufficient to fund our current operations for at least the next 12 months; however, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates if we are not able to partner our immunology (anti-TNF) franchise by the end of 2016. 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. Whereas CHS-1701 has completed clinical development, CHS-0214 and CHS-1420 are still completing several clinical trials, and we have not yet initiated clinical trials for CHS-5217 and CHS-3351.

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.

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 and in the United States for the full originator label but received a much narrower 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 altered the manufacturing processes 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. In October 2016, we completed two clinical pharmacokinetic bioequivalence studies for CHS-0214, and the results will be provided to European and Japanese regulatory authorities.



***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 PHS Act. 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.

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 ten-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 ten-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 and such patents may or may not be susceptible to challenges to their validity and enforceability.

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

We expect other companies to seek approval to manufacture and market biosimilar versions of Neulasta, Enbrel, or Humira. If other biosimilars of Neulasta, Enbrel or Humira 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 pegfilgrastim (Neulasta), etanercept (Enbrel) or adalimumab (Humira) 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) and certain Latin American countries (through our licensee Orox). We intend to market our pegfilgrastim (Neulasta) biosimilar product, CHS-1701, and future oncology biosimilar candidates in the United States and may seek to partner commercially all oncology biosimilars outside the United States. We intend to find favorable strategic commercialization partners or retain rights for some or all of our immunology (anti-TNF) biosimilar candidates.

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, 2016, we had 139 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 contract research organization, or 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, Amgen Inc., or Amgen, has licensed its adalimumab (Humira) biosimilar candidate to our partner Daiichi Sankyo in July 2016;
- 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 and Orox for the commercialization of our biosimilar product candidates in certain major markets and may seek additional commercialization partners, and their failure to commercialize in those markets could have a material adverse effect on our business and operating results.***

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-1701, CHS-0214 and CHS-1420, in certain Caribbean and Latin American countries (excluding Brazil). We intend to seek a commercialization partner for CHS-0214 in Europe and other jurisdictions outside the U.S. (excluding Japan and certain Caribbean and Latin American countries). We may also seek a commercialization partner for CHS-0214 in the U.S. 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 trials were resumed in December 2014 and are 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 costlier 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-1701, CHS-0214 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-1701, CHS-0214 and CHS-1420 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, and Samsung Bioepis, Ltd., or Samsung Bioepis, (a Merck/Biogen/Samsung biosimilar venture), as well as other smaller companies. We are currently aware that such competitors are engaged in the development of biosimilar product candidates to pegfilgrastim (Neulasta), etanercept (Enbrel) and adalimumab (Humira). For example, we understand that Sandoz and Apotex have each submitted a Neulasta (pegfilgrastim) biosimilar product candidate for market approval in the United States and that Sandoz received a complete response letter from the FDA at the end of June 2016. We understand that Mylan Inc. appears to have submitted a Neulasta biosimilar candidate for market approval in the E.U. Similarly, we understand that Sandoz and Samsung Bioepis are each currently engaged in the development of competing biosimilar product candidates for etanercept (Enbrel). Both Sandoz and Samsung Bioepis have each submitted an etanercept biosimilar product candidate for market approval in the E.U. and Sandoz has filed a BLA for its candidate in the United States. On January 16, 2016, the European Commission (EC) approved Samsung Bioepis' etanercept biosimilar (Benepali), also known as SB4, for the treatment of rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis) and plaque psoriasis. In August 2016, the FDA approved Sandoz' etanercept biosimilar (Erelzi, etanercept-szss) for multiple inflammatory diseases. Boehringer, Amgen, Sandoz, Samsung Bioepis and Pfizer are examples of companies engaged in development of biosimilar product candidates for adalimumab (Humira). We understand Boehringer's program and Pfizer's program are in Phase 3, and that Amgen and Samsung Bioepis have each submitted a Humira biosimilar candidate for market approval in the United States and in the E.U., respectively. In September 2016, the FDA approved Amgen's adalimumab biosimilar (Amjevita, adalimumab-atto) for multiple inflammatory diseases.

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, Samsung Bioepis, 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, in 2012, 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 2012. 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. On October 30, 2015, CMS finalized the proposed rule, which clarifies that the payment amount for a biosimilar is based on the ASP of all National Drug Codes assigned to the biosimilars included within the same billing and payment code.

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, AbbVie Inc., or AbbVie, and Genentech, 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. We are aware of third-party patents or patent applications with claims, for example, 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-1701, CHS-0214 and CHS-1420, 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. With respect to products we are evaluating for inclusion in our future biosimilar product pipeline, our freedom to operate analyses, including our research on the timing of potentially relevant patent expirations, are ongoing.

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.



On November 7, 2015 and December 9, 2015, we filed petitions for *Inter Partes* Review (“IPR”) in the United States Patent Office against three AbbVie patents: U.S. patents 8,889,135 (or ‘135); 9,017,680 (or ‘680); and 9,073,987 (or ‘987), all of which concern a 40 mg biweekly subcutaneous dosing regimen for treating rheumatoid arthritis (“RA”) with Humira® (Adalimumab). This treatment regimen is referenced in the approved FDA label for Humira. In addition, on May 9, 2016, we filed a petition for IPR of AbbVie U.S. Patent 9,114,166 (or ‘166) entitled “Formulation of Human Antibodies for Treating TNF- $\alpha$  Associated Disorders”. The ‘166 patent generally concerns an isotonic formulation of TNF- $\alpha$  IgG1 antibody at a protein concentration of 50 mg/ml and pH of 4.0 to 8.0.

IPR filings, including ours, are a matter of public record and can be viewed at the USPTO website. On May 17, 2016 and on June 13, 2016, the Patent Trial and Appeal Board (“PTAB”) of the USPTO instituted our petition for IPR of the ‘135 patent, the ‘680 and ‘987 patents, respectively. On November 7, 2016, the PTAB did not institute our petition for IPR of the ‘166 patent; however, we and others will be able to challenge this patent in further IPRs or in district court litigation. If the arguments we raise in any instituted IPR fail to persuade the USPTO, after trial, that the challenged patent claims are unpatentable, we will not be able to raise those same arguments in district court litigation. However, other biosimilar entities may be in a position to challenge the patents in IPRs or district court litigation, and we could still assert certain bases of invalidity or unenforceability that are not subject to review in IPR proceedings. If the ‘166 patent is not invalidated and we are not successful in developing a formulation that does not infringe the ‘166 patent, we may be precluded from marketing a biosimilar of adalimumab until the expiration of the ‘166 patent which we understand is August, 2022. We note that on December 29, 2015, Boehringer Ingelheim filed two IPRs against the ‘135 patent, which were instituted by the PTAB in July 2016. If we do not prevail in the IPRs or in any subsequent litigation that may occur between us and AbbVie concerning AbbVie’s RA dosing patents, and if other parties are not successful in challenging the validity of these patents, we could be precluded from marketing a 40 mg biweekly subcutaneous dosage for RA until the expiration of AbbVie’s dosing patents directed to this treatment regimen.

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.***

We may discover that competitors are infringing our issued and pending 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 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 have issued patents and 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. We have developed our own proprietary formulations for these products which we believe are not covered by valid, enforceable third party patents, including Amgen or AbbVie’s formulation patents, and we have filed patent applications covering our formulations, some of which have now issued in the U.S., namely U.S. patents 9,340,611; 9,340,612; 9,346,880; and 9,382,371, and others of which are currently pending in the U.S. and globally. 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 any of our issued patents or pending patent applications directed to formulations of etanercept (Enbrel) and adalimumab (Humira) would cover the formulations of any competitors. As in the case of formulations, originators have also filed patents directed to methods for manufacturing their products. We have filed patent applications, currently pending, both in the U.S. and globally, directed to aspects of our manufacturing processes for CHS-0214 and CHS-1420. We believe the proprietary technologies embodied in our process-related patent filings may provide us with competitive advantage and are not covered by valid, enforceable intellectual property rights of third party patents, including AbbVie and Amgen. However, 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, and we cannot guarantee that the methods we use to manufacture our products will avoid infringement of third party patents.

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 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, CHS-1420 and CHS-5217) 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, if we choose to implement it, could prevent us from launching our product candidates in the United States or could substantially delay such launches.

The BPCIA establishes a patent disclosure and briefing process between the biosimilar applicant and the originator that is demanding and time-sensitive. While certain aspects of this process are still being tested in the federal courts, the Federal Circuit, as discussed further below, recently ruled that this process is not mandatory, such that a biosimilar applicant may elect to engage in this process, but is not required to do so. The following is an overview of the patent exchange and patent briefing procedures established by the BPCIA for biosimilar applicants that elect to employ them:

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 may elect to provide a copy of its application to the originator if it chooses to engage in the BPCIA patent exchange mechanism.
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. The federal courts have not yet settled the issue as to when, or under what circumstances, the biosimilar applicant must provide the 180 notice of commercial marketing provided in the BPCIA.

On July 21, 2015 the Federal Circuit court in litigation between Amgen and Sandoz ruled that the BPCIA patent exchange process is optional and that applicants that choose not to engage in it must comply with the BPCIA's requirement to provide the originator 180 days prior notice of commercial marketing. The court also ruled that such notice is not effective unless given after FDA licensure. Thus, biosimilar applicants that opt out of the BPCIA patent exchange process must wait at least 180 days after licensure to launch their biosimilar products. On February 16, 2016 Sandoz filed a petition for writ of *certiorari* to the United States Supreme Court, asking the Court to reverse the Federal Circuit court's decision that the BPCIA 180-day pre-marketing notification can only be given after FDA has approved the biosimilar product. The Supreme Court may or may not choose to review the Federal Circuit decision. Regardless of how the 180-day notice provision is applied by the courts, patent infringement lawsuits filed by originators could result in preliminary or permanent injunctions extending beyond the 180-day notice period.

On December 9, 2015, in litigation between Amgen and Apotex (relating to Apotex's biosimilar for Neulasta (pegiflgrastim), the Florida District court ruled that although Apotex had engaged in the BPCIA patent exchange process voluntarily, it was nonetheless required to provide 180 days prior notice of commercial marketing to Amgen, and that it could only provide such notice upon regulatory approval. Apotex appealed this decision to the Federal Circuit. In July 2016, the Federal Circuit affirmed the Florida District Court decision and if such decision is not overturned upon reconsideration by a full panel of the Federal Circuit or by the US. Supreme Court, all 351(k) biosimilar applicants will be required to refrain from launching an approved biosimilar product for 180 days following 351(k) regulatory approval, without regard to whether such applicants elected to participate in the BPCIA patent exchange process.

A significant legal risk for a biosimilar applicant that pursues regulatory approval under the 351(k) regulatory approval route, and also elect to engage in the above-described BPCIA patent exchange mechanism, is that the process 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 the biosimilar product. However, even if biosimilar applicants opt out of the BPCIA patent exchange process, originators will still have the right to assert patent infringement as a basis to enjoin a biosimilar product launch. Thus, whether or not we engage in the BPCIA patent exchange process, there is risk that patent infringement litigation initiated by originators could prevent us indefinitely from launching our biosimilar products.



The legal and strategic considerations weighing for or against a decision to voluntarily engage in the BPCIA patent exchange process are complex and will differ on a product-by-product basis. If we decide to engage in the BPCIA patent exchange process, 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.

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, or both; but we may ultimately not be successful in that strategy and could be prevented, indefinitely, 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. Under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we previously took 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. Based on our non-affiliated market capitalization as of June 30, 2015, we ceased to be an emerging growth company under the JOBS Act on January 1, 2016 and therefore are now required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting.

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 and in connection with the audit of our financial statements for 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 \$21,000 of cash in Russian banks as of September 30, 2016. 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 \$12.04 to \$38.10 per share during the period from November 6, 2014 through November 7, 2016 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, 2016 our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 68.3% 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.

***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, 2016, there were 43,626,695 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, 2016, approximately 10.9 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans were eligible or may become 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 and convertible notes, 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. Pursuant to our 2016 Employment Commencement Incentive Plan, or the 2016 Plan, our management is authorized to grant stock options and other equity-based awards to our new employees. The 2016 Plan is designed to comply with the inducement exemption contained in Nasdaq's Rule 5635(c)(4), which provides for the grant of non-qualified stock options, restricted stock units, restricted stock awards, performance awards, dividend equivalents, deferred stock awards, deferred stock units, stock payment and stock appreciation rights to a person not previously an employee or director, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with us. We reserved for future issuance under the 2016 Plan a total of 1,000,000 share of common stock for new employees. The 2016 Plan does not provide for any annual increases in the number of shares available.

In February 2016, we issued and sold \$100.0 million aggregate principal amount of our 8.2% senior convertible notes due March 2022. The holders may convert their convertible notes at their option at any time prior to the close of business on the business day immediately preceding March 31, 2022. Upon conversion of the convertible notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. The initial conversion rate is 44.7387 shares of common stock per \$1,000 principal amount of convertible notes, which is equivalent to an initial conversion price of approximately \$22.35 per share, and is subject to adjustment in certain events.

In October 2016, we entered into a Sales Agreement with Cowen under which we may offer and sell our common stock, having aggregate gross sale proceeds of up to \$100.0 million, from time to time through an at-the-market equity offering program.

***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**

Not applicable

**ITEM 3. Defaults Upon Senior Securities**

Not applicable

**ITEM 4. Mine Safety Disclosures**

Not applicable

**ITEM 5. Other Information**

Not applicable

**ITEM 6. Exhibits**

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits 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 9, 2016

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

Date: November 9, 2016

/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	
10.1	Second Amendment, dated September 21, 2016, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.	8-K	10.1	9/26/16	
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, 2016, formatted in eXtensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at September 30, 2016 (unaudited) and December 31, 2015, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2016 and 2015, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2016 and 2015, (iv) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2016 and 2015, and (v) Notes to the Condensed Consolidated 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 internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

/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 internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

/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, 2016 (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 9, 2016

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

Date: November 9, 2016

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.*